neuren

pharmaceuticals

ANNUAL REPORT 2019

Neuren Pharmaceuticals Limited

Neuren Pharmaceuticals is developing new therapies for debilitating neurodevelopmental disorders that emerge in early childhood and 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 2019, authorised on 29 April 2020.

For, and on behalf of, the Board

Dr Richard Treagus
Chairman

Dr Trevor Scott
Director

WHY INVEST IN NEUREN?

Two novel drugs targeting broad impact on debilitating childhood disorders with urgent unmet need

Trofinetide in Phase 3 for Rett syndrome, funded by US commercial partner ACADIA

- Phase 3 results expected in 2021, potential marketing approval in 2022
- Neuren receives double digit percentage royalties on all sales in North America plus payments of up to US$455 million on achievement of development and annual sales milestones plus one third of market value of Priority Review Voucher

Neuren retains 100% of value of trofinetide outside North America

- Neuren has free and full access to utilise the US regulatory package for registration and will select the optimum commercial outcome after Rett syndrome US Phase 3 results

Compelling data package for NNZ-2591 – moving to clinical trials

- FDA granted 3 Orphan Drug designations for Phelan-McDermid, Angelman and Pitt Hopkins syndromes following positive results in each animal model
- High blood-brain barrier penetration and clear dose response, indicating optimum dose
- Phase 2 trials planned for all three disorders

CHAIRMAN'S LETTER

DR RICHARD TREAGUS

Neuren closed 2019 in a very strong position having achieved some highly significant milestones. Firstly, our North American partner ACADIA commenced the trofinetide Phase 3 trial for Rett syndrome in the US on schedule at the end of October 2019. This had been keenly anticipated by all stakeholders including the Rett community. Secondly, after reviewing the positive results in mouse models and the mechanism of action of NNZ-2591, the FDA granted to Neuren Orphan Drug designation in each of 3 new indications that have no approved therapies. These indications represent large commercial opportunities for Neuren.

Since the end of 2019 the world has been hit by the Covid-19 pandemic, which has caused enrolment of new patients into the Phase 3 trial to pause until ACADIA believes it has the ability to collect data from new patients while ensuring their safety. This modification did not impact patients already enrolled. For patients, their families and shareholders, we look forward to that pause ending and enrolment continuing in this very important trial.

The pandemic has had little impact on Neuren's day-to-day operations and we have continued to make good progress on the manufacturing and non-clinical studies for NNZ-2591, as we prepare for clinical trials. We recently announced compelling results in the shank3 model of Phelan-McDermid syndrome, which clearly indicated the dose we should be targeting and confirmed our expectation of improved efficacy with increased treatment duration.

The first clinical trial for NNZ-2591 will be another major step forward in our plan to demonstrate the value of this therapy, which we believe has the potential to make a real impact on the treatment of three debilitating childhood disorders.

The impact of Covid-19 on financial markets has been stark. Neuren's share price was $3.00 in February, $1.00 in March and is approximately $1.50 at the time of writing. However, the underlying value of Neuren's business has not changed. There are three large value-drivers that we expect will crystallise over the next two years:

- ACADIA's Rett syndrome Phase 3 results and New Drug Application for trofinetide in the US;
- Selecting the optimum commercial outcome for trofinetide outside North America using the US regulatory package; and
- Phase 2 clinical results for NNZ-2591 to confirm the positive effects we have seen in the animal models of all 3 indications.

The first of these unlocks the milestone payments, royalties and share of the value of a Priority Review Voucher that together represent Neuren's significant share of trofinetide's value in the US. We retain full confidence in ACADIA's capabilities, capacity and commitment as our North American partner. It also unlocks the second value-driver, for which we believe there may be a number of different options. Neuren's preparations for the third value-driver are on course and we intend to accelerate execution of the Phase 2 trials as soon as we are able.

I would like to thank my fellow directors and the Neuren team for their commitment and achievements over the last year, always remaining focused in this challenging environment and ready to pursue the great opportunities ahead of us.

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.

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.

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, providing the capabilities and funding required to bring trofinetide to market in the United States.

ACADIA commenced the Phase 3 program for trofinetide to treat Rett syndrome at the end of October 2019. A Phase 2 clinical trial has also been conducted by Neuren in Fragile X syndrome. Neuren is now preparing for clinical trials of NNZ-2591 for three disorders.

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 and Fast Track designation for trofinetide in each of Rett syndrome and Fragile X syndrome
- Orphan Drug designation for NNZ-2591 in each of Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome

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.

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.

OPERATING REVIEW

CONTINUED

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. 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 Israel; and autism spectrum disorders in Australia. Patent applications for trofinetide in autism spectrum disorders are still under examination in Canada and Brazil.

For NNZ-2591, Neuren owns issued composition of matter patents in the United States, Europe and Japan which expire in 2024. Neuren also owns issued patents that expire in 2034 concerning the use of NNZ-2591 to treat neurodevelopmental disorders in the United States, Europe and Japan.

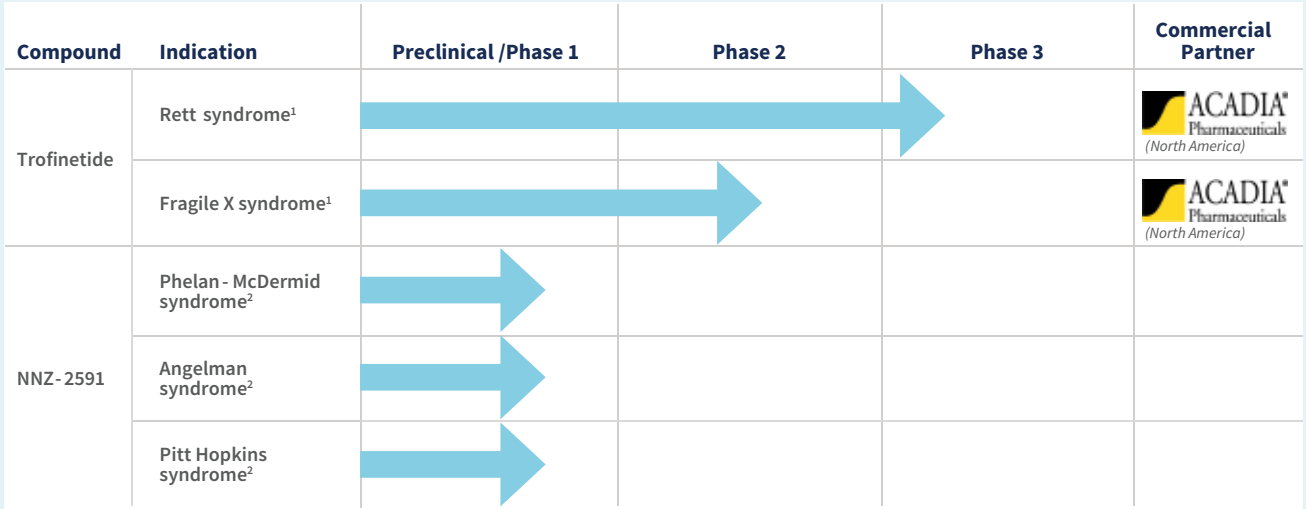
For each of trofinetide and NNZ-2591, following the first marketing authorisation one patent may potentially be extended by up to 5 years in the United States, Europe and Japan.

ESTIMATES OF PATIENT POPULATIONS AGED <60

Disorder	Gene mutation	Published prevalence estimates	Potential patients US[1]	Potential patients EU/JP[1]
Rett	*MECP2*	1/10,000 to 1/15,000 females	10,000	16,000
Fragile X	*FMR1*	1/4,000 to 1/7,000 males 1/12,000 to 1/22,000 females	30,000	48,000
Phelan-McDermid	*SHANK3*	1/8,000 to 1/15,000 males and females	22,000	35,000
Angelman	*UBE3A*	1/12,000 to 1/24,000 males and females	14,000	22,000
Pitt Hopkins	*TCF4*	1/11,000 to 1/41,000 males and females[2]	10,000	16,000

1 The estimates of potential patients are derived by applying the mid-point of the prevalence estimate range to the populations under 60 years
2 The prevalence of chromosome 18q21 deletions was estimated as 1/34,000 to 1/41,000. If deletions are found in one third of individuals with Pitt Hopkins syndrome, the frequency of the syndrome could be as high as 1:11,000

PRODUCT PIPELINE



1 Orphan Drug designation in US and EU, Fast Track designation in US
2 Orphan Drug designation in US

OPERATING REVIEW

CONTINUED

ACADIA PARTNERSHIP FOR TROFINETIDE

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.

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 2018 Annual Report on Form 10-K, which is available to view via the SEC Filings section of ACADIA's website.

As well as ACADIA fully funding the Phase 3 development program and commercialisation, Neuren secured significant participation in the future value of trofinetide in the US, through the following payments from ACADIA:

- 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$500m.
- Payments of up to US$455 million on achievement of development and annual sales milestones. US$105million is to be paid on achievement of development milestones, split between Rett and Fragile X. The remaining US$350million, is to be paid on achievement of a series of 4 thresholds of total annual sales for all indications.
- 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 published sales in 2019 fetched between US$95 million and US$105 million. ACADIA's eligibility for a voucher was recently confirmed by receiving Rare Pediatric Disease Designation from the FDA for the Rett syndrome program.

In addition, under the agreement Neuren retained all rights to trofinetide for countries outside North America with free and full access to utilise the US regulatory package for registration in those countries. Advised by Torreya, a global investment bank specialising in life sciences, Neuren conducted a thorough process to illicit and evaluate proposals for further partnering transactions. After considering a range of proposals and recognising the strong progress made with both the trofinetide and NNZ-2591 programs, the Board concluded that selecting the optimum commercial outcome after the Phase 3 results for Rett syndrome in 2021 may capture substantially greater value. Neuren is now moving forward with European regulatory authority meetings in 2020 to discuss the Rett syndrome development program.

OPERATING REVIEW

CONTINUED

TROFINETIDE FOR RETT SYNDROME

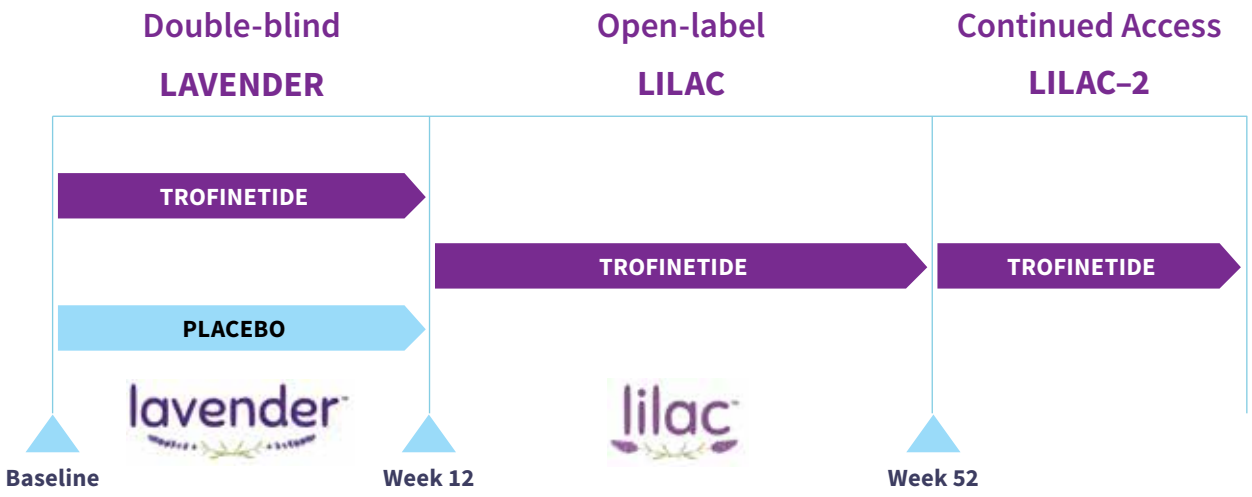
About Rett syndrome

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..

The Phase 3 program

The Phase 3 program was 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. The program has continuing strong support from leading Rett syndrome physicians and the largest advocacy group (rettsyndrome.org).

A randomised double-blind placebo-controlled study for 12 weeks (LAVENDER) is followed by an open label extension study (LILAC) in which all participants, including those on placebo in LAVENDER, are eligible to receive trofinetide. In LILAC, all participants will be followed to evaluate long term tolerability and safety of trofinetide. A continued access program (LILAC 2) will enable participants to continue to receive trofinetide during the period before marketing approval.



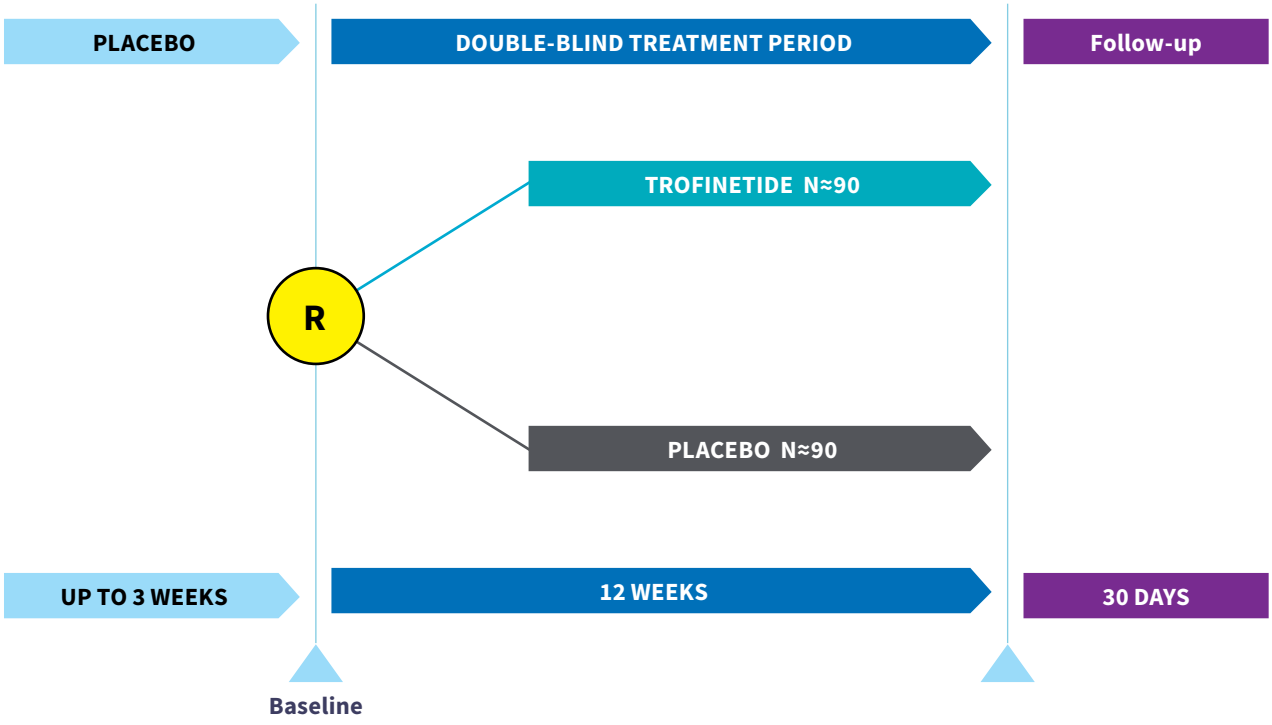
OPERATING REVIEW

CONTINUED

Approximately 180 females with Rett syndrome aged 5 to 20 years will be enrolled at US sites only, randomised into one active group and a placebo group. Change after 12 weeks measured by each of the Rett Syndrome Behaviour Questionnaire (RSBQ) and the Clinical Global Impression – Improvement scale (CGI-I) are the co-primary efficacy endpoints. RSBQ is an assessment by the caregiver and CGI-I is an assessment by the physician.

ACADIA initiated the LAVENDER study at the end of October 2019 and the first patients have completed LAVENDER and commenced LILAC. Results from LAVENDER are expected in 2021, with potential marketing approval in 2022. As an Orphan Drug, the marketing application will qualify for an expedited Priority Review period of 6 months.

In March 2020, due to the COVID-19 pandemic, ACADIA temporarily paused the enrolment of new patients in the LAVENDER study until it believes it has the ability to collect data from new patients while ensuring their safety. This modification did not impact patients already enrolled in the LAVENDER study.



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 published online with free access and appeared in the 16 April 2019 issue of *Neurology* (Glaze et al. 2019). This publication 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.

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.

OPERATING REVIEW

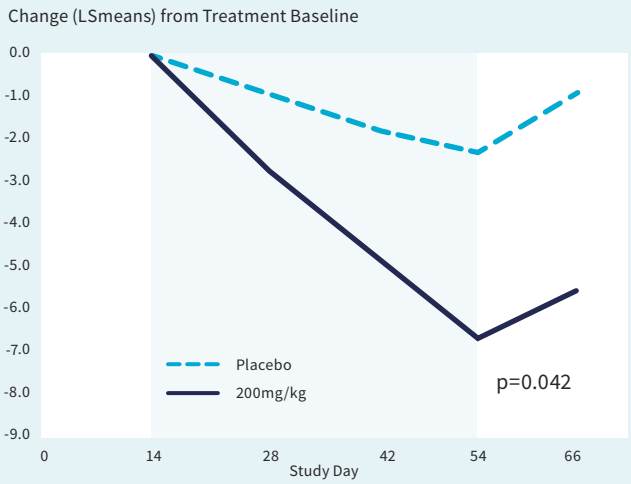
CONTINUED

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

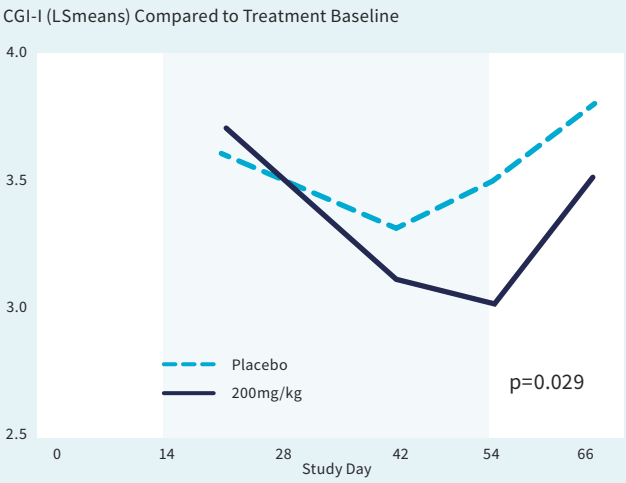
Neuren's Phase 2 trial was a double-blind, randomized, placebo-controlled study that tested three doses of trofinetide compared with placebo in 82 girls with Rett syndrome aged 5 to 15. Trofinetide was well tolerated and had a good safety profile in these younger subjects, with no dose-limiting effects observed. The highest dose achieved statistically significant and clinically relevant benefit compared with placebo measured by each of RSBQ and CGI-I. 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.

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:

Clinical improvement measured by RSBQ



Clinical improvement measured by CGI-I



The Phase 3 trial design builds on the Phase 2 trial:

- The Phase 3 co-primary endpoints were both positive in the Phase 2 trial
- In the Phase 2 trial clinical improvement continued increasing through to end of treatment - the Phase 3 trial at 12 weeks is twice the duration of the Phase 2 trial
- The Phase 3 sample size at approx. 90 per group is more than 3 times the Phase 2 sample size and therefore has much greater statistical power to detect a difference between active and placebo
- The dosing regimen in the active group for the Phase 3 trial is optimised, informed by the PK-PD analyses of the Phase 2 subjects
- The age range for the Phase 3 trial is 5 to 20 years, compared with 5 to 15 years in the Phase 2 trial
- Both trials are at US sites only, with most Phase 2 sites participating in Phase 3

TROFINETIDE FOR FRAGILE X SYNDROME

Trofinetide is in Phase 2 development for Fragile X syndrome, which 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, which is the most common inherited cause of intellectual disability. It 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. Generally, males are more severely affected than females, with approximately 50% of the females having features of the syndrome. Neuren conducted a randomized, double-blind, placebo-controlled Phase 2 clinical trial in the United States in 70 males aged 12 to 45 years with Fragile X syndrome. The trial was overseen by leading clinical experts in Fragile X syndrome. Trofinetide was 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, including higher sensory tolerance, reduced anxiety, better self-regulation and more social engagement.

OPERATING REVIEW

CONTINUED

NNZ-2591 FOR THREE NEURODEVELOPMENTAL DISORDERS WITH URGENT UNMET NEED

Neuren is developing NNZ-2591 for Phelan-McDermid, Angelman and Pitt Hopkins syndrome, each of which currently has no approved therapy. Each is caused by a different genetic mutation, however they share the feature of impaired signalling between neurons, with abnormal length and density of the dendritic spines that connect the neurons via synapses. In turn this means that they share many common characteristics, as shown in the table below.

	Phelan-McDermid	Angelman	Pitt Hopkins
Gene mutation:	***SHANK3***	***UBE3A***	***TCF4***
Characteristic:			
Intellectual disability	√	√	√
Anxiety and hyperactivity	√	√	
Speech impairment	√	√	√
Motor and balance problems	√	√	
Sleep disturbance	√	√	√
Seizures	√	√	√
Breathing irregularities	√		√
Gastrointestinal issues	√	√	√
Autistic features	√	√	√

Preparing for clinical development program

An extensive program of non-clinical toxicology and manufacturing studies required to open an Investigational New Drug (IND) application in the United States and enable clinical trials for 12 weeks in pediatric patients is currently in progress. In addition Neuren is nearing completion of preparations for a Phase 1 safety trial in healthy volunteers in Australia.

In designing and executing the NNZ-2591 development program, Neuren is able to leverage the extensive and highly relevant experience gained from the trofinetide Rett syndrome and Fragile X syndrome programs across manufacturing, non-clinical, clinical and regulatory. To date a compelling package of results has been achieved from pre-clinical studies.

Clear efficacy in mouse models reviewed by FDA to grant 3 Orphan Drug designations

During 2019, Neuren tested NNZ-2591 in mouse models of each of the three disorders. The studies in these models compared normal mice (“wild type”) and mice with a disrupted gene (“knockout”). The knockout mice exhibit behavioural and biochemical deficits that mimic each disorder in humans. The wild type mice and the knockout mice were each treated with placebo and NNZ-2591. The performance of the mice on a series of behavioural tests, and the number of seizures, were then measured. In each model treatment with NNZ-2591 for 6 weeks eliminated all the deficits so that the knockout mice were indistinguishable from the wild type mice. Treatment had no impact on the wild type mice, which is important from a safety point of view.

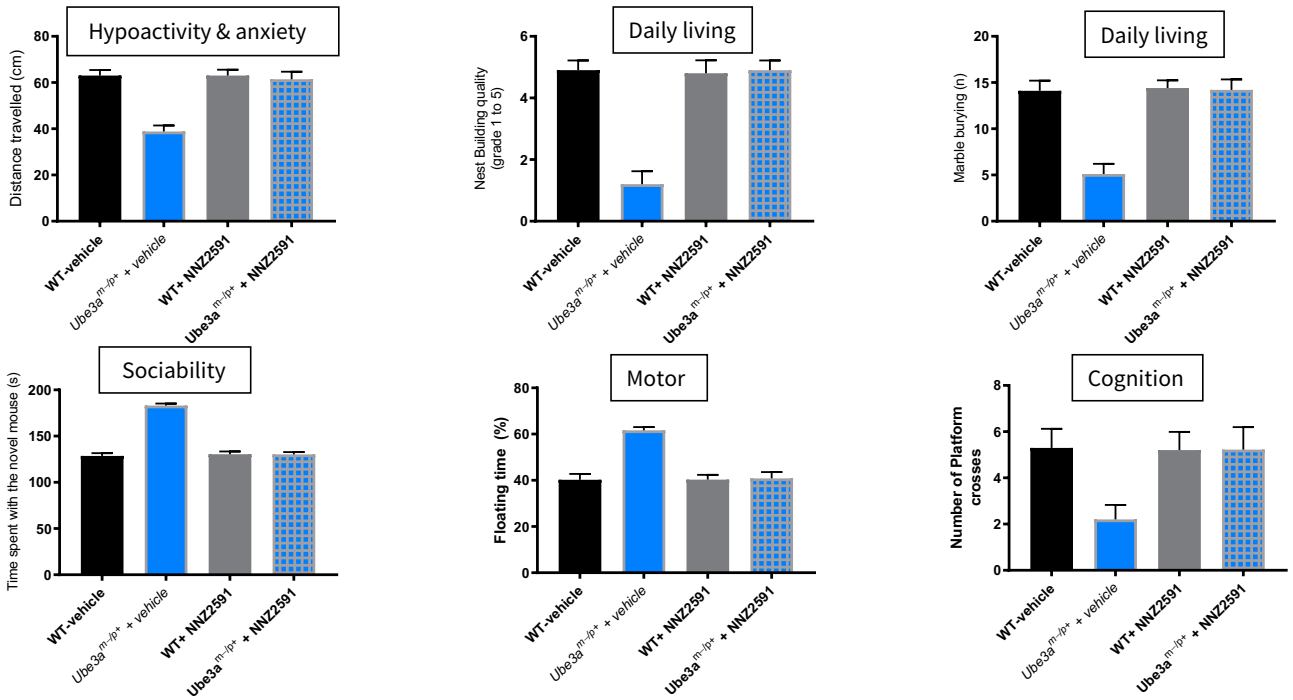
The study results were reviewed by the FDA before granting to Neuren in October 2019 Orphan Drug designation for each of Phelan-McDermid, Angelman and Pitt Hopkins syndrome.

OPERATING REVIEW

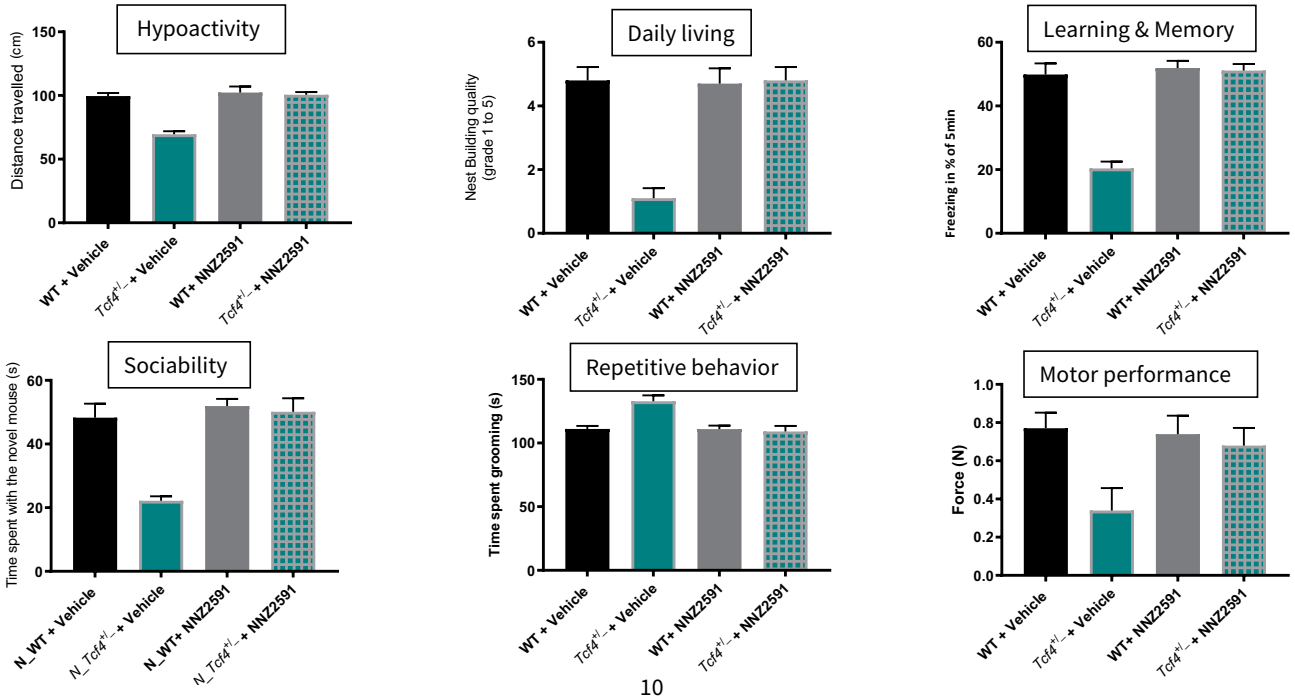
CONTINUED

The charts below show the results in Angelman syndrome and Pitt Hopkins syndrome models. The knockout mice treated with placebo (the second bar) show clear deficits compared with the wild type mice treated with placebo (the first bar). However, the knockout mice treated with NNZ-2591 (the fourth bar) are indistinguishable from the wild type mice. The wild type mice treated with NNZ-2591 (the third bar) are also indistinguishable from the wild type mice treated with placebo. In the Angelman model, treatment also eliminated seizures in the knockout mice.

Efficacy in mouse model of Angelman



Efficacy in mouse model of Pitt Hopkins



OPERATING REVIEW

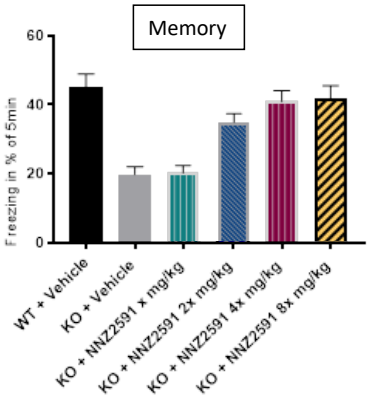
CONTINUED

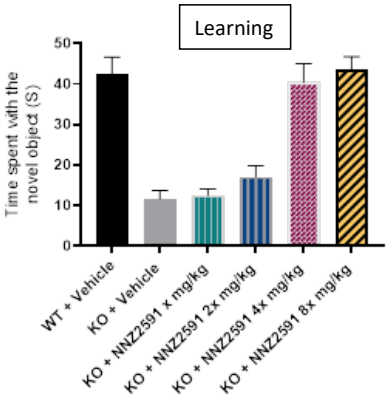
Optimum dose identified and biochemical effects confirmed

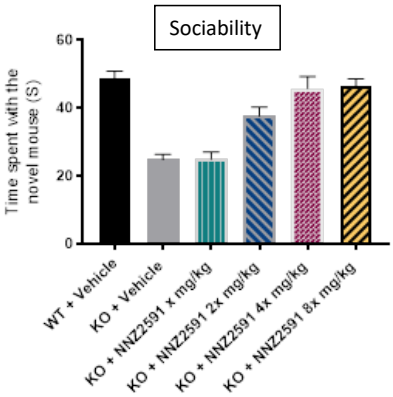
In the Phelan-McDermid syndrome model, additional studies were undertaken to investigate the effective of four escalating dose levels and the biochemical effects of treatment.

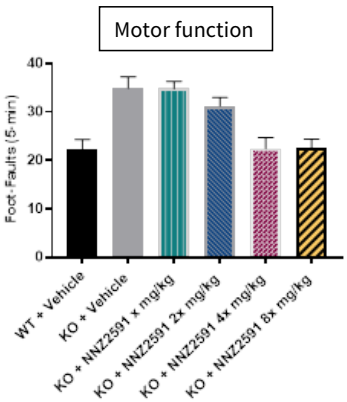
The clear and consistent results of the dose ranging study are shown in the charts below. They were consistent across all 8 behavioural tests and the incidence of seizures, showing that the lowest dose ("x" mg/kg) was not effective, the 2x mg/kg dose was partially effective, the 4x mg/kg dose was fully effective and indistinguishable from the highest dose of 8x mg/kg. This clearly demonstrated that the 4x mg/kg dose was the optimum dose level in the mouse model. Comparison with human pk data from a planned Phase 1 clinical trial will inform the equivalent human dose for the Phase 2 trials in patients.

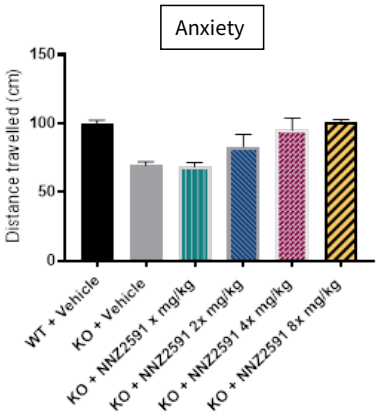
A further observation was that the 4x mg/kg dose in the 6 weeks study showed better efficacy than the same dose in an earlier 3 weeks study, indicating that efficacy increases with treatment duration. Neuren plans to test treatment with NNZ-2591 for 12 weeks in the Phase 2 trials. The 4x mg/kg dose level was also shown to be an effective dose in the Angelman and Pitt Hopkins models.

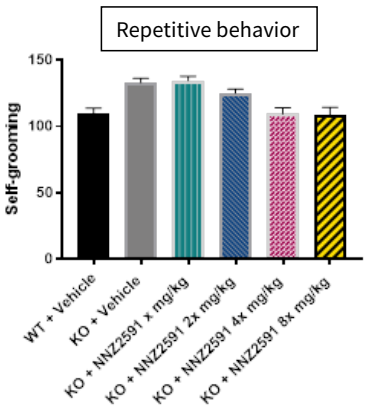


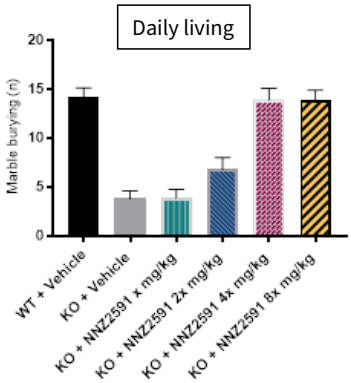


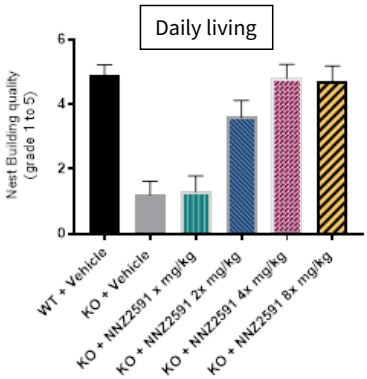












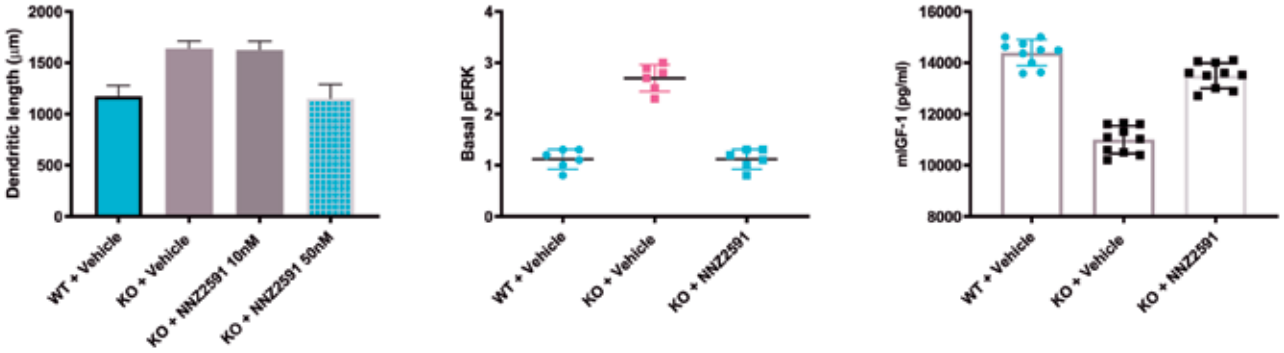
Incidence of seizures

WT + vehicle	KO + vehicle	KO + x mg/kg
0%	60%	50%
KO + 2x mg/kg	**KO + 4x mg/kg**	**KO + 8x mg/kg**
30%	10%	10%

OPERATING REVIEW

CONTINUED

In the Phelan-McDermid syndrome model, compared with normal mice the shank3 knockout mice have abnormally long dendritic spines between brain cells, an excess of activated ERK protein (pERK) and a depressed level of IGF-1, all of which are thought to contribute to abnormal signalling between the brain cells. Treatment with NNZ-2591 normalised each of these features, as shown in the charts below.



Blood-brain barrier penetration confirmed

Very good penetration of the blood-brain barrier by NNZ-2591 was demonstrated in a rodent study. A single dose was administered at 2 dose levels, with the high dose twice the low dose. The concentration of NNZ-2591 in the blood and cerebrospinal fluid after 1.5 hours and again after 4 hours. The amount in the brain was also measured after 4 hours. In each case the amount was approximately proportional to the dose and after 4 hours the concentration in blood and brain tissue was approximately equivalent.

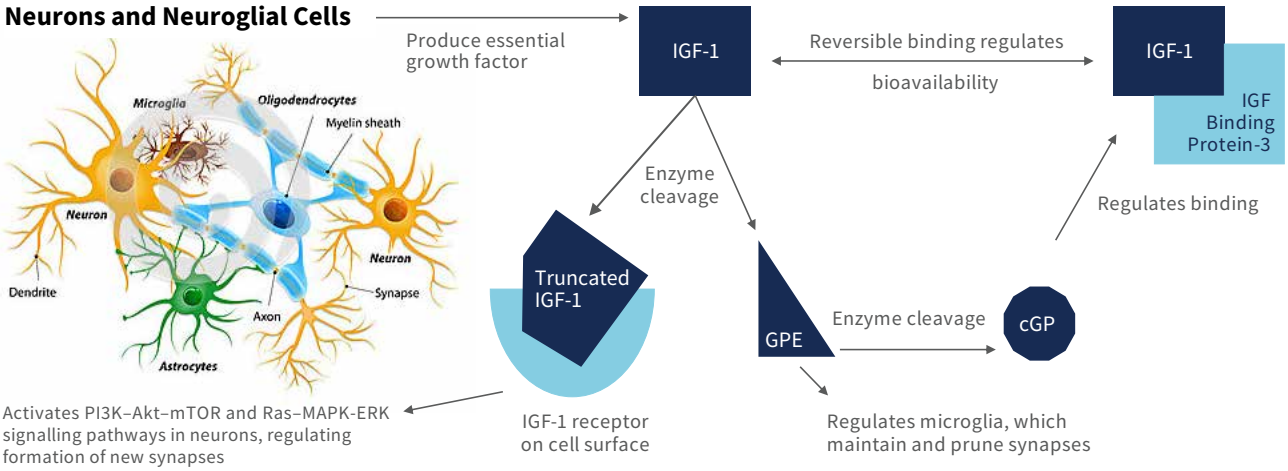
	Mean exposure to NNZ-2591		
Dose	**"A"mg/kg**	**2A mg/kg**	**Ratio of 2A mg/kg: A mg/kg**
1.5 hours post-dose:			
Cerebrospinal fluid (µg/ml)	40.4	82.2	2.03 : 1
Blood (µg/ml)	58.5	116.0	1.98 : 1
4 hours post-dose:			
Cerebrospinal fluid (µg/ml)	11.0	24.7	2.25 : 1
Blood (µg/ml)	15.6	34.2	2.19 : 1
Brain (µg/g)	22.6	37.0	1.63 : 1

OPERATING REVIEW

CONTINUED

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, which 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 ("truncated 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 truncated 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.

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

Although different conditions – brain injury, neurodevelopmental disorders and neurodegenerative diseases – can result in very different symptoms and outcomes, many share common, underlying pathological features. These include inflammation, over-activation of microglia, dysfunction of synapses (the connections between neurons through which information is transmitted) and reduced levels of IGF-1. In other words, diseases and conditions 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:

OPERATING REVIEW

CONTINUED

1. Inflammation

Inflammation in the brain (neuroinflammation) is perhaps the most common pathological feature of neurological 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.

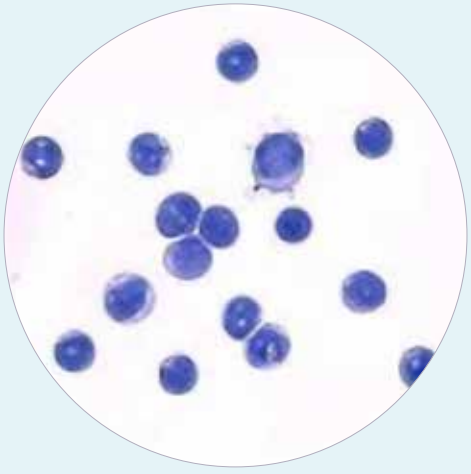
2. Over-activation of microglia

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.

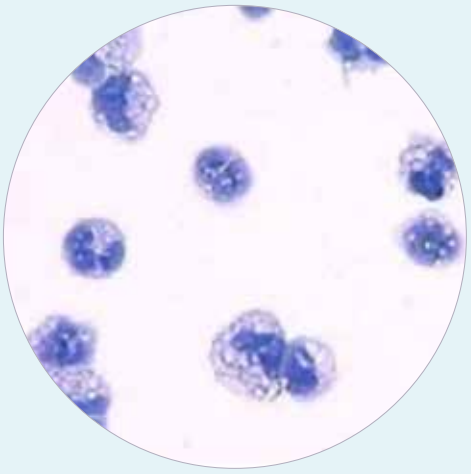
Microglia are not only activated in response to infection and injury. They also are activated by inflammation that accompanies acute brain injury and chronic conditions. In this activated state, they not only lose their ability to effectively perform their normal function in synaptic maintenance but 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

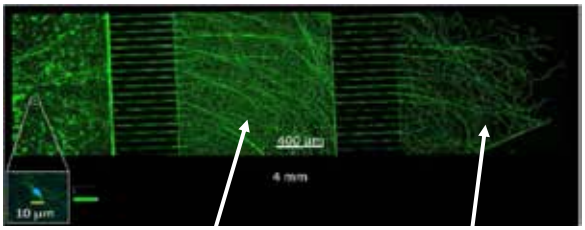
3. Dysfunction of synapses

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 (the branches on 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.

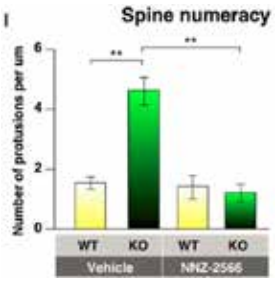
In models of Fragile X syndrome and Phelan-McDermid syndrome, NNZ-2591 normalised an excessive level of activated ERK enzyme (pERK), which has been implicated in abnormal synaptic signalling.



Abnormal dendrites in shank3 knockout mice

Normalisation after treatment with NNZ-2591

Correction of abnormal dendritic spines in mouse models:
Left - Phelan-McDermid syndrome (*shank3*)
Right - Fragile X syndrome (*fmr1*)



Correction in fmr1 knockout mice after treatment with trofinetide (NNZ-2566)

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

	2019 $'m	2018 $'m
Revenue from ACADIA agreement	–	13.5
R&D Tax Incentive	0.5	0.5
Interest income	0.4	0.2
Foreign exchange gain	0.1	1.0
Total income	**1.0**	**15.2**
Research & Development	(9.8)	(6.1)
Corporate & Administration	(1.7)	(2.1)
Loss in fair value of Lanstead settlements	(0.3)	(3.9)
(Loss) / Profit after tax	**(10.8)**	**3.1**
Cash flow from operations	(11.7)	6.4
Cash flow from financing	1.9	11.7
Effect of exchange rates on cash balances	0.1	0.7
Cash at 31 December	**13.8**	**23.6**

The loss after tax for 2019 was $10.8 million compared with profit after tax of $3.1 million in 2018, mainly due to revenue of $13.5 million received in 2018 under the licence agreement with ACADIA. In addition, foreign exchange gains decreased by $0.8 million and research and development costs increased by $3.8 million, resulting from higher expenditure on manufacturing scale-up and non-clinical toxicity studies. These were offset by a decrease in the loss of $0.3 million (2018: $3.9 million) 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 Sharing Agreement with Lanstead Capital concluded in June 2019 with the final settlement received in July 2019. The aggregate amount received from Lanstead Capital throughout the course of the arrangement was $12.2 million. This delivered to Neuren additional cash funding of $2.2 million, with no additional shares issued to Lanstead Capital.

Cash reserves at 31 December 2019 were $13.8 million (2018: $23.6 million). Net cash used in operating activities was $11.7 million, compared with cash inflow of $6.4 million in 2018. Financing provided cash of $1.9 million, received from the Lanstead Capital settlements, compared with $11.7 million in 2018 from the issue of shares in May 2018 under the exclusivity deed with ACADIA and the settlements from Lanstead Capital.

OPERATING REVIEW

CONTINUED

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.

3. DIANNE ANGUS

Non-Executive Director

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

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. 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 Ondek Pty Ltd, QUTbluebox and Creative Enterprise Australia.

5. PATRICK DAVIES

Non-Executive Director

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 joined Neuren in 2004 and was an Executive Director from 2012 to 2018. 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.

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.

In accordance with Recommendation 1.6, there is a process to evaluate periodically the performance of the Board, its committees and individual directors. 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 formal performance evaluation was not undertaken during 2019.

In accordance with Recommendation 1.7, there is a process for the Board to evaluate periodically the performance of the Executive Chairman and for the Executive Chairman to evaluate periodically 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. Formal performance evaluations were not undertaken during 2019.

CORPORATE GOVERNANCE

CONTINUED

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.
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.

CORPORATE GOVERNANCE

CONTINUED

The Board is highly engaged in the oversight and direction of the business. Five members served during the year to 31 December 2019, as set out in the table below. Details of the relevant skills, experience and expertise of each Board member are set out on page 27 of this report.

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

[1] Richard Treagus is not considered independent due to his executive role.

There is 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.

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

CORPORATE GOVERNANCE

CONTINUED

- 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, which consists of only independent non-executive directors, has at least 3 members and is chaired by an independent director as suggested in Recommendation 4.1. The relevant qualifications and experience of the members are set out on page 27 of this report. The Committee met twice during 2019, 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.

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 Equivalents to International Financial Reporting Standards (NZ FRS) 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 25 February 2020.

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.

CORPORATE GOVERNANCE

CONTINUED

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 2019.

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

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

PRINCIPLE 8. REMUNERATE FAIRLY AND RESPONSIBLY

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

The Board has a Remuneration Committee, which consists of only independent non-executive directors, has at least three members and is chaired by an independent director as suggested in Recommendation 8.1. The Committee met once in 2019, 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.

CORPORATE GOVERNANCE

CONTINUED

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.

REVIEW OF OPERATIONS

Neuren is developing new therapies for five neurodevelopmental disorders with high un-met need, utilizing synthetic analogs of peptides that occur naturally in the brain. Neuren has granted an exclusive license to ACADIA Pharmaceuticals Inc. (ACADIA) for the development and commercialization of trofinetide in North America, whilst retaining all rights outside North America. Trofinetide is in a Phase 3 clinical trial in the United States for Rett syndrome and has completed a Phase 2 clinical trial in Fragile X syndrome. The programs in Rett syndrome and Fragile X syndrome have each received Fast Track designation by the US Food and Drug Administration (FDA) and Orphan Drug designation in both the United States and the European Union. Neuren is advancing the development of its second drug candidate NNZ-2591 for Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome.

Neuren's new product pipeline expanded and advanced substantially during 2019, with the Rett syndrome program moving into the final stage (Phase 3) and development commencing in three new indications. Neuren ended the year in a strong position, advancing 2 valuable drugs to treat 5 debilitating childhood disorders which currently have no approved therapies. The lead program is in Phase 3 in the US, fully funded and executed by ACADIA.

ACADIA commenced the Rett syndrome Phase 3 program in October 2019. The program involves treatment of approximately 180 females aged 5 to 20 with trofinetide or placebo for 12 weeks to evaluate efficacy and safety (the "LAVENDER" study), following which patients are eligible to continue treatment with trofinetide for 40 weeks to provide longer-term safety data (the "LILAC" study). Results from the LAVENDER study are expected in 2021. Positive results potentially will enable a New Drug Application, which should be eligible for "Priority Review" by the FDA in an abbreviated period of 6 months. ACADIA has also established "LILAC-2" under which eligible patients who complete LAVENDER and LILAC will be able to continue to receive trofinetide during the period before marketing approval.

In March 2019 the results of Neuren's Phase 2 study of trofinetide in pediatric Rett syndrome were published in Neurology®, the highly regarded peer-reviewed medical journal of the American Academy of Neurology. The publication was also the basis for an editorial in the journal titled "Turning the tide on targeted treatments for neurodevelopmental disorders".

In February and May 2019, Neuren announced positive results for NNZ-2591 in separate mouse models of Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome. These are three debilitating neurodevelopmental disorders with no approved drug therapy. The cause of each disorder is a mutation or deletion in a different gene or chromosomal region, however they share an underlying impairment in the connections and signalling between brain cells. The aim of treatment with NNZ-2591 is to restore normal functional connectivity and signalling.

In October 2019, Neuren received three Orphan Drug designations from the FDA for NNZ-2591 in each of Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome. Orphan Drug designation is a special status that the FDA may grant to a drug to treat a rare disease or condition. Orphan Drug designation qualifies the sponsor of the drug for incentives including 7 years of marketing exclusivity, plus 6 additional months if approved for pediatric use, as well as waiver of the prescription drug user fee for a marketing application.

Neuren is continuing the manufacturing development and non-clinical studies required before submitting an Investigational New Drug (IND) Application for NNZ-2591 in the United States. Neuren aims to commence clinical trials in the second half of 2020. The NNZ-2591 program is benefiting from the extensive experience gained by Neuren during the development of trofinetide for Rett syndrome and Fragile X syndrome.

During the year, Neuren's patent portfolio for trofinetide and NNZ-2591 was enhanced further by the grant of new patents in the key markets of the United States, Europe and Japan. Additional patent applications are under examination.

Assisted by Torreya, a global investment bank specialising in life sciences, Neuren is conducting a process to evaluate proposals for potential corporate transactions, engaging with third parties in the US, Europe and Japan.

The consolidated financial statements are presented on pages 30 to 47. All amounts in the Financial Statements are shown in Australian dollars unless otherwise stated.

The Group's loss after tax attributable to equity holders of the Company for the year ended 31 December 2019 was $10.8 million compared with the Group's profit after tax of $3.1 million in 2018, mainly due to revenue of $13.5 million received in 2018 under the licence agreement with ACADIA. In addition, foreign exchange gains decreased by $0.8 million and research and development costs were higher by by $3.8 million, resulting from increased expenditure on manufacturing scale-up and non-clinical toxicity studies. These were offset by a decrease in the loss of $0.3 million (2018: $3.9 million) on the fair value of the remaining settlements from Lanstead Capital under the

DIRECTORS' REPORT

CONTINUED

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 Sharing Agreement with Lanstead Capital concluded in June 2019 with the final settlement received in July 2019. The aggregate amount received from Lanstead Capital throughout the course of the arrangement was $12.2 million. This delivered to Neuren additional cash funding of $2.2 million, with no additional shares issued to Lanstead Capital.

The basic loss per share for 2019 was $0.108 (2018: earnings of $0.031 per share), based on a weighted average number of shares outstanding of 100,168,413 (2018: 99,038,854).

Cash reserves at 31 December 2019 were $13.8 million (2018: $23.6 million). Net cash used in operating activities was $11.7 million, compared with cash inflow of $6.4 million in 2018. Financing provided cash of $1.9 million, received from the settlements from the Sharing Agreement with Lanstead Capital, compared with $11.7 million in 2018 from the issue of shares in May 2018 under the exclusivity deed with ACADIA and settlements from the Lanstead Sharing Agreement.

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.

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.

Dianne Angus BSc (Hons), Master of Biotechnology, IPTA (Non-Executive Director)

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.

Patrick Davies B EC, MBA (Non-Executive Director)

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.

DIRECTORS' REPORT

CONTINUED

Dr Jenny Harry BSc (Hons), PhD (Non-Executive Director)

Jenny joined the Neuren Board in 2018. She has 20 years' experience in executive management of companies in the biotechnology and biopharmaceutical sectors. 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 Ondek Pty Ltd, 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. There were no entries during or since the end of 2019.

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 (2018: $nil).

REMUNERATION OF DIRECTORS

Remuneration of the Directors is shown in the table below.

Remuneration of Directors	2019 $'000	2018 $'000
Dr Richard Treagus	360	536
Larry Glass	–	310
Dr Trevor Scott	72	72
Dianne Angus	60	30
Patrick Davies	60	30
Dr Jenny Harry	60	30

DIRECTORS' REPORT

CONTINUED

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	2019 $'000	2018 $'000
$240,000 - $249,999	1	1
$270,000 - $279,999	1	1
$280,000 - $289,999	1	–
$410,000 - $419,999	–	1

Including shared based payments	2019 $'000	2018 $'000
$240,000 - $249,999	1	–
$270,000 - $279,999	1	–
$290,000 - $299,999	–	1
$410,000 - $419,999	1	–

AUDITORS

Grant Thornton New Zealand Audit Partnership ('Grant Thornton') is the independent auditor of the Company. Audit fees in relation to the annual and interim financial statements were $59,649 (2018: $58,538). Grant Thornton did not receive any other fees in relation to other financial advice and services. Grant Thornton Australia (member firm) received $15,000 fees in relation to other financial advice and services in 2018. No amounts were payable to an auditor by subsidiary companies in 2019 or 2018.

For and on behalf of the Board of Directors who authorised the issue of these consolidated financial statements on 25 February 2020.

Dr Richard Treagus
Chairman

Dr Trevor Scott
Director

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE YEAR ENDED 31 DECEMBER 2019

	Note	2019 $'000	2018 $'000
Interest		389	218
Revenue from licence agreement		–	13,544
Foreign exchange gain		132	961
Australian R&D Tax Incentive		495	446
Total income		1,016	15,169
Research and development costs		(9,858)	(6,101)
Corporate and administrative costs		(1,713)	(2,074)
Losses on financial assets measured at fair value through profit or loss	9	(261)	(3,921)
(Loss)/Profit before income tax		(10,816)	3,073
Income tax	5	–	–
(Loss)/Profit after income tax		(10,816)	3,073
Other comprehensive loss, net of tax			
Amounts which may be subsequently reclassified to profit or loss:			
Exchange differences on translation of foreign operations		(6)	(58)
Total comprehensive (loss)/income for the year		(10,822)	3,015
(Loss)/Profit after tax attributable to Equity holders of the Company:		(10,816)	3,073
Total comprehensive (loss)/profit attributable to Equity holders of the Company:		(10,822)	3,015
Basic (loss)/earnings per share	6	($0.108)	$0.031
Diluted (loss)/earnings per share	6	($0.108)	$0.031

The notes on pages 34 to 47 form part of these consolidated financial statements

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT 31 DECEMBER 2019

	Note	2019 $'000	2018 $'000
ASSETS			
Current Assets:			
Cash and cash equivalents	7	13,844	23,576
Trade and other receivables	8	552	942
Financial assets measured at fair value through profit or loss	9	–	2,121
Total current assets		14,396	26,639
Non-current assets:			
Property, plant and equipment		10	2
Intangible assets		–	1
Total non-current assets		10	3
TOTAL ASSETS		14,406	26,642
LIABILITIES AND EQUITY			
Current liabilities:			
Trade and other payables	10	559	1,973
Total current liabilities		559	1,973
Total liabilities		559	1,973
EQUITY			
Share capital	11	126,426	126,426
Other reserves		(8,503)	(8,497)
Accumulated deficit		(104,076)	(93,260)
Total equity attributable to equity holders		13,847	24,669
TOTAL LIABILITIES AND EQUITY		14,406	26,642

The notes on pages 34 to 47 form part of these consolidated financial statements

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE YEAR ENDED 31 DECEMBER 2019

	Share Capital $'000	Share Option Reserve $'000	Currency Translation Reserve $'000	Accumulated Deficit $'000	Total Equity $'000
Equity as at 1 January 2018	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 loss			(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
Loss after income tax				(10,816)	(10,816)
Other comprehensive loss			(6)		(6)
Total Comprehensive loss for the year			(6)	(10,816)	(10,822)
Equity as at 31 December 2019	126,426	2,186	(10,689)	(104,076)	13,847

The notes on pages 34 to 47 form part of these consolidated financial statements

CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 31 DECEMBER 2019

	Note	2019 $'000	2018 $'000
Cash flows from operating activities:			
Receipts from licence agreement		–	13,544
Receipts from Australian R&D Tax Incentive		450	631
Interest received		413	165
GST refunded		102	95
Payments for employees and directors		(1,742)	(1,909)
Payments to other suppliers		(10,942)	(6,118)
Net cash flow (to)/from operating activities		(11,719)	6,408
Cash flows from investing activities:			
Purchase of property, plant and equipment		(12)	–
Net cash used in investing activities		(12)	–
Cash flows from financing activities:			
Proceeds from the issue of shares	9	1,860	11,730
Payment of share issue expenses		–	(16)
Net cash provided from financing activities		1,860	11,714
Net (decrease)/increase in cash		(9,871)	18,122
Effect of exchange rate changes on cash balances		141	748
Cash and cash equivalents at the beginning of the year		23,576	4,706
Cash and cash equivalents at the end of the year		13,846	23,576
Reconciliation with (loss)/profit after income tax:			
(Loss)/Profit after income tax		(10,816)	3,073
Non-cash items requiring adjustment:			
Depreciation of property, plant and equipment		4	5
Amortisation of intangible assets		–	72
Foreign exchange gain		(144)	(806)
Loss on financial assets		261	3,921
Changes in working capital:			
Trade and other receivables		390	(250)
Trade and other payables		(1,414)	393
Net cash flow from operating activities		(11,719)	6,408

The notes on pages 34 to 47 form part of these consolidated financial statements

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 DECEMBER 2019

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 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 25 February 2020.

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 yet to be proven technology; the Group's ability to sufficiently complete the clinical trials process; and technological developments by the Group's competitors could render its products obsolete.
- The Group's revenue from licence agreements is contingent on future events and will be intermittent until product sales commence. The business plan therefore may require expenditure in excess of revenue and in the future the Group 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 Group.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

These general-purpose consolidated financial statements of the Group are for the year ended 31 December 2019 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) issued by the New Zealand Accounting Standards Board 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 External Reporting 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 2019 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 consolidated financial statements have been prepared under the historical cost convention as modified by certain policies below. Amounts are expressed in Australian Dollars and are rounded to the nearest thousand, except for earnings per share.

Critical accounting estimates

The preparation of financial statements requires the use of certain critical accounting estimates. It also requires the Group to exercise its judgement in the process of applying the 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 a loss after tax of $10.8 million for the year ending 31 December 2019 and had negative operating cash flows of $11.7 million for the year ended 31 December 2019. The Group had net assets at 31 December 2019 of $13.8 million, including cash balances of $13.8 million.

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 consolidated financial statements. The consolidated financial statements do not include any adjustments that would result if the Group was unable to continue as a going concern.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Changes in accounting policies
There is no significant impact of changes in accounting policies for the year ended 31 December 2019. The Group adopted NZ IFRS 16 'Leases' as at 1 January 2019. The Group does not have any qualifying lease agreements, therefore there is no impact on the consolidated financial statements for the current year.

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 currency of the Company and the presentation currency of 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;
- revenue 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.

(d) Revenue

Revenue arises mainly from grants received and interest. In the prior reporting period revenue from licence agreements was recognised in relation to the partnering agreement signed with ACADIA Pharmaceuticals Inc ("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 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 as 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 recognised in the prior year was a Phase II reimbursement fee and was recognised as a separate performance obligation as it is distinct from all the other obligations within the Acadia licence agreement. The revenue from this performance obligation was recognised at a point in time when Neuren had transferred its intellectual property to ACADIA and Neuren had an enforceable right to receive payment.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(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) 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.

(h) 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.

(i) Cash and cash equivalents

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

(j) 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 assesses trade receivables on an individual basis, and uses its historical experience, external indicators and forward-looking information to calculate the expected credit losses.

(k) 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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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

Scientific equipment	4 years
Computer equipment	2-10 years
Office furniture, fixtures & fittings	3-4 years

(l) 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.

(m) Employee benefits

Wages and salaries, annual leave, long service leave and superannuation

Liabilities for wages and salaries, bonuses, annual leave, long service leave and superannuation 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.

Contributions are made by the Group to employee superannuation funds and are charged as expenses when the obligation to pay them arises.

Share-based payments

Neuren has operated 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.

(n) 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.

(o) 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 'Revenue from contracts with customers', 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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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 within the Statement of Comprehensive Income. 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.

(p) Financial liabilities

The Group's financial liabilities include trade and other payables. Financial liabilities are initially measured at fair value, and, where applicable, adjusted for transaction costs.

Subsequently, financial liabilities are measured at amortised cost using the effective interest method.

(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

	2019 $'000	2018 $'000
Loss/(Profit) before income tax includes the following expenses:		
Depreciation – property, plant and equipment		
Computer equipment	4	4
Fixtures and fittings	–	1
Total depreciation	4	5
Amortisation – intangible assets		
Intellectual property	–	73
Total amortisation	–	73
Remuneration of auditors		
Audit and review of financial statements (Grant Thornton NZ)	60	59
Advisory services (Grant Thornton Australia – member firm)	–	15
Audit and review of financial statements (PwC)	–	67
Total remuneration of auditors	60	141
Employee benefits expense		
Short-term benefits	754	1,031
Post-employment benefits	70	73
Other employee benefits expenses	75	–
Total employee benefits expense	899	1,104
Directors' compensation		
Short-term benefits	602	1,003
Post-employment benefits	10	5
Total Directors' compensation	612	1,008

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

5. INCOME TAX

	2019 $'000	2018 $'000
Income tax		
Current tax	–	–
Deferred tax	–	–
	–	–
Numerical reconciliation of income tax to prima facie tax receivable:		
(Loss)/Profit before income tax	(10,816)	3,073
Tax at applicable rates 27.5% (2018: 27.5%)	(2,974)	845
Non-taxable Australian R&D Tax Incentive income	(136)	(123)
Non deductible expenses for R&D incentive	310	282
Non-taxable loss in fair value of equity derivative	72	1,078
Taxable (loss)/gain on settlement of equity derivative	(268)	728
Utilisation of previously unrecognised tax losses	–	(2,710)
Deductible temporary differences and tax losses for which no deferred tax asset was recognised	2,996	(100)
Income tax benefit	–	–
Gross tax losses for which no deferred tax asset has been recognised[(a)]	100,883	88,914

(a) Of these gross tax losses, $64.6 million relates to New Zealand tax losses, which are unlikely to be utilised unless future taxable income is generated in New Zealand.

6. EARNINGS PER SHARE

The Group has potentially dilutive ordinary shares in the form of 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. In 2019, the loan funded shares are excluded from the diluted weighted average shares outstanding as they are anti-dilutive.

	2019	2018
(Loss)/Profit after income tax attributable to equity holders (basic) ($'000)	(10,816)	3,073
Weighted average shares outstanding (basic) (No.)	100,168,413	99,038,854
Basic (loss)/earnings per share	($0.108)	$0.031
(Loss)/Profit after income tax attributable to equity holders (diluted) ($'000)	(10,816)	3,073
Weighted average shares outstanding (diluted) (No.)	100,168,413	99,751,382
Diluted (loss)/earnings per share	($0.108)	$0.031

7. CASH AND CASH EQUIVALENTS

	2019 $'000	2018 $'000
Cash	820	3,738
Demand and short-term deposits	13,024	19,838
	13,844	23,576

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

8. TRADE AND OTHER RECEIVABLES

	2019 $'000	2018 $'000
Trade receivables	13	423
Other receivables	15	16
Interest receivables	33	57
Australian R&D tax incentive	491	446
	552	942

The Group applies the 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 2019 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 (2018: nil).

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

	2019 $'000	2018 $'000
Current		
Equity derivative	–	2,121

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

	2019 $'000	2018 $'000
Opening fair value	2,121	12,466
Cash settlements received	(1,860)	(6,424)
Net loss through profit or loss	(261)	(3,921)
Closing fair value	–	2,121

Financial instruments classified under the equity derivative were measured at fair value using a fair value hierarchy reflecting the significance of the inputs used in making the measurements. These financial assets were classified as level 2. Fair value calculations were 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. The arrangement concluded in June 2019 with the final settlement received in July 2019.

The aggregate amount received from Lanstead Capital throughout the course of the arrangement was $12.2 million, compared with the commitment of $10.0 million in the placement. This delivered to Neuren additional cash funding of $2.2 million, with no additional shares issued to Lanstead Capital.

The calculation of each monthly settlement was dependent upon the volume weighted average price at which Neuren's shares were traded during the 20 days prior to settlement (VWAP). If the VWAP for each settlement was equal to $1.77 per share (Benchmark Price), Neuren received $472,222 (one eighteenth of $8.5 million). For each settlement, if the VWAP was higher than the Benchmark Price, Neuren received proportionately more than $472,222 and if the VWAP was lower than the Benchmark Price, Neuren received proportionately less than $472,222.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

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

The key assumption for the calculation of the fair value of the equity derivative was the estimated VWAP applicable to each settlement. 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. The fair value calculations were adjusted to reflect the time value of money and the estimated credit risk associated with the counterparty.

10. TRADE AND OTHER PAYABLES

	2019 $'000	2018 $'000
Trade payables	340	1,335
Accruals	26	83
Employee Benefits	193	555
	559	1,973

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.

11. SHARE CAPITAL

	2019 Shares	2018 Shares	2019 $'000	2018 $'000
Issued Share Capital				
Ordinary shares on issue at beginning of year	102,668,413	101,840,020	126,426	121,136
Shares bought back under Loan Funded Share Plan	–	(501,607)	–	–
Shares issued in private placement	–	1,330,000	–	5,306
Share issue expenses - cash issue costs	–	–	–	(16)
	102,668,413	102,668,413	126,426	126,426

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 for a period of 3 months.

At 31 December 2019 and 31 December 2018, 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

No securities were issued under any share based payment plans in 2019 or 2018. At 31 December 2019 and 2018, all services required for instruments issued under share based payment plans had been received. There were no equity-settled share based payments expensed in the Statement of Comprehensive Income in 2019 or 2018.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

11. SHARE CAPITAL (CONTINUED)

Loan funded shares

The Company has a Loan Funded Share Plan to support the achievement of the Company's business strategy by linking executive reward to improvements in the financial performance of the Company and aligning the interests of executives with shareholders. Under the Loan Funded Share Plan, loan funded shares may be offered to employees or consultant ("Participants") by the Remuneration and Audit Committee. The Company issues new ordinary shares, which are placed in a trust to hold the shares on behalf of the Participant. The trustee issues a limited-recourse, 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
Issued shares at 1 January 2018	4,500,000	$1.320	2,000,000	$0.78
Exercised	(2,000,000)	$0.780	(2,000,000)	$0.78
Issued shares at 31 December 2018 and 31 December 2019	2,500,000	$1.76		
Forfeited at 31 December 2019	(1,500,000)	$1.84		
Unvested at 31 December 2019	1,000,000	$1.64	–	

The loans in respect of 1.5 million Loan Funded Shares expired in May 2019, with the share price at that time below the exercise price of $1.84. The Loan Funded Shares were therefore forfeited and are to be bought back by the Company at the amount of the loans and cancelled.

The exercise price for 1.0 million unvested Loan Funded Shares is $1.64 per share. The directors deferred making a determination on the vesting conditions until the loan expiry date in April 2020, or an earlier date as determined by the directors.

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

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
Neuren Pharmaceuticals Inc.	20-Aug-02	Development services	100%	USA
Neuren Pharmaceuticals (Australia) Pty Ltd	9-Nov-06	Dormant	100%	AUS
Neuren Trustee Limited	29-May-13	Holds loan funded shares	100%	NZ

All subsidiaries have a reporting date of 31 December.

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 consolidated financial statements as at 31 December 2019 or 31 December 2018.

(b) Legal claims

The Group had no significant legal matter contingencies as at 31 December 2019 or at 31 December 2018.

(c) Commitments

The Group was not committed to the purchase of any property, plant or equipment or intangible assets as at 31 December 2019 (2018: nil).

At 31 December 2019, the Group had commitments under product development contracts amounting to approximately $6.6 million, comprising approximately US$4.0 million and approximately GBP 0.5 million. At 31 December 2018, the Group had commitments under product development contracts amounting to approximately $12.4 million.

(d) Contingent liabilities

The Group had no contingent liabilities at 31 December 2019 or at 31 December 2018 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:

	2019 $'000	2018 $'000
Short-term benefits	1,345	1,867
Post-employment benefits	62	60
Other long-term benefits	71	–
	1,478	1,927

In 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.

(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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

15. EVENTS AFTER REPORTING DATE

As at the date of these consolidated financial statements authorised for issue, there are no events arising since 31 December 2019 that require disclosure.

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
2019					
Cash and cash equivalents	7	13,844	–	–	13,844
Trade and other receivables	8	–	552	–	552
Total financial assets		13,844	552	–	14,397
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

Financial liabilities		**2019 $'000**	**2018 $'000**
Amortised cost – Non-Interest Bearing:			
Trade and other payables		559	1,973
Total financial liabilities	10	559	1,973

At 31 December 2019, the reporting value of all financial instruments approximated to the fair value.

(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 and interest rates 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.

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 rate between the Australian dollar and the US dollar. The Group holds cash denominated in US dollars and Australian dollars and has material expenditure in each of these currencies. Where possible, the Group matches foreign currency income and foreign currency expenditure as a natural hedge, holding foreign currency cash to facilitate this natural hedge. When foreign currency expenditure exceeds foreign currency revenue and foreign currency cash, the group purchases foreign currency to meet anticipated requirements under spot and forward contracts. The Group does not designate formal hedges. At 31 December 2019, there were no forward contracts outstanding (2018: None).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

16. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT (CONTINUED)

During the year, the US dollar fluctuated against the Australian dollar. A foreign exchange gain of $132,000 is included in results for the year ended 31 December 2019 (2018: gain $961,000). The majority of the gain relates to gains on the translation for reporting purposes of the Group's US dollar cash reserves into Australian dollars.

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

	2019 $'000	2018 $'000
Assets		
US dollars	8,084	15,818
Liabilities		
US dollars	180	572

An increase of 10% in the cross rate of the US dollar against the Australian dollar as at the reporting date would have increased the consolidated loss after income tax by $719,000. A decrease of 10% in the cross rate of the US dollar against the Australian dollar as at the reporting date would have decreased the consolidated loss after income tax by $878,000.

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:

	2019 $'000	2018 $'000
Financial Assets		
Cash and cash equivalents		
Australian dollar cash deposits	5,773	5,625
Australian dollar interest rate	1.54%	2.46%
US dollar cash deposits	8,071	15,800
US dollar interest rate	1.73%	2.32%

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 loss after tax by approximately $39,000 and in 2018 changed reported profit after tax by approximately $22,000.

Credit risk

The Group incurs credit risk from transactions with financial institutions. The total credit risk on 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.

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 up to June 2019, are monitored and managed to ensure financial liabilities can be repaid when due.

Capital risk

The Group 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, as described in Note 11. Capital risk is impacted by the inherent uncertainties described in Note 1.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

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 2019 the Group has recorded other revenue of $0.5 million (2018: $0.4 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 Group is subject to income taxes in Australia because it is domiciled in that country. There are transactions and calculations undertaken during the ordinary course of business for which the ultimate tax determination may be uncertain. 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

Grant Thornton New Zealand Audit Partnership
L4, Grant Thornton House
152 Fanshawe Street
PO Box 1961
Auckland 1140

T +64 (0)9 308 2570
F +64 (0)9 309 4892
www.grantthornton.co.nz

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 30 to 47 which comprise the consolidated statement of financial position as at 31 December 2019, 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 2019 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") issued by the New Zealand Accounting Standards Board.

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.

Other than in our capacity as auditor we have no relationship with, or interests in, the Group.

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 matter is significant	How our audit addressed the key audit matter
Going concern The financial statements have been prepared on a going concern basis, refer to note 2 in the financial statements. The Group made a loss of $10.8m for the year ended 31 December 2019 and it has not forecast to receive any revenue in the next 12 months as research and development continues. We included the going concern assumption as a key audit matter as the Group is reliant on the existing cash reserves of $13.8m to cover necessary expenditure.	In obtaining sufficient appropriate audit evidence to assess the appropriateness of the going concern assumption used in preparing the consolidated financial statements we: • Assessed the cash flow requirements of the Group over 14 months from 31 December 2019 based on approved budgets and forecasts. • Evaluated what forecast expenditure is committed and what could be considered discretionary. • Performed a sensitivity analysis on forecast cash flows and the impact of this on available funds.

Other Information

The Directors are responsible for the other information. The other information comprises the information included in the directors' report and additional information (but does not include the consolidated financial statements and our auditor's report thereon), which we obtained prior to the date of this auditor's report and the annual report which 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, 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 consolidated 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 and 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

Grant Thornton

Ryan Campbell
Partner
Auckland

25 February 2020

ADDITIONAL INFORMATION

DIRECTORS' INTERESTS IN EQUITY SECURITIES AS AT 24 FEBRUARY 2020

	Interests in Ordinary Shares	
Director	**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 2019

	Richard Treagus	Larry Glass	Trevor Scott
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 shares are 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 1 April 2020.

The number of ordinary shareholdings held in less than marketable parcels at 1 April 2020 was 993, holding 196,613 ordinary shares.

DISTRIBUTION OF SECURITY HOLDERS

Ordinary shares

Size of holding	Number of ordinary shares	%	Number of holders	%
100,001 and Over	68,136,023	68.02	114	2.41
10,001 to 100,000	22,938,177	22.90	767	16.21
5,001 to 10,000	4,144,916	4.14	530	11.20
1,001 to 5,000	4,158,985	4.15	1,517	32.05
1 to 1,000	790,312	0.79	1,805	38.14
Total	**100,168,413**	**100.00**	**4,733**	**100.00**

ADDITIONAL INFORMATION

CONTINUED

Twenty largest holders of ordinary shares

	Number of ordinary shares	% of issued share capital
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSCO ECA	14,276,172	14.25
CAMERON RICHARD PTY LTD	5,815,830	5.81
CITICORP NOMINEES PTY LIMITED	5,091,305	5.08
ESSEX CASTLE LIMITED	2,769,251	2.76
STUART ANDREW PTY LTD	2,633,586	2.63
LINWIERIK SUPER PTY LTD	2,535,000	2.53
SMITHLEY SUPER PTY LTD	2,121,000	2.12
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	2,108,470	2.10
DR RICHARD SPENCER TREAGUS	1,979,163	1.98
INVESTMENT CUSTODIAL SERVICES LIMITED	1,480,587	1.48
MXB INVESTMENTS LLC	1,330,000	1.33
BRISPOT NOMINEES PTY LTD	1,163,357	1.16
DR TREVOR SCOTT	1,000,000	1.00
DR ROBIN LANCE CONGREVE	991,637	0.99
UBS NOMINEES PTY LTD	839,021	0.84
CS FOURTH NOMINEES PTY LIMITED	755,507	0.75
J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	732,175	0.73
FIRST COLBYCO PTY LTD	624,649	0.62
NAMARONG INVESTMENTS PTY LTD	555,556	0.55
ROXTRUS PTY LIMITED	545,000	0.54
Total	**49,347,266**	**49.26**
Balance of share register	50,821,147	50.74
Total ordinary shares quoted on ASX	**100,168,413**	**100.00**
Unquoted loan funded shares held by Neuren Trustee Limited[1]	2,500,000	
Total issued ordinary shares	**102,668,413**	

[1] *Loan Funded Share Plan described in Note 11 to the Financial Statements.*

pharmaceuticals

NEUREN PHARMACEUTICALS LIMITED
Suite 201, 697 Burke Rd
Camberwell
Victoria 3124
Australia

Tel: +61 3 9092 0480
ABN: 72 111 496 130
ASX code: NEU

New Zealand Registered Office:
At the offices of Lowndes Jordan
Level 15 PWC Tower
188 Quay Street
Auckland 1141
New Zealand

Share Registry:
Link Market Services Limited
Tower 4, 727 Collins Street
Docklands
Victoria 3008
Australia

Postal address:

Locked Bag A14
Sydney South NSW 1235

Tel: +61 1300 554 474
Fax: +61 2 9287 0303

www.neurenpharma.com