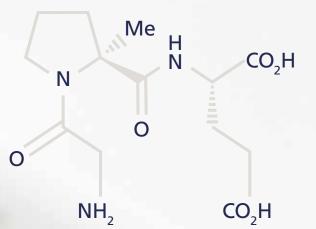


pharmaceuticals



Annual Report **2015**

Company Snapshot

Neuren Pharmaceuticals is a biopharmaceutical company developing new therapies for brain injury, neurodevelopmental and neurodegenerative disorders.

Incorporated in New Zealand and based in Melbourne, Australia, Neuren is listed on the ASX under the code NEU.

Business progress since 1 January 2015

- US Food and Drug Administration (FDA) granted Orphan Drug designation for trofinetide in Rett syndrome
- European Medicines Agency (EMA) granted Orphan Drug designation for trofinetide in both Rett syndrome and Fragile X syndrome
- Rettsyndrome.org committed funding of up to US\$1 million towards the cost of Neuren's pediatric Phase 2 trial
- New patent granted in the US covering the use of trofinetide to treat Rett syndrome
- Enrolment of subjects completed in the Phase 2 trial of trofinetide in moderate to severe traumatic brain injury

- New capital of \$6.3 million raised in share placement
- New patent granted in Europe covering the composition of NNZ-2591
- Top-line results from the Fragile X syndrome Phase 2 trial established proof of concept and provided a strong rationale to move forward with developing trofinetide for Fragile X syndrome
- Significant investments made in trofinetide manufacturing processes
- Leading US healthcare investment bank Leerink Partners appointed to advise Neuren's board
- Pediatric Phase 2 trial in Rett syndrome commenced in the United States

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Neuren share price in 2015

Expected milestones for trofinetide in 2016

Datt ave drama	Commence pediatric Phase 2 trial	Q1 2016
Rett syndrome	Complete pediatric Phase 2 trial	Q4 2016
Fragile X syndrome FDA meeting on remaining development		H1 2016
Moderate to severe TBI Phase 2 trial top-line results		April 2016
Manufacturing	Complete commercial manufacturing optimisation and scale-up	H2 2016

Product Development Pipeline

	Pre-clinical & Phase 1	Phase 2	Phase 3
Trofinetide: Rett syndrome			
Trofinetide: Fragile X syndrome			
Trofinetide: moderate to severe TBI			
Trofinetide: Concussion (mild TBI)			
NNZ-2591: Other neurological conditions			



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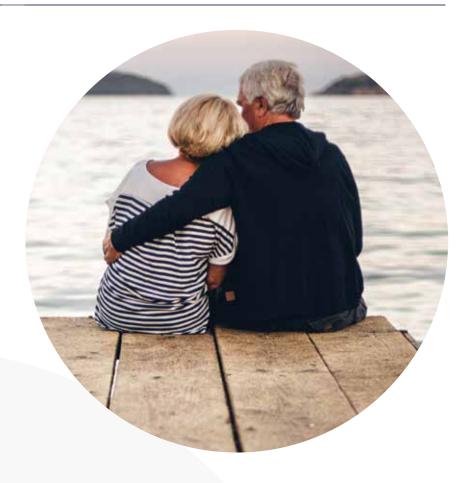
The Board of Directors is pleased to present the Annual Report of Neuren Pharmaceuticals Limited for the year ended 31 December 2015, authorised on 15 April 2016

For, and on behalf of, the Board



Dr Richard Treagus Chairman





neuren pharmaceuticals

Chairman's Letter

Dear Shareholders,

I am pleased to report that Neuren's business has advanced significantly on a number of important fronts since 1 January 2015.



Our commercial position has been greatly strengthened following the grant of Orphan Drug designation in the two main markets of the United States and Europe for both Rett syndrome and Fragile X syndrome, as well as by the grant of a new US patent for trofinetide to treat Rett syndrome.

Our mission to make trofinetide available to patients as quickly as possible has been advanced meaningfully across three indications. Firstly, the top-line results from the Fragile X syndrome Phase 2 trial established proof of concept and provided a strong rationale to move forward with developing trofinetide for Fragile X syndrome, secondly we completed enrolment in the moderate to severe traumatic brain injury Phase 2 trial and thirdly we commenced the next Rett syndrome Phase 2 trial in children and adolescents. In anticipation of pivotal clinical trials, New Drug Applications and commercial supply, we have also made significant investments in the manufacturing processes and chronic toxicity studies that will benefit all potential clinical uses for trofinetide.

In November 2015, we raised new capital of \$6.3 million in a share placement to further strengthen the cash reserves from which we will fund the development of trofinetide for Rett syndrome through into 2017. This is in addition to the important support we have received from rettsyndrome.org, which has committed grant funding of up to US\$1 million towards the cost of the pediatric trial. We are very grateful to the advocacy organisations in both Rett syndrome and Fragile X syndrome, which have continued to assist us towards our common goal.

This year represents another important and busy period for Neuren. We will meet with the US Food and Drug Administration to discuss the remaining development for Fragile X syndrome, finalise and announce the results of our traumatic brain injury clinical trial and we expect to complete the Rett syndrome pediatric trial and the optimisation and scale-up of the manufacturing processes.

Neuren's board believes that trofinetide holds significant value as a potential new medicine, but also recognises the extent of the resources required to ensure that full value can be achieved across all potential clinical indications.

We consider it appropriate to examine all available options to ensure that trofinetide is developed and commercialised as quickly as possible for the benefit of all stakeholders. A number of international pharmaceutical companies have expressed interest in the trofinetide development programs as we have released clinical trial results. Neuren has therefore engaged Leerink Partners, a leading US investment banking firm specialising in healthcare, as its sole corporate adviser to assist the board in evaluating the different options available to the Company.

On behalf of the Board, I wish to thank our shareholders as well as the Neuren team, clinical experts, patient support groups and the families who together make this very important drug development program possible.

Dr Richard Treagus Chairman

03

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.

Strategy, funding and commercialisation

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 five important attributes: solid scientific rationale, significant unmet medical need, compelling market opportunity, strong support from advocacy groups 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

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, potentially plus 6 months if approved for pediatric use, as well as 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 lifethreatening 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.

In July and August 2015, the European Medicines Agency also granted Orphan Designation for trofinetide in both Rett syndrome and Fragile X syndrome. Orphan Designation in the European Union qualifies the sponsor of the drug for 10 years of marketing exclusivity following marketing authorisation, potentially plus 2 years if authorised for pediatric use.

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. Neuren owns issued composition of matter patents for trofinetide in the United States and Europe, which expire in 2022, with the potential to extend to 2027. In October 2015, following examination, the US Patent and Trademark Office confirmed the issue of a new patent concerning the use of trofinetide to treat Rett syndrome. The patent is expected to expire in January 2032. Other method of treatment patent applications for trofinetide in autism spectrum disorders are under examination in the United States, Europe and other territories.

In anticipation of pivotal clinical trials, New Drug Applications and commercial supply, Neuren is making significant investments in manufacturing processes and chronic toxicity studies that will benefit all potential clinical uses for trofinetide. This includes optimisation and scale up of the drug substance synthesis and development of the commercial finished product presentation, which are expected to be completed by the end of 2016. The chronic toxicity studies required for New Drug Applications are commencing in the first half of 2016.

In November 2015, Neuren raised new capital of \$6.3 million in a share placement to further strengthen the cash reserves from which Neuren will fund the development of trofinetide for Rett syndrome through into 2017.





⁰⁶ Operating Review

continued

The science behind Neuren's products

Trofinetide is the World Health Organisation's recommended name for our lead clinical-stage drug candidate (also known 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 to maintain or restore the biological balance required for normal functioning.

In the brain, IGF-1 gets rapidly broken down by an enzyme into two separate molecules, glypromate or "GPE" and Des(1-3)IGF-1. Both are biologically active neuropeptides with a wide range of effects. GPE, which comprises the last three peptides of IGF-1, primarily affects glial cells (astrocytes and microglia) while Des(1-3)IGF-1 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.

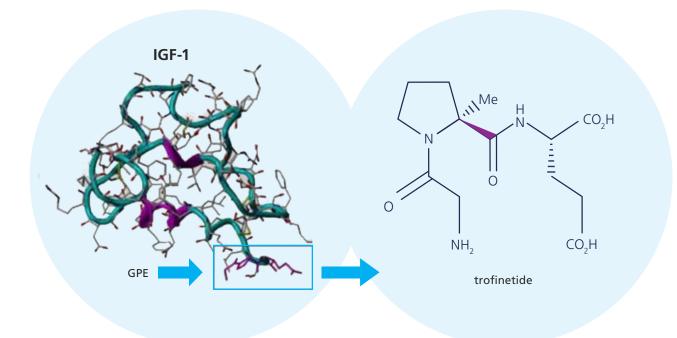
During development, the brain and the cells that make it up change rapidly and in complex ways. IGF-1 and GPE play a significant role in regulating these changes. In the mature brain, IGF-1 and GPE both play an important role in responding to disease, stress and injury. Whereas most drugs typically exert 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, overactivation 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 that manifest differently are considered to arise from similar 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 CNS 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.

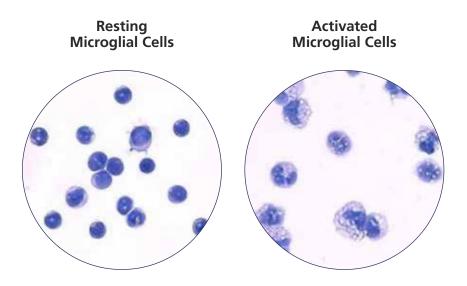
In animal models ranging from brain injury and stroke to Fragile X syndrome to age-associated cognitive impairment, trofinetide has shown an ability to significantly reduce the levels of inflammatory cytokines. This has resulted in improvement in a wide range of symptoms including posttraumatic seizures,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

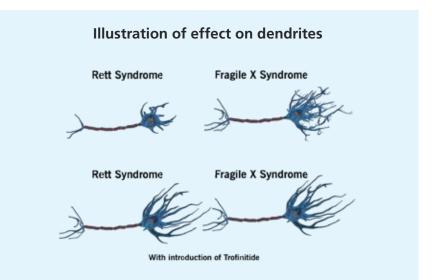


3. Dysfunction of synapses

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

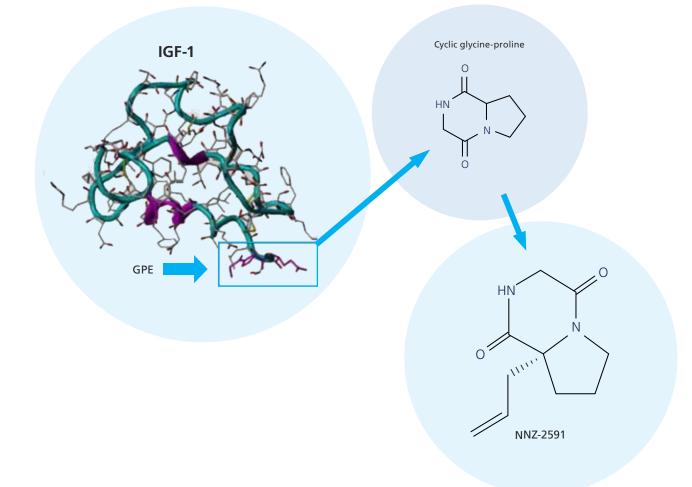
IGF-1 levels in the brain have been reported to be depressed in a number of conditions, particularly in Rett and Fragile X syndromes and brain injury. In these conditions, the critical role of IGF-1 and GPE in maintaining and repairing brain cells and synapses is impaired.

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.

NNZ-2591 is Neuren's lead preclinical drug candidate. It is a synthetic analog of cyclic glycine-proline (cGP), a naturally occurring metabolite of GPE. NNZ-2591 exhibits potent neuroprotective and neurotrophic properties. It has been shown to be effective in a number of well-validated animal models of neurological disorders including cognitive impairment, Fragile X syndrome, traumatic brain injury, stroke, Parkinson's disease, peripheral neuropathy and multiple sclerosis. In addition to preclinical evidence of strong therapeutic potential in a range of applications and a promising safety profile, NNZ-2591 has a number of attributes that make it an attractive candidate for further development. These include excellent oral bioavailability, likely suitability for development of a solid oral dosage form and potential for improved stability compared to other peptidelike compounds.





Many central nervous system (CNS) disorders exhibit common cellular and molecular pathology that manifest as a wide range of phenotypes. In particular, the role of microglia in active maintenance and support of synapses and the effects of inflammation are increasingly being recognised as central to many CNS conditions. Target indications potentially addressable by trofinetide and NNZ-2591 are summarised in the table below.

Multiple CNS disorders with common pathologic etiology							
	Neuro- inflammation	Microglial Activation	Neuronal Signaling	Apoptosis	Impaired Neurogenesis	Oxidative Stress	
Rett	•	•	•	•	•	•	
Fragile X	•	•	•		•	•	
Idiopathic Autism	•	•	•		•	•	
Traumatic Brain Injury	•	•	•	•	•	•	
Depression	•	•	•	•	•	•	
Post Traumatic Stress Disorder	•	•	•			•	
Cognitive Impairment	•	•	•	•	•	•	
Parkinson's Disease	•	•	•	•	•	•	
Multiple Scierosis	•	•	•	•	•	•	
Alzheimer's Disease	•	•	•	•	•	•	
Stroke	•	•	•	•	•	•	
Anxiety	•	•	•		•	•	
Schizophrenia	•	•	•	•	•	•	

¹⁰ Operating Review

continued

Neuren's clinical 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 June 2015, Neuren attended a productive meeting with the Division of Neurology of the FDA, which provided guidance on the remaining development required for trofinetide in Rett syndrome. Neuren recently commenced the next Phase 2 clinical trial, which is a randomised, doubleblind, placebo controlled, doseranging trial of trofinetide in children and adolescents, aged 5 to 15 years, with Rett Syndrome. The trial is being conducted at 11 sites in the United States, overseen by clinicians experienced in Rett syndrome. Three dose levels of trofinetide are being tested; 50mg/kg, 100mg/kg and 200mg/kg each twice daily.

Neuren's previous Phase 2 clinical trial demonstrated clinical benefit from treatment with trofinetide in subjects aged 16 to 45 years at a dose level of 70mg/kg twice daily. The aims of the new trial are to test the safety and efficacy of trofinetide in a younger age group, at higher doses and for a longer duration of treatment, as well as to confirm the optimum dose levels for a subsequent Phase 3 trial in children, adults and adolescents. Rettsyndrome.org has provided strong support to Neuren's trofinetide program and continues to do so, including grant funding of up to US\$1 million towards the cost of the pediatric trial.

Neuren aims to complete the trial by the end of 2016. In the meantime, Neuren is continuing to work with the FDA to reach agreement on the primary efficacy endpoint to be used for pivotal trials, derived from the Motor Behaviour Assessment (MBA). The MBA has been used to assess over 1,100 children, adolescents and adults with Rett syndrome enrolled in the Rett Natural History Study, a study sponsored by the National Institutes of Health (NIH).

Fragile X syndrome

Fragile X syndrome is the most common inherited cause of intellectual disability and the most common known cause of autism. Fragile X syndrome is due to a single gene defect on the X chromosome that impacts the FMRP protein, which is responsible for regulating the synapses of nerve cells. Approximately one in 4,000 males and one in 6,000 females are estimated to have the full gene mutation. Generally, males are more severely affected than females, with approximately 50% of the females having features of Fragile X syndrome. Clinically, Fragile X syndrome is characterised by intellectual disability, hyperactivity and attentional problems, autistic symptoms, anxiety, emotional lability and epilepsy.

The epilepsy seen in Fragile X syndrome is most commonly present in childhood, but then gradually improves towards adulthood. Physical features such as prominent ears and jaw, and hyper-extensibility of joints are frequently present but are not diagnostic. Currently, there are no medicines approved for the treatment of Fragile X syndrome.

In December 2015, Neuren announced top-line results from its Phase 2 clinical trial, which established proof of concept and provided a strong rationale for Neuren to move forward with developing trofinetide for Fragile X syndrome. In this initial small trial with a relatively short treatment period, trofinetide was very well tolerated, with the high dose (70 mg/kg twice daily) demonstrating a consistent pattern of clinical improvement, observed in both clinician and caregiver assessments. After only 28 days of treatment, improvements were seen across core symptoms of Fragile X syndrome, including higher sensory tolerance, reduced anxiety, better self-regulation and more social engagement.

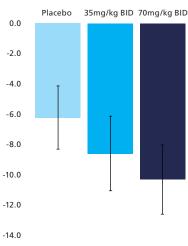
The trial was a randomised, doubleblind, placebo-controlled, parallel group, fixed dose trial enrolled males aged 12 to 45 years with confirmed Fragile X syndrome at 16 sites in the United States. The trial was overseen by leading clinical experts in Fragile X syndrome. 70 subjects received treatment in three groups; placebo (25 subjects), 35 mg/kg twice per day (24 subjects) and 70 mg/kg twice per day (21 subjects). The dosage form was a strawberry-flavoured liquid that was taken orally.

The primary objective of the trial was to evaluate the safety and tolerability of each of the two dose levels of trofinetide as compared to placebo. The trial also incorporated a number of secondary and exploratory outcome measures that provided insight into efficacy, including two rating scales developed in consultation with Fragile X syndrome clinical experts. The following five measures were pre-specified in the statistical analysis plan as core measures for the efficacy analyses:

Core measure	Type of measure
Fragile X Syndrome Rating Scale	Clinician-completed syndrome-specific
Fragile X Domain Specific Concerns	Clinician-completed syndrome-specific
Clinical Global Impression - Improvement Scale (CGI-I)	Clinician-completed syndrome-specific global
Caregiver Top 3 Concerns	Caregiver-completed syndrome-specific
Aberrant Behavior Checklist (ABC) Total Score	Caregiver-completed non-syndrome specific

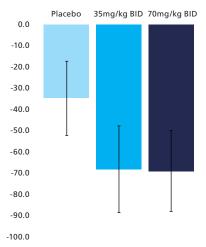
The analyses compared the mean clinical responses in the three treatment groups for each core measure, as well as comparing the collective clinical responses in all the core measures for each subject individually. The individual analysis was designed to confirm that the treatment benefit shown by the group mean responses was broadly evident and not simply due to a few large outlier responses.

The following charts illustrate the clinical responses measured at the end of treatment. The direction of benefit is *downwards* for the five core measures and *upwards* for the individual subject analysis.

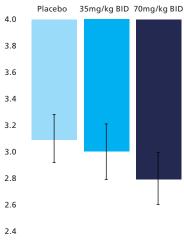


Fragile X Syndrome Rating Scale

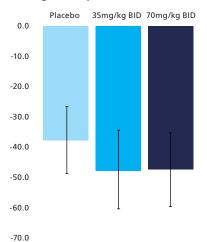
Fragile X Domain Specific Concerns



Clinical Global Impression – Improvement Scale

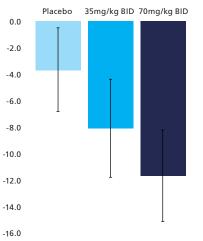


Caregiver Top 3 Concerns



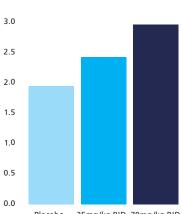
pharmaceuticals

Aberrant Behaviour Checklist (ABC) Total Score



Individual Subject Score

3.5



Placebo 35mg/kg BID 70mg/kg BID

The trial design anticipated the potential for placebo response and this was taken into account in the analyses. Following the methodology defined in the pre-specified analyses, the data was subjected to permutation testing in order to estimate the probability that the observed clinical improvement in both the group-level and subjectlevel analyses was observed purely by chance (the "false-positive" rate). This probability was estimated as 4.5% (p=0.045).

Based on these results and feedback from clinical experts in Fragile X syndrome, Neuren is strongly encouraged to advance to the next step in clinical development. This will likely involve a study in younger children with Fragile X syndrome and may examine a longer treatment duration with higher doses. This next study will also refine the outcome measures that may be used in a Phase 3 study. Neuren will discuss the trial results and drug development plan with the FDA in the first half of 2016.

The Fragile X Alliance (FRAXA) and the National Fragile X Foundation representing the Fragile X community have provided important support to Neuren's trofinetide program.

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. Concussion can have wide-ranging physical and psychological effects including nausea, dizziness, problems with balance, impairment of memory and attention, depression, other alterations of mood and personality, and sleep disturbances. In the majority of patients, symptoms resolve within 90 days or less, but as many as 25% of patients experience a prolonged period of residual disability, referred to as post-concussive syndrome. Particularly among people who sustain multiple concussions, long term changes in cognitive function and mood can be accompanied by chronic effects in the brain including chronic traumatic encephalopathy which significantly increases the risk of dementia and other neuropsychological problems.

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 postinjury seizures, addressing symptoms that are of primary concern in TBI patients. Neuren's partnership with the US Army has made it feasible to target both moderate to severe TBI and concussion with trofinetide.

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 of approximately US\$29 million in support of the development of trofinetide for TBI.

Moderate to severe TBI trial

In October 2015, Neuren completed enrolment of 260 subjects at hospital trauma centres in the United States for its Phase 2 clinical trial ("INTREPID-2566") using the intravenous dosage form of trofinetide in moderate to severe TBI. The trial is assessing the safety and efficacy of treatment with intravenous NNZ-2566 for 72 hours post-injury. The randomised, double-blind, placebocontrolled trial involved treatment with trofinetide or placebo in hospital for 72 hours and follow-up assessments for up to 3 months after randomisation. Top-line results are expected to be available before the end of April 2016.

Concussion trial

Neuren's Phase 2 clinical trial of the oral dosage form of trofinetide in concussion is being conducted with the US Army's 82nd Airborne Division at Fort Bragg in North Carolina. Achieving voluntary enrolment into the trial has proven to be much more challenging than was anticipated by Neuren and the US Army. All aspects of the trial design and execution are currently under review to determine the best way forward.

Finance

Summary of consolidated financial results for the year to 31 December 2015

	2015 \$′m	2014 \$′m
Grant income	1.7	2.9
Interest income	0.3	0.6
Foreign exchange gain	1.1	0.9
Total revenue	3.1	4.4
Research & Development	(14.1)	(10.0)
Corporate & Administration	(1.9)	(1.7)
Share based payments amortisation	(1.2)	(0.9)
Impairment loss	_	(0.1)
Loss before tax	(14.1)	(8.3)
R&D Tax Incentive	0.7	_
Loss after tax	(13.4)	(8.3)
Operating cash outflow	(12.7)	(6.4)
New share capital	7.5	2.2
Effect of exchange rates on cash balances	1.0	0.7
Cash at 31 December	16.6	20.8

The consolidated loss after tax for the year ended 31 December 2015 was \$13.4 million. The loss increased by \$5.1 million, mainly due to the following:

- An increase of \$4.1 million in research and development costs, with higher costs for completion of the Fragile X syndrome clinical trial, drug supply for trials and manufacturing scale-up, partly offset by the completion of the Rett syndrome clinical trial at the end of 2014;
- A decrease of \$1.3 million in grant revenue from the US government as the funding reached the maximum in May 2015; and
- An increase of \$0.3 million in the non-cash share based payments expense; offset by:
- Research and development tax credits refunded of \$0.7 million (2014: nil).

Cash reserves at 31 December 2015 were \$16.6 million (2014: \$20.8 million). Operating cash outflow increased from \$6.4 million to \$12.7 million, mainly due to the higher development costs and lower grant receipts, partly offset by the R&D tax credits refunded. Financing provided cash of \$7.5 million (2014: \$2.2 million), due to the share placement proceeds of \$6.3 million and options exercise proceeds of \$1.2 million.

¹⁴ Leadership Team

Board



Dr Richard Treagus

Executive Chairman BScMed, MBChB, MPharmMed, MBA

Dr Treagus joined the Neuren Board as Executive Chairman in January 2013. He is a physician, with more than 20 years' experience in all aspects of the international biopharmaceutical industry. 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 from 2006 to 2012.

Under his leadership Acrux gained FDA approval for three drug products and concluded a product licensing transaction with Eli Lilly worth US\$335m plus royalties. In 2010 Dr Treagus was awarded the Ernst and Young Entrepreneur-ofthe-Year (Southern Region) in the Listed Company Category and in subsequent years has served on the judging panel. Dr Treagus is Chairman of Biotech Capital Limited and a non-executive director of QRx Pharma Limited, both Australian listed companies.



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.



Bruce Hancox 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. He is a non-executive director of Australian listed companies Medical Australia Limited, Biotech Capital Limited and QRx Pharma Limited.



Dr Trevor Scott

Non-Executive Director MNZM, LLD (Hon), BCom, FCA, FNZIM, DF Inst DDr

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



Dr 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.



Dr Nancy Jones Vice President, **Clinical Development** PhD

Nancy joined Neuren in January 2013. Prior to joining Neuren, she held a senior position at Autism Speaks, the largest science and advocacy organisation in the US focused on autism spectrum and related disorders. Nancy was at Autism Speaks for 6 years, directing the overall operations of the Autism Treatment Network, a network of hospitals and medical centers dedicated to improving access to comprehensive, coordinated medical care for individuals with ASD. She also oversaw the Autism Clinical Trials Network, a network developed to promote and expedite clinical trials in ASD, and played a lead role in an initiative to enhance the development of syndromespecific outcome measures for treatment trials in ASD. Nancy received her Ph.D. in Applied Linguistics from the University of California, Los Angeles where she focused on the neurobiology of language and developmental disorders



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 vears 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). Jon is a non-executive director of Biotech Capital Limited (ASX: BTC).



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.



¹⁶ Corporate Governance

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 costeffective 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") 3rd Edition issued by the ASX Corporate Governance Council in March 2014.

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.

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.

In accordance with Recommendation 1.2, the Board undertakes appropriate checks before appointing a new director, or putting forward to shareholders a candidate for election and provides shareholders with all material information in its possession relevant to a decision on whether or not to elect or re-elect a director.

The Group has a written agreement with each director and senior executive, setting out the terms of their appointment, in accordance with Recommendation 1.3. The Company Secretary is accountable directly to the Board on all matters to do with the proper functioning of the Board, in accordance with Recommendation 1.4.

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, as recommended in Recommendation 1.5. 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. Currently the four directors are male. One of the four senior executives (defined as those who report to an executive director) is female. The Group currently has 12 employees and consultants, from a number of different cultural backgrounds, of which 8 are women.

The performance of the Board, its committees and individual directors is periodically evaluated in accordance with Recommendation 1.6. Each director completes a quantitative evaluation questionnaire and is able to provide qualitative comments. The Company Secretary collates the responses and reports back to the board for discussion. A performance evaluation was undertaken during 2015.

In accordance with Recommendation 1.7, the Board periodically evaluates the performance of the Executive Chairman and the Executive Chairman periodically evaluates the performance of senior executives. The evaluation of the Executive Chairman is part of the board performance evaluation process. For the evaluation of senior executives, an Individual discussion is held after each senior executive complete a qualitative questionnaire, covering past individual and team achievements and challenges, as well as forward-looking outcomes and areas of personal focus. Performance evaluations were undertaken during 2015.

Principle 2. Structure the Board to add value

The Board has not considered it necessary or value-adding to establish a separate Nomination Committee (Recommendation 2.1). The selection, appointment and retirement of directors is considered by the full Board, within the framework of the skills matrix described below. The Board may also engage an external consultant where appropriate to identify and assess suitable candidates who meet the Board's specifications. The composition of the board is discussed regularly and each director may propose changes for discussion.

In accordance with Recommendation 2.2, the Company has a skills matrix setting out the mix of skills that the Board is looking to achieve in its membership. The matrix is summarised in the table below.

Skill	Requirements Overview
Professional Director Skills	
Risk & Compliance	Identify key risks to the organisation related to each key area of operations. Ability to monitor risk and compliance and knowledge of legal and regulatory requirements.
Financial & Audit	Experience in accounting and finance to analyse statements, assess financial viability, contribute to financial planning, oversee budgets, oversee funding arrangements.
Strategy	Ability to identify and critically assess strategic opportunities and threats to the organisation. Develop strategies in context to our policies and business objectives.
Policy Development	Ability to identify key issues for the organisation and develop appropriate policy parameters within which the organisation should operate.
Executive Management	Experience in evaluating performance of senior management, and oversee strategic human capital planning.
Previous Board Experience	The board's directors should have director experience and have completed formal training in governance and risk.
Industry Specific Skills	
Pharmaceutical product development	Experience in and/or understanding of the issues in clinical development, interactions with international regulators and/or CMC development.
International pharmaceutical commercialisation	Experience in and/or understanding of the issues in entering international pharmaceutical markets, including pricing, distribution and exclusivity.
Pharmaceutical partnering	Experience in and/or understanding of the issues in partnering transactions and/or relevant contacts in international pharma companies.
Risk capital management	Experience in raising funding from equity markets and/or relevant contacts in relevant funds and/or investment banks.
Intellectual property	Understanding of the importance and value of market exclusivity and the various ways of protecting it across different jurisdictions, including patents and data exclusivity.
Interpersonal Skills	
Leadership	Make decisions and take necessary actions in the best interest of the organisation, and represent the organisation favourably. Analyse issues and contribute at board level to solutions. Recognise the role of the board versus the role of management.
Ethics and Integrity	Understand role as director and continue to self educate on legal responsibility, ability to maintain board confidentiality, declare any conflicts.
Contribution	Ability to constructively contribute to board discussions and communicate effectively with management and other directors.
Crisis Management	Ability to constructively manage crises, provide leadership around solutions and contribute to communications strategy with stakeholders.

18 **Corporate Governance** continued

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 14 of this report.

	Appointment	Role	Independent	Committees
Richard Treagus	2013	Executive Chairman	No ¹	
Larry Glass	Board – 2012 Management – 2014	Executive director Chief Science Officer	No ¹	
Bruce Hancox	2012	Non-executive director	No ¹	Member of Audit Committee and Remuneration Committee
Trevor Scott	2002	Non-executive director	Yes	Chair of Audit Committee and Remuneration Committee

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

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 Recommendations 2.4 and 2.5. The Board currently does not have a majority of independent directors (Recommendation 2.4), the chair is not independent (Recommendation 2.5) and the chair and principal executive officer roles are not separate (Recommendation 2.5). The Board will continue to assess whether this is the optimum membership and structure for the business as it grows and develops.

In accordance with Recommendation 2.6, the Company has a program for inducting new directors and provides appropriate professional development opportunities for directors to develop and maintain the skills and knowledge needed to perform their role as directors effectively.



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 decisionmaking.
- 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; and
- 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.

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 4.1, but it does not have at least 3 members or a majority of independent members. The Committee met twice during 2015, 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; and
- 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.



20 Corporate Governance continued

Notwithstanding that the New Zealand Companies Act 1993 does not require it, in accordance with Recommendation 4,2, 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 2016.

Since Neuren is incorporated in New Zealand and applies New Zealand financial reporting standards, its auditor is located in New Zealand. The Board has considered it impractical and an unnecessary expense for the auditor to travel to Australia to attend the annual general meeting, as suggested in Recommendation 4.3. The board intends to provide shareholders with the opportunity to submit questions to the auditor in advance of the next annual general meeting.

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.

In accordance with Recommendation 5.1, 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.

In accordance with Recommendation 6.1, comprehensive information about the Company and its governance is provided via the website www.neurenpharma.com. This includes information about the Board and senior executives, as well as corporate governance policies. All announcements, presentations, financial information and meetings materials disclosed to the ASX are placed on the website, so that current and historical information can be accessed readily.

The Company's investor relations program facilitates effective two-way communication with investors (Recommendation 6.2). The Executive Chairman and the Chief Financial Officer interact with institutional investors, private investors, analysts and media on an ad hoc basis, conducting meetings in person or by teleconference and responding personally to enquiries.

The Board seeks practical and cost-effective ways to promote informed participation at shareholder meetings (Recommendation 6.3). This includes providing access to clear and comprehensive meeting materials and electronic proxy voting.

In accordance with Recommendation 6.4, shareholders are provided with and encouraged to use electronic methods to communicate with the Company and with the share registry.

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. In accordance with Recommendation 7.1, risk is overseen by the Audit Committee, the membership of which is described under Principle 4 above.

In accordance with Recommendation 7.2, the Audit Committee reviews the Group's risk management framework at least annually to satisfy itself that it continues to be sound. A review was conducted in 2015.

The size and complexity of the Group's business is not sufficient to warrant an internal audit function (Recommendation 7.3). The risk management policy is designed to involve the entire organisation in risk management and to ensure that the effectiveness of the risk management and internal control processes are continually improved.

The Group does not have a material exposure to economic, environmental or social sustainability risks (Recommendation 7.4).

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 8.1, but it does not have at least 3 members or a majority of independent members. The Committee met twice during 2015, 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 Group's remuneration policies and practices are summarised below, in accordance with Recommendation 8.2

The Remuneration Committee assesses the appropriateness of the nature and amount of remuneration of executive directors and senior executives 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 executive team. To assist in achieving these objectives, the nature and amount of executive remuneration is linked to the Company's performance. Remuneration consists of fixed cash remuneration including superannuation contributions required by law and equity-based remuneration. Fixed cash remuneration takes into account labour market conditions, as well as the scale and nature of the Group's business. Equity-based remuneration is provided by participation in a share option plan, a loan funded share plan and equity performance rights. These are designed to ensure that key executives are aligned with shareholders through an interest in the long-term growth and value of the Company. Senior executive service agreements generally include a requirement for 3 months' notice of termination by the executive or the Group. There are no other termination payments. Termination for misconduct does not require notice or payment.

Remuneration of non-executive directors comprises fixed cash fees only. The 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 benefits.

Participants in equity based remuneration schemes are not permitted to enter into transactions which limit the economic risk of participating in the scheme (Recommendation 8.3).



Principal Activities

Neuren Pharmaceuticals Limited (Neuren or the Company, and its subsidiaries, or the Group) is a publicly listed biopharmaceutical company developing drugs for neurological disorders.

Performance Overview

During 2015 Neuren made significant progress on the development of trofinetide for Rett syndrome, Fragile X syndrome and brain injury. Key developments in the business included:

- The US Food and Drug Administration (FDA) granted Orphan Drug designation for trofinetide in Rett syndrome;
- The European Medicines Agency (EMA) granted Orphan Drug designation for trofinetide in both Rett syndrome and Fragile X syndrome;
- Rettsyndrome.org (International Rett Syndrome Foundation) committed funding of up to US\$1 million towards the cost of Neuren's planned pediatric Phase 2 trial;
- A new patent was granted in the United States covering the use of trofinetide to treat Rett syndrome;
- Enrolment of subjects was completed in the Phase 2 clinical trial of trofinetide in moderate to severe traumatic brain injury;
- New capital of \$6.3 million was raised in a share placement;
- A new patent was granted in Europe covering the composition of NNZ-2591;
- Top-line results from the Phase 2 clinical trial in Fragile X syndrome successfully established proof of concept and provided a strong rationale for Neuren to move forward with developing trofinetide for Fragile X syndrome;
- Significant investment was made in the optimisation and scale-up of manufacturing processes and in the manufacture of drug for chronic toxicity studies; and
- Leerink Partners, a leading US investment bank, was appointed to advise directors.

The detailed financial statements are presented on pages 26 to 47. 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 2015 was \$13,397,000 (2014: \$8,297,000). The loss increased by \$5.1 million, mainly due to the following:

- An increase of \$4.1 million in research and development costs, with higher costs for completion of the Fragile X syndrome clinical trial, drug supply for trials and manufacturing scale-up, partly offset by the completion of the Rett syndrome clinical trial at the end of 2014;
- A decrease of \$1.3 million in grant revenue from the US government as the funding reached the maximum in May 2015; and
- An increase of \$0.3 million in the non-cash share based payments expense; offset by:
- Research and development tax credits refunded of \$0.7 million (2014: nil).

The net loss per share for 2015 was \$0.008 (2014: \$0.005) based on a weighted average number of shares outstanding of 1,680,362,334 (2014: 1,552,481,203).

Cash reserves at 31 December 2015 were \$16.6 million (2014: \$20.8 million). Operating cash outflow increased from \$6.4 million to \$12.7 million, mainly due to the higher development costs and lower grant receipts, partly offset by the R&D tax credits refunded. Financing provided cash of \$7.5 million (2014: \$2.2 million), due to the share placement proceeds of \$6.3 million and options exercise proceeds of \$1.2 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 in January 2013. He is a physician, with more than 20 years' experience in all aspects of the international biopharmaceutical industry. 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 from 2006 to 2012. Under his leadership Acrux gained FDA approval for three drug products, concluded a product licensing transaction with Eli Lilly worth US\$335m plus royalties and became profitable. 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. Dr Treagus is Chairman of Biotech Capital Limited and a non-executive director of QRx Pharma Limited, both Australian listed companies.

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. He is a non-executive director of Australian listed companies Medical Australia Limited, Biotech Capital Limited and QRx Pharma 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 2015 are as follows:

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 B Hancox

On 1 September 2015, Mr Hancox became a non-executive director of Biotech Capital Limited, listed on the Australian Securities Exchange.

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.



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 2015 \$'000	Share based payments 2015 \$'000	Remuneration 2014 \$'000	Share based payments 2014 \$'000
Dr Richard Treagus	360	475	370	475
Mr Larry Glass	479	_	405	_
Mr Bruce Hancox	50	_	50	_
Dr Trevor Scott	60	_	60	_

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	2015 \$'000	2014 \$′000
\$90,000 - \$99,999	1	1
\$100,000 - \$109,999	1	-
\$140,000 - \$149,999	1	1
\$240,000 - \$249,999	1	1
\$260,000 - \$269,999	-	1
\$270,000 - \$279,999	2	-

Including shared based payments	2015 \$'000	2014 \$′000
\$90,000 - \$99,999	1	_
\$100,000 - \$109,999	1	-
\$140,000 - \$149,999	1	1
\$180,000 - \$189,999	-	1
\$350,000 - \$359,999	_	1
\$390,000 - \$399,999	1	-
\$460,000 - \$469,999	_	1
\$560,000 - \$569,999	1	-
\$570,000 - \$579,999	1	-

Donations

The Company made nil donations during the year (2014: \$2,255).

Auditors

PricewaterhouseCoopers are the auditors of the Company. Audit fees in relation to the annual and interim financial statements were \$52,310 (2014: \$66,241). PricewaterhouseCoopers did not receive any fees in relation to other financial advice and services (2014: Nil).

For and on behalf of the Board of Directors who authorised the issue of these financial statements on 24 February 2016.

Dr Richard Treagus Chairman

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Dr Trevor Scott Director

Financial Statements

for the year ended 31 December 2015



Statements of Comprehensive Income for the year ended 31 December 2015 26

	_		nsolidated	Parent		
No	tes	Dec 2015 \$'000	Dec 2014 \$'000	Dec 2015 \$′000	Dec 2014 \$'000	
Interest income		335	561	334	560	
		335	561	334	560	
Other income						
Grants		1,673	2,931	-	_	
Foreign exchange gain		1,098	876	1,131	876	
		2,771	3,807	1,131	876	
Total income		3,106	4,368	1,465	1,436	
Research and development costs		(14,132)	(10,016)	(12,698)	(6,913)	
Corporate and administrative costs		(1,888)	(1,690)	(1,764)	(1,648)	
Share based payment expense		(1,232)	(947)	(1,232)	(947)	
Impairment loss – Intangible Assets	9	-	(31)	-	-	
Impairment loss – Investments	13	-	_	-	(52)	
Provision for doubtful debt	8	-	_	-	(901)	
Loss before income tax		(14,146)	(8,316)	(14,229)	(9,025)	
Income tax benefit	5	749	_	749	_	
Loss after income tax		(13,397)	(8,316)	(13,480)	(9,025)	
Other comprehensive expense, net of tax						
Disposal of Minority Interest		(221)	_	-	_	
Exchange differences on translation of foreign						
operations		(60)	(138)	-		
Total comprehensive loss for the period		(13,678)	(8,454)	(13,480)	(9,025)	
Loss after tax attributable to:						
Equity holders of the company		(13,397)	(8,297)	(13,480)	(9,025)	
Minority interest		_	(19)	-	_	
		(13,397)	(8,316)	(13,480)	(9,025)	
Total comprehensive loss attributable to:						
Equity holders of the company		(13,678)	(8,435)	(13,480)	(9,025)	
Minority interest		-	(19)	-	-	
		(13,678)	(8,454)	(13,480)	(9,025)	
Basic and diluted loss per share	6	\$0.008	\$0.005			

Statements of Financial Position

as at 31 December 2015

	Со	nsolidated	Parent		
Notes	As at Dec 2015 \$'000	As at Dec 2014 \$'000	As at Dec 2015 \$'000	As at Dec 2014 \$'000	
ASSETS					
Current Assets:					
Cash and cash equivalents 7	16,642	20,824	16,565	20,236	
Trade and other receivables8	34	963	264	1,231	
Total current assets	16,676	21,787	16,829	21,467	
Non-current assets:					
Property, plant and equipment	11	29	11	29	
Intangible assets 9	217	290	217	290	
Total non-current assets	228	319	228	319	
TOTAL ASSETS	16,904	22,106	17,057	21,786	
LIABILITIES AND EQUITY					
Current liabilities:					
Trade and other payables 10	2,502	3,028	2,169	2,199	
Total current liabilities	2,502	3,028	2,169	2,199	
Non-current liabilities:					
	-	_	-	_	
Total liabilities	2,502	3,028	2,169	2,199	
EQUITY					
Share capital 11	111,912	104,363	111,912	104,363	
Other reserves	(7,764)	(916)	(7,048)	(260)	
Accumulated deficit	(89,746)	(84,148)	(89,976)	(84,516)	
Total equity attributable to equity holders	14,402	19,299	14,888	19,587	
Minority interest in equity	_	(221)	-	_	
Total equity	14,402	19,078	14,888	19,587	
TOTAL LIABILITIES AND EQUITY	16,904	22,106	17,057	21,786	

Statements of Changes in Equity for the year ended 31 December 2015 28

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
Equity as at 1 January 2014	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)
Equity as at 31 December 2014	104,363	9,677	(10,593)	(84,148)	19,299	(221)	19,078
Shares issued on option exercise	1,211	-,	(**/****/	(,,	1,211	()	1,211
Shares issued in private placement	6,350				6,350		6,350
Share issue costs expensed	(12)				(12)		(12)
Share based payments		1,232			1,232		1,232
Exercised options		(8,020)		8,020	-		-
Loss after income tax for the period				(13,397)	(13,397)		(13,397)
Other comprehensive expenses			(60)	(221)	(281)	221	(60)
Equity as at 31 December 2015	111,912	2,889	(10,653)	(89,746)	14,402	_	14,402



Statements of Changes in Equity

continued

Parent	Share Capital \$'000	Share Option Reserve \$'000	Currency Translation Reserve \$'000	Accumulated Deficit \$'000	Total Attributable to Equity Holders \$'000
Equity as at 1 January 2014	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)
Equity as at 31 December 2014	104,363	9,677	(9,937)	(84,516)	19,587
Shares issued on option exercise	1,211				1,211
Shares issued in private placement	6,350				6,350
Share issue costs expensed	(12)				(12)
Share based payments		1,232			1,232
Exercised options		(8,020)		8,020	-
Comprehensive loss for the period				(13,480)	(13,480)
Equity as at 31 December 2015	111,912	2,889	(9,937)	(89,976)	14,888



³⁰ Statements of Cash Flows

for the year ended 31 December 2015

	Consolidated		Parent	
	2015 \$′000	2014 \$′000	2015 \$′000	2014 \$′000
Cash flows from operating activities:				
Receipts from grants	2,642	3,549	-	_
Interest received	363	569	362	568
GST refunded	92	194	92	194
Payments for employees and directors	(1,993)	(1,488)	(1,993)	(1,488)
Payments to other suppliers	(14,584)	(9,234)	(12,418)	(6,182)
R&D Tax Refund	749	_	749	_
Net cash used in operating activities	(12,731)	(6,410)	(13,208)	(6,908)
Cash flows from investing activities:				
Purchase of property, plant and equipment	(3)	(34)	(3)	(34)
Purchase of intangible assets	-	(3)	-	(3)
Proceeds from sale of property, plant and equipment	4	3	4	3
Advance from subsidiaries	-	_	932	53
Net cash used in investing activities	1	(34)	933	19
Cash flows from financing activities:				
Proceeds from the issue of shares	6,350	_	6,350	_
Proceeds from the exercise of options	1,211	2,270	1,211	2,293
Payment of share issue expenses	(12)	(61)	(12)	(84)
Net cash provided from financing activities	7,549	2,209	7,549	2,209
Net decrease in cash	(5,181)	(4,235)	(4,726)	(4,680)
Effect of exchange rate changes on cash balances	999	680	1,055	630
Cash at the beginning of the year	20,824	24,379	20,236	24,286
Cash at the end of the year	16,642	20,824	16,565	20,236
Reconciliation with loss after income tax:				
Loss after income tax	(13,397)	(8,316)	(13,480)	(9,025)
Non-cash items requiring adjustment:				
Depreciation of property, plant and equipment	17	24	17	24
Amortisation of intangible assets	73	76	73	74
Impairment loss	-	31	-	52
Provision for doubtful debt	-	_	-	901
Share based payment expense	1,232	947	1,232	947
Foreign exchange gain	(1,059)	(817)	(1,056)	(818)
Changes in working capital:				
Trade and other receivables	929	746	36	134
Trade and other payables	(526)	899	(30)	803
Net cash used in operating activities	(12,731)	(6,410)	(13,208)	(6,908)

Notes to the Financial Statements

for the year ended 31 December 2015

1. Nature of business

Neuren Pharmaceuticals Limited (Neuren or the Company, and its subsidiaries, or the Group) is a publicly listed biopharmaceutical company developing 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 2016.

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 2015 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 2015 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.



³² Notes to the Financial Statements

continued

2. Summary of significant accounting policies (continued)

Changes in accounting policies

There were no changes in accounting policies in the year ended 31 December 2015.

New standards first applied in the period

There were no new standards adopted by the group for the first time for the financial year beginning on or after 1 January 2015 which had 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.

(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

The functional and presentation currency of the Company and Group is Australian Dollars.

(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.

Notes to the Financial Statements

continued

2. Summary of significant accounting policies (continued)

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.

(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.

(I) 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.



³⁴ Notes to the Financial Statements

continued

2. Summary of significant accounting policies (continued)

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.

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.

continued

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.

4. Expenses

	Consolidated			Parent	
	2015 \$′000	2014 \$′000	2015 \$'000	2014 \$'000	
Loss before income tax includes the following expenses:					
Depreciation – property, plant and equipment					
Computer equipment	14	21	14	21	
Fixtures and fittings	3	3	3	3	
Total depreciation	17	24	17	24	
Amortisation – intangible assets					
Intellectual property	72	73	72	71	
Software	1	3	1	3	
Total amortisation	73	76	73	74	
Remuneration of auditors (PwC)					
Audit and review of financial statements	52	66	52	66	
Total remuneration of auditors	52	66	52	66	
Employee benefits expense					
Salaries and wages – research & development	961	558	961	558	
Salaries and wages – corporate & adminstrative	406	391	406	391	
Share based payments	757	412	757	412	
Total employee benefits expense	2,124	1,361	2,124	1,361	
Directors' fees					
Directors' fees – research & development	479	405	-	405	
Directors' fees – corporate & administrative	470	480	470	480	
Directors' share based payment compensation	475	475	475	475	
Total Directors' fees	1,424	1,360	945	1,360	
Other shared based payments	-	60	-	60	
Lease expense	165	115	165	115	

³⁶ Notes to the Financial Statements

continued

5. Income tax

	Consolidated			Parent	
	2015 \$′000	2014 \$′000	2015 \$′000	2014 \$'000	
Income tax benefit					
Current tax	(749)	_	(749)	_	
Deferred tax	-	_	-	_	
Income tax benefit	(749)	_	(749)	_	
Numerical reconciliation of income tax benefit to prima facie tax receivable:					
Loss before income tax	(14,146)	(8,316)	(14,229)	(9,025)	
Tax at applicable rates	(4,244)	(2,495)	(4,269)	(2,708)	
Tax effect of amounts not deductible in calculating taxable income:					
Share option compensation	370	284	370	284	
Impairment loss	-	9	_	16	
Provision for doubtful debt	-	_	-	270	
	(3,874)	(2,202)	(3,899)	(2,138)	
Subsidiary tax losses in prior years not recoverable	-	4,319	_	_	
(Over) under provision in prior years	(819)	(497)	(818)	205	
Deferred tax assets not recognised	3,944	(1,620)	3,968	1,933	
Income tax benefit	(749)	_	(749)	-	

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 2015 and 2014, the Company's potentially dilutive ordinary share equivalents (being the options over ordinary shares set out in Note 12) 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.

	Consolidated		
	2015 \$′000	2014 \$′000	
Loss after income tax attributable to equity holders	(13,397)	(8,297)	
Weighted average shares outstanding (basic)	1,680,362,334	1,552,481,203	
Weighted average shares outstanding (diluted)	1,680,362,334	1,552,481,203	
Basic and diluted loss per share	(\$0.008)	(\$0.005)	

7. Cash and cash equivalents

	Consolidated		Parent	
	2015 \$'000	2014 \$'000	2015 \$′000	2014 \$'000
Cash	4,238	8,014	4,161	7,915
Demand and short-term deposits	12,404	12,810	12,404	12,321
	16,642	20,824	16,565	20,236

8. Trade and other receivables

	Consolidated		Parent	
	2015 \$'000	2014 \$'000	2015 \$'000	2014 \$′000
Trade receivables	10	912	9	18
Interest receivables	24	51	24	51
Due from subsidiaries	_	_	231	2,675
Provision for Doubtful debt	-	_	-	(1,513)
	34	963	264	1,231

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.

continued

9. Intangible assets

Consolidated	Intellectual Property \$'000	Acquired Software \$'000	Total \$'000
As at 1 January 2014			
Cost	1,134	7	1,141
Accumulated amortisation	(743)	(4)	(747)
Net Book Value	391	3	394
Movements in the year ended 31 December 2014			
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
As at 31 December 2014			
Cost	1,074	10	1,084
Accumulated amortisation	(787)	(7)	(794)
Net book value	287	3	290
Movements in the year ended 31 December 2015			
Opening net book value	287	3	290
Amortisation	(72)	(1)	(73)
Closing net book value	215	2	217
As at 31 December 2015			
Cost	1,074	10	1,084
Accumulated amortisation	(859)	(8)	(867)
Net book value	215	2	217
Intellectual Property	NNZ-2566		
Opening net book value	287		
Amortisation	(72)		
Closing net book value	215		
Remaining amortisation period	3 years		

The impairment charge of approximately \$31,000 in 2014 relates to the write down to nil recoverable value of the intellectual property owned by the subsidiary Perseis Therapeutics Limited.



continued

9. Intangible assets (continued)

Parent	Intellectual Property \$'000	Acquired Software \$'000	Total \$'000
As at 1 January 2014			
Cost	1,074	7	1,081
Accumulated amortisation	(716)	(4)	(720)
Net Book Value	358	3	361
Movements in the year ended 31 December 2014			
Opening net book value	358	3	361
Additions	-	3	3
Amortisation	(71)	(3)	(74)
Closing net book value	287	3	290
As at 31 December 2014			
Cost	1,074	10	1,084
Accumulated amortisation	(787)	(7)	(794)
Net book value	287	3	290
Movements in the year ended 31 December 2015			
Opening net book value	287	3	290
Amortisation	(72)	(1)	(73)
Closing net book value	215	2	217
As at 31 December 2015			
Cost	1,074	10	1,084
Accumulated amortisation	(859)	(8)	(867)
Net book value	215	2	217

10. Trade and other payables

	Consolidated		Parent	
	2015 \$′000	2014 \$'000	2015 \$'000	2014 \$′000
- Trade payables	1,771	2,755	1,524	1,927
Accruals	648	135	562	134
Employee Benefits	83	138	83	138
Due to subsidiaries	-	_	-	_
	2,502	3,028	2,169	2,199

⁴⁰ Notes to the Financial Statements

continued

11. Share capital

Consolidated and Parent	2015 Shares	2014 Shares	2015 \$′000	2014 \$′000
Issued Share Capital				
Ordinary shares on issue at beginning of year	1,625,241,426	1,512,528,963	104,363	102,177
Shares issued in Loan Funded Share Plan	20,000,000	30,000,000	-	_
Shares issued on option exercise	51,206,757	82,712,463	1,211	2,270
Shares issued in private placement	70,555,555	_	6,350	_
Share issue expenses – cash issue costs	-	-	(12)	(84)
	1,767,003,738	1,625,241,426	111,912	104,363

(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\$)
Outstanding at 1 January 2014	198,419,220	\$0.023	193,419,220	\$0.023
Exercised	(82,712,463)	\$0.027		
Outstanding at 31 December 2014	115,706,757	\$0.019	115,706,757	\$0.019
Lapsed	(2,500,000)	\$0.019		
Exercised	(51,206,757)	\$0.024		
Outstanding at 31 December 2015	62,000,000	\$0.015	62,000,000	\$0.015

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 2015 there were 62,000,000 options outstanding under the Share Option Plan (2014: 99,000,000).

No options were granted during 2015 or 2014.

continued

11. Share capital (continued)

The weighted average remaining contractual life of outstanding share options at 31 December 2015 is 0.8 years (2014: 1.3 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\$)
57,000,000	26/10/2016	0.0130	\$741,000
5,000,000	26/10/2016	0.0377	\$188,500
62,000,000			\$929,500

(c) Loan funded shares

The Company has 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 consultant ("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, interestfree 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 2015 have been issued subject to the following vesting conditions:

a. 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

- b. 50% of the Loan Funded Shares shall each vest where the following performance conditions are met:
 - i. 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
 - ii. Within the Vesting Period, either:
 - 1. 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
 - 2. A material partnering or licensing transaction is concluded.

Before the shares can be issued, the New Zealand Companies Act requires the Company to disclose to shareholders the provision of 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.



⁴² Notes to the Financial Statements

continued

11. Share capital (continued)

Details of the shares issued prior to 31 December 2015, the estimated fair value and variable inputs into the valuation model are shown in the following table:

Number of shares	40 million	30 million	20 million
Issue date	29 May 2013	28 May 2014	7 May 2015
Issue price per share	\$0.039	\$0.092	\$0.082
Share price on date of valuation	\$0.039	\$0.069	\$0.082
Fair value per share	\$0.03	\$0.04	\$0.05
Estimated future volatility	119%	101%	95%

(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 2015, 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%

continued

12. Deferred tax

	Co	nsolidated	Parent		
	2015 \$'000	2014 \$′000	2015 \$′000	2014 \$'000	
Deferred tax asset (liability)					
Amounts recognised in profit or loss					
Provisions and accruals	21	19	21	19	
Intangible assets	206	27	206	27	
Exchange Differences	(321)	(190)	(322)	(190)	
Tax losses	24,582	20,688	24,607	20,688	
	24,488	20,544	24,512	20,544	
Unrecognised deferred tax assets	(24,488)	(20,544)	(24,512)	(20,544)	
Deferred tax asset (liability)	-	-	_	_	
Movements					
Deferred tax asset (liability) at the beginning of the year	-	_	-	_	
Credited (charged) to the income statement (Note 5)	3,944	(1,620)	3,968	1,933	
Change in unrecognised deferred tax assets	(3,944)	1,620	(3,968)	(1,933)	
Deferred tax asset (liability) at the end of the year	-	-	-	-	

The unrecognised deferred tax assets at 31 December 2015 include \$18.1 million (2014: \$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.

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).

					Investment		Amour to p	nt due parent
Name of entity	Date of incorporation	Principle activities	Interest held	Domicile	2015 \$'000	2014 \$'000	2015 \$′000	2014 \$′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 Clinical	100%	USA	-	_	231	1,162
Hamilton Pharmaceuticals Inc.	2-Apr-04	research	100%	USA	4,548	3,868	_	680
Less: Impairment loss and provis	sion for doubtfu	l debt:			(4,548)	(3,868)	-	(680)
Neuren Pharmaceuticals (Australia) Pty Ltd	9-Nov-06	Dormant Preclinical	100%	Australia	-	_	-	_
Perseis Therapeutics Limited	Deregistered	research	72.20%	NZ	N/A	52	N/A	833
Less: Impairment loss and provis	sion for doubtfu	l debt:			N/A	(52)	N/A	(833)

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.

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 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.

Group	Dec 15 \$'000	Dec 14 \$'000
Non-cancellable operating lease commitments		
Not later than one year	74	128
Later than one year and not later than five years	12	85
	86	213

(b) Legal claims

The Company had no significant legal matter contingencies as at 31 December 2015 or at 31 December 2014.

(c) Capital commitments

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



continued

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:

Consolidated and Parent	2015 \$′000	2014 \$′000
Directors:		
Fees and other short term benefits	949	885
Share based payment compensation	475	475
Management:		
Short-term benefits	1,203	948
Share based payment compensation	757	473
	3,384	2,781

As detailed in Note 11 (c), during the year ended 31 December 2015, 20 million (2014: 30 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 \$1,640,000 (2014: \$2,760,000) 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 2015, nil (2014: 4,618,793) equity performance rights (EPR) were issued to KMP. Further details of the terms and conditions of the EPR are disclosed in Note 11 (d).

(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 2015 Neuren Pharmaceuticals Inc charged the Parent fees of US\$1,055,827 (2014: US\$1,088,276) for pharmaceutical research services, and US\$971,623 (2014: US\$nil) for reimbursement of third party development expenses. The Parent charged Neuren Pharmaceuticals Inc fees of US\$56,000 (2014: US\$56,000) for administrative services.

16. Events after balance date

As at the date of these financial statements there were no events arising since 31 December 2015 which require disclosure.

17. Financial instruments and risk management

(a) Categories of financial instruments

	Co	onsolidated	Parent		
	2015 \$′000	2014 \$′000	2015 \$′000	2014 \$′000	
- Financial assets					
Cash and cash equivalents	16,642	20,824	16,565	20,236	
Trade and other receivables	34	963	264	1,231	
Total financial assets (loans and receivables classification)	16,676	21,787	16,829	21,467	
Financial liabilities					
Amortised cost:					
Trade and other payables	2,502	3,028	2,169	2,199	
Total financial liabilities	2,502	3,028	2,169	2,199	



⁴⁶ Notes to the Financial Statements

continued

17. Financial instruments and risk management (continued)

(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.

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 2015, there were no forward contracts outstanding.

During the year, the US dollar strengthened significantly against the Australian dollar. A foreign exchange gain of \$1,081,000 is included in results for the year ended 31 December 2015 (2014: \$876,000). The majority of the gain relates to gains on the revaluation for reporting purposes of the Company's US dollar denominated cash reserves into Australian dollars and a gain on the settlement of a forward contract to purchase US\$3 million on 31 August 2015 at a rate of 0.79, for which the rate on the day of settlement was 0.71.

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

	Co	nsolidated	Parent		
	2015 \$'000	2014 \$'000	2015 \$'000	2014 \$′000	
Assets					
US dollars	4,151	9,387	4,305	9,073	
Liabilities					
US dollars	1,676	2,121	1,344	1,294	

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 \$225,000 (2014: \$661,000). 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 \$275,000 (2014: \$807,000).

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 \$269,000 (2014: \$707,000). 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 \$329,000 (2014: \$864,000).



continued

17. Financial instruments and risk management (continued)

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:

	Co	onsolidated	Parent		
	2015 \$′000	2014 \$′000	2015 \$′000	2014 \$′000	
- Financial assets					
Cash and cash equivalents					
Australian dollar cash deposits	12,491	12,311	12,491	12,311	
Australian dollar interest rate	2.85%	3.47%	2.85%	3.47%	
US dollar cash deposits	4,151	8,499	4,074	7,911	
US dollar interest rate	0.03%	0.03%	0.03%	0.03%	
New Zealand dollar cash deposits	-	14	-	14	
New Zealand dollar interest rate	-	3.22%	-	3.22%	

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 \$33,000 (2014: \$56,000).

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 2015 nil (2014: \$888,000), was receivable from the US government. 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. Refer to Note 1 for inherent uncertainties.

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. Refer to Note 1 for inherent uncertainties.

18. Going concern assumption

In the year ended 31 December 2015, the Group used cash of \$12.7 million in operating activities. Following the raising of \$6.3 million in additional share capital in November 2015, the Group had cash balances at 31 December 2015 of \$16.6 million. In 2016, the Group will continue to invest in research and development and use cash in operating activities. The Directors monitor the Group's cash position and initiatives to ensure that adequate funding continues to be available for the Group to meet its business objectives. In January 2016 Neuren engaged Leerink Partners, a leading US investment banking firm specializing in healthcare, as its corporate adviser to assist the Directors in evaluating all future options available to the Group. Such options may include transactions that will provide additional share capital or revenue. The timing and terms of any such transactions are presently unknown, however the Directors have a view that a transaction will proceed successfully. After making enquiries, and considering the uncertainties described above, the Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future, without a material dependency on a transaction proceeding or additional capital or funding being made available. For these reasons, they continue to adopt the going concern basis in preparing these financial statements. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or to the amounts and classification of liabilities that may be necessary should the Group be unable to continue as a going concern.



⁴⁸ Independent Auditors' Report



Independent Auditors' Report

to the shareholders of Neuren Pharmaceuticals Limited

Report on the Consolidated Financial Statements

We have audited the consolidated financial statements of Neuren Pharmaceuticals Limited ("the Company") on pages 26 to 47, which comprise the consolidated statement of financial position as at 31 December 2015, the consolidated statement of comprehensive income, the consolidated statement of movements in equity and the consolidated 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 2015 or from time to time during the financial year.

Directors' Responsibility for the Consolidated Financial Statements

The Directors are responsible on behalf of the Company for the preparation and fair presentation of these consolidated financial statements in accordance with New Zealand Equivalents to International Financial Reporting Standards and International Financial Reporting Standards and for such internal controls as the Directors determine are necessary to enable the preparation of consolidated 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 consolidated 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 consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditors' judgement, including the assessment of the risks of material misstatement of the consolidated 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 and fair presentation of the consolidated financial statements 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 consolidated financial statements.

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

We are independent of the Group. Other than in our capacity as auditors and providers of other related assurance services we have no relationship with, or interests in, the Group.

PricewaterhouseCoopers, 188 Quay Street, Private Bag 92162, Auckland 1142, New Zealand T: +64 9 355 8000, F: +64 9 355 8001, pwc.co.nz

Independent Auditors' Report

continued



Independent Auditors' Report

Neuren Pharmaceuticals Limited

Opinion

In our opinion, the consolidated financial statements on pages 26 to 47 present fairly, in all material respects, the financial position of the Group as at 31 December 2015, and its financial performance and cash flows for the year then ended in accordance with New Zealand Equivalents to International Financial Reporting Standards and International Financial Reporting Standards.

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 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.

Incenterhure Capers.

Chartered Accountants 24 February 2016

Auckland



⁵⁰ Additional Information

Equity Securities Held by Directors as at 24 February 2016

	Interests Ordinary S		Interests in Options		Interests ir Equity Performanc	
Director	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	_	_	_	-

On 5 February 2015, Larry Glass acquired 20,000,000 shares, issued on the exercise of options to acquire ordinary shares at an exercise price of \$0.03 per share, and sold 35,000,000 options to acquire ordinary shares for consideration of \$0.137 cents per share.

Directors of subsidiary companies at 31 December 2015

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

The director's remuneration for the year to Larry Glass disclosed on page 24 was received from Neuren Pharmaceuticals Inc. During the year, no donations were made by subsidiary companies, no amounts were payable to an auditor and the subsidiary companies had no employees.

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, Financial Markets Conduct Act 2013, Securities Act 1978, Takeovers Act 1993, Overseas Investment Act 1973, Commerce Act 1986 and various regulations and codes promulgated under such Acts.

Corporations Act, Australia – Directors' declaration

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

- 1. The financial statements on pages 26 to 47 of Neuren and its subsidiaries for the year ended 31 December 2015 and the notes to those financial statements:
 - (a) comply with the accounting standards issued by the Institute of Chartered Accountants of New Zealand; and
 - (b) give a true and fair view of the financial position as at 31 December 2015 and of the performance for the year ended on that date of Neuren and its subsidiaries.
- 2. 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 2016.

On behalf of the Board

N

Dr Richard Treagus Chairman



Additional Information

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 30 March 2016.

The number of ordinary shareholdings held in less than marketable parcels at 30 March 2016 was 461, holding 688,338 ordinary shares.

Distribution of security holders

Ordinary shares

Size of holding	Number of ordinary shares	%	Number of holders	%
	1,663,074,917	94.12	1,245	26.95
10,001 to 100,000	97,556,879	5.52	2,150	46.54
5,001 to 10,000	4,713,403	0.27	568	12.29
1,001 to 5,000	1,614,330	0.09	406	8.79
1 to 1,000	44,209	0.00	251	5.43
Total	1,767,003,738	100.00	4,620	100.00

Unquoted options to acquire ordinary shares

Size of holding	Number of options	%	Number of holders	%
100,001 and Over	62,000,000	100.00	3	100.00
Total	62,000,000	100.00	3	100.00

Unquoted equity performance rights to acquire ordinary shares (EPR)

Size of holding	Number of EPR	%	Number of holders	%
	14,234,178	100.00	4	100.00
Total	14,234,178	100.00	4	100.00

Substantial Security Holders

Langley Alexander Walker – relevant interest in 327,342,357 ordinary shares at 30 March 2016.

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Twenty largest holders of ordinary shares

Twenty largest holders of ordinary shares:	Number of ordinary shares	% of issued share capital
AUCKLAND TRUST COMPANY LIMITED	305,092,357	17.27%
UBS NOMINEES PTY LTD	71,024,444	4.02%
CAMERON RICHARD PTY LTD	70,418,018	3.99%
ESSEX CASTLE LIMITED	45,707,595	2.59%
CITICORP NOMINEES PTY LIMITED	42,279,510	2.39%
NEUREN TRUSTEE LIMITED	90,000,000	5.09%
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	38,629,120	2.19%
INVESTMENT CUSTODIAL SERVICES LIMITED	29,611,730	1.68%
SMITHLEY SUPER PTY LTD	28,450,000	1.61%
WALKER GROUP HOLDINGS PTY LTD	22,250,000	1.26%
NATIONAL NOMINEES LIMITED	21,105,400	1.19%
LINWIERIK SUPER PTY LTD	21,000,000	1.19%
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSCO ECA	20,314,451	1.15%
LARRY GLASS	20,000,000	1.13%
DR TREVOR SCOTT	20,000,000	1.13%
FORSYTH BARR CUSTODIANS LTD	19,076,226	1.08%
ROXTRUS PTY LIMITED	19,000,000	1.08%
J P MORGAN NOMINEES AUSTRALIA LIMITED	17,086,286	0.97%
VLADIMIR EFROS	13,666,146	0.77%
BNP PARIBAS NOMS PTY LTD	12,640,521	0.72%
Total	927,351,804	52.48%
Balance of share register	839,651,934	47.52%
Total issued share capital	1,767,003,738	100.00%





pharmaceuticals

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