neuren

pharmaceuticals

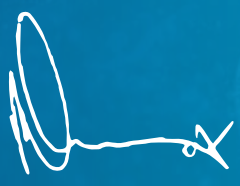
ANNUAL REPORT 2018

Neuren Pharmaceuticals Limited

Neuren Pharmaceuticals is a biopharmaceutical company developing new therapies for debilitating neurodevelopmental disorders that are characterised by impaired connections and signalling between brain cells. Incorporated in New Zealand and based in Melbourne, Australia, Neuren is listed on the ASX under the code NEU.

The Board of Directors is pleased to present the Annual Report of Neuren Pharmaceuticals Limited for the year ended 31 December 2018, authorised on 24 April 2019.

For, and on behalf of, the Board



Dr Richard Treagus
Chairman

Dr Trevor Scott
Director

WHY INVEST IN NEUREN?

Two drugs (trofinetide and NNZ-2591) targeting broad impact on debilitating childhood disorders with urgent unmet need

- Regulatory incentives – Orphan Drug, Fast Track, Priority Review
- Strong support from advocacy groups and leading physicians
- Protected by Orphan Drug exclusivity periods as well as issued patents

Trofinetide in Phase 3, with US commercial partner secured

- ACADIA Pharmaceuticals provides capabilities, strategic intent and funding required to bring trofinetide to market in the US
- ACADIA commencing Rett syndrome Phase 3 trial in 2019
- Neuren receives double digit percentage royalties on all sales of trofinetide in North America, plus payments of up to US$455 million (approximately A$640 million) on achievement of development and annual sales milestones, plus one third of the value of any Rare Pediatric Disease Priority Review Voucher
- Neuren retains 100% of value of trofinetide outside North America

NNZ-2591 advancing to clinical trials in neurodevelopmental disorders

- Recent positive results in model of Phelan-McDermid syndrome, a disorder related to autism with high unmet need
- Following first payment from ACADIA, Neuren had $24 million cash at 31 December 2018, enabling acceleration to clinical trials in 2020

CHAIRMAN'S LETTER

DR RICHARD TREAGUS

During the past year, Neuren's business has made substantial progress and based on fundamentals alone is in its strongest position yet. We now have a late-stage drug in development for a condition with high unmet need commencing Phase 3 later this year and is fully funded by a highly capable US partner, we have a commercial partnership in place that can deliver revenue to Neuren of many hundreds of millions of dollars if the drug is successful in the US, we have retained the strategically important rights to trofinetide outside North America and we have secured non-dilutive funding enabling us to advance our second very promising drug NNZ-2591 into human clinical trials.

Notwithstanding our very much stronger position, we have received a stark reminder that in small companies with relatively low liquidity the price at which shares are traded may not always appropriately reflect the intrinsic risk-adjusted value of the assets. As shareholders ourselves and owning approximately 10% of Neuren, the board and management are extremely disappointed with the price the market has placed on Neuren since the deal with ACADIA in August 2018 was announced. Our confidence in ACADIA's strength and capabilities has increased since entering into the partnership and the collaboration between our companies is both strong and productive. Back in August ACADIA was for a period of time negatively impacted by some adverse publicity, which we judged to be incorrect. ACADIA's position was soon thereafter clarified with the FDA, and this was followed by positive clinical trial results and a successful capital raising. ACADIA has a current market capitalisation of more than US$3.5 billion.

The board recently appointed Torreya, a global investment bank specialising in life sciences, as Neuren's corporate advisor and we are now working closely with Torreya to identify and evaluate all potential corporate transactions including individual products, territories, or Neuren's entire business.

We continue to work very effectively with the ACADIA team as they prepare for the Rett syndrome Phase 3 trial. The final design of the trial which has been agreed with the FDA was well informed by the results of Neuren's ground-breaking Phase 2 pediatric trial, which were recently published in *Neurology®*, the most widely read and highly cited peer-reviewed neurological journal. In the United States this publication has received favourable commentary and been widely reported in medical and industry media.

We are also very excited about the prospects of our second drug NNZ-2591. Enabled by the funding we received from the ACADIA partnership we are executing the required non-clinical development as quickly as we can in order to advance it into human clinical trials. The recent results in the *Shank3* model of Phelan-McDermid syndrome were very promising and we look forward to working with physicians and families as we expand Neuren's business into additional neurodevelopmental disorders with a high unmet need.

During the year we made a number of changes to our board of directors to achieve a composition that we felt best meets the needs of the business as we move forwards to the next stage. The new board has a majority of independent non-executive directors as well as a good mix of pharmaceutical and commercial experience. I would like to thank my fellow directors and Neuren's management for their commitment and achievements during this pivotal year for the business.

We now look forward to commencement of the Rett syndrome Phase 3 trial, evaluating potential commercial partnerships for trofinetide in Europe and Japan and advancing NNZ-2591 into clinical trials. In parallel we will continue to actively promote the very strong position of the Company and build support from a broader range of biotech investors.

Dr Richard Treagus
Chairman

OPERATING REVIEW

COMMERCIAL STRATEGY

Neuren has two novel patented drugs, trofinetide and NNZ-2591, which potentially have broad utility in the treatment of neurological disorders. Each drug is currently in development to treat debilitating neurodevelopmental disorders that emerge in early childhood, for which there are currently no approved drug therapies. The disorders stem from problems in brain development which lead to a wide range of serious issues, both physical and mental.

Neurodevelopmental disorders are caused by different genetic mutations, but in many cases they share similar symptoms and the common characteristic of impaired connections and signalling between brain cells. Trofinetide and NNZ-2591, which are synthetic analogues of important molecules that occur naturally in the brain, induce improvements in the impaired connections and signalling, which means that the target is a broad improvement in the underlying disorder rather than aiming to treat one symptom.

A critical feature of Neuren's work to develop therapies for these disorders is close collaboration with the leading specialist physicians and with the well-organised patient advocacy organisations.

Neuren's strategy is to commercialise these therapies in global pharmaceutical markets through partnerships with established companies in those markets, leveraging the expertise, infrastructure and financial capacity of those companies. In August 2018, Neuren executed a very important partnership with NASDAQ-listed ACADIA Pharmaceuticals for trofinetide in North America, which enabled Neuren to transition into a fundamentally stronger position. The many benefits of the partnership are described in detail later in this Operating Review.

Neuren completed Phase 2 development for trofinetide to treat Rett syndrome and ACADIA is scheduled to start the Phase 3 trial in the second half of 2019. A Phase 2 clinical trial has also been conducted in Fragile X syndrome. Currently, there are no drugs approved for 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.

As these are serious medical conditions with unmet need, drugs being developed to treat them qualify for favourable regulatory pathways intended to expedite the development and approval of therapeutically important drugs.

The US Food and Drug Administration (FDA) 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 traumatic brain injury

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, plus 6 months if approved for paediatric use, as well as waiver of the prescription drug user fee for a marketing application.

OPERATING REVIEW

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

The European Medicines Agency has 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, plus 2 years if authorised for paediatric use.

These 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. Neuren also owns issued patents that expire in 2032 concerning the use of trofinetide to treat Rett syndrome and Fragile X syndrome in the United States; autism spectrum disorders in Europe; Rett syndrome, Fragile X syndrome and autism in Japan; and autism spectrum disorders in Australia. Patent applications for trofinetide in autism spectrum disorders are still under examination in Canada, Brazil and Israel.

For NNZ-2591, Neuren owns issued composition of matter patents in the United States, Europe and Japan which expire in 2024, with the potential to extend to 2029. Neuren also owns an issued patent that expires in 2034 concerning the use of NNZ-2591 to treat neurodevelopmental disorders in the United States. Patent applications for NNZ-2591 in neurodevelopmental disorders are still under examination in Europe and Japan.

PRODUCT PIPELINE

Compound	Indication	Preclinical and Phase 1	Phase 2	Phase 3	Commercial Partner
Trofinetide	Rett syndrome			Commencing trial in H2 2019	ACADIA Pharmaceuticals *(North America)*
Trofinetide	Fragile X syndrome				ACADIA Pharmaceuticals *(North America)*
NNZ-2591	Phelan-McDermid syndrome				
NNZ-2591	Other neurodevelopmental disorders				

OPERATING REVIEW

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ACADIA PARTNERSHIP

In August 2018 Neuren secured the considerable funding and additional capabilities required to bring trofinetide to the US market by entering into a partnership with ACADIA Pharmaceuticals, under which ACADIA has exclusive rights to trofinetide in all indications for the United States, Canada and Mexico. Important factors for Neuren were the proven capabilities within the ACADIA team in the development and commercialisation of novel neurology therapies in the US, their strong commitment to achieve a treatment option for Rett syndrome patients, and the strategic importance that ACADIA attaches to trofinetide. In the partnering agreement, as well as securing significant participation in the future value of trofinetide in the US, Neuren retained all rights to countries outside North America.

A redacted version of the licence agreement with ACADIA was filed with the US Securities and Exchange Commission as a material contract exhibit to ACADIA's Annual Report on Form 10-K, which is available to view via the SEC Filings section of ACADIA's website.

The partnership with ACADIA has provided five key financial benefits to Neuren:

1. ACADIA is investing circa. US$55 million (approximately A$77 million) into the Rett syndrome Phase 3 program. This would otherwise have been a minimum capital raise requirement for Neuren in order to continue development for Rett syndrome.
2. Receipt of the first payment from ACADIA of $13.5 million provided non-dilutive funding necessary for Neuren to retain ownership and advance the development of NNZ-2591 as a therapy for neurodevelopmental disorders, which is now a major focus for the Company.
3. ACADIA provides expert execution capabilities in the US for Phase 3 and commercialization of trofinetide. The Neuren and ACADIA teams are collaborating very effectively, including the ongoing preparations for the Rett syndrome Phase 3 trial, due to commence in the second half of 2019.
4. Neuren secured strong participation in the future value of trofinetide in the US through the following:
   - Double digit percentage royalties on sales of trofinetide in all indications. The annual sales are recorded in tiers and an escalating percentage is applied to each successive tier. ACADIA has stated the peak annual sales potential for Rett syndrome alone as being more than US$500 million. There are about 4 times as many patients with Fragile X as with Rett syndrome.
   - Payments of up to US$455 million (approximately A$640 million) on achievement of development and annual sales milestones. US$105 million is to be paid on achievement of development milestones, split between Rett and Fragile X. The remaining US$350 million, is to be paid on achievement of a series of 4 thresholds of total annual sales. If both indications are approved in the US, Neuren expects to collect all of these payments.
   - One third of the market value of any Rare Pediatric Disease Priority Review Voucher, if awarded to ACADIA by the US Food and Drug Administration upon approval of a New Drug Application for trofinetide. These vouchers are tradeable and those on-sold in 2017 fetched between US$110 million and US$150 million.
5. Neuren retained 100% of the rights to trofinetide outside North America, with free and full access to utilise the US regulatory package for registration in other territories. This has enabled Neuren now to pursue additional value from further commercial partnerships in those territories.

OPERATING REVIEW

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TROFINETIDE FOR RETT SYNDROME

About Rett syndrome

Rett syndrome is a seriously debilitating and life-threatening neurological disorder, for which there are no approved medicines. It is first recognized in infancy and seen predominantly in girls, but can occur very rarely in boys. At diagnosis, Rett syndrome has often been misdiagnosed as autism, cerebral palsy, or non-specific developmental delay. Most cases of Rett syndrome are caused by mutations on the X chromosome on a gene called *MECP2*. Rett syndrome strikes all racial and ethnic groups and has been estimated to occur worldwide in 1 of every 10,000 to 15,000 female births, causing problems in brain function that are responsible for cognitive, sensory, emotional, motor and autonomic function. These problems can include learning, speech, sensory sensations, mood, movement, breathing, cardiac function, and even chewing, swallowing, and digestion. Rett syndrome symptoms appear after an early period of apparently normal or near normal development until six to eighteen months of life, when there is a slowing down or stagnation of skills. A period of regression then follows, with loss of communication skills and purposeful hand use, loss or impairment of walking, and the onset of stereotypic hand movements. Other problems frequently include seizures and erratic breathing patterns, an abnormal side-to-side curvature of the spine (scoliosis), and sleep disturbances.

Partnership with Rettsyndrome.org

Rettsyndrome.org has provided valuable advice to Neuren on clinical trial strategy, introductions to leading clinical investigators, a start-up grant to Baylor College of Medicine for Neuren's first Phase 2 trial, and a grant towards the cost of Neuren's second Phase 2 trial in pediatric subjects. The ongoing support from Rettsyndrome.org has been instrumental in Neuren's discussions with the FDA and in communications with families, patients and investigators. This was reflected in the rapid enrolment of 82 subjects in seven months for the pediatric trial. Neuren has every reason to believe this will continue to be a very productive partnership as ACADIA moves into the Phase 3 trial.

Phase 2 paediatric trial published in *Neurology*®, the Medical Journal of the American Academy of Neurology

Neuren's Phase 2 trial in paediatric Rett syndrome was recently published online with free access and appeared in the 16 April 2019 issue of *Neurology*. This publication (Glaze et al. 2019) in the most widely read and highly cited peer-reviewed neurology journal provides strong validation of the results from Neuren's ground-breaking work in Rett syndrome. The publication was also featured in an editorial titled "Turning the tide on targeted treatments for neurodevelopmental disorders" and in the "in-focus" section of the journal. The publication has been widely reported in the US media.

A further article appeared in the March 2019 *Rare Neurological Disease Special Report – a supplement to Neurology Reviews*, authored by Neuren, ACADIA and Rettsyndrome.org (Glass et al. 2019). The article "Pathophysiology of Rett Syndrome" explained the biochemistry of Rett syndrome and the potential role of IGF-1 and trofinetide.

The Phase 3 program

The Phase 3 program has been agreed with the FDA Division of Neurology Products. Recognising the urgent unmet need and the small population, it involves a single trial rather than the standard 2 trials and provision for a smaller than standard safety database.

ACADIA is scheduled to commence the randomised double-blind placebo-controlled Phase 3 trial in the second half of 2019, with the following key features:

- Approximately 180 female participants in the US, aged 5 to 20, randomised into one active group and a placebo group
- Rett Syndrome Behaviour Questionnaire (RSBQ) and Clinical Global Impression – Improvement Scale (CGI-I) after 12 weeks of treatment as co-primary efficacy endpoints
- Optimised weight-banded dosing

The Phase 3 study will be followed by a nine month open label extension study in which all participants, including those on placebo in the Phase 3 study, will be eligible to receive trofinetide. In the open label extension study, all participants will be followed to evaluate long term tolerability and safety of trofinetide.

If results from the Phase 3 trial are positive, ACADIA expects to file a marketing application with the FDA in 2021. As an Orphan Drug, the application will qualify for an expedited Priority Review period of 6 months.

Results of Neuren's Phase 2 paediatric trial highly relevant for Phase 3

Neuren's Phase 2 trial was a double-blind, randomized, placebo-controlled study that tested three doses of trofinetide compared with placebo in 82 girls with Rett syndrome aged 5 to 15. Trofinetide was well tolerated and had a good safety profile in these younger subjects, with no dose-limiting effects observed. The highest dose achieved statistically significant and clinically relevant benefit compared with placebo measured by each of RSBQ (an assessment by the caregiver) and CGI-I (an assessment by the physician). The improvement increased through to the time that treatment ceased after 6 weeks, suggesting that further benefit may be achieved with a longer treatment duration.

OPERATING REVIEW

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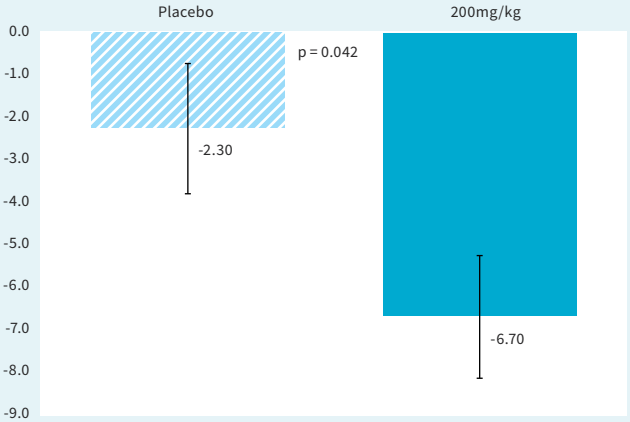
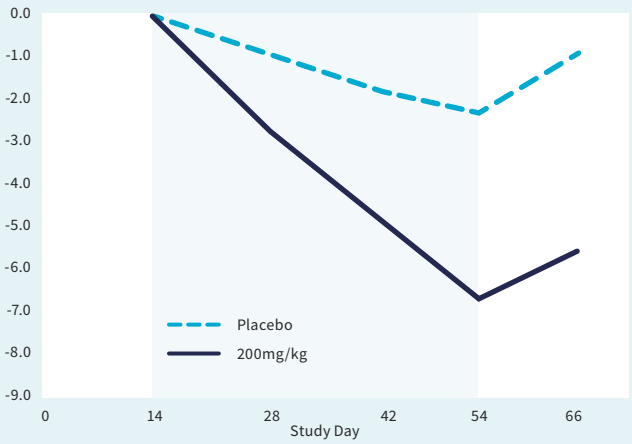
These efficacy results are illustrated in the following charts, in which a downward movement represents an improvement from day 14 baseline and study day 54 to 66 is the period after treatment ceased:

RSBQ

Day 54 Change (LSmeans) from Treatment Baseline

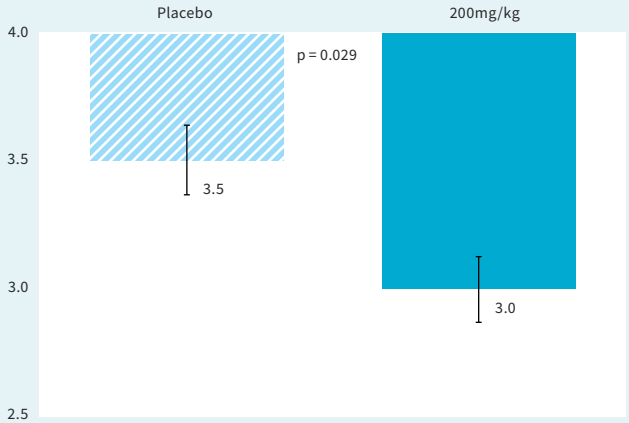


Change (LSmeans) from Treatment Baseline

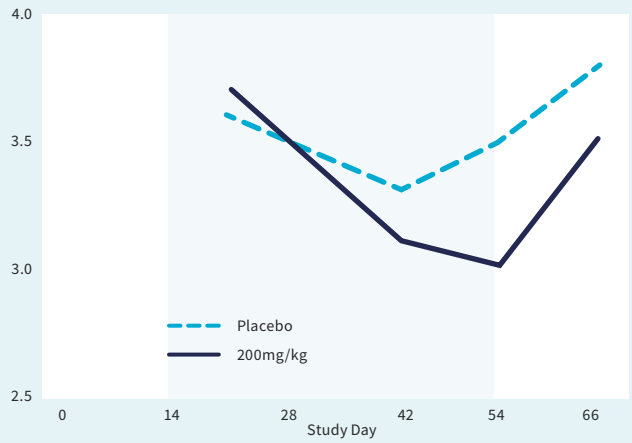


CGI-I

Day 54 Change (LSmeans) Compared to Treatment Baseline



CGI-I (LSmeans) Compared to Treatment Baseline



22% of subjects in the 200mg/kg dose group received a CGI-I score of 2 (“much improved”) compared with 4% of subjects in the placebo group.

It was observed that lighter subjects experienced lower levels of drug in their blood compared with heavier subjects receiving the same dose per kg. This meant that lighter subjects received lower than expected exposure to drug.

Building on the Phase 2 trial, the Phase 3 trial design has four important features:

- RSBQ and CGI-I will be the primary efficacy endpoints
- The sample size will be more than 3 times larger, greatly increasing the statistical power to detect a treatment effect
- The treatment period of 12 weeks will be twice as long as Phase 2
- Weight banded dosing will mean that lighter subjects receive a higher dose and are expected to achieve exposure comparable with heavier subjects.

OPERATING REVIEW

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Manufacturing and non-clinical

During the year, Neuren invested significant time and funds into the manufacturing program and the non-clinical studies required to enable the Phase 3 trial. For manufacturing this encompassed the optimisation and increase to commercial scale of the drug substance synthesis and the development of the commercial finished product presentation. That responsibility passed to ACADIA following commencement of the partnership, with Neuren continuing to provide assistance and complete some in-progress activities.
For non-clinical development Neuren completed the second chronic dosing toxicity study that is required prior to dosing for the longer period in a Phase 3 trial and to support a New Drug Application.

TROFINETIDE FOR 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 caused by a gene defect on the X chromosome that impacts the FMRP protein, which is responsible for regulating the synapses of nerve cells. 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 characterized by intellectual disability, hyperactivity and attentional problems, autistic symptoms, anxiety, emotional lability and epilepsy. Currently, there are no medicines approved for the treatment of Fragile X syndrome.

Neuren previously conducted a randomized, double-blind, placebo-controlled Phase 2 clinical trial in 70 males aged 12 to 45 years with a confirmed diagnosis of Fragile X syndrome. The trial was conducted in the United States and was overseen by leading clinical experts in Fragile X syndrome. Two dose levels of trofinetide were tested and compared with placebo. Trofinetide was very well tolerated and the high dose demonstrated a consistent pattern of clinical improvement, observed in both clinician and caregiver assessments. After a relatively short treatment period of 28 days, improvements were seen across core symptoms of Fragile X syndrome, including higher sensory tolerance, reduced anxiety, better self-regulation and more social engagement.

The FDA Division of Psychiatry Products required the chronic dosing toxicity studies that have recently been completed for the Rett syndrome Phase 3 trial to be completed before a clinical trial of longer duration could be conducted in children with Fragile X syndrome. The next Fragile X trial also requires drug supply from the commercial process being developed to supply the Rett syndrome Phase 3 trial. In the meantime, Neuren is working with ACADIA to design the most efficient development program for Fragile X.

NNZ-2591 IN PHELAN-MCDERMID SYNDROME AND OTHER NEURODEVELOPMENTAL DISORDERS

The funds of $13.5 million received as the first payment from ACADIA in August 2018 have enabled Neuren to advance NNZ-2591 as quickly as possible to clinical trials. The program of standard non-clinical safety studies required is in progress, with the aim of filing an Investigational New Drug application (IND) with the FDA and commencing clinical trials in 2020. In addition to preclinical evidence of strong therapeutic potential in a range of applications and a promising safety profile, Neuren expects that NNZ-2591 may have technical and commercial advantages compared with trofinetide due to its physical and biochemical characteristics.

In February 2019, Neuren announced positive effects of NNZ-2591 in the *Shank3* knockout mouse model of Phelan-McDermid syndrome (PMS). PMS is a rare genetic condition caused by a deletion or other change in the 22q13 region of chromosome 22, which includes the *SHANK3* gene, or a mutation of the gene. PMS is also known as 22q13 deletion syndrome. The *SHANK3* gene codes for the Shank3 protein, which supports the structure of synapses between nerve cells in the brain and the function of other critical synaptic proteins. The most common characteristics of PMS are intellectual disability, delayed or absent speech, symptoms of autism, low muscle tone, motor delays, and epilepsy. There is currently no treatment specifically for PMS.

The study compared normal mice (“wild type”) and mice with a disrupted *Shank3* gene (“knockout”). In the knockout mice, deficits in anxiety, repetitive behaviour, motor performance and social interaction were restored to the wild type state following treatment with NNZ-2591 for 3 weeks. Treated knockout mice also showed a 60% reduction in susceptibility to seizures. In addition, the abnormal length of dendritic spines between brain cells, the excess activated ERK protein (pERK) and the depressed level of IGF-1 in the knockout mice were all normalised after treatment with NNZ-2591.

Neuren anticipates that PMS meets the criteria for Orphan Drug designation. It is estimated that 1% of people with autism have PMS, which implies that between 1 in 8,000 and 1 in 15,000 people have PMS. This may be an underestimate since not all patients with PMS are autistic. Neuren is also investigating the effects of NNZ-2591 in models of other neurodevelopmental disorders, with a view to initiating clinical trials in more than one indication.

OPERATING REVIEW

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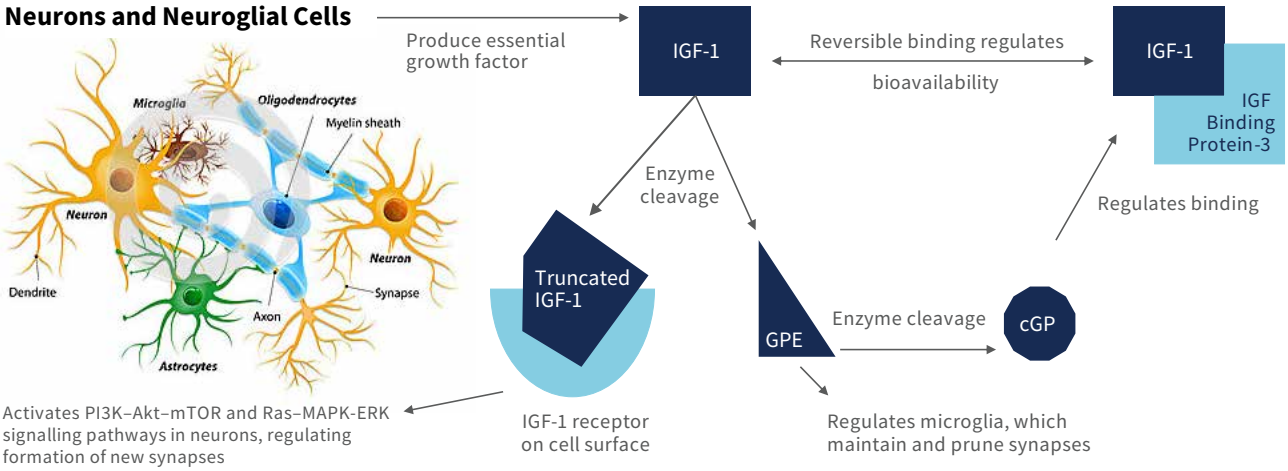
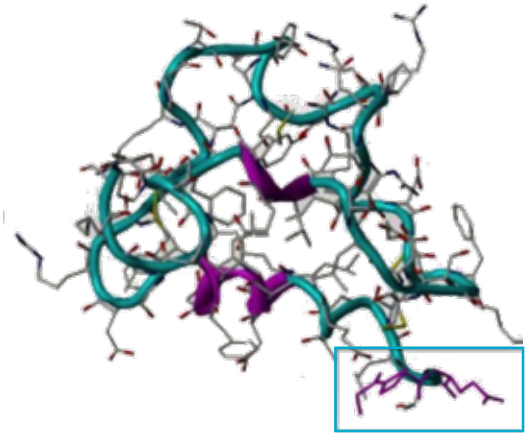
THE SCIENCE BEHIND NEUREN'S PRODUCTS

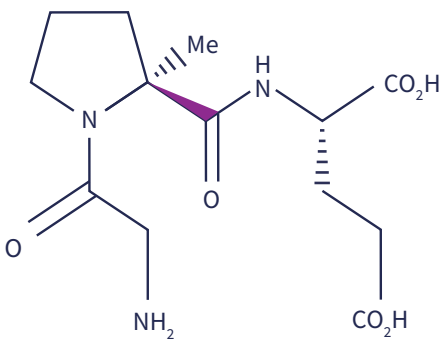
Trofinetide (also known as NNZ-2566) and NNZ-2591 are synthetic analogues of glypromate ("GPE") and cyclic glycine-proline ("cGP") respectively, each of which occurs naturally in the brain and is related to IGF-1. IGF-1 is a growth factor stimulated by growth hormone. In the central nervous system, IGF-1 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 is rapidly broken down by an enzyme into two separate molecules, GPE and Des(1-3) IGF-1. GPE is further metabolised to cGP. All three 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. During development, the brain and the cells that comprise it change rapidly and in complex ways. IGF-1 and its metabolism play a significant role in regulating these changes. In the mature brain, it plays an important role in responding to disease, stress and injury.



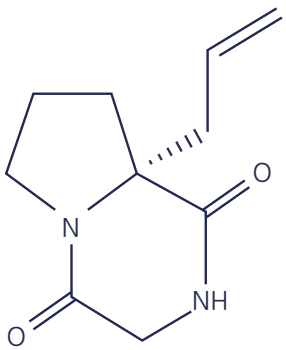
Trofinetide and NNZ-2591 mimic the natural function of GPE and cGP in the brain. Small modifications result in the drugs having an increased half-life in the circulation, better stability for longer and easier storage and shipping, and suitability for use as an oral medication, whereas the naturally occurring molecules and IGF-1 itself can only be administered by injection.

IGF-1





trofinetide



NNZ-2591

OPERATING REVIEW

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Whereas most drugs typically exert a specific effect on a specific target, trofinetide and NNZ-2591 exert several effects which collectively can help to control or normalise abnormal biological processes in the brain.

Although different conditions – brain injury, neurodevelopmental disorders and neurodegenerative diseases – can result in very different symptoms and outcomes, many share common, underlying pathological features. These include inflammation, over-activation of microglia, dysfunction of synapses (the connections between neurons through which information is transmitted) and reduced levels of IGF-1. In other words, diseases and conditions that manifest differently are considered to arise from similar pathology at the cellular and molecular level.

In models of the genetic mutations that cause neurodevelopmental disorders, including Rett syndrome (*MeCP2*), Fragile X syndrome (*Fmr1*) and Phelan-McDermid syndrome (*Shank3*), treatment with GPE and cGP or their analogues trofinetide and NNZ-2591 has fully or partially corrected the following four hallmark pathological features restoring the natural balance of brain function:

1. Inflammation

Inflammation in the brain (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 and NNZ-2591 have shown an ability to significantly reduce the levels of inflammatory cytokines. This has resulted in improvement in a wide range of symptoms including post-traumatic seizures, anxiety, memory impairment and hyperactivity.

OPERATING REVIEW

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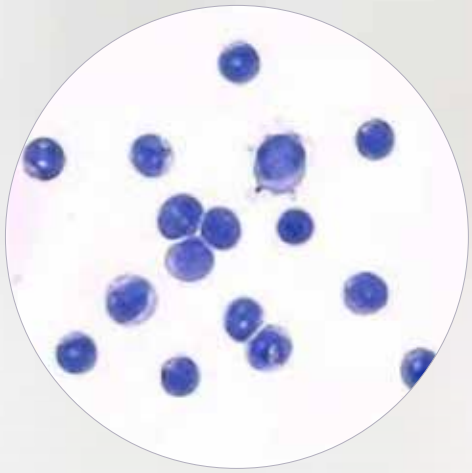
2. Over-activation of microglia

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

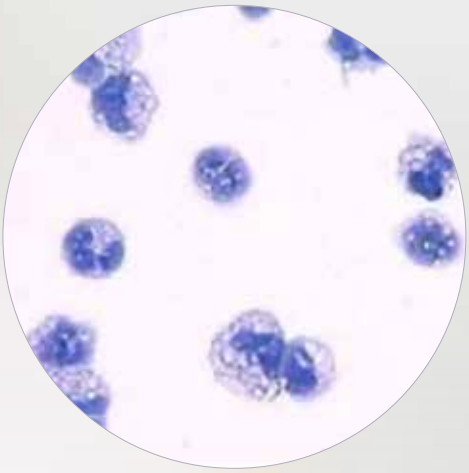
Microglia are not only activated in response to infection and injury. They also are activated by inflammation that accompanies acute brain injury and chronic conditions. In this activated state, they not only lose their ability to effectively perform their normal function in synaptic maintenance but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

Trofinetide and NNZ-2591 have been shown to normalize 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.

Resting Microglial Cells



Activated Microglial Cells



OPERATING REVIEW

CONTINUED

3. Dysfunction of synapses

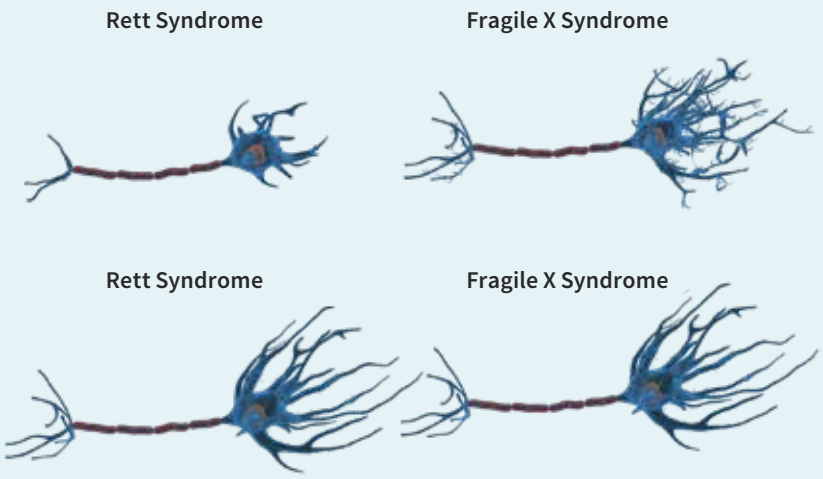
Neurons communicate with each other by chemical and electrical signals transmitted via synapses. Normal synaptic function is essential for healthy brain function and underlies memory, cognition, behaviour and other brain activities. Normal synaptic function requires that the dendrites (part of the neurons) 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 a model of Fragile X syndrome.

In models of Fragile X syndrome and Phelan-McDermid syndrome, NNZ-2591 normalised an excessive level of activated ERK enzyme (pERK), which has been implicated in abnormal synaptic signalling.

Illustration of effect on dendrites



With introduction of Trofinetide

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 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 normalized 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.

OPERATING REVIEW

CONTINUED

FINANCE

Following the ACADIA partnership, Neuren ended 2018 in a much stronger financial position, with cash reserves of $23.6 million, cash inflow from operations of $6.4 million and cash inflow from financing of $11.7 million.

Summary of consolidated financial results for the year to 31 December 2018

	2018 $'m	2017 $'m
Interest income	0.2	–
Revenue from licence agreement	13.5	–
Foreign exchange gain	1.0	–
Australian R&D tax incentive	0.5	0.6
Gains on financial assets measured at fair value through profit or loss	–	9.5
Total revenue	**15.2**	**10.1**
Research & Development	(6.1)	(5.1)
Corporate & Administration	(2.1)	(1.5)
Foreign exchange loss	–	(0.2)
Losses on financial assets measured at fair value through profit or loss	(3.9)	–
Profit before and after tax	**3.1**	**3.3**
Operating cash inflow / (outflow)	6.4	(5.6)
Financing cash inflow	11.7	5.3
Effect of exchange rates on cash balances	0.7	(0.1)
Cash at 31 December	**23.6**	**4.7**

The profit after tax for the year ended 31 December 2018 was $3.1 million compared with $3.3 million in 2017. Revenue of $13.5 million was received under the licence agreement with ACADIA (2017: nil) and foreign exchange gains were $0.9 million compared with foreign exchange losses of $0.2 million in 2017. These were offset by an increase of $1.0 million in research and development costs, resulting from higher expenditure on manufacturing scale-up and non-clinical toxicity studies, and a loss of $3.9 million compared with a gain of $9.5 million in 2017 on the fair value of the remaining settlements from Lanstead Capital under the Sharing Agreement that was entered into as part of the capital raising in July 2017. Prudent control of expenditure continues to be an important principle in the Group's operations and financing.

Cash reserves at 31 December 2018 were $23.6 million (2017: $4.7 million). Cash generated from operations was $6.4 million, compared with cash outflow of $5.6 million in 2017, due mainly to the receipt of $13.5 million from ACADIA. Financing provided cash of $11.7 million, comprising $5.3 million from the issue of shares in May 2018 under the exclusivity deed with ACADIA and $6.4 million from settlements under the Lanstead Sharing Agreement, compared with cash of $5.3 million in 2017, including $3.9 million under the Lanstead agreement. At 31 December 2018, Neuren had already received $10.3 million from Lanstead with 6 settlements still to be received in the first half of 2019.

LEADERSHIP TEAM

BOARD

1. DR RICHARD TREAGUS

Executive Chairman

BScMed, MBChB,
MPharmMed, MBA

Richard 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. Richard 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 Richard 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. Richard is Chairman of BTC Health Limited, which is listed on the ASX.

2. DR TREVOR SCOTT

Non-Executive Director

MNZM, LLD (Hon), BCom, FCA, FNZIM, DF Inst D

Trevor 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. Trevor serves on numerous corporate boards and is chairman of several. He chair's Neuren's Audit Committee and Remuneration Committee as an independent director.

3. DIANNE ANGUS

Non-Executive Director
(Appointed 1 July 2018)

BSc (Hons), Master of Biotechnology, IPTA

Dianne joined the Neuren Board in July 2018. She has worked as a senior executive and non-executive director within the biotechnology, biopharmaceutical and agritech industries for over twenty-five years. She has created numerous global industry partnerships which include Prana Biotechnology, Gerolymatos International, Florigene, Suntory & Monsanto to yield novel and competitive medical, pharmaceutical and agricultural products. Dianne has successfully forged strong partnerships with key medical opinion leaders to create innovative clinical research programs and driven the development path for novel neurological pre-clinical agents to late-stage clinical assets before the FDA and European regulators. With over fifteen years' experience in an ASX and NASDAQ listed company, she has expertise in business development, capital raising, investor relations, regulatory affairs and intellectual property, together with corporate governance and compliance capabilities. Dianne holds a Masters degree in biotechnology and is a registered patent attorney.

4. DR JENNY HARRY

Non-Executive Director
(Appointed 7 July 2018)

BSc (Hons), PhD

Jenny joined the Neuren Board in 2018. She has 20 years' experience in executive management of companies in the biotechnology and biopharmaceutical sectors. She is currently the Managing Director of Ondek Pty Ltd, an Australian biopharmaceutical company developing new treatments for paediatric allergy. In her previous role, as CEO and Managing Director of Tyrian Diagnostics, Jenny transformed the company from an R&D business to a diagnostics company and oversaw development of the company's first products through to commercialisation and early revenue generation. She is a graduate of the Harvard Business School General Manager Program and the Australian Institute of Company Directors. Jenny is currently Chair of QUT Enterprise Holdings and a non-executive director on the boards of QUTbluebox and Creative Enterprise Australia.

5. PATRICK DAVIES

Non-Executive Director
(Appointed 1 July 2018)

B EC, MBA

Patrick joined the Neuren Board in July 2018. He has held executive management roles in the Australian and New Zealand healthcare industry for over twenty five years having performed successfully in senior roles across many industry sectors including pharmacy, primary care, pharmaceutical and consumer products. During his ten year period as Chief Executive Officer of EBOS Group Limited (and previously Symbion), the enterprise value of the group achieved compound annual growth in enterprise value of +20% (from circa $450M to in excess of $3.1B). He is a director on other corporate boards and provides strategic advice to a range of healthcare businesses and investors.

LEADERSHIP TEAM

MANAGEMENT

1. LARRY GLASS

Chief Science Officer

BA (Biology)

Larry retired from the Neuren Board on 31 December 2018 and continues as Chief Science Officer. He joined Neuren in 2004 and was an Executive Director from 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. Larry is a biologist with additional graduate training in epidemiology and biostatistics.

2. JON PILCHER

Chief Financial Officer and Company Secretary

BSc (Hons), FCA

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

3. 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.

4. 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 syndrome-specific 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.

5. 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.

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 cost-effective for the current size and stage of development of the business.

This Statement provides a description of the framework and practices, 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.

As anticipated in the Corporate Governance Statement in the 2017 Annual Report, during 2018 the membership and structure of the Board was reviewed and changed significantly to meet the future needs of the business. Dianne Angus, Patrick Davies and Jenny Harry all joined as independent non-executive directors in July 2018. Larry Glass retired from the Board on 31 December 2018, continuing his executive position in the management team. The transition in the Board composition is summarised in the following table:

Period	Executive directors	Independent non-executive directors
January 2018 to June 2018	2	1
July 2018 to December 2018	2	4
From 1 January 2019	1	4

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, religion, gender or sexuality and when a position becomes vacant the Group seeks to employ the best candidate available for the position. Currently there are three male and two female directors. One of the six senior executives is female. The Group currently has eight employees and consultants, from different cultural backgrounds, of which three are female.

CORPORATE GOVERNANCE

CONTINUED

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 not undertaken during 2018, being deferred to an evaluation in 2019 after some experience of the new Board composition.

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 not undertaken during 2018, being deferred until 2019 after some experience of the new board composition.

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 analyze statements, assess financial viability, contribute to financial planning, oversee budgets and oversee funding arrangements.
Strategy	Ability to identify and critically assess strategic opportunities and threats to the organization. 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 organization 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.

CORPORATE GOVERNANCE

CONTINUED

Skill	Requirements Overview
Interpersonal Skills	
Leadership	Make decisions and take necessary actions in the best interest of the organisation, and represent the organisation favorably. Analyze 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.

The Board is highly engaged in the oversight and direction of the business. Six members served during the year to 31 December 2018, as set out in the table below. Details of the relevant skills, experience and expertise of each Board member are set out on page 23 of this report.

	Appointment	Retirement	Role	Independent	Committees
Richard Treagus	2013		Executive Chairman	No[1]	
Larry Glass	2012	31 December 2018	Executive director	No[1]	
Trevor Scott	2002		Non-executive director	Yes	Chair of Audit Committee and Remuneration Committee
Dianne Angus	1 July 2018		Non-executive director	Yes	Member of Audit Committee and Remuneration Committee
Patrick Davies	1 July 2018		Non-executive director	Yes	Member of Audit Committee and Remuneration Committee
Jenny Harry	7 July 2018		Non-executive director	Yes	Member of Audit Committee and Remuneration Committee

[1] Richard Treagus and Larry Glass are not considered independent due to their executive roles.

From July 2018, there has been a majority of independent directors in accordance with 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 directors believe that the structure and membership profile of the Board has provided and continues to provide the maximum value to the business at its stage of its development.

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.

CORPORATE GOVERNANCE

CONTINUED

PRINCIPLE 3. PROMOTE ETHICAL AND RESPONSIBLE DECISION-MAKING

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

- will act honestly, in good faith and in the best interests of the whole Company
- owe a fiduciary duty to the Company as a whole
- have a duty to use due care and diligence in fulfilling the functions of office and exercising the powers attached to that office
- will undertake diligent analysis of all proposals placed before the Board
- will act with a level of skill expected from Directors and key executives of a publicly listed Company
- will use the powers of office for a proper purpose, in the best interests of the Company as a whole
- will demonstrate commercial reasonableness in decision-making
- will not make improper use of information acquired as Directors and key executives
- will not disclose non-public information except where disclosure is authorised or legally mandated
- will keep confidential information received in the course of the exercise of their duties and such information remains the property of the Company from which it was obtained and it is improper to disclose it, or allow it to be disclosed, unless that disclosure has been authorised by the person from whom the information is provided, or required by law
- will not take improper advantage of the position of Director or use the position for personal gain or to compete with the Company
- will not take advantage of Company property or use such property for personal gain or to compete with the Company
- will protect and ensure the efficient use of the Company's assets for legitimate business purposes
- will not allow personal interests, or the interest of any associated person, to conflict with the interests of the Company
- have an obligation to be independent in judgement and actions and Directors will take all reasonable steps to be satisfied as to the soundness of all decisions of the Board
- will make reasonable enquiries to ensure that the Company is operating efficiently, effectively and legally, towards achieving its goals
- will not engage in conduct likely to bring discredit upon the Company
- will encourage fair dealing by all employees with the Company's customers, suppliers, competitors and other employees
- will encourage the reporting of unlawful/unethical behaviour and actively promote ethical behaviour and protection for those who report violations in good faith
- will give their specific expertise generously to the Company
- have an obligation, at all times, to comply with the spirit, as well as the letter of the law and with the principles of this Code of Conduct

PRINCIPLE 4. SAFEGUARD INTEGRITY IN FINANCIAL REPORTING

The Board has an Audit Committee, consisting of only independent non-executive directors and chaired by an independent director as suggested in Recommendation 4.1. Following the appointment of the three additional non-executive directors, the Committee had at least three members as recommended in Recommendation 4.1. The Committee met twice during 2018, 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. In respect of financial reporting, it is also responsible for:

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

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

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 New Zealand Accounting Standards 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 27 February 2019.

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 Company's constitution has been amended to enable the Board in future to convene virtual shareholder meetings, with participation by electronic means.

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. The Company's constitution has been amended to enable the Board in future to convene virtual shareholder meetings, with participation by electronic means.

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. The Board does not have a separate committee to oversee risk, judging that the whole Board is better able to conduct that function efficiently and effectively, given the small size of the Board and the specialised nature of the business (Recommendation 7.1).

In accordance with Recommendation 7.2, the Board reviews the Group's risk management framework at least annually to satisfy itself that it continues to be sound. A review was conducted in 2018.

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).

CORPORATE GOVERNANCE

CONTINUED

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 a Remuneration Committee, which consists of only independent non-executive directors and is chaired by an independent director as suggested in Recommendation 8.1. Following the appointment of the three additional non-executive directors, the Committee had at least three members as recommended in Recommendation 8.1. The Committee met twice in 2018, 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 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. Non-executive directors on payroll receive retirement benefits as part of their fixed fee. All other 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).

DIRECTORS' REPORT

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 the year Neuren transitioned into a fundamentally stronger position due to the licence agreement with ACADIA Pharmaceuticals Inc ("ACADIA") for trofinetide in North America, which was executed in August 2018. Cash reserves at 31 December 2018 were $23.6 million, compared with $4.7 million at the start of the year. Cash inflow of $6.4 million was generated from operations, compared with an outflow of $5.6 million in 2017.

Under the licence agreement ACADIA was granted exclusive rights to develop and commercialise trofinetide for all clinical indications in North America. The partnership with ACADIA has provided five key financial benefits to Neuren:

- ACADIA is investing circa. US$55 million (A$77 million at the current exchange rate) into the Rett syndrome Phase 3 program. This would otherwise have been a minimum capital raise requirement for Neuren in order to be able to continue development for Rett syndrome.
- Receipt of the first payment from ACADIA of US$10 million (A$13.5 million) provided non-dilutive funding necessary for Neuren to retain ownership and advance the development of its highly promising drug candidate NNZ-2591 as a therapy for neurodevelopmental disorders, which is now a major focus for the Company. These disorders include Phelan-McDermid syndrome (PMS), for which Neuren recently announced positive effects in a pre-clinical model. The program of standard characterisation and non-clinical safety studies required before filing an Investigational New Drug application (IND) with the FDA and commencing clinical trials are now in progress.
- ACADIA provides expert execution capabilities in the US for Phase 3 and commercialization of trofinetide. The Neuren and ACADIA teams are collaborating very effectively on all the preparations for the Rett syndrome Phase 3 trial, which include manufacturing the drug supplies, finalising the trial protocols, preparing clinical sites and completing standard non-clinical studies.
- Neuren secured strong participation in the future value of trofinetide in the US through double digit percentage royalties on all sales plus further payments of up to US$455 million (A$640 million at the current exchange rate) on achievement of development and sales milestones, as well as one third of the market value of any Rare Pediatric Disease Priority Review Voucher, if awarded by the US Food and Drug Administration upon approval of a New Drug Application for trofinetide. The potential milestone payments to Neuren consist of US$105 million subject to achievement of development milestones in Rett syndrome and Fragile X syndrome and up to US$350 million subject to achievement of thresholds of annual net sales of trofinetide in North America.
- Neuren retained all commercial rights to trofinetide outside North America and has free access and rights to use all the technical, clinical and regulatory data that will be generated by ACADIA in the United States. Anticipating discussions with interested parties, Neuren recently appointed Torreya, a global investment bank specialising in life sciences, as its corporate advisor. Torreya is working closely with Neuren management and will assist the board in considering all potential corporate transactions including individual products, territories, or Neuren's entire business.

The licence agreement with ACADIA followed a period of exclusive negotiations under an exclusivity deed executed in May 2018. Under the deed, Neuren received US$4 million and issued 1,330,000 Neuren shares at A$4.00 per share, which was a premium of approximately 33% over the 10-day volume-weighted average share price of $3.00.

Under the terms of the licence agreement for North America, Neuren granted ACADIA a right of first negotiation for other territories prior to Neuren negotiating with other parties, which was exercised in October 2018. On 1 February 2019 Neuren reported that the period of exclusive negotiation had concluded and that having considered the terms of a proposal received from ACADIA, the board determined it would not be in the best interests of Neuren's shareholders to accept the offer.

In April 2018 Neuren announced the grant of the first patent by the Japan Patent Office for trofinetide. The new patent titled "Treatment of autism spectrum disorders using glycyl-L-2-methylprolyl-L-glutamic acid" will expire in January 2032, with the potential to be extended for up to 5 years.

During the year the composition of the board was refreshed through the appointment in July 2018 of Dianne Angus, Patrick Davies and Jenny Harry as non-executive directors. The new directors have brought highly relevant skills, diversity and experience in drug development and commercialisation. Larry Glass retired from the board at the end of 2018, continuing in his executive role as Neuren's Chief Science Officer. Following these changes, the composition of the board is 4 independent non-executive directors and 1 executive director.

The consolidated financial statements are presented on pages 26 to 45. All amounts in the Financial Statements are shown in Australian dollars unless otherwise stated.

DIRECTORS' REPORT

CONTINUED

The Group's profit after tax attributable to equity holders of the Company for the year ended 31 December 2018 was $3.1 million compared with $3.3 million in 2017. Revenue of $13.5 million was received under the licence agreement with ACADIA (2017: nil) and foreign exchange gains were $0.9 million compared with foreign exchange losses of $0.2 million in 2017. These were offset by an increase of $1.0 million in research and development costs, resulting from higher expenditure on manufacturing scale-up and non-clinical toxicity studies, and a loss of $3.9 million compared with a gain of $9.5 million in 2017 on the fair value of the remaining settlements from Lanstead Capital under the Sharing Agreement that was entered into as part of the capital raising in July 2017. Prudent control of expenditure continues to be an important principle in the Group's operations and financing.

The basic earnings per share for 2018 was $0.031 (2017: $0.036 per share) based on a weighted average number of shares outstanding of 99,038,854 (2017: 91,960,841).

Cash reserves at 31 December 2018 were $23.6 million (2017: $4.7 million). Cash generated from operations was $6.4 million, compared with cash outflow of $5.6 million in 2017, due mainly to the receipt of $13.5 million from ACADIA. Financing provided cash of $11.7 million from the issue of shares in May 2018 under the exclusivity deed with ACADIA and settlements from the Lanstead Sharing Agreement, compared with $5.3 million in 2017 from the issue of shares in the July 2017 capital raising and subsequent settlements from the Sharing Agreement. At 31 December 2018, Neuren had already received $10.3 million from Lanstead with 6 settlements still to be received in the first half of 2019.

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)

Richard 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. Richard 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 Richard 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. Richard is Chairman of BTC Health Limited, which is listed on the ASX.

Larry Glass (Executive Director and Chief Science Officer)

Larry retired from the Neuren Board on 31 December 2018 and continues as Chief Science Officer. He joined Neuren in 2004 and was an Executive Director from 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. Larry is a biologist with additional graduate training in epidemiology and biostatistics.

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

Trevor 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. Trevor serves on numerous corporate boards and is chairman of several. He chair's Neuren's Audit Committee and Remuneration Committee as an independent director.

Dianne Angus BSc (Hons), Master of Biotechnology, IPTA (Non-Executive Director) - Appointed 1 July 2018

Dianne joined the Neuren Board in July 2018. She has worked as a senior executive and non-executive director within the biotechnology, biopharmaceutical and agritech industries for over twenty-five years. She has created numerous global industry partnerships which include Prana Biotechnology, Gerolymatos International, Florigene, Suntory & Monsanto to yield novel and competitive medical, pharmaceutical and agricultural products. Dianne has successfully forged strong partnerships with key medical opinion leaders to create innovative clinical research programs and driven the development path for novel neurological pre-clinical agents to late-stage clinical assets before the FDA and European regulators. With over fifteen years' experience in an ASX and NASDAQ listed company, she has expertise in business development, capital raising, investor relations, regulatory affairs and intellectual property, together with corporate governance and compliance capabilities. Dianne holds a Masters degree in biotechnology and is a registered patent attorney.

DIRECTORS' REPORT

CONTINUED

Patrick Davies B EC, MBA (Non-Executive Director) – Appointed 1 July 2018

Patrick joined the Neuren Board in July 2018. He has held executive management roles in the Australian and New Zealand healthcare industry for over twenty five years having performed successfully in senior roles across many industry sectors including pharmacy, primary care, pharmaceutical and consumer products. During his ten year period as Chief Executive Officer of EBOS Group Limited (and previously Symbion), the enterprise value of the group achieved compound annual growth in enterprise value of +20% (from circa $450M to in excess of $3.1B). He is a director on other corporate boards and provides strategic advice to a range of healthcare businesses and investors.

Dr Jenny Harry BSc (Hons), PhD (Non-Executive Director) – Appointed 7 July 2018

Jenny joined the Neuren Board in 2018. She has 20 years' experience in executive management of companies in the biotechnology and biopharmaceutical sectors. She is currently the Managing Director of Ondek Pty Ltd, an Australian biopharmaceutical company developing new treatments for paediatric allergy. In her previous role, as CEO and Managing Director of Tyrian Diagnostics, Jenny transformed the company from an R&D business to a diagnostics company and oversaw development of the company's first products through to commercialisation and early revenue generation. She is a graduate of the Harvard Business School General Manager Program and the Australian Institute of Company Directors. Jenny is currently Chair of QUT Enterprise Holdings and a non-executive director on the boards of QUTbluebox and Creative Enterprise Australia.

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 2018 are as follows:

Dr Richard Treagus

In accordance with the rules of the Loan Funded Share Plan, on 30 May 2018 the Company bought back 501,607 ordinary shares from Neuren Trustee Limited at the volume weighted average price for the 5 days ended 29 May 2018 in order to settle the outstanding loan of $1,560,000 relating to 2 million vested Loan Funded Shares that were held in trust for Dr Treagus pending repayment to the Company of the loan. The remaining 1,498,393 shares were transferred from Neuren Trustee Limited to Richard.

On 28 October 2018, Dr Treagus purchased 16,000 shares at $1.24 per share.

Patrick Davies

On 10, 13 and 14 August 2018, Mr Davies purchased 69,646 shares at $1.44 per share.

Dr Jenny Harry

On 10 August 2018, Dr Harry purchased 14,084 shares at $1.46 per share.

INFORMATION USED BY DIRECTORS

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

INDEMNIFICATION AND INSURANCE OF DIRECTORS AND OFFICERS

Neuren has entered into a deed of indemnity, insurance and access with Directors and Officers, 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 indemnity does not cover criminal liability or liability in respect of a breach of a director's duty to act in good faith and in what the director believes to be the best interests of the Company or a breach of any fiduciary duty owed to the Company or a subsidiary.

DONATIONS

No donations were made by the Company or its subsidiary companies during the year (2017: $nil).

AUDITORS

Grant Thornton New Zealand Partnership (2017: PricewaterhouseCoopers) is the independent auditor of the Company. Grant Thornton audit fees in relation to the 2018 annual and interim financial statements were $58,538. PricewaterhouseCoopers fees in relation to the 2017 financial statements were $67,654 in 2018 and $59,255 in 2017. Grant Thornton Australia (member firm) received $15,000 fees in relation to other financial advice and services in 2018. PricewaterhouseCoopers did not receive fees in relation to other financial advice and services in 2017 or 2018. No amounts were payable to an auditor by subsidiary companies in 2018 or 2017.

DIRECTORS' REPORT

CONTINUED

REMUNERATION OF DIRECTORS

Remuneration of the Directors is shown in the table below. Remuneration for Larry Glass was receivable from a subsidiary company, Neuren Pharmaceuticals Inc. Remuneration for 2018 and 2017 includes the settlement of deferred amounts following the waivers and reductions in fees that were implemented as cash conservation measures in October 2016, as disclosed in the Directors' Report and Financial Statements for the year ended 31 December 2017.

Remuneration of Directors	2018 $'000	2017 $'000
Dr Richard Treagus	536	418
Mr Larry Glass	310	528
Dr Trevor Scott	72	–
Dianne Agnus	30	–
Patrick Davies	30	–
Dr Jenny Harry	30	–

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	2018 $'000	2017 $'000
$150,000 - $159,999	–	1
$240,000 - $249,999	1	1
$270,000 - $279,999	1	1
$320,000 - $329,999	–	1
$410,000 - $419,999	1	–

Including shared based payments	2018 $'000	2017 $'000
$150,000 - $159,999	–	1
$240,000 - $249,999	1	–
$270,000 - $279,999	1	–
$290,000 - $299,999	–	1
$410,000 - $419,999	1	–
$430,000 - $439,999	–	1

For and on behalf of the Board of Directors who authorised the issue of these financial statements on 27 February 2019.

Dr Richard Treagus
Chairman

Dr Trevor Scott
Director

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE YEAR ENDED 31 DECEMBER 2018

	Notes	2018 $'000	2017 $'000
Interest income		218	47
Revenue from licence agreement		13,544	–
Foreign exchange gain		961	–
Australian R&D tax incentive		446	631
Gains on financial assets measured at fair value through profit or loss	9	–	9,482
Total income		15,169	10,160
Research and development costs		(6,101)	(5,136)
Corporate and administrative costs		(2,074)	(1,568)
Losses on financial assets measured at fair value through profit or loss	9	(3,921)	–
Foreign exchange loss		–	(168)
Profit before income tax		3,073	3,288
Income tax	5	–	–
Profit after income tax		3,073	3,288
Other comprehensive expense, net of tax			
Amounts which may be subsequently reclassified to profit or loss:			
Exchange differences on translation of foreign operations		(58)	34
Total comprehensive income for the year		3,015	3,322
Profit after tax attributable to Equity holders of the company:		3,073	3,288
Total comprehensive profit attributable to Equity holders of the company:		3,015	3,322
Basic earnings per share	6	$0.031	$0.036
Diluted earnings per share	6	$0.031	$0.035

The notes on pages 30 to 45 form part of these financial statements

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT 31 DECEMBER 2018

	Notes	2018 $'000	2017 $'000
ASSETS			
Current Assets:			
Cash and cash equivalents	7	23,576	4,706
Trade and other receivables	8	942	692
Financial assets measured at fair value through profit or loss	9	2,121	10,688
Total current assets		26,639	16,086
Non-current assets:			
Property, plant and equipment		2	7
Intangible assets		1	73
Financial assets measured at fair value through profit or loss	9	–	1,778
Total non-current assets		3	1,858
TOTAL ASSETS		26,642	17,944
LIABILITIES AND EQUITY			
Current liabilities:			
Trade and other payables	10	1,973	1,580
Total current liabilities		1,973	1,580
Total liabilities		1,973	1,580
EQUITY			
Share capital	11	126,426	121,136
Other reserves		(8,497)	(7,332)
Accumulated deficit		(93,260)	(97,440)
Total equity attributable to equity holders		24,669	16,364
TOTAL LIABILITIES AND EQUITY		26,642	17,944

The notes on pages 30 to 45 form part of these financial statements

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE YEAR ENDED 31 DECEMBER 2018

	Share Capital $'000	Share Option Reserve $'000	Currency Translation Reserve $'000	Accumulated Deficit $'000	Total Equity $'000
Equity as at 1 January 2017	112,829	2,841	(10,659)	(100,828)	4,183
Shares issued in private placement	8,351				8,351
Share issue costs expensed	(44)				(44)
Share based payments		552			552
Transfer on exercise of options		(100)		100	–
Transactions with owners	8,307	452		100	8,859
Profit after income tax				3,288	3,288
Other comprehensive expense			34		34
Total Comprehensive income for the year			34	3,288	3,322
Equity as at 31 December 2017	121,136	3,293	(10,625)	(97,440)	16,364
Shares issued in private placement	5,306				5,306
Share issue costs expensed	(16)				(16)
Transfer on exercise of options		(1,107)		1,107	–
Transactions with owners	5,290	(1,107)		1,107	5,290
Profit after income tax				3,073	3,073
Other comprehensive expense			(58)		(58)
Total Comprehensive income for the year			(58)	3,073	3,015
Equity as at 31 December 2018	126,426	2,186	(10,683)	(93,260)	24,669

The notes on pages 30 to 45 form part of these financial statements

CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 31 DECEMBER 2018

	2018 $'000	2017 $'000
Cash flows from operating activities:		
Receipts from licence agreement	13,544	–
Receipts from Australian R&D Tax Incentive	631	981
Interest received	165	49
GST refunded	95	70
Payments for employees and directors	(1,909)	(1,494)
Payments to other suppliers	(6,118)	(5,196)
Net cash flow (to)/from operating activities	6,408	(5,590)
Cash flows from financing activities:		
Proceeds from the issue of shares	11,730	5,367
Payment of share issue expenses	(16)	(44)
Net cash provided from financing activities	11,714	5,323
Net increase / (decrease) in cash	18,122	(267)
Effect of exchange rate changes on cash balances	748	(78)
Cash and cash equivalents at the beginning of the year	4,706	5,051
Cash and cash equivalents at the end of the year	23,576	4,706
Reconciliation with profit after income tax:		
Profit after income tax	3,073	3,288
Non-cash items requiring adjustment:		
Depreciation of property, plant and equipment	5	6
Amortisation of intangible assets	72	72
Share based payment expense	–	552
Foreign exchange loss/(gain)	(806)	111
Gain on financial assets	3,921	(9,482)
Changes in working capital:		
Trade and other receivables	(250)	310
Trade and other payables	393	(447)
Net cash flow from operating activities	6,408	(5,590)

The notes on pages 30 to 45 form part of these financial statements

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 DECEMBER 2018

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 treatment of chronic neurodevelopmental and neurodegenerative disorders, as well as acute traumatic brain injury.

The Company is a limited liability company incorporated in New Zealand. The address of its registered office in New Zealand is at the offices of Lowndes Jordan, Level 15 PWC Tower, 188 Quay Street, Auckland 1141. Neuren 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 27 February 2019.

Inherent Uncertainties

- 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's revenue from licence agreements is contingent on future events and will be intermittent until product sales commence. The Company's business plan therefore may require expenditure in excess of revenue and 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.
- The Company entered a Sharing Agreement with Lanstead Capital LP as a part of the capital raising completed in July 2017, under which the Company receives 18 settlements calculated with reference to both the volume weighted average price at which Neuren's shares are traded during the 20 days prior to each settlement (VWAP), and a rate of return which effectively results in a discount to the VWAP. Movements in the share price could materially impact the fair value of the 6 monthly instalments that remained outstanding at 31 December 2018 and the cash amounts received from those instalments (Refer Note 9).

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

These general-purpose consolidated financial statements of the Group are for the year ended 31 December 2018 and have been prepared in accordance with and comply with generally accepted accounting practice in New Zealand (GAAP), New Zealand equivalents to International Financial Reporting Standards (NZ IFRS) which comply with International Financial Reporting Standards, the requirements of the Financial Markets Conduct Act 2013, and other applicable Financial Reporting Standards as appropriate for profit-oriented entities that fall into Tier 1 as determined by the New Zealand Accounting Standards Board.

(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 2018 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.

Statutory Base

Neuren is registered under the New Zealand Companies Act 1993. Neuren is also registered as a foreign company under the Australian Corporations Act 2001.

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. Actual results may differ from those estimates. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements are disclosed in Note 17.

Going concern basis

The directors monitor the Group's cash position and initiatives to ensure that adequate funding continues to be available for the Group to meet its business objectives. The Group recorded operating cash inflow of $6.4 million for the year ended 31 December 2018 and had net assets at 31 December 2018 of $24.7 million, including cash balances of $23.6 million and fair value of the outstanding cash settlements due from Lanstead Capital of $2.1m. The amounts of the settlements from Lanstead have a dependency on the Company's share price, as described in Note 9.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

It is the considered view of the Directors that the Group will have access to adequate resources to meet its ongoing obligations for at least a period of 12 months from the date of signing these financial statements. On this basis, the Directors have assessed it is appropriate to adopt the going concern basis in preparing its financial statements. The financial statements do not include any adjustments that would result if the Group was unable to continue as a going concern.

Changes in accounting policies

Implementation of NZ IFRS15: Revenue from contracts

NZ IFRS 15 'Revenue from Contracts with Customers' and the related 'Clarifications to NZ IFRS 15 Revenue from Contracts with Customers' (hereinafter referred to as 'NZ IFRS 15') replace NZ IAS 18 'Revenue', NZ IAS 11 'Construction Contracts', and several revenue-related Interpretations. The new Standard has not been applied retrospectively and no restatement to comparative numbers made. There are no adjustments to retained earnings at 1 January 2018 from the implementation of this standard.

Implementation of NZ IFRS9: Financial instruments

NZ IFRS 9 replaces NZ IAS 39 'Financial Instruments: Recognition and Measurement'. It makes major changes to the previous guidance on the classification and measurement of financial assets and introduces an 'expected credit loss' model for the impairment of financial assets. When adopting NZ IFRS 9, the Group has applied transitional relief and opted not to restate prior periods. There have been no differences arising from the adoption of IFRS9 in relation to classification, measurement, and impairment.

There have also been no financial instruments which have been assigned a new category on transition.

There is no significant impact of changes in accounting policies for the year ended 31 December 2018.

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. None are expected to impact the 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) 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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(d) Revenue

Revenue arises mainly from grants received and interest. In the current reporting period Licence revenue was recognised in relation to the partnering agreement signed with Acadia.

Revenue is recognised either at a point in time or over time, when (or as) the Group satisfies performance obligations by transferring the promised goods or services to its customers.

Grants

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

Interest income

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

Revenue from Licence agreements

The revenue from the Acadia license agreement is a Phase II reimbursement fee and has been recognised as a separate performance obligation as it is distinct from all the other obligations within the Acadia licensing agreement. The revenue from this performance obligation has therefore been recognised at a point in time when Neuren had transferred its intellectual property to Arcadia and Neuren had an enforceable right to receive payment.

(e) 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.

(f) 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 or substantively enacted at the reporting 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 reporting 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.

(g) 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.

(h) Impairment of non-financial assets

Assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment. All non-financial assets are also 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 value less costs of disposal and value in use of the long-lived asset. Fair market value is determined using the anticipated cash flows discounted at a rate commensurate with the risk involved.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(i) 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.

(j) 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.

(k) Trade and other receivables

The Group makes use of a simplified approach in accounting for trade and other receivables and records the loss allowance as lifetime expected credit losses. These are the expected shortfalls in contractual cash flows, considering the potential for default at any point during the life of the financial instrument. In calculating, the Group uses its historical experience, external indicators and forward-looking information to calculate the expected credit losses using a provision matrix.

(l) 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 Group 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

(m) Intangible assets

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.

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.

(n) 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 a loan funded share plan and equity performance rights plan. Both plans are accounted for as share options. 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 reporting date, except for options that are subject to a market condition for vesting, 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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(o) 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.

(p) Financial instruments

Recognition and derecognition

Financial assets and financial liabilities are recognised when the Group becomes a party to the contractual provisions of the financial instrument.

Financial assets are derecognised when the contractual rights to the cash flows from the financial asset expire, or when the financial asset and substantially all the risks and rewards are transferred.

A financial liability is derecognised when it is extinguished, discharged, cancelled or expires.

Classification and initial measurement of financial assets

Except for those trade receivables that do not contain a significant financing component and are measured at the transaction price in accordance with NZ IFRS 15, all financial assets are initially measured at fair value adjusted for transaction costs (where applicable).

Financial assets, other than those designated and effective as hedging instruments, are classified into the following categories:

- amortised cost
- fair value through profit or loss (FVTPL)
- fair value through other comprehensive income (FVOCI).

In the periods presented the corporation does not have any financial assets categorised as FVOCI.

The classification is determined by both:

- the entity's business model for managing the financial asset
- the contractual cash flow characteristics of the financial asset.

All income and expenses relating to financial assets that are recognised in profit or loss are presented within finance costs, finance income or other financial items, except for impairment of trade receivables which is presented within other expenses.

Subsequent measurement of financial assets

Financial assets at amortised cost

Financial assets are measured at amortised cost if the assets meet the following conditions (and are not designated as FVTPL):

- they are held within a business model whose objective is to hold the financial assets and collect its contractual cash flows
- the contractual terms of the financial assets give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding

After initial recognition, these are measured at amortised cost using the effective interest method.

Discounting is omitted where the effect of discounting is immaterial. The Group's cash and cash equivalents, trade and most other receivables fall into this category of financial instruments.

Financial assets at fair value through profit or loss (FVTPL)

Financial assets that are held within a different business model other than 'hold to collect' or 'hold to collect and sell' are categorised at fair value through profit and loss. Further, irrespective of business model financial assets whose contractual cash flows are not solely payments of principal and interest are accounted for at FVTPL. All derivative financial instruments fall into this category, except for those designated and effective as hedging instruments, for which the hedge accounting requirements apply.

Assets in this category are measured at fair value with gains or losses recognised in profit or loss. The fair values of financial assets in this category are determined by reference to active market transactions or using a valuation technique where no active market exists.

(q) Earnings per share

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

3. SEGMENT INFORMATION

The Group operates as a single operating segment and internal management reporting systems present financial information as a single segment. The segment derives its revenue and incurs expenses through the development of pharmaceutical products. Grant income arises from the Australian R&D Tax Incentive and revenue from licence agreements is derived from the United States. The Board of the Company has been identified as the chief operating decision maker. The Board assesses the financial performance and position of the group, and makes strategic decisions.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

4. EXPENSES

	2018 $'000	2017 $'000
Loss before income tax includes the following expenses:		
Depreciation – property, plant and equipment		
Computer equipment	4	4
Fixtures and fittings	1	2
Total depreciation	5	6
Amortisation – intangible assets		
Intellectual property	73	71
Software	–	1
Total amortisation	73	72
Remuneration of auditors		
Audit and review of financial statements (PwC)	67	59
Audit and review of financial statements (Grant Thornton NZ)	59	–
Advisory services (Grant Thornton Australia – member firm)	15	–
Total remuneration of auditors	141	59
Employee benefits expense		
Short-term benefits	1,104	1,240
Share based payments	–	552
Total employee benefits expense	1,104	1,792
Directors' compensation		
Short-term benefits	1,008	946
Total Directors' compensation	1,008	946
Lease expense	3	27
Foreign exchange loss on fair value of forward contracts	–	46

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

5. INCOME TAX

	2018 $'000	2017 $'000
Income tax		
Current tax	–	–
Deferred tax	–	–
	–	–
Numerical reconciliation of income tax to prima facie tax receivable:		
Profit before income tax	3,073	3,288
Tax at applicable rates	845	904
Non-taxable Australian R&D tax incentive income	(123)	(174)
Non deductible expenses for R&D incentive	282	399
Non deductible share option expenses	–	152
Non-taxable loss/(gain) in fair value of equity derivative	1,806	(2,476)
Utilisation of previously unrecognised tax losses	(2,710)	–
Deductible temporary differences and tax losses for which no deferred tax asset was recognised	(100)	1,195
Income tax	–	–
Gross tax losses for which no deferred tax asset has been recognised[(a)]	88,914	95,902

(a) Of these gross tax losses, NZ$63.9 million relates to New Zealand tax losses, which are unlikely to be utilised.

6. EARNINGS PER SHARE

The Group has two categories of dilutive potential ordinary shares: loan funded shares and equity performance rights. For loan funded shares, a calculation is performed to determine the number of shares that could have been acquired at fair value (determined as the average annual market share price of the Company's shares) based on the monetary value of the exercise price attached to the outstanding loan funded shares. The number of loan funded shares calculated as above is compared with the number of shares that would have been issued assuming the exercise of the loan funded shares. Any "out-of-money" loan funded shares are also excluded. For equity performance rights, shares are assumed issued.

	2018	2017
Profit after income tax attributable to equity holders (basic) - ($000)	3,073	3,288
Weighted average shares outstanding (basic) - (No.)	99, 038,854	91,960,841
Basic earnings per share	$0.031	$0.036
Profit after income tax attributable to equity holders (diluted) - ($'000)	3,073	3,288
Weighted average shares outstanding (diluted) - (No.)	99,751,382	93,029,924
Diluted earnings per share	$0.031	$0.035

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

7. CASH AND CASH EQUIVALENTS

	2018 $'000	2017 $'000
Cash	3,738	1,736
Demand and short-term deposits	19,838	2,970
	23,576	4,706

8. TRADE AND OTHER RECEIVABLES

	2018 $'000	2017 $'000
Trade receivables	423	44
Other receivables	16	14
Interest receivables	57	3
Australian R&D tax incentive	446	631
	942	692

The Group applies the NZIFRS 9 simplified model of recognising lifetime expected credit losses for all trade receivables as these items do not have a significant financing component.

In measuring the expected credit losses, the trade receivables have been assessed on an individual basis due to the limited number of receivables.

The expected loss rates are based on the payment profile of the individual receivable and other transactions with that debtor over the past 12 months before 31 December 2018 as well as the corresponding historical credit losses during that period.

Trade receivables are written off (i.e. de-recognised) when there is no reasonable expectation of recovery. Failure to make payments within 180 days from the invoice date and failure to engage with the Group on alternative payment arrangements amongst others are considered indicators of no reasonable expectation of recovery. No credit losses have been determined for the current year (2017: nil).

9. FINANCIAL ASSETS MEASURED AT FAIR VALUE THROUGH PROFIT OR LOSS

	2018 $'000	2017 $'000
Current		
Equity derivative	2,121	10,688
Non-Current		
Equity derivative	–	1,778
TOTAL	2,121	12,466

Reconciliation of the fair values at the end of the current financial year are set out below:

	2018 $'000	2017 $'000
Initial recognition of equity derivative	–	5,351
Opening fair value	12,466	–
Cash settlements received	(6,424)	(2,367)
Net (loss) or gain through profit or loss	(3,921)	9,482
Closing fair value	2,121	12,466

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

9. FINANCIAL ASSETS MEASURED AT FAIR VALUE THROUGH PROFIT OR LOSS (CONTINUED)

Financial instruments classified under the equity swap arrangement are measured at fair value using a fair value hierarchy reflecting the significance of the inputs used in making the measurements. These financial assets are classified as level 2. Fair value calculations are based on a discounted cash flow model.

In July 2017, Neuren completed a placement of new ordinary shares, the subscribers for which included Lanstead Capital. Neuren entered into a Sharing Agreement with Lanstead Capital, under which Neuren's economic interest was an equity derivative, determined and payable in 18 cash settlements commencing in September 2017. In August 2018 Neuren agreed with Lanstead to pause for 120 days the monthly settlements, which means that 8 settlements were received in 2018 and the final monthly settlement, which was originally due in February 2019 will now be calculated and received in June 2019. Therefore 6 settlements remained outstanding at 31 December 2018.

The calculation of each monthly settlement is dependent upon the volume weighted average price at which Neuren's shares are traded during the 20 days prior to settlement (VWAP). If the VWAP for each settlement is equal to $1.77 per share (Benchmark Price), Neuren receives $472,222 (one eighteenth of $8.5 million). For each settlement, if the VWAP is higher than the Benchmark Price, Neuren receives proportionately more than $472,222 and if the VWAP is lower than the Benchmark Price, Neuren receives proportionately less than $472,222. Should the Company's share price drop significantly, the cumulative remaining settlement amount could reduce to zero. $6.4 million was received from the 8 settlements in 2018 (compared with $3.8 million that would have been received if the VWAP had been the Benchmark Price).

The key assumption for the calculation of the fair value of the equity derivative is the estimated VWAP applicable to each settlement. For the fair value on recognition, the VWAP was assumed to be $1.22 per share, which was the lowest traded price of Neuren's shares on 17 July 2017. For the fair value at 31 December 2018, the VWAP was assumed to be $1.40 per share which was the closing price on 31 December 2018. (31 December 2017 : $3.12 per share, which was the lowest traded price of Neuren's shares on 29 December 2017). The fair value calculations were adjusted to reflect the time value of money and the estimated credit risk associated with the counterparty.

A sensitivity analysis of the fair value at 31 December 2018 for different VWAP assumptions within a reasonably possible range is presented in the following table:

2018 Assumed VWAP ($)	Fair value ($'m)
1.0	1.4
1.5	2.3
2.0	3.2

10. TRADE AND OTHER PAYABLES

	2018 $'000	2017 $'000
Trade payables	1,335	723
Accruals	83	265
Employee Benefits	555	592
	1,973	1,580

Trade payables and accruals relate to operating expenses, primarily research and development expenses. Trade payables comprise amounts invoiced prior to the reporting date and accruals comprise the value of work done but not invoiced at each reporting date.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

11. SHARE CAPITAL

	2018 Shares	2017 Shares	2018 $'000	2017 $'000
Issued Share Capital				
Ordinary shares on issue at beginning of year	101,840,020	1,841,929,015	121,136	112,829
Shares issued on exercise of Equity Performance Rights	–	1,308,901	–	–
Shares bought back under Loan Funded Share Plan	(501,607)	–	–	–
Shares issued in private placement	1,330,000	193,548,389	5,306	8,351
Share issue expenses - cash issue costs	–	–	(16)	(44)
	102,668,413	2,036,786,305	126,426	121,136
Share Consolidation	–	(1,934,946,285)	–	–
	102,668,413	101,840,020	126,426	121,136

In May 2018 Neuren issued 1,330,000 ordinary shares at A$4.00 per share, which was a premium of approximately 33% over the 10-day volume-weighted average share price, under the terms of an Exclusivity Deed that provided for exclusive negotiations with ACADIA Pharmaceuticals for a period of 3 months.

In July 2017, Neuren completed a placement of new ordinary shares in return for $3 million in cash and an equity derivative under a Sharing Agreement with Lanstead Capital, the fair value of which was $5.4 million.

In November 2017 all issued ordinary shares were consolidated, with 20 ordinary shares being consolidated into 1 ordinary share. Fractional entitlements were rounded up to the nearest whole share. The total number of shares on issue prior to the consolidation was 2,036,786,305. After the share consolidation and at 31 December 2017 this was reduced to 101,840,020 shares.

At 31 December 2018 and 31 December 2017, 2.5 million ordinary shares were held as treasury stock in respect of the Loan Funded Share Plan described in section (a) below.

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.

Share based payments

Neuren has operated 3 equity-settled share based payment plans; a share option plan, a loan funded share plan and an equity performance rights plan.

No securities were issued under any of these plans in 2018 or 2017. At 31 December 2017, all services required for the instruments issued under share based payment plans had been received.

Equity-settled share based payments expensed in the Income Statement were as follows:

	2018 $'000	2017 $'000
Loan funded shares	–	532
Equity performance rights	–	20
Total	–	552

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

11. SHARE CAPITAL (CONTINUED)

(a) 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 consultants ("Participants") by the Remuneration and Audit Committee. The Company issues new ordinary shares, which are placed in a trust to hold the shares on behalf of the Participant. The trustee issues a limited-recourse, interest-free loan to the participant, which is equal to the number of shares multiplied by the issue price. A limited-recourse loan means that the repayment amount will be the lesser of the outstanding loan and the market value of the shares that are subject to the loan. The trustee continues to hold the shares on behalf of the Participant until all vesting conditions have been satisfied and the Participant chooses to settle the loan, at which point ownership of the shares is transferred from the trust to the Participant. Any dividends paid by the Company while the shares are held by the trust are applied as repayment of the loan at the after-tax value of the dividend. On request by the participant, the Company may dispose of, or buy back, vested shares and utilise the proceeds to settle the outstanding loan. The directors may apply vesting conditions to be satisfied before the shares can be transferred to the Participant. Before the loan can be given, the New Zealand Companies Act requires the Company to disclose to shareholders the provision of financial assistance to the Participant. The maximum loan term is 5 years.

All shares issued under the plan were 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.

Movements in the number of Loan Funded Shares were as follows:

	Loan Funded Shares	Weighted Average Exercise Price	Exercisable	Weighted Average Exercise Price
Outstanding at 1 January 2017	90,000,000	$0.066	–	$0.039
Share consolidation	(85,500,000)			
Outstanding at 31 December 2017	4,500,000	$1.32	2,000,000	$0.78
Exercised	(2,000,000)	$0.78	(2,000,000)	$0.78
Outstanding at 31 December 2018	2,500,000	$1.76	–	

The exercise prices for the outstanding loan funded shares are $1.84 per share in respect of 1.5 million shares and $1.64 per share in respect of 1 million shares.

On 30 May 2018 the Company bought back 501,607 ordinary shares from Neuren Trustee Limited at the volume weighted average price for the 5 days ended 29 May 2018 in order to settle the outstanding loan of $1,560,000 relating to 2,000,000 vested Loan Funded Shares held in trust pending repayment of the loan. The remaining 1,498,393 shares were transferred from Neuren Trustee Limited to the participant.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

11. SHARE CAPITAL (CONTINUED)

In 2018 the directors deferred making a determination on the vesting conditions in respect of 2.5 million Loan Funded Shares until 31 March 2019, or an earlier date determined by the directors. In 2017 the directors deferred making a determination on the vesting conditions in respect of 2.5 million Loan Funded Shares until 1 September 2018, or an earlier date determined by the directors.

(b) Equity Performance Rights

The Company previously 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.

Movements in the number of EPR were as follows:

	EPR	Weighted Average Exercise Price	Weighted Average Share Price on exercise	Exercisable	Weighted Average Exercise Price
Outstanding at 1 January 2017	1,308,901	nil		1,308,901	nil
Exercised	(1,308,901)	nil	$0.061		
Outstanding at 31 December 2017	–			–	
Outstanding at 31 December 2018	–			–	

12. SUBSIDIARIES

(a) Investment in subsidiaries

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

Name of entity	Date of incorporation	Principle activities	Interest held	Domicile
AgVentures Limited	07-Oct-03	Dormant	100%	NZ
NeuroendocrinZ Limited	10-Jul-02	Dormant	100%	NZ
Neuren Pharmaceuticals Inc.	20-Aug-02	Development services	100%	USA
Neuren Pharmaceuticals (Australia) Pty Ltd	09-Nov-06	Dormant	100%	AUS
Neuren Trustee Limited	29-May-13	Hold loan funded shares	100%	NZ

All subsidiaries have a reporting date of 31 December.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

13. COMMITMENTS AND CONTINGENCIES

(a) Operating leases

There were no aggregate future non-cancellable minimum lease payments for premises committed to by the Group, but not recognised in the financial statements as at 31 December 2018 or 31 December 2017.

(b) Legal claims

The Group had no significant legal matter contingencies as at 31 December 2018 or at 31 December 2017.

(c) Commitments

The Group was not committed to the purchase of any property, plant or equipment or intangible assets as at 31 December 2018 (2017: nil).

At 31 December 2018, the Group had commitments under contracts for the manufacture and development of trofinetide amounting to approximately 4.5 million Euros and approximately 0.3 million US dollars (2017: nil).

In addition, the Company has entered into agreements with ACADIA Pharmaceuticals under which ACADIA provides cash funding to Neuren to match Neuren's commitments under further contracts for the manufacture and development of trofinetide. At 31 December 2018 such commitments amounted to approximately 2.6 million Euros and approximately 0.3 million US dollars, matched by rights to receive the same amounts of cash from ACADIA.

(d) Contingent liabilities

The Group had no contingent liabilities at 31 December 2018 or at 31 December 2017 that require disclosure.

14. 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:

	2018 $'000	2017 $'000
Short-term benefits	1,867	1,814
Post-employment benefits	60	60
Share based payment compensation	–	552
	1,927	2,426

On 30 May 2018 the Company bought back 501,607 ordinary shares from Neuren Trustee Limited at the volume weighted average price for the 5 days ended 29 May 2018 in order to settle the outstanding loan of $1,560,000 relating to 2,000,000 vested Loan Funded Shares held in trust for KMP pending repayment of the loan. The remaining 1,498,393 shares were transferred from Neuren Trustee Limited to KMP.

During the year ended 31 December 2017, 1,308,901 ordinary shares were issued to KMP, following vesting of Equity Performance Rights.

(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 12. All amounts due between entities in the Group are payable on demand and bear no interest.

15. EVENTS AFTER REPORTING DATE

As at the date of these financial statements authorised for issue, there were no events arising since 31 December 2018 that require disclosure.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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16. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

(a) Categories of financial instruments

		At amortised cost		At fair value through profit or loss	
Financial assets		Floating Interest Rate $'000	Non-Interest Bearing $'000	Non-Interest Bearing $'000	Total $'000
2018					
Cash and cash equivalents	7	23,576	–	–	23,576
Trade and other receivables	8	–	942	–	942
Equity derivative	9	–	–	2,121	2,121
Total financial assets		23,576	942	2,121	26,639
2017					
Cash and cash equivalents	7	4,706	–	–	4,706
Trade and other receivables	8	–	692	–	692
Equity derivative	9	–	–	12,466	12,466
Total financial assets		4,706	692	12,466	17,864

Financial liabilities		**2018 $'000**	**2017 $'000**
Amortised cost - Non-Interest Bearing:			
Trade and other payables		1,973	1,580
Total financial liabilities	10	1,973	1,580

At 31 December 2018, the reporting value of all financial instruments approximated to the fair value.

These categories used above are consistent for both IAS39 and IFRS9.

(b) Risk management

The Group is subject to a number of financial risks which arise as a result of its activities.

Market risk

Market risk is the risk that changes in market prices, such as foreign exchange rates, interest rates and equity prices will affect the Group's income or the value of its holdings of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimising the return.

Equity price risk

The Group has an equity derivative for which market risk arises with movements in the share price of the Company, as described in Note 9 above.

Currency risk

During the normal course of business the Group enters 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 rates between the Australian dollar, the US dollar and the EURO. The Group holds cash denominated in US dollars, Australian dollars and Euro and has material expenditure in each of these currencies. Where possible, the Group matches foreign currency income and expenditure as a natural hedge. When foreign currency expenditure exceeds revenue, the group purchases foreign currency to meet future anticipated requirements under spot and forward contracts. The Group does not designate formal hedges. At 31 December 2018, there were no forward contracts outstanding.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

16. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT (CONTINUED)

During the year, the US dollar and Euro fluctuated against the Australian dollar. A foreign exchange gain of $961,000 is included in results for the year ended 31 December 2018 (2017: loss $168,000). The majority of the gain relates to gains on the fair value movement for reporting purposes of the Company's US dollar and EURO denominated cash reserves into Australian dollars.

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

	2018 $'000	2017 $'000
Assets		
US dollars	15,818	631
EURO	2,556	–
Liabilities		
US dollars	572	112
EURO	824	527

An increase of 10% in the cross rate of the US dollar against the Australian dollar as at the reporting date would have decreased the consolidated profit after income tax by $1,386,000 (2017: $47,000). A decrease of 10% in the cross rate of the US dollar against the Australian dollar as at the reporting date would have increased the consolidated profit after income tax by $1,694,000 (2017: $58,000).

An increase of 10% in the cross rate of the Euro against the Australian dollar as at the reporting date would have decreased the consolidated profit after income tax by $157,000 and increased it by $48,000 in 2017. A decrease of 10% in the cross rate of the Euro against the Australian dollar as at the reporting date would have increased the consolidated profit after income tax by $192,000 and decreased it by $59,000 in 2017.

Interest rate risk

The Group is 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:

	2018 $'000	2017 $'000
Financial assets		
Cash and cash equivalents		
Australian dollar cash deposits	5,625	4,075
Australian dollar interest rate	2.46%	1.94%
US dollar cash deposits	15,800	631
US dollar interest rate	2.32%	0.00%
EURO cash deposits	2,150	–
EURO interest rate	0.00%	–

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

A 10% change in average market interest rates would have changed reported profit after tax by approximately $22,000 (2017:$5,000).

Credit risk

The Group incurs credit risk from transactions with financial institutions. The total credit risk on an equity derivative (as described in Note 9 above) and cash and cash equivalents, which have been recognised in the statement of financial position, is the carrying amount. The Company and its subsidiaries do not retain any collateral or security to support transactions with financial institutions. Cash and cash equivalents are held and transacted with National Australia Bank, Western Union and Sonabank. The equity derivative counterparty is Lanstead Capital L.P. The estimated credit risk associated with the unsecured equity derivative has been considered in the estimation of the fair value of the equity derivative, as described in Note 9.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

16. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT (CONTINUED)

Liquidity risk

The Group's financial liabilities, comprising trade and other payables, are generally repayable within 1 – 2 months. The maturity and availability of financial assets, comprising cash and cash equivalents, receivables and monthly cash settlements from the equity derivative, are monitored and managed to ensure financial liabilities can be repaid when due.

Capital risk

The Company manages its capital, which is its equity, to ensure that the Group entities are able to meet their estimated commitments as they fall due. In this regard, the Company raised additional equity capital during 2018 and 2017, as described in Note 11. Capital risk is impacted by the inherent uncertainties described in Note 1.

17. CRITICAL ACCOUNTING ESTIMATES AND ASSUMPTIONS

The Group makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing material adjustment to the carrying amounts of assets and liabilities within the next financial year are as discussed below.

The Group's research and development activities are eligible under the Australian R&D tax incentive. The Group has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. For the period to 31 December 2018 the Group has recorded other income of $0.4 million (2017: $0.6 million).

The Group has assessed that all research and development expenditure to date does not meet the requirements for capitalisation as an intangible asset because it is not yet probable that the expected future economic benefits that are attributable to the asset will flow. The Group's current assessment is that future expenditure will not meet that requirement prior to the approval of a New Drug Application by the US Food and Drug Administration.

The fair value of the equity derivative described in Note 9 is dependent on an estimate of the 20 day VWAP each month over 6 months. Differences in the actual VWAP compared to the estimate may cause a material difference in the fair value.

The Group is subject to income taxes in Australia. There are transactions and calculations undertaken during the ordinary course of business for which the ultimate tax determination may be uncertain, including the taxation of the changes in fair value of the equity derivative described in Notes 1 and 9. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred tax provisions in the period in which such determination is made.

Grant Thornton

Independent Auditor's Report

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To the Shareholders of Neuren Pharmaceuticals Limited

Report on the Audit of the Consolidated Financial Statements

Opinion

We have audited the consolidated financial statements of Neuren Pharmaceuticals Limited (the Company) and its subsidiaries (the Group) on pages 26 to 45 which comprise the consolidated statement of financial position as at 31 December 2018, and the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Group as at 31 December 2018 and of its financial performance and cash flows for the year then ended in accordance with New Zealand Equivalents to International Financial Reporting Standards (NZ IFRS).

Basis for Opinion

We conducted our audit in accordance with International Standards on Auditing (New Zealand) (ISAs (NZ)) issued by the New Zealand Audit and Assurance Standards Board. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Consolidated Financial Statements section of our report. We are independent of the Group in accordance with Professional and Ethical Standard 1 (Revised) Code of Ethics for Assurance Practitioners issued by the New Zealand Auditing and Assurance Standards Board, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our firm carries out review procedures over the interim financial statements and financial advisory services of the Group. The provision of these services has not impaired our independence as the independent auditor of the Group.

Other Matter

The consolidated financial statements of the Group for the year ended 31 December 2017 were audited by another auditor who expressed an unmodified opinion on those statements on 29 March 2018

Key Audit Matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Why the matter is significant	How our audit addressed the key audit matter
The Company entered into a Sharing Agreement with Lanstead Capital L.P. as part of a capital raising. Under the arrangement the Company would receive 18 monthly settlements. At 31 December 2018 there were still six settlements outstanding. (2017: 14) The arrangement gives rise to a financial asset being receivable with an embedded derivative. The Company has elected to measure the whole instrument at fair value through profit or loss. At 31 December 2018 the value of the derivative is $2.12m (2017: $12.466m) (Refer note 9). The fair value of the instrument has been valued using valuation techniques that are subject to management estimation and judgements and therefore could materially influence the determination of the fair value at the end of each reporting period.	We obtained an understanding of the arrangement by reviewing the key contracts, accounting treatment applied and valuation methodology utilised. We considered the appropriateness of the accounting treatment adopted with reference to the requirements set out in the accounting standards. Our internal valuation experts evaluated the appropriateness of the methodology and inputs applied for the derivative. We independently recalculated the fair value of the derivative and compared it to what is reflected in the financial statements. We challenged the key assumptions applied by management and agreed the underlying data to contracts or other supporting documentation. The appropriateness of the disclosures in the financial statements in relation to the arrangement were considered for completeness and accuracy.

Other Information

The Directors are responsible for the other information. The other information comprises the Director's report and information included in the annual report, but does not include the consolidated financial statements and our auditor's report thereon. We obtained the Director's report prior to the date of this auditor's report. The Annual report is expected to be made available to us after that date.

Our opinion on the consolidated financial statements does not cover the other information and we will not express any form of audit opinion or assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information identified above when it becomes available and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

If, based on the work we have performed on the other information that we obtained prior to the date of this auditor's report, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Directors' responsibilities for the Consolidated Financial Statements

The Directors are responsible on behalf of the Group for the preparation and fair presentation of the consolidated financial statements in accordance with New Zealand equivalents to International Financial Reporting Standards issued by the New Zealand Accounting Standards Board, and for such internal control as the Directors determine is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the directors are responsible on behalf of the Group for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a

guarantee that an audit conducted in accordance with ISAs (NZ) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

A further description of the auditor's responsibilities for the audit of the financial statements is located on the External Reporting Board's website at https://www.xrb.govt.nz/assurance-standards/auditors-responsibilities/audit-report-1/

Restriction on use of our report

This report is made solely to the Company's shareholders, as a body. Our audit work has been undertaken so that we might state to the Company's shareholders, as a body those matters which we are required to state to them in an auditor's 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 its shareholders, as a body, for our audit work, for this report or for the opinion we have formed.

Grant Thornton New Zealand Audit Partnership

Kerry Price
Partner
Auckland

27 February 2019

ADDITIONAL INFORMATION

EQUITY SECURITIES HELD BY DIRECTORS AS AT 27 FEBRUARY 2019

Director	Interests in Ordinary Shares	
	Direct	Indirect
Richard Treagus	1,979,163	105,517
Trevor Scott	1,000,000	2,989,784
Dianne Angus	–	–
Patrick Davies	–	69,646
Jenny Harry	–	14,084

DIRECTORS OF SUBSIDIARY COMPANIES AT 31 DECEMBER 2018

	Richard Treagus	Larry Glass	Trevor Scott	Jon Pilcher
AgVentures Limited			√	
NeuroendocrinZ Limited				√
Neuren Pharmaceuticals Inc.	√	√		
Neuren Pharmaceuticals (Australia) Pty Ltd	√	√		
Neuren Trustee Limited			√	

AUSTRALIAN STOCK EXCHANGE DISCLOSURES

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

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

Limitations on the acquisition of securities imposed under New Zealand law are as follows:

(a) In general, securities in the Company are freely transferable and the only significant restrictions or limitations in relation to the acquisition of securities are those imposed by New Zealand laws relating to takeovers and overseas investment.

(b) The New Zealand Takeovers Code creates a general rule under which the acquisition of 20% or more of the voting rights in the Company or the increase of an existing holding of 20% or more of the voting rights of the Company can only occur in certain permitted ways. These include a full takeover offer in accordance with the Takeovers Code, a partial takeover in accordance with the Takeovers Code, an acquisition approved by an ordinary resolution, an allotment approved by an ordinary resolution, a creeping acquisition (in certain circumstances), or compulsory acquisition of a shareholder holding 90% or more of the shares.

(c) The New Zealand Overseas Investment Act 2005 and Overseas Investment Regulations 2005 (New Zealand) regulate certain investments in New Zealand by overseas interests. In general terms, the consent of the New Zealand Overseas Investment Office may be required where an 'overseas person' acquires shares in the Company that amount to 25% or more of the shares issued by the Company, or if the overseas person already holds 25% or more, the acquisition increases that holding.

ADDITIONAL INFORMATION

CONTINUED

EQUITY SECURITIES INFORMATION

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

The following information is based on share registry information processed up to and including 27 March 2019.

The number of ordinary shareholdings held in less than marketable parcels at 27 March 2019 was 920, holding 169,911 ordinary shares.

DISTRIBUTION OF SECURITY HOLDERS

Ordinary shares

Size of holding	Number of ordinary shares	%	Number of holders	%
100,001 and Over	68,742,183	66.96	117	2.45
10,001 to 100,000	24,818,630	24.17	815	17.08
5,001 to 10,000	4,019,272	3.92	519	10.88
1,001 to 5,000	4,326,036	4.21	1,561	32.71
1 to 1,000	762,292	0.74	1,760	36.88
Total	102,668,413	100.00	4,772	100.00

Substantial Security Holders

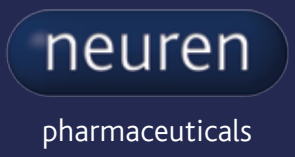
Langley Alexander Walker – relevant interest in 18,267,119 ordinary shares at 27 March 2019.

ADDITIONAL INFORMATION

CONTINUED

Twenty largest holders of ordinary shares

Twenty largest holders of ordinary shares:	Number of ordinary shares	% of issued share capital
AUCKLAND TRUST COMPANY LIMITED	16,904,619	16.47%
CITICORP NOMINEES PTY LIMITED	5,553,261	5.41%
CAMERON RICHARD PTY LTD	4,426,387	4.31%
ESSEX CASTLE LIMITED	2,769,251	2.70%
NEUREN TRUSTEE LIMITED	2,500,000	2.44%
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	2,042,858	1.99%
DR RICHARD SPENCER TREAGUS	1,979,163	1.93%
STUART ANDREW PTY LTD	1,964,609	1.91%
LINWIERIK SUPER PTY LTD	1,550,000	1.51%
SMITHLEY SUPER PTY LTD	1,525,000	1.49%
INVESTMENT CUSTODIAL SERVICES LIMITED	1,480,587	1.44%
WALKER GROUP HOLDINGS PTY LTD	1,362,500	1.33%
MXB INVESTMENTS LLC	1,330,000	1.30%
DR TREVOR SCOTT	1,000,000	0.97%
DR ROBIN LANCE CONGREVE	991,637	0.97%
ROXTRUS PTY LIMITED	850,000	0.83%
J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	648,420	0.63%
JOJO ENTERPRISES PTY LTD	613,478	0.60%
FIRST COLBYCO PTY LTD	591,949	0.58%
NAMARONG INVESTMENTS PTY LTD	555,556	0.54%
Total	50,639,275	49.35%
Balance of share register	52,029,138	50.65%
Total issued share capital	102,668,413	100.00%



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