

neuren

pharmaceuticals

*Improving the lives of people with
neurodevelopmental disabilities*

Neuren Pharmaceuticals Limited

ANNUAL REPORT 2022

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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.

Contents

- 1** Neuren's value proposition
- 2** Chair and CEO message
- 3** Operating Review
- 17** Board
- 18** Management Team
- 20** Corporate Governance
- 26** Consolidated Statement of Comprehensive Income
- 27** Consolidated Statement of Financial Position
- 28** Consolidated Statement of Changes in Equity
- 29** Consolidated Statement of Cash Flows
- 30** Notes to the Consolidated Financial Statements
- 45** Independent Auditor's Report
- 48** Additional Information

NEUREN'S VALUE PROPOSITION

Leading pipeline in neurodevelopmental disorders

Compound	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Commercial rights	
Trofinetide	Rett North America							
	Rett Rest of World							
	Fragile X							NA: RoW:
NNZ-2591	Phelan-McDermid							
	Angelman							
	Pitt Hopkins							
	Prader-Willi							

Three key drivers of future value

- 1 Realise Neuren's share of trofinetide value in the US through successful commercialization of DAYBUE
- 2 Implement commercial strategy for trofinetide ex-North America, using US data for registration
- 3 Confirm efficacy of NNZ-2591 in Phase 2 trials for 4 valuable indications

Transforming catalysts in 2023

Commercial



Trofinetide North America

Trofinetide Rest of World

NNZ-2591

- ✓ **DAYBUE for Rett syndrome approved by FDA**
- ✓ **Priority Review Voucher awarded to Acadia**
 - First US commercial sale (end Apr 2023) - US\$40m milestone payment
 - Quarterly royalties on net sales
 - Priority Review Voucher value one third share - estimated as US\$33m
- Commercial partnerships ex-North America for Rett syndrome
- Initiate Prader-Willi syndrome Phase 2 trial
- Enrolment completion in Phelan-Mcdermid, Pitt Hopkins and Angelman syndromes
- Phase 2 trial results, commencing with Phelan-Mcdermid syndrome

Development

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CHAIR AND CEO MESSAGE

PATRICK DAVIES & JON PILCHER

Dear Shareholders,

The recent approval by the US Food and Drug Administration (FDA) of DAYBUE™ as the first ever treatment for Rett syndrome was the most important milestone in Neuren’s history. As we foreshadowed in our message to you last year, the approval has transformed our financial position and outlook, placing us in a very strong position to make the most of the opportunities ahead as we strive to make a difference to patients and families impacted by neurodevelopmental disabilities.

Many people showed great determination over the journey to reach this historic milestone. The greatest was shown by the Rett syndrome community and we are delighted for them. Ten years ago, the Neuren team embarked on the first ever multi-centre trial in Rett syndrome and painstakingly created the path forward with all stakeholders. Our partner Acadia has done an outstanding job executing the final stage of development and the FDA application and review process.

The broad approved label for DAYBUE means that all people with Rett syndrome aged 2 years and older can be eligible for treatment. We are also very pleased that Acadia is able to launch DAYBUE so soon after approval, made possible by the very extensive preparations they made during the

FDA review process. We are confident that they are very well placed for successful commercialisation.

The next payment from Acadia is US\$40 million, payable following the first commercial sale, which is anticipated at the end of April 2023. This will be followed by quarterly royalties, plus potential milestone payments of up to US\$350 million on achievement of a series of four thresholds of total annual net sales, plus Neuren’s one third share of the market value of the Rare Pediatric Disease Priority Review Voucher awarded to Acadia by the FDA. In the meantime, we are advancing discussions with potential partners for the registration and commercialisation of trofinetide outside North America. Our revenue from trofinetide partners will flow through to pre-tax profit, as no royalties or similar costs are payable by Neuren.

The first in a series of results from the Phase 2 trials of our second drug NNZ-2591 in four neurodevelopmental disorders are anticipated before the end of 2023. The number of potential patients targeted is more than five times the number for Rett syndrome and Neuren retains global rights, which means NNZ-2591 has the potential to generate larger value for shareholders than trofinetide.

We are now carefully evaluating all options to maximize this value, preparing actively for Phase 3 studies while remaining receptive to partnering alternatives.

Neuren’s market capitalisation at 31 March 2023 was 3.6 times higher than at the end of 2021, against the backdrop of a bear market for healthcare stocks. This resulted in promotion into the S&P/ASX 300 index in September 2022, with the S&P/ASX 200 becoming a potential prospect in the near term. The institutional audience for our investor relations activities is now much broader and Neuren is now covered actively by 6 broker analysts.

The transformation of Neuren is just beginning, and the Board is committed to maximizing value for our shareholders by maintaining a robust balance sheet that can facilitate the pursuit of all value-adding opportunities to their fullest potential.

Finally, we would like to thank the Neuren team and Board, the patient communities and our many development partners for their dedication and achievements over the last year. We anticipate that the coming year can be even more productive.

Neuren’s Values

- We are passionate about making a difference to the lives of patients and their families
- We aim to earn the respect of everyone we deal with
- We are determined and creative to break through barriers
- We harness the power of collaboration and different perspectives
- We recognise the importance of all stakeholders and endeavour to use financial resources efficiently

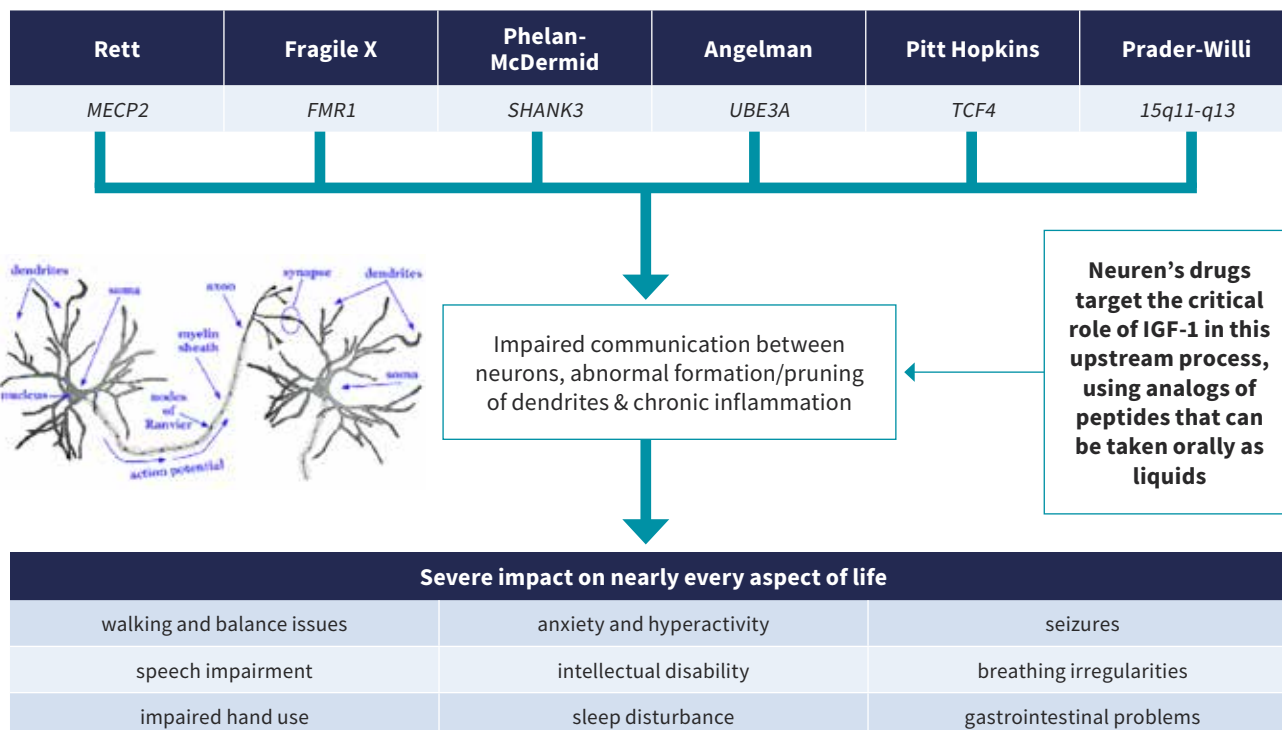


Patrick Davies
Chair

Jon Pilcher
CEO

OPERATING REVIEW

Treating neurodevelopmental disorders



NEUREN'S GROUND-BREAKING THERAPIES

Neuren has two novel patented drugs, trofinetide and NNZ-2591, which potentially have broad utility in the treatment of neurological disorders. Both drugs can be administered orally in a patient-friendly liquid dose. Each drug is in clinical development to treat debilitating neurodevelopmental disorders that emerge in early childhood and stem from problems in brain development which lead to a wide range of serious issues affecting nearly every aspect of life. This has a severe life-long impact on the patients and their families.

Each neurodevelopmental disorder is caused by a different genetic mutation, but in many cases they share similar symptoms and the common characteristic of impaired connections and signalling between brain cells. Neuren's drugs, which are synthetic analogues of important molecules that occur naturally in the brain, aim to improve the impaired connections and signalling, meaning that the drug's target is to have a broad impact on the disorder rather than aiming to treat one symptom.

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

THE IMPORTANCE OF ORPHAN DRUG DESIGNATION

The US Food and Drug Administration (FDA) and European Medicines Agency (EMA) have both granted Orphan Drug designation for trofinetide in Rett syndrome and Fragile X syndrome and for NNZ-2591 in each of Phelan-McDermid, Angelman and Pitt Hopkins syndromes. The FDA has also granted orphan drug designation for Prader-Willi syndrome.

Orphan Drug designation is a special status that the regulators 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 exclusivity periods during which the regulators will not approve a generic competitor product. 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. The exclusivity periods after marketing authorisation of products approved for pediatric use are 7.5 years in the US and 12 years in the EU. Japan, South Korea and Taiwan also have Orphan Drug programs.

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OPERATING REVIEW

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As well as the exclusivity periods, Orphan Drugs have many other commercial advantages compared with existing markets that have apparently attractive large sales in which established products and companies have to be displaced. The serious and urgent unmet need results in a more supportive regulatory and pricing environment and strong engagement from the patient community and leading physicians. Historical data indicates a higher probability of achieving regulatory approval and the potential for immediate access to known patients means that a large sales organisation is less important.

In short, the Orphan Drug business model targets a leadership position in markets with urgent need, at an attractive price and with a higher probability of getting to market.

The neurodevelopmental disorders that Neuren is aiming to treat are “rare diseases”, however they are not “ultra-rare”, and in each disorder there are tens of thousands of potential patients. Combined with Neuren’s strategy to develop treatments for multiple disorders in parallel, this results in a substantial commercial opportunity.

COMMERCIAL EXCLUSIVITY

In addition to the primary protection of the important exclusivity periods from Orphan Drug designation explained above, Neuren has additional commercial protection from issued patents, which extend as far as 2032 for trofinetide and 2034 for NNZ-2591. Further international patent applications have been filed for both drugs which, if granted, will extend to 2040. Since trofinetide and NNZ-2591 are new chemical entities, following the first marketing authorisation for each drug, the term of one patent may potentially be extended by up to 5 years in many countries, including the United States, Europe and Japan.

TROFINETIDE FOR RETT SYNDROME

FDA approval of DAYBUE™ (trofinetide)

In March 2023, Neuren’s partner for trofinetide in North America, Acadia Pharmaceuticals (NASDAQ: ACAD), received US Food and Drug Administration (FDA) approval of DAYBUE™ (trofinetide) for the treatment of Rett syndrome in adult and pediatric patients two years of age and older. Acadia expects DAYBUE to be available by the end of April 2023. DAYBUE is the first and only approved treatment for Rett syndrome.



The FDA approval for DAYBUE was supported by pivotal efficacy from the positive Lavender™ Phase 3 trial, supportive safety and efficacy data from Lilac™ open-label extension trial, Neuren’s positive Phase 2 trial and the Daffodil™ safety and pharmacokinetic trial in children aged 2-5 years.

OPERATING REVIEW

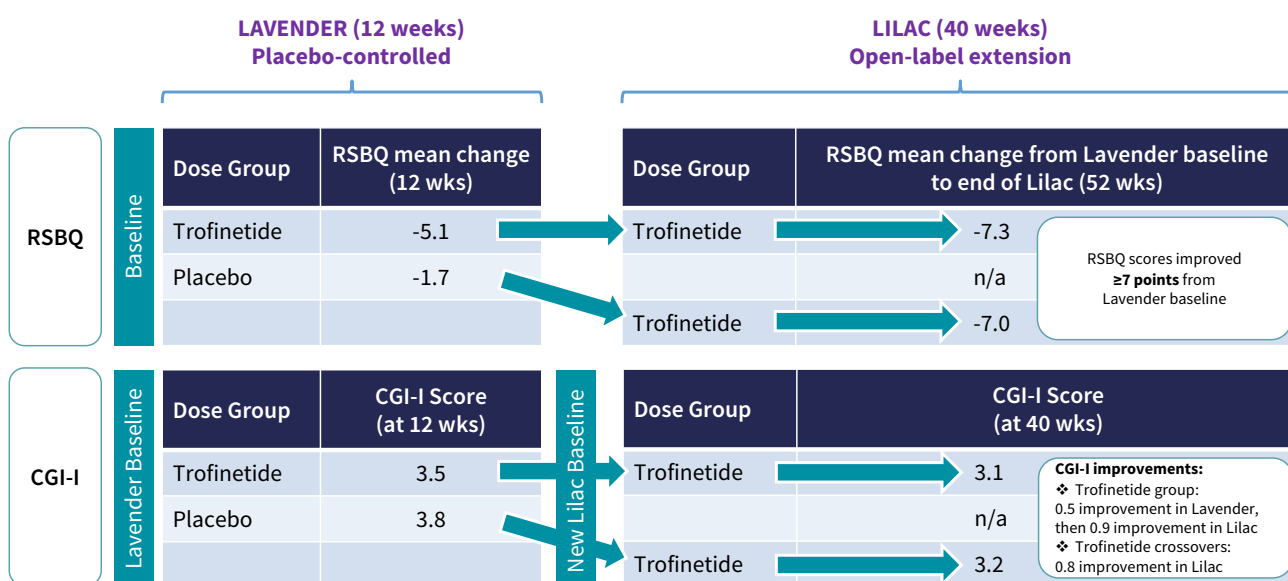
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Positive Lavender Phase 3 results

	Placebo	Trofinetide
Primary Endpoints:		
Rett Syndrome Behaviour Questionnaire (RSBQ) (Change from baseline to week 12)	-1.7 (0.98)	-5.1 (1.38)
<i>p-value</i>		<i>p=0.0175</i>
Effect Size: Cohen's d		0.37
Clinical Global Impression of Improvement (CGI-I) (Score at week 12)	3.8 (0.06)	3.5 (0.08)
<i>p-value</i>		<i>p=0.0030</i>
Effect Size: Cohen's d		0.47
Key Secondary Endpoint:		
CSBS-DP-IT Social Composite Score (Change from baseline to week 12)	-1.1 (0.28)	-0.1 (0.28)
<i>p-value</i>		<i>p=0.0064</i>
Effect Size: Cohen's d		0.43

Source: Acadia Lavender Study Top-Line Results Presentation <https://ir.acadia-pharm.com/static-files/84457c64-60ab-4b2f-a166-edc1d465f4a8>

Sustained and continued improvement observed in Lilac



Source: Acadia presentation (Acadia Corporate Presentation (4Q22 Earnings), Lavender Study Results (acadia.com))

RSBQ: n=161 for Lavender at 12 weeks; n=88 for Lilac at 40 weeks.

CGI-I: n=163 for Lavender at 12 weeks; n=91 for Lilac at 40 weeks. CGI-I uses a 7-point Likert scale; a score of 4 = no improvement; >4 = worsening and <4 = improvement.

OPERATING REVIEW

CONTINUED

Consistent safety and tolerability findings

LAVENDER (12 weeks) Placebo-controlled

	Adverse Events (AEs) >10% observed in Trofinetide group
Diarrhea	80.7% (97% Mild and Moderate)
Vomiting	27.0% (96% Mild and Moderate)

LILAC (40 weeks) Open-label extension

	Adverse Events (AEs) >10% observed in Lilac
Diarrhea	74.7% (96% Mild and Moderate)
Vomiting	28.6% (100% Mild and Moderate)
COVID-19	11%
<i>Discontinuations due to AE of diarrhea: 21%</i>	

No new safety or tolerability findings in Lilac

Source: Acadia presentation (Acadia Corporate Presentation (4Q22 Earnings), Lavender Study Results (acadia.com))

Further information about DAYBUE, including prescribing information can be accessed at www.DAYBUE.com

Neuren's attractive economics from the Acadia partnership

A redacted version of the licence agreement between Neuren and Acadia was filed with the US Securities and Exchange Commission as a material contract exhibit to Acadia's 2018 10-K Annual Report, which is available to view via the SEC Filings section of Acadia's website. Under the terms of the agreement, the development and commercialisation of trofinetide in North America is fully funded by Acadia. In October 2022, Neuren received from Acadia a milestone payment of US\$10 million following the acceptance of the New Drug Application (NDA) for review by the FDA. The next milestone payment to Neuren is US\$40 million, payable following the first commercial sale of trofinetide in the United States, which is anticipated at the end of April 2023.

Neuren is eligible to receive ongoing royalties on net sales of trofinetide in North America, plus milestone payments of up to US\$350m on achievement of a series of four thresholds of total annual net sales, plus one third of the market value of the Rare Pediatric Disease Priority Review Voucher that was awarded to Acadia by the FDA upon approval of the NDA, with one third share estimated by Neuren as US\$33 million.

No royalties or similar costs are payable by Neuren to third parties, which means Neuren's revenue from Acadia will flow through to pre-tax profit. The royalty rates and sales milestone payments are related to the total amount of annual net sales in trofinetide in all indications, as set out in the following tables:

Tiered royalty rates (% of net sales) ¹	
Annual Net Sales	Rates
≤US\$250m	10%
>US\$250m, ≤US\$500m	12%
>US\$500m, ≤US\$750m	14%
>US\$750m	15%

Sales Milestone payments ¹	
Net Sales in one calendar year	US\$m
≥US\$250m	50
≥US\$500m	50
≥US\$750m	100
≥US\$1bn	150

¹ Royalty rates payable on the portion of annual net sales that fall within the applicable range. Each sales milestone payment is payable once only.

OPERATING REVIEW

CONTINUED

Currently there are approximately 4,500 patients diagnosed with Rett syndrome in the US. Based on published prevalence studies, Neuren estimates that the total number of potential patients in the US may be up to 10,000.

Acadia has projected that DAYBUE access will be covered by Medicaid for 60% of patients and by commercial health insurance for 30% of patients. It is anticipated that there will be nominal or zero out-of-pocket expense for families. The list price of DAYBUE will be \$21.10 per mL and Acadia expects the average annual net realised cost per patient will be approximately US\$375,000. This includes assumptions for the average weight of the expected patient population, compliance rates to therapy and mandatory government discounts.

Development and commercialisation outside North America

Acadia has exclusive rights to trofinetide in all indications for the United States, Canada and Mexico. Neuren retained all rights to trofinetide for countries outside North America and has a fully paid-up, irrevocable licence for use in those countries to all data generated by Acadia.

There is urgent unmet need for a treatment for Rett syndrome around the world, evidenced by communications received from families, patient support groups and physicians. The estimated number of potential patients and currently identified patients are shown in the table below. Neuren expects rates of diagnosis to increase with greater awareness and accelerate with the availability of a treatment.

Rett Syndrome Patients	Europe	Japan	Israel	China urban	Other Asia
Potential patients ¹	13,000	3,000	300	28,000	6,000
Patients currently identified	4,000	1,000	200	2,000	'00s

¹ Potential patient estimates derived by applying the mid-point of the published prevalence estimate range to the populations under 60 years

Neuren intends to pursue registration and commercialisation of trofinetide through partners and is currently advancing discussions with a number of third parties.

i About Rett syndrome

Rett syndrome is a seriously debilitating and life-threatening neurological disorder. 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.

OPERATING REVIEW

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NNZ-2591 FOR MULTIPLE NEURODEVELOPMENTAL DISORDERS

In July and August 2022, Neuren announced the commencement of Phase 2 clinical trials of its second drug candidate NNZ-2591 for Phelan-McDermid syndrome (PMS), Angelman syndrome (AS) and Pitt Hopkins syndrome (PTHS) after receiving in March 2022 approval from the FDA for Investigational New Drug (IND) applications to conduct the trials. In December 2022, Neuren submitted an IND application to the FDA for approval to proceed with a Phase 2 trial in Prader-Willi syndrome (PWS) and received approval from the FDA in January 2023. There are currently no approved therapies for these debilitating neurodevelopmental disorders, other than human growth hormone to treat some aspects of PWS.

The estimated number of potential patients being targeted across these four disorders is more than five times larger than Rett syndrome. Neuren retains all global rights to NNZ-2591.

Five times larger opportunity for NNZ-2591

Disorder	Gene mutation	Published prevalence estimates	Potential patients		
			US ¹	Europe ¹	Asia ^{1,2}
Phelan-McDermid	<i>SHANK3</i>	1/8,000 to 1/15,000 males and females	22,000	28,000	81,000
Angelman	<i>UBE3A</i>	1/12,000 to 1/24,000 males and females	14,000	18,000	52,000
Pitt Hopkins	<i>TCF4</i>	1/34,000 to 1/41,000 males and females	7,000	9,000	25,000
Prader-Willi	<i>15q11-q13</i>	1/10,000 to 1/30,000 males and females	13,000	16,000	47,000
			56,000	71,000	205,000

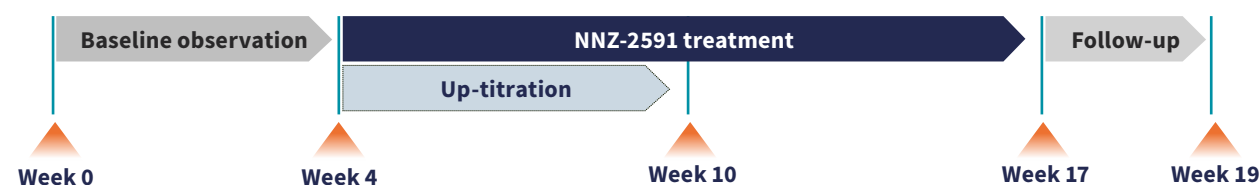
¹ Estimates derived by applying the mid-point of the prevalence estimate range to the populations under 60 years

² Asia comprises Japan, Korea, Taiwan, Israel and urban populations of China and Russia

Phase 2 trials in AS, PMS and PTHS – results expected from H2 2023

The open label Phase 2 trials are each enrolling up to 20 children to examine safety, tolerability, pharmacokinetics and efficacy over 13 weeks of treatment with NNZ-2591. All subjects receive NNZ-2591 as an oral liquid dose daily, with escalation in two stages up to the target dose during the first 6 weeks of treatment, subject to independent review of safety and tolerability data. The trials are enrolling subjects in three age groups. Safety and tolerability data in the oldest age group must be independently reviewed before proceeding with dosing in the second age group and then safety and tolerability data in the second age group must be independently reviewed before proceeding with dosing in the youngest age group. The study begins with 4 weeks of observation to thoroughly examine baseline characteristics prior to treatment, against which safety and efficacy are assessed for each child. This is followed by the treatment period of 13 weeks. A follow-up assessment is made 2 weeks after the end of treatment.

	Angelman	Phelan-McDermid	Pitt Hopkins
n subjects	Up to 20	Up to 20	Up to 20
Age range	3 to 17	3 to 12	3 to 17
	(Sequential enrolment in three age groups following DSMC review)		
Location	Australia	US	US



Phase 3 preparation
Non-clinical toxicity studies and optimisation of drug product and drug substance manufacturing

OPERATING REVIEW

CONTINUED

In December 2022, Neuren announced that the first subject in the oldest age group had completed treatment in the AS trial and in the PMS trial. Each subject was successfully escalated up to the target dose following safety and tolerability reviews by an independent data and safety monitoring committee (DSMC). No serious adverse events were reported and no dose modifications were required. Most of the adverse events reported were mild and not considered to be related to study drug. There were no clinically relevant observations in safety laboratory measurements or cardiac tests.

A series of top-line results announcements from the trials are anticipated, commencing with Phelan-McDermid syndrome in H2 2023.

The overall aim of these first trials is to expedite the generation of data that will enable the subsequent trials to be designed as registration trials.

The primary aim is to confirm the safety and pharmacokinetics of NNZ-2591 in pediatric patients. However, each trial will also assess the treatment impact across multiple efficacy measures to generate data to select the best primary efficacy endpoint or endpoints for the registration trials. The trials maximise the opportunity to demonstrate effects by focusing on pediatric patients and treating them for 13 weeks.

Preparation for Phase 3

In order to expedite the overall development plan, in parallel with conducting the Phase 2 trials Neuren is executing the additional development work required to be ready for Phase 3 development. This includes non-clinical toxicity studies to support longer clinical trials and commercial use of the product, as well as optimisation of the drug product and drug substance manufacturing arrangements.

Strong foundations for Phase 2 trials

In designing and executing the NNZ-2591 development program, Neuren has been able to leverage the extensive and highly relevant experience the management team has gained from the trofinetide Rett syndrome program across manufacturing, non-clinical, clinical and regulatory. Neuren has meticulously built strong foundations in each of these areas to enable Phase 2 trials in multiple indications.

✓ Clear and consistent efficacy in mouse models of all four 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. In all four models, 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.

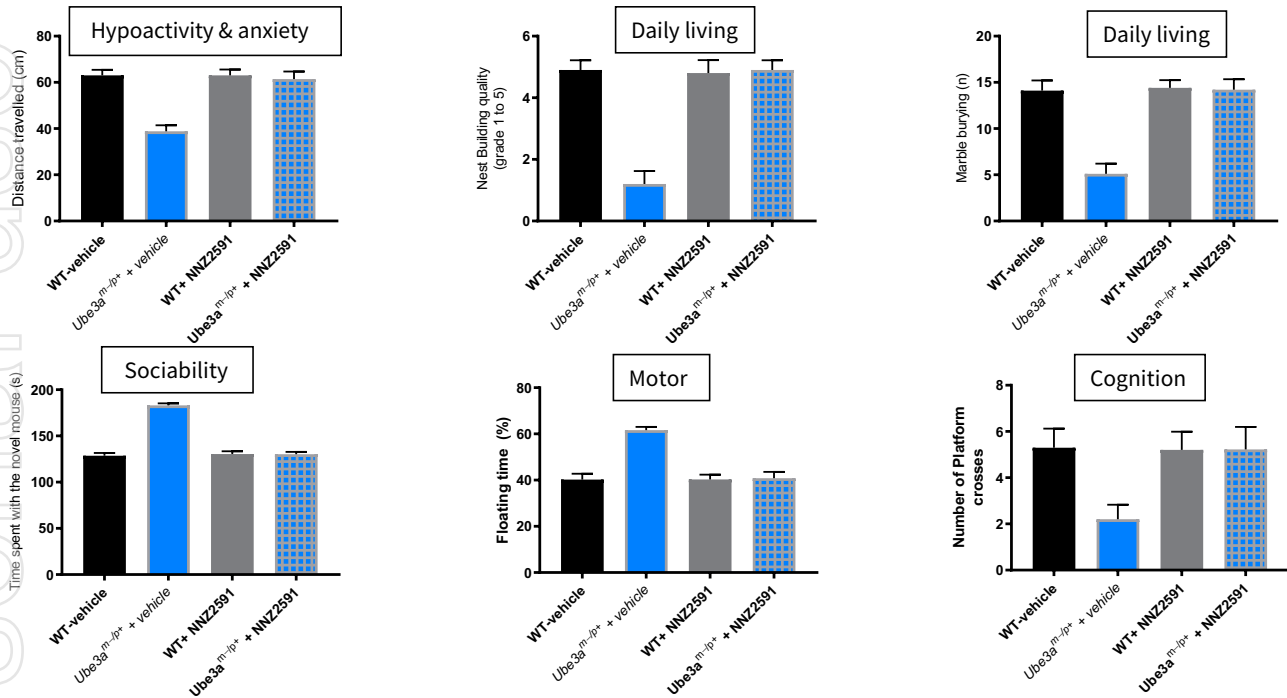
Following review of the data from the mouse models and the mechanistic rationale for treatment, FDA granted Orphan Drug designation for NNZ-2591 in each of the four disorders.

OPERATING REVIEW

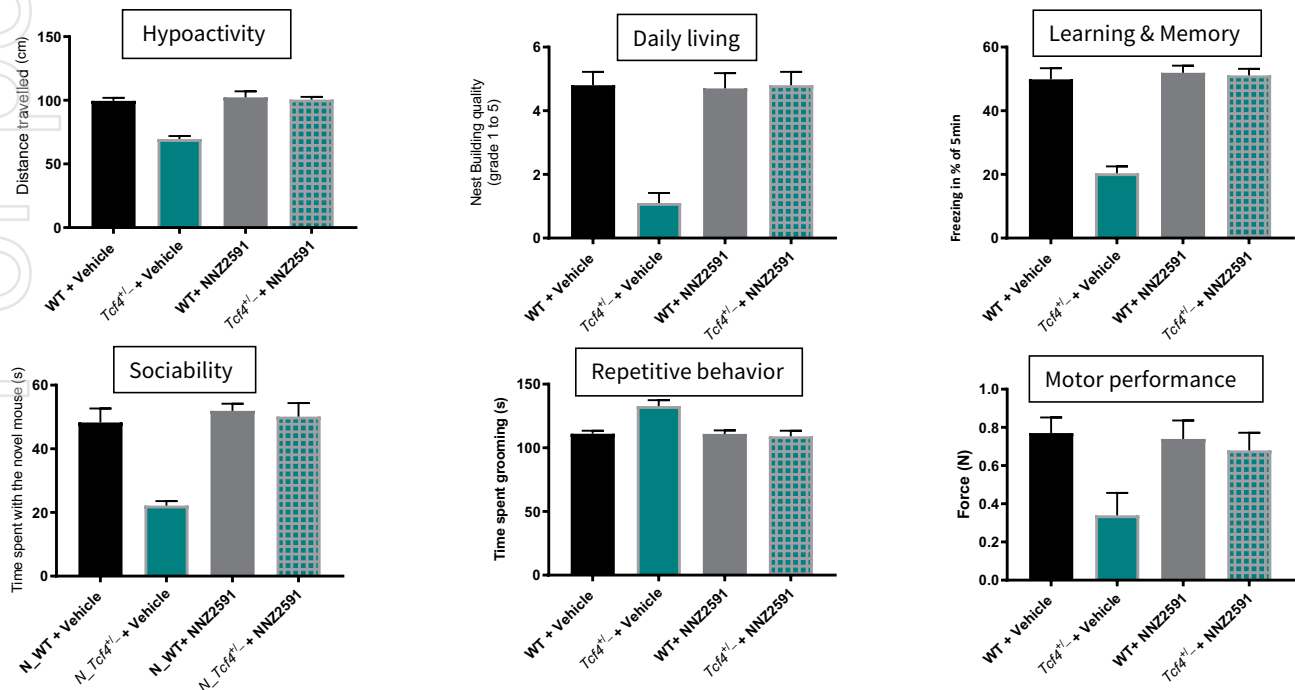
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The charts below show the results in the Angelman syndrome, Pitt Hopkins and Prader-Willi syndrome models. In the Angelman model, treatment also eliminated seizures in the knockout mice.

Efficacy in mouse model of Angelman (*Ube3a*)



Efficacy in mouse model of Pitt Hopkins (*Tcf4*)



OPERATING REVIEW

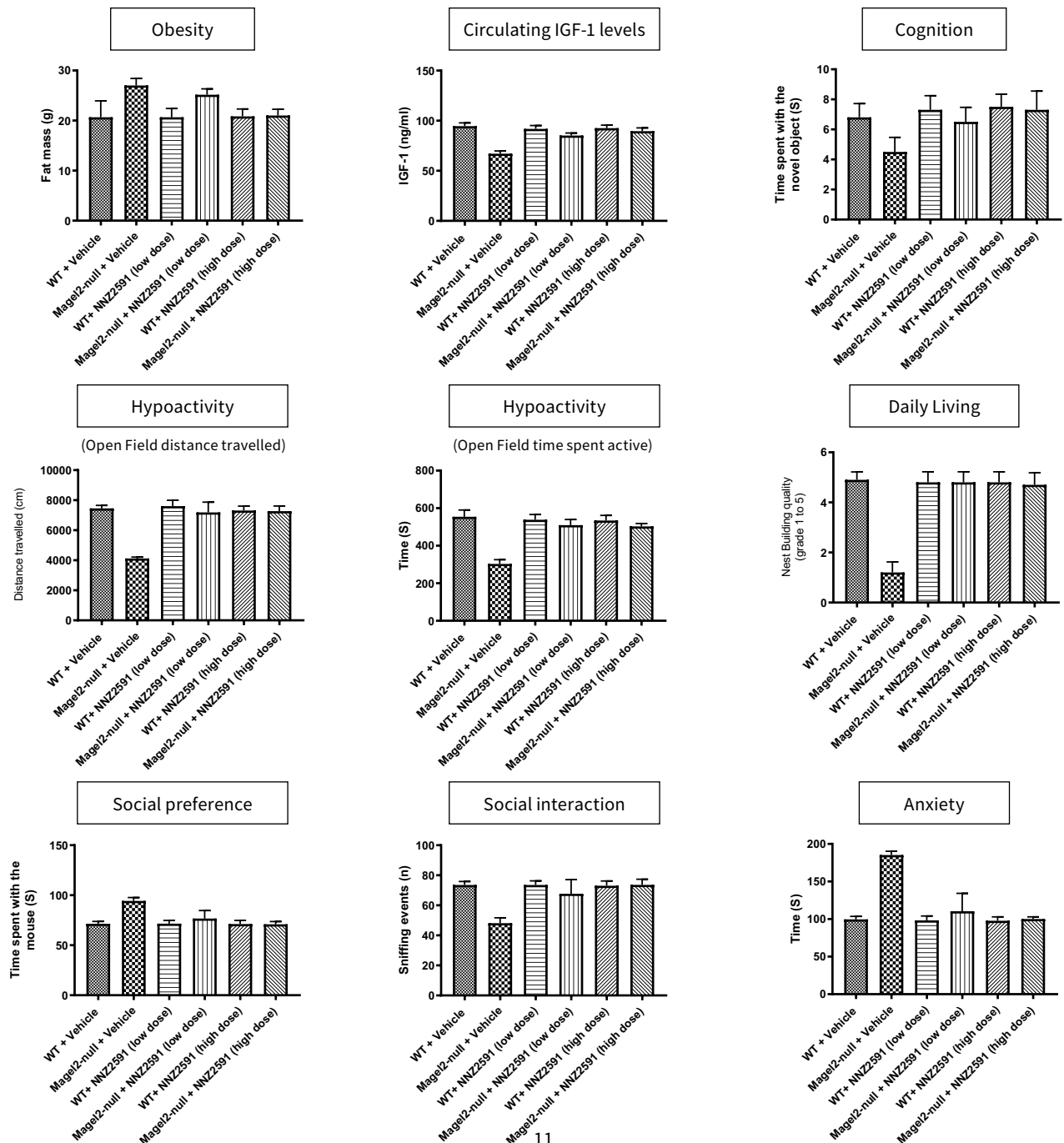
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Efficacy in mouse model of Prader-Willi (*Magel2*-null)

Prader-Willi is caused by mutations in the *15q11-q13* region of chromosome 15. In the *Magel2*-null mouse model, which exhibits features of Prader-Willi in humans, wild type mice and knockout mice were treated with placebo (vehicle) or NNZ-2591 for 6 weeks. Treatment with NNZ-2591 normalized fat mass (obesity) insulin levels, IGF-1 levels and all the behavioral deficits in the knockout mice and had no effect on the wild type mice.

Insulin levels (pM)

WT plus vehicle	<i>Magel2</i> -null plus vehicle	WT plus NNZ-2591 low dose	<i>Magel2</i> -null plus NNZ-2591 low dose	WT plus NNZ-2591 high dose	<i>Magel2</i> -null plus NNZ-2591 high dose
110	173	112	143	115	119



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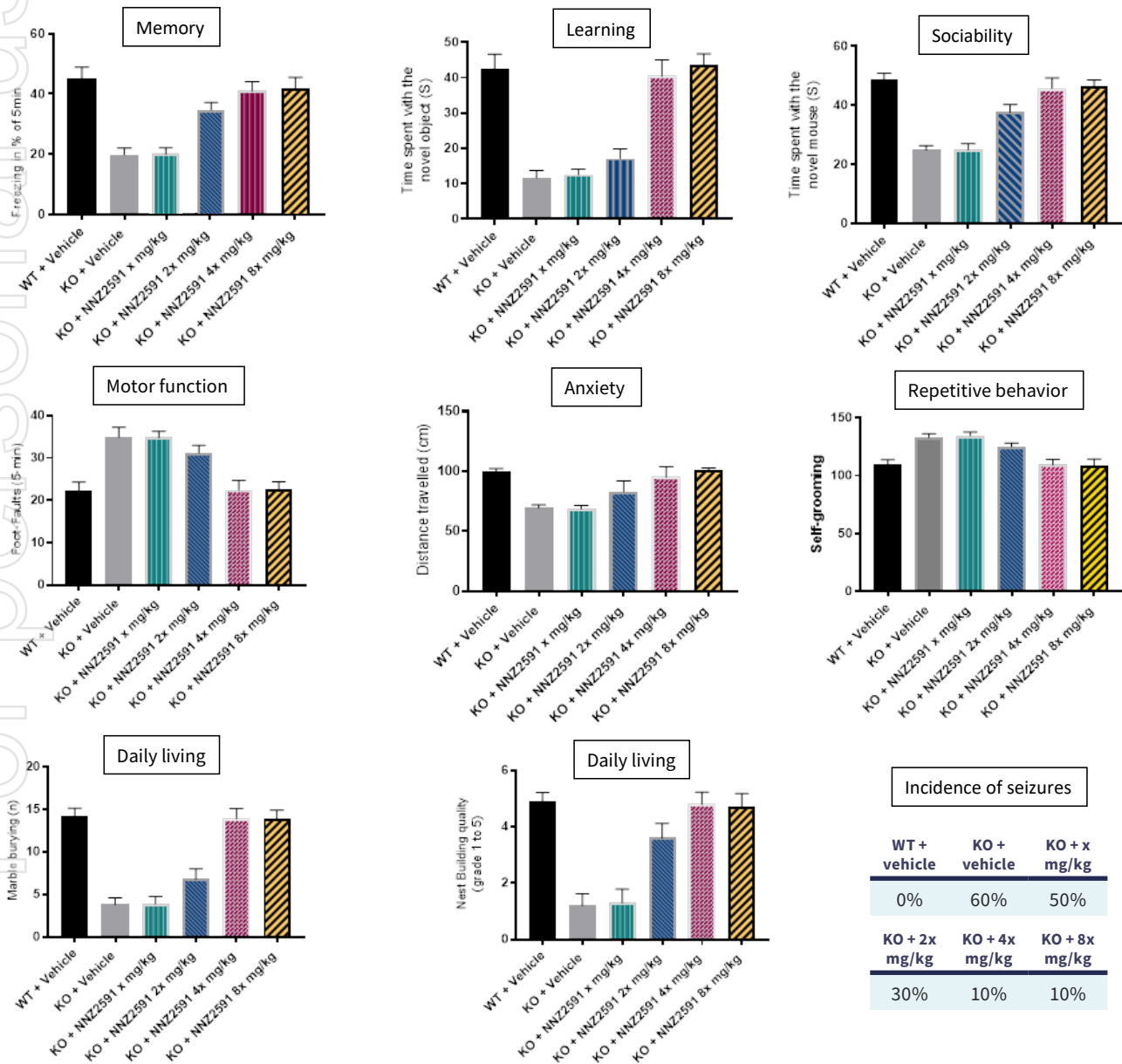
OPERATING REVIEW

CONTINUED

Optimum dose identified

In the Phelan-McDermid syndrome model, the effect of four escalating dose levels was investigated. The results of this dose ranging study are shown in the charts below. They were consistent across all 8 behavioral tests and the incidence of seizures, demonstrating that the second highest dose was the optimum dose level in the mouse model. Comparison with human pharmacokinetic data from the Phase 1 clinical trial has informed the equivalent human dose for the Phase 2 trials in patients.

A further observation was that the optimum dose in this 6-week study showed better efficacy than the same dose in an earlier study for 3 weeks, indicating that efficacy increases with treatment duration. In the Phase 2 trials Neuren is testing treatment with NNZ-2591 for 13 weeks.

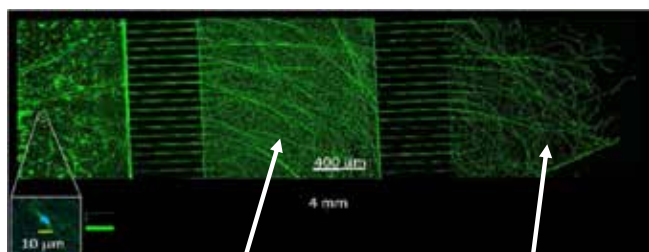
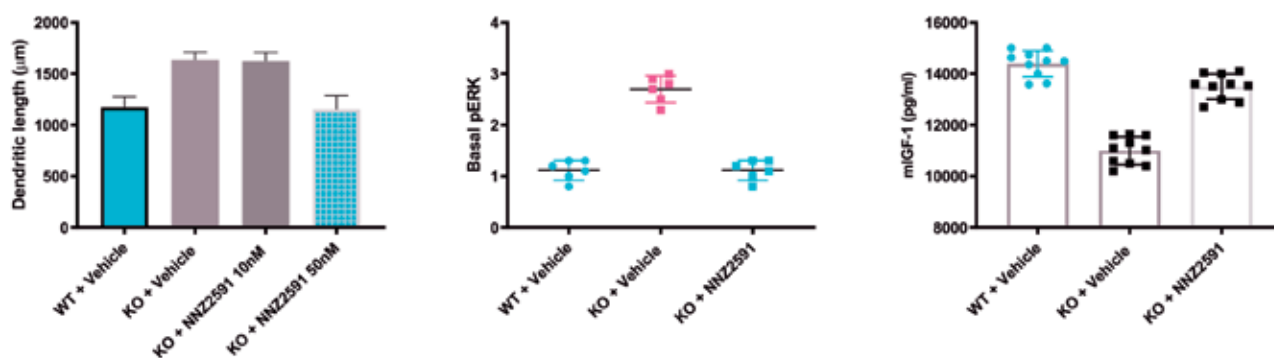


OPERATING REVIEW

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✔ Effects on biochemistry and brain cell structure confirmed

Biochemical testing in the Phelan-McDermid model showed that the abnormal length of dendritic spines between brain cells, the excess activated ERK protein (pERK) and the depressed level of IGF-1 in the knockout mice were all normalised after treatment with NNZ-2591, as shown in the charts below.



Abnormal dendrites in shank3 knockout mice

Normalisation after treatment with NNZ-2591

✔ Blood-brain barrier penetration confirmed

As well as very high oral bioavailability, good penetration of the blood-brain barrier by NNZ-2591 has been 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 was determined after 1.5 hours and again after 4 hours. The amount in the brain tissue was also measured after 4 hours. In each case the concentration was approximately proportional to the dose and after 4 hours the concentration in blood and brain tissue was approximately equivalent.

✔ Large scale manufacturing process developed

Neuren has successfully developed a proprietary process for manufacturing drug substance at large scale with exceptional purity and high yield. Manufacturing has been completed to supply all four Phase 2 trials.

✔ Positive Phase 1 clinical trial results

In 2021, Neuren completed a Phase 1 clinical in Australia, in which twice daily oral dosing of NNZ-2591 for seven days was safe and well tolerated in healthy volunteers at doses expected to be within the effective therapeutic range. This was an important milestone for NNZ-2591 to be able to move forward to Phase 2 clinical trials in patients.

The primary objective was to evaluate safety and tolerability, with a secondary objective to evaluate pharmacokinetic parameters. Two double-blind placebo-controlled cohorts of eight healthy adult volunteers were dosed orally twice per day for seven days. Each cohort was titrated up to the target dose, with the target dose in the second cohort double the target dose in the first cohort. These two cohorts were preceded by preliminary testing of single doses of NNZ-2591, which enabled modelling of potential multiple dosing regimens.

OPERATING REVIEW

CONTINUED

No Serious Adverse Events (SAEs) were reported. All reported Adverse Events (AEs) were mild or moderate and resolved during the trial. There were no clinically significant findings from safety laboratory tests, vital signs, or cardiac tests. In the cohorts dosed for seven days, the most common AE reported was drowsiness. In the higher dose cohort, only one of the reported AEs was moderate, the remainder were mild. All subjects completed the scheduled dosing, apart from one of the eight subjects in the lower dose cohort, who ceased dosing after receiving the first starting dose following moderate drowsiness and incoordination.

✔ IND-enabling program of non-clinical toxicology and CMC studies completed

An extensive program of non-clinical toxicology and manufacturing studies required to open an IND in the United States and enable clinical trials for 13 weeks in pediatric patients has been completed.

To find out more about these disorders:



www.pmsf.org



www.pitthopkins.org



www.angelman.org



www.fpwr.org

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 involved in the metabolism of 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. During development, the brain and the cells that comprise it change rapidly and in complex ways. IGF-1 and its metabolites play a significant role in regulating these changes. In the mature brain, these molecules play an important role in responding to disease, stress and injury.

Trofinetide and NNZ-2591 mimic the function of the natural molecules in the brain, however each drug is designed to have a longer half-life in circulation, be suitable for use as an oral medication, more readily cross the blood brain barrier and have better stability for longer and easier storage and shipping.

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

Many neurological conditions share four common, underlying pathological features:

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 syndrome, neurodegenerative diseases like Alzheimer’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, and disturb electrical functions which can lead to seizures and other abnormalities and even result in premature cell death.

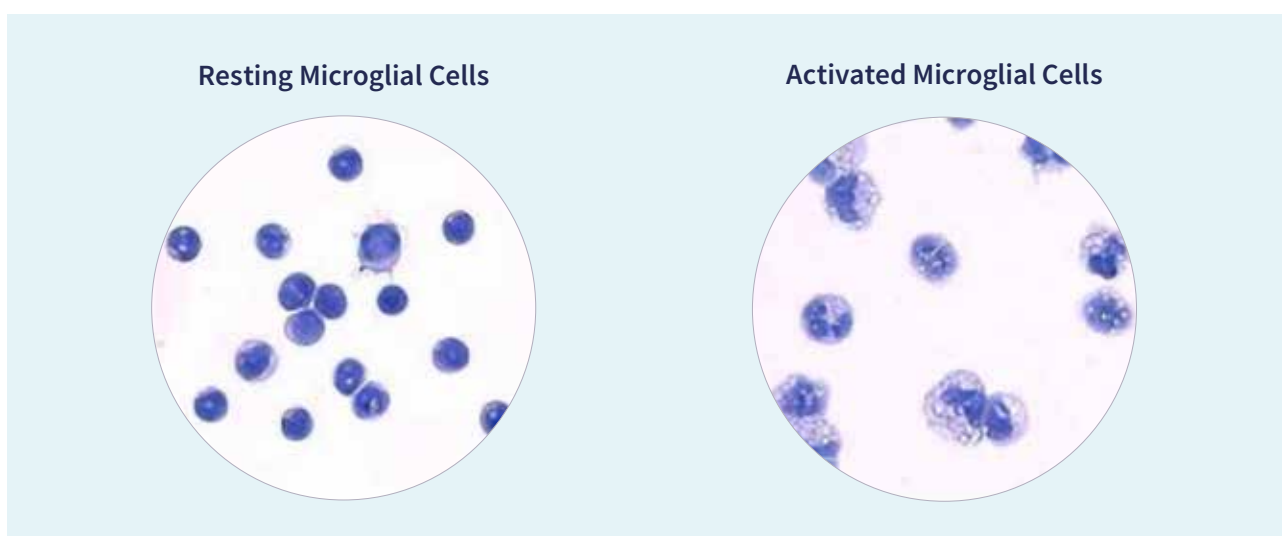
OPERATING REVIEW

CONTINUED

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. 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.



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.

4. Reduced levels of IGF-1

IGF-1 levels in the brain have been reported to be depressed in a number of conditions, which means that the critical role of IGF-1 in maintaining and repairing brain cells and synapses is impaired.

The aim of treatment with Neuren’s drugs is to restore the natural balance of brain function by:

- reducing inflammation
- restoring the normal functioning of microglia
- improving the dendritic structure of synapses
- normalising the levels of IGF-1 in the brain

OPERATING REVIEW

CONTINUED

FINANCE

Summary Financials	2022 \$'m	2021 \$'m
Revenue from contracts with customers	14.5	-
R&D Tax Incentive	0.9	3.2
Interest income	0.4	-
Other income (Government cash-flow boost)	-	-
Foreign exchange gain	1.2	0.4
Total income	17.0	3.6
Research & Development	(12.7)	(9.5)
Corporate & Administration	(3.4)	(1.9)
Loss on financial derivatives measured at fair value	(0.7)	-
Foreign exchange loss	-	-
(Loss)/Profit after tax	0.2	(7.8)
Cash flow from operations	3.6	(10.0)
Cash flow from financing	-	22.2
Effect of exchange rates on cash balances	(0.2)	0.4
Cash at 31 December	40.2	36.8

The consolidated financial statements are presented on pages 26 to 44. All amounts in the consolidated Financial Statements are shown in Australian dollars unless otherwise stated.

The consolidated profit after tax attributable to equity holders of the Company for the year ended 31 December 2022 was \$0.2 million compared with a loss of \$7.8 million in 2021. Revenue of \$14.5 million was received under the licence agreement with Acadia (2021: nil) and foreign exchange gains were \$1.2 million (2021: \$0.4 million). These were offset by an increase of \$3.2 million in research and development costs, due to higher expenditures in 2022 for the NNZ-2591 Phase 2 clinical trials and the foundational work to prepare for Phase 3 development of NNZ-2591 across multiple indications. There was also an increase in corporate and administrative costs of \$1.5 million, mainly due to share-based payments and higher employee benefits expense, reflecting some expansion for the NNZ-2591 program. In addition, a loss of \$0.7 million on the fair value of outstanding forward contracts to sell Australian dollars and buy US dollars was recognised at 31 December 2022. Prudent control of expenditure continues to be an important principle in Neuren's operations and financing.

The basic earnings per share for 2022 was \$0.001 (2021: loss per share of \$0.066), based on a weighted average number of shares outstanding of 125,965,676 (2021: 117,770,052).

Cash reserves at 31 December 2022 were \$40.2 million (2021: \$36.8 million). Net cash received from operating activities was \$3.6 million, compared with net cash used in operating activities of \$10.0 million in 2021. The increase of \$13.6 million was due to the receipt of the first milestone payment from Acadia of \$15.9 million (2021: nil), offset by higher payments for employees and directors of \$2.8 million (2021: \$1.8 million) and a lower receipt under the R&D Tax Incentive program of \$1.4 million (2021: \$2.5 million). Net cash from financing activities for 31 December 2022 was \$22.2 million lower than 2021, when \$22.2 million was received for the issue of new ordinary shares in a share placement and share purchase plan.

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

BOARD



PATRICK DAVIES

Non-Executive Chair

B EC, MBA

Patrick joined the Neuren Board in 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.



JON PILCHER

Chief Executive Officer/Managing Director

BSc (Hons), FCA

Jon joined Neuren in 2013 as CFO and was appointed CEO in May 2020. He has played a central role in all aspects of Neuren's R&D, commercial and corporate activities. Before joining Neuren he was a member of the leadership team at Acrux (ASX: ACR) throughout a period that 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. He formerly spent seven years in a series of executive positions in the R&D and corporate functions of international pharmaceutical groups Medeva and Celltech, which are now part of UCB. Jon is a Chartered Accountant and holds a degree in Biotechnology from the University of Reading in the UK. He is a non-executive director of BTC Health Limited (ASX: BTC).



DR TREVOR SCOTT

Non-Executive Director

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

Trevor joined the Neuren Board in 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

Non-Executive Director

BSc (Hons), Master of Biotechnology, IPTA

Dianne joined the Neuren Board in 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.



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 industry. Jenny is an accomplished CEO and Managing Director with experience in growing companies from start-up to commercialisation. She has served on Board's of a number of listed and unlisted companies and is currently a Non-Executive Director of Aeris Environmental Limited (ASX:AEI) and on the Board's IP sub-committee of the Children's Medical Research Institute. Jenny is a graduate of the Harvard Business School General Manager Program and the Australian Institute of Company Directors.



MR JOE BASILE

Non-Executive Director

FIPA, FFA

Joe joined the Neuren Board in March 2023. He has held a number of executive roles in the pharmaceutical industry for over 30 years, most recently as Group CFO at iNova Pharmaceuticals based in Singapore and prior to that with Novartis in senior Finance leadership and Commercial Sales leadership roles in Australia and Asia.

MANAGEMENT TEAM



JON PILCHER

Chief Executive Officer/Managing Director

BSc (Hons), FCA

Jon joined Neuren in 2013 as CFO and was appointed CEO in May 2020. He has played a central role in all aspects of Neuren's R&D, commercial and corporate activities. Before joining Neuren he was a member of the leadership team at Acrux (ASX: ACR) throughout a period that 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. He formerly spent seven years in a series of executive positions in the R&D and corporate functions of international pharmaceutical groups Medeva and Celltech, which are now part of UCB. Jon is a Chartered Accountant and holds a degree in Biotechnology from the University of Reading in the UK. He is a non-executive director of BTC Health Limited (ASX: BTC).



LARRY GLASS

Chief Science Officer

BA (Biology)

Larry joined Neuren in 2004 and was an Executive Director from 2012 to 2018. He directs Neuren's scientific and non-clinical development, as well as playing a leading role in clinical and regulatory strategy. Larry 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 provided management, strategic and business development services. Prior to that, he was CEO of a contract research organisation 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.



LIZA SQUIRES, M.D.

Chief Medical Officer

Liza joined Neuren in 2022 and has medical oversight of Neuren's development programs, as well as a leading role in clinical and regulatory strategy. Liza is a board certified physician in General Pediatrics and Neurology with Special Competence in Child Neurology. Over the past 20 years, she has held positions of increasing responsibilities in both early and late-stage drug development at Johnson and Johnson, Shire Pharmaceuticals, Lumos Pharma, Aevi Genomic Medicine and Origin Biosciences. She has led and contributed to multiple New Drug Applications resulting in global regulatory approvals and has extensive experience in orphan drug development. Liza received her B.S. from the University of Michigan and M.D. from Michigan State University. She trained in general pediatrics at Yale University and did her residency in Child Neurology at Massachusetts General Hospital.



DR NANCY JONES

Vice President, Clinical Development

PhD

Nancy joined Neuren in 2013. She leads the design and implementation of Neuren's clinical studies in neurodevelopmental disorders. Prior to joining Neuren, Nancy held a senior position at Autism Speaks, the largest science and advocacy organization in the US focused on autism spectrum and related disorders. She 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.

MANAGEMENT TEAM

CONTINUED



JAMES SHAW

Vice President, Clinical & Regulatory Operations

BSc (Hons), MBA

James joined Neuren in 2013, bringing twenty years of development and commercialisation experience in the Pharmaceutical Industry, having worked for both large Pharma and Clinical Research Organisations. He leads the clinical and regulatory execution of Neuren's programs. Before joining Neuren, James was CEO of a Clinical Research and Site Management Organisation providing full service clinical trial support in ANZ. Prior to that he spent seven 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 2 through to FDA submission and commercialisation during six years with AstraZeneca at their Global headquarters in the UK.



DR CLIVE BLOWER

Vice President, Product Development

BSc (Hons), PhD

Clive joined Neuren in 2014, bringing over twenty years of global drug development experience. He has led all aspects of CMC (Chemistry, Manufacturing and Controls) development of both trofinetide and NNZ-2591. Before joining Neuren, Clive was at Acrux (ASX: ACR) for seven years as Director of Product Development and Technical Affairs and then Chief Operating Officer. During this period he led the CMC 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.



LAUREN FRAZER

Chief Financial Officer & Company Secretary

BBus (Acc), CA

Lauren joined Neuren in 2020 and brings over fifteen years of experience in accounting and finance. Prior to joining Neuren, Lauren was at Boundary Bend, one of Australia's leading agribusinesses and owner of Australian olive oil brands Cobram Estate and Red Island. Lauren was at Boundary Bend for ten years as Financial Controller and then Senior Manager of Accounting & Tax. Lauren is a Chartered Accountant and began her career with Pitcher Partners.



GERRY ZHAO

Vice President, Corporate Development

B Com (Hons Finance), B Law (Hons)

Gerry joined Neuren in 2022 and has more than 16 years of global investment banking and financial services experience, with approximately 12 years at Bank of America Merrill Lynch responsible for healthcare investment banking coverage. He has advised numerous local and international corporations and private equity funds on public and private mergers and acquisitions, capital management and financing. Since 2019, Gerry has been consulting to several Australian and global biotech companies regarding strategic projects, including successfully facilitating the A\$400m strategic licence and commercial partnership between China Grand Pharmaceutical and Healthcare Holdings and Telix Pharmaceuticals in November 2020.



VIRGINIE DUREZ

Senior Director, Product Development & Project Management

MSc, MBA, PMP®

Virginie joined Neuren in 2021 and brings over twenty years of global pharmaceutical experience ranging from product ideation to product launch. Prior to joining Neuren, she worked with Pfizer for seventeen years through the legacy of Hospira and Mayne Pharma, in the Program Management, Commercial and Early Stage Development Groups and most recently worked as the Pipeline Development Lead for the Hospital Business Unit. Virginie has assessed, developed, and led over 100 global product strategies (US, EU, CAN, ANZ, China and Japan) and launched 3 products to the market. She is focused on bringing novel therapies that change patients' lives. Virginie received her Master of Chemistry and her Master of Chemical Engineering in France (University of Aix-Marseilles and Ecole Nationale Supérieure de Chimie de Toulouse), earned an MBA from the Australian Graduate School of Entrepreneurship, and is a PMP® practitioner.

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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") 4th 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 Chief Executive Officer. The Board has delegated the responsibility for the operation and administration of the Group to the Chief Executive Officer 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. At 31 December 2022 there were three male and two female directors. Four of the nine senior executives were female. The Group had fifteen employees and consultants, of which ten were 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 performance evaluation was undertaken during 2022.

In accordance with Recommendation 1.7, there is a process for the Board to evaluate periodically the performance of the Chief Executive Officer and for the Chief Executive Officer to evaluate periodically the performance of senior executives. The evaluation of the Non-Executive Chair is part of the board performance evaluation process. For the evaluation of senior executives, an individual discussion is held after each senior executive complete a qualitative questionnaire, covering past individual and team achievements and challenges, as well as forward-looking outcomes and areas of personal focus. Performance evaluations were undertaken during 2022.

CORPORATE GOVERNANCE

CONTINUED

PRINCIPLE 2. STRUCTURE THE BOARD TO BE EFFECTIVE AND 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 favourably. Analyse issues and contribute at board level to solutions. Recognise the role of the board versus the role of management.
Ethics and Integrity	Understand role as director and continue to self educate on legal responsibility, ability to maintain board confidentiality, declare any conflicts.
Contribution	Ability to constructively contribute to board discussions and communicate effectively with management and other directors.
Crisis Management	Ability to constructively manage crises, provide leadership around solutions and contribute to communications strategy with stakeholders.

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 2022, as set out in the table below. Details of the relevant skills, experience and expertise of each Board member are set out on page 17 of this report.

	Appointment	Retirement	Role	Independent	Committees
Patrick Davies	Appointment as director: 2018		Non-executive chair	Yes	Member of Audit Committee and Remuneration Committee
Trevor Scott	Appointment as Chair: 2020	2002	Non-executive director	Yes	Chair of Audit Committee and member of Remuneration Committee
Dianne Angus	2018		Non-executive director	Yes	Member of Audit Committee and Remuneration Committee
Jenny Harry	2018		Non-executive director	Yes	Member of Audit Committee and Chair of Remuneration Committee
Jon Pilcher	2021		Chief Executive Officer and Managing Director	No ¹	

¹ Jon Pilcher 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 independent and the chair and chief executive officer roles are 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. INSTIL A CULTURE OF ACTING LAWFULLY, ETHICALLY AND RESPONSIBLY

In accordance with Recommendation 3.1, the Group has articulated its values, which are disclosed on the Company website

- We are passionate about making a difference to the lives of patients and their families
- We aim to earn the respect of everyone we deal with
- We are determined and creative to break through barriers
- We harness the power of collaboration and different perspectives
- We recognise the importance of all stakeholders and endeavour to use financial resources efficiently

The Board has established a Code of Conduct (Recommendation 3.2), 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

CORPORATE GOVERNANCE

CONTINUED

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

Neuren is committed to the highest standards of conduct and ethical behaviour in all business activities. The Group's Whistleblower Policy is available on the Company website (Recommendation 3.3). Any material breaches of the Whistleblower Policy are to be reported to the Board.

The Group's Anti-bribery and Corruption is available on the Company website (Recommendation 3.4). Any material breaches of the Anti-bribery and Corruption Policy are to be reported to the Board.

PRINCIPLE 4. SAFEGUARD INTEGRITY OF CORPORATE REPORTS

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 Committee met twice during 2022, 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.

In accordance with Recommendation 4.2, the Board also, before it approves the entity's financial statements for a financial period, receives a declaration in writing from the Chief Executive Officer and the Chief Financial Officer that the financial records of the company have been properly maintained and that the financial statements are in accordance with New Zealand Equivalents to International

CORPORATE GOVERNANCE

CONTINUED

Financial Reporting Standards (NZ FRS) and present a true and fair view, in all material respects, of the Group's financial position and performance and that this opinion is founded on a sound system of risk management and internal control that is operating effectively in all material respects with regard to business and financial reporting risks. The Board received those assurances for the annual financial statements on 23 February 2023.

For other periodic corporate reports released to the market that are not audited or reviewed by an external auditor, processes are in place to ensure that the reports are materially accurate, balanced and provide investors with appropriate information to make informed investment decisions (Recommendation 4.3). Reports are prepared by the Chief Financial Officer and reviewed by the Chief Executive Officer, or are prepared by the Chief Executive Officer and reviewed by the Board. The Board receives a declaration in writing from the Chief Financial Officer and Chief Executive Officer regarding those reports.

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, and the Board receives copies of all material market announcements promptly after they have been made (Recommendation 5.2).

All investor or analyst presentations with new information are released on the ASX Market Announcements Platform ahead of such presentations, in accordance with Recommendation 5.3.

PRINCIPLE 6. RESPECT THE RIGHTS OF SECURITY HOLDERS

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 Chief Executive Officer interacts with institutional investors, private investors, analysts and media on an ad hoc basis, conducting meetings in person or by video/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 Annual Shareholders' Meeting in 2022 was conducted as a hybrid meeting, with participation both in-person and by electronic means.

All resolutions at the Company's Annual Shareholders' Meeting in 2022 were decided by a poll (Recommendation 6.4).

In accordance with Recommendation 6.5, 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).

CORPORATE GOVERNANCE

CONTINUED

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 2022.

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 twice during 2022.

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

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

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

The Group's remuneration policies and practices are summarised below, in accordance with Recommendation 8.2.

The Remuneration Committee assesses the appropriateness of the nature and amount of remuneration of executive directors and senior executives on a regular basis by reference to relevant employment market conditions, with the overall objective of ensuring maximum shareholder benefit from the retention of a high quality executive team. To assist in achieving these objectives, the nature and amount of executive remuneration is linked to the Company's performance. Remuneration consists of fixed cash remuneration, including superannuation contributions required by law, and equity-based remuneration. Fixed cash remuneration takes into account labour market conditions, as well as the scale and nature of the Group's business. Equity-based remuneration is provided by participation in a share option plan and/or a loan funded share plan. 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).

PRINCIPLE 9. ADDITIONAL RECOMMENDATIONS

Neuren is incorporated in New Zealand and ensures meetings of security holders are held at a reasonable place and time (Recommendation 9.2).

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 in person, as suggested in Recommendation 9.3. The Company's constitution enables the Board to convene virtual shareholder meetings, with participation by electronic means.

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE YEAR ENDED 31 DECEMBER 2022

	Note	2022 \$'000	2021 \$'000
Revenue from contracts with customers	4	14,553	-
Other income	4	2,480	3,636
Total income		17,033	3,636
Research and development costs		(12,712)	(9,516)
Corporate and administrative costs		(3,437)	(1,914)
Loss on financial derivatives measured at fair value through profit or loss		(700)	-
Profit/(loss) before income tax		184	(7,794)
Income tax	6	-	-
Profit/(loss) after income tax		184	(7,794)
Other comprehensive income, net of tax			
Amounts which may be subsequently reclassified to profit or loss:			
Exchange differences on translation of foreign operations		2	(4)
Total comprehensive income/(loss) for the year		186	(7,798)
Profit/(loss) after tax attributable to Equity holders of the Company:		184	(7,794)
Total comprehensive income/(loss) attributable to Equity holders of the Company:		186	(7,798)
Basic earnings/(loss) per share	7	\$0.001	(\$0.066)
Diluted earnings/(loss) per share	7	\$0.001	(\$0.066)

The notes on pages 30 to 44 form part of these consolidated financial statements.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT 31 DECEMBER 2022

	Note	2022 \$'000	2021 \$'000
ASSETS			
Current Assets:			
Cash and cash equivalents	8	40,180	36,783
Trade and other receivables	9	3,066	3,261
Total current assets		43,246	40,044
Non-current assets:			
Property, plant and equipment		21	12
Total non-current assets		21	12
TOTAL ASSETS		43,267	40,056
LIABILITIES AND EQUITY			
Current liabilities:			
Trade and other payables	10	978	803
Derivative liabilities	11	700	-
Total current liabilities		1,678	803
Total liabilities		1,678	803
EQUITY			
Share capital	12	167,740	167,578
Share option reserve		3,222	1,234
Currency translation reserve		(10,680)	(10,682)
Accumulated deficit		(118,693)	(118,877)
Total equity attributable to equity holders		41,589	39,253
TOTAL LIABILITIES AND EQUITY		43,267	40,056

The notes on pages 30 to 44 form part of these consolidated financial statements.

For and on behalf of the Board of Directors who authorised the issue of these consolidated financial statements on 23 February 2023.



Patrick Davies
Non-Executive Chair



Dr Trevor Scott
Director

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE YEAR ENDED 31 DECEMBER 2022

	Share Capital \$'000	Share Option Reserve \$'000	Currency Translation Reserve \$'000	Accumulated Deficit \$'000	Total Equity \$'000
Equity as at 1 January 2021	145,567	394	(10,678)	(111,083)	24,200
Shares issued in capital raising	20,000	-	-	-	20,000
Shares issued in share purchase plan	3,281	-	-	-	3,281
Share issue costs	(1,270)	-	-	-	(1,270)
Share based payments	-	840	-	-	840
Transactions with owners	22,011	840	-	-	22,851
Loss after income tax	-	-	-	(7,794)	(7,794)
Other comprehensive loss	-	-	(4)	-	(4)
Total Comprehensive income for the year	-	-	(4)	(7,794)	(7,798)
Equity as at 31 December 2021	167,578	1,234	(10,682)	(118,877)	39,253
Reversal of share issue costs	162	-	-	-	162
Share based payments	-	1,988	-	-	1,988
Transactions with owners	162	1,988	-	-	2,150
Profit after income tax	-	-	-	184	184
Other comprehensive income	-	-	2	-	2
Total Comprehensive income for the year	-	-	2	184	186
Equity as at 31 December 2022	167,740	3,222	(10,680)	(118,693)	41,589

The notes on pages 30 to 44 form part of these consolidated financial statements.

CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 31 DECEMBER 2022

	Note	2022 \$'000	2021 \$'000
Cash flows from operating activities:			
Receipts from licence agreement		15,921	-
Receipts from Australian R&D Tax Incentive		1,393	2,521
Interest received		188	54
GST refunded		252	372
Payments for employees and directors		(2,814)	(1,756)
Payments to other suppliers		(11,341)	(11,161)
Net cash flow received from/(used in) operating activities		3,599	(9,970)
Cash flows from investing activities:			
Purchase of property, plant and equipment		(19)	(10)
Net cash used in investing activities		(19)	(10)
Cash flows from financing activities:			
Proceeds from the issue of shares	12	-	23,281
Payment of share issue expenses		(2)	(1,106)
Net cash flow received from/(used in) financing activities		(2)	22,175
Net increase in cash		3,578	12,195
Effect of exchange rate changes on cash balances		(181)	400
Cash and cash equivalents at the beginning of the year		36,783	24,188
Cash and cash equivalents at the end of the year		40,180	36,783
Reconciliation with loss after income tax:			
Profit/(loss) after income tax		184	(7,794)
<i>Non-cash items requiring adjustment:</i>			
Depreciation of property, plant and equipment		10	8
Loan funded share payments expense		1,988	840
Foreign exchange loss/(gain)		184	(404)
Loss on financial assets		700	-
<i>Changes in working capital:</i>			
Trade and other receivables		194	(2,506)
Trade and other payables		339	(114)
Net cash received from/(used in) operating activities		3,599	(9,970)

The notes on pages 30 to 44 form part of these consolidated financial statements.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 DECEMBER 2022

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 HSBC 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 23 February 2023.

Material 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 2022 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 2022 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 18.

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 profit after tax of \$0.2 million for the year ending 31 December 2022 and had positive operating cash flows of \$3.6 million for the year ended 31 December 2022. The Group had net assets as at 31 December 2022 of \$41.6 million, including cash balances and receivables of \$43.2 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)

Impact of COVID-19 on our business

On March 11, 2020 the World Health Organization declared a pandemic resulting from the disease known as COVID-19 caused by a novel strain of coronavirus, SARS-CoV-2. In an effort to contain COVID-19 or slow its spread, state or federal governments around the world have enacted various measures, including orders to close businesses not deemed “essential”, isolate residents to their homes or places of residence, and practice social distancing when engaging in essential activities. In certain jurisdictions, such orders have been lifted, although subsequent trends in COVID-19 infections have led to the reinstatement of such orders in various jurisdictions.

To date there has been no financial impact of COVID-19 on the Group. It is possible that clinical trials or other research and development activities for NNZ-2591 could be impacted in the future by COVID-19 restrictions or risks. The Group is continuing to monitor the situation and may take further actions affecting its business operations as are deemed necessary.

Changes in accounting policies

There are no changes in accounting policies for the year ended 31 December 2022.

Standards, interpretations and amendments to published standards that are not yet effective

At the date of authorisation of these consolidated financial statements, several new, but not yet effective, Standards and amendments to existing Standards, and Interpretations have been published by the IASB. None of these Standards or amendments to existing Standards have been adopted early by the Group. Management anticipates that all relevant pronouncements will be adopted for the first period beginning on or after the effective date of the pronouncement. New Standards, amendments and Interpretations not adopted in the current year have not been disclosed as they are not expected to have a material impact on the Group’s consolidated financial statements.

(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.

All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation. 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 the 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 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 a separate component of equity.

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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(d) Revenue

NZ IFRS 15 establishes a five-step model to account for revenue arising from contracts with customers and requires that revenue be recognised at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer. The five-step process is as follows:

- identify the contract(s) with a customer;
- identify the performance obligations in the contract(s);
- determine the transaction price;
- allocate the transaction price to the performance obligations in the contract(s); and
- recognise revenue when (or as) the performance obligations are satisfied.

Licence revenue

Licence revenues in connection with licensing of the Group's intellectual property to customers are recognised as a right to use the entity's intellectual property as it exists at the point in time at which the licence is granted. This is because the contracts for the licence of intellectual property are distinct and do not require, nor does the customer reasonably expect, that the Group will undertake further activities that significantly affect the intellectual property to which the customer has rights.

Although the Group is entitled to sales-based royalties from any eventual sales of goods and services to third parties using the intellectual property transferred, these royalty arrangements do not of themselves indicate that the customer would reasonably expect the Group to undertake such activities, and no such activities are undertaken or contracted in practice. Accordingly, the promise to provide rights to the Group's intellectual property is accounted for as a performance obligation satisfied at a point in time.

The following consideration is received in exchange for licences of intellectual property:

- (i) Up-front payments - These are fixed amounts and are recognised at the point in time when the Group transfers the intellectual property to the customer.
- (ii) Milestone payments – This is variable consideration that is contingent on the customer reaching certain clinical, regulatory or commercial targets in relation to the intellectual property licenced. Variable consideration is estimated using the most likely amount method, variable consideration is constrained such that amounts are only recognised when it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur when the uncertainty associated with the variable consideration (that is, the customer meeting the conditions) is subsequently resolved. Milestone payments that are not in control of the Group, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received.
- (iii) Sales-based royalties – Licences of intellectual property can include royalties, which are variable consideration that are based on the sale of products that are produced using the intellectual property. The specific exception to the general requirements of estimating variable consideration for sales or usage-based royalties promised in a licence of intellectual property is applied. The exception requires such revenue to be recognised at the later of when (a) subsequent sales or usage occurs and (b) the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated is satisfied (or partially satisfied).

Grants

Grant income is 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 there is reasonable assurance that the grant will be received and all attached conditions will be complied with.

Research and development tax incentives

Other income from the Australian government Research and Development tax incentive (RDTI) program is recognised when there is reasonable assurance that the tax incentive will be received and all attached conditions will be complied with. The research and development activities and expenditure are assessed to determine eligibility under the RDTI program.

Interest income

Interest income is recognised as it is earned using the effective interest method.

(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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(f) Income tax

The income tax expense or benefit 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, adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and unused tax losses.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to apply when the assets are realised 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 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 the temporary differences will reverse in the foreseeable future and 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 tested for impairment if an indicator of impairment exists. 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 of the asset or the cash-generating unit to which the asset belongs exceeds the recoverable amount, being the higher of its fair value less costs of disposal and its value in use.

(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.

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

(l) 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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Share-based payments

Neuren operates a loan funded share plan and share option plan. Both plans are accounted for as share options and the loan is not recognised as an asset. 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 the share option reserve 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. It recognises the impact of these revisions, 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.

(m) Share issue costs

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

(n) 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 Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risks and rewards of ownership.

When it has neither transferred nor retained substantially all of the risks and rewards of the asset, nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of its continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

A financial liability is derecognised when it is extinguished, i.e. the obligation is discharged, cancelled or expired.

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 FVTPL or 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 cost or finance income, except for impairment of trade receivables which is presented within other expenses.

Subsequent measurement of financial assets

Financial assets at amortised cost

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

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

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

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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Trade and other payables

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.

Derivative financial instruments

Derivative financial instruments are initially recognised at fair value on the date on which a derivative contract is entered into and subsequently remeasured at fair value. Derivatives are carried as financial assets when the fair value is positive and as financial liabilities when the fair value is negative. Gains or losses on derivative financial instruments are recognised in the profit or loss.

3. SEGMENT INFORMATION

The Group has a single reportable 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.

4. REVENUE

Disaggregation of revenue from contracts with customers

The Group derives revenue from the sale and transfer of goods and services at a point in time under the following major business activities:

	2022 \$'000	2021 \$'000
Revenue from contracts with customers		
Licences of intellectual property - at a point in time	14,553	-
All revenue from licences of intellectual property is from the United States.		
Other income		
Interest income	391	41
Australian R&D tax incentive	864	3,197
Net foreign currency gains	1,225	398
Total other income	2,480	3,636

The net foreign currency gain of \$1.2 million includes a \$1.4 million gain on the milestone revenue from Acadia, offset by a loss on the translation for reporting purposes of the Group's US dollar cash balances into Australian dollars.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

5. EXPENSES

	2022 \$'000	2021 \$'000
Profit/(loss) before income tax includes the following expenses:		
Depreciation – property, plant and equipment		
Computer equipment	10	8
Total depreciation	10	8
Remuneration of auditors		
Audit and review of financial statements (Grant Thornton NZ)	70	66
Total remuneration of auditors	70	66
Employee benefits expense		
Short-term benefits	1,607	1,093
Post-employment benefits	153	91
Other employee benefits	34	26
Share based payments	868	611
Total employee benefits expenses	2,662	1,821
Directors' compensation		
Short-term benefits	732	498
Post-employment benefits	38	23
Share based payments	126	229
Total Directors' compensation	896	750
Other		
Consultants - share based payments	994	-

In the comparative figures, Jon Pilcher is included in Employee benefits until 14 June 2021, when he was appointed Managing Director. His remuneration post 14 June 2021 is included in Director's compensation.

6. INCOME TAX

	2022 \$'000	2021 \$'000
Income tax expense		
Current tax expense	-	-
Deferred tax expense	-	-
Numerical reconciliation of income tax to prima facie tax receivable:		
Profit / (Loss) before income tax	184	(7,794)
Tax at applicable rates 25.0% (2021: 26.0%)	46	(2,026)
Non-taxable Australian R&D tax incentive income	(216)	(831)
Non-deductible expenses for R&D incentive	497	1,973
Non-deductible share option expenses	497	218
Non-deductible loss in fair value of derivative	175	-
Other non-assessable income	(68)	-
Utilisation of previously unrecognised tax losses	(946)	-
Deductible temporary differences and tax losses for which no deferred tax asset was recognised	15	666
Income tax expense	-	-

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

6. INCOME TAX (CONTINUED)

Unrecognised deferred tax asset

Deferred tax is recognised on the basis there is probable realisation through future profits. The future income tax benefit of tax losses and other deferred tax assets in relation to temporary timing differences, have therefore not been recognised at 31 December 2022.

	Opening balance \$'000	Recognised in profit or loss \$'000	Closing balance \$'000
2022			
Patents	(217)	34	(183)
Capital raising costs	(403)	127	(276)
Employee benefits	(76)	(16)	(92)
Unrealised foreign exchange	-	(177)	(177)
Other temporary differences	(10)	47	37
	(706)	15	(691)
Deferred tax not recognised	706	(15)	691
Net deferred tax asset	-	-	-
2021			
Patents	(208)	(9)	(217)
Capital raising costs	(234)	(169)	(403)
Employee benefits	(55)	(21)	(76)
Other temporary differences	(4)	(6)	(10)
	(501)	(205)	(706)
Deferred tax not recognised	501	205	706
Net deferred tax asset	-	-	-
		2022 \$'000	2021 \$'000
Gross tax losses for which no deferred tax asset has been recognised ^(a)		106,115	110,750

(a) Of these gross tax losses, \$62.6 million (2021: \$63.3 million) relates to New Zealand tax losses, which are unlikely to be utilised unless future taxable income is generated in New Zealand. The movement is due to the New Zealand tax losses being translated at the closing foreign exchange rate at each reporting date.

There are no franking credits available for use as at 31 December 2022 (2021: nil).

7. EARNINGS PER SHARE

Basic earnings per share is calculated by dividing the profit for the year attributable to the equity holders of the company by the weighted average number of ordinary shares on issue during the year excluding shares held as treasury stock.

Diluted earnings per share is calculated by dividing the profit attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

	2022	2021
Earnings/(loss) after income tax attributable to equity holders (basic) - (\$'000)	184	(7,794)
Weighted average shares outstanding (basic) - (No.)	125,965,676	117,770,052
Basic earnings/(loss) per share	\$0.001	(\$0.066)
Earnings/(loss) after income tax attributable to equity holders (diluted) - (\$'000)	184	(7,794)
Weighted average shares outstanding (diluted) - (No.)	128,908,995	118,524,002
Diluted earnings/(loss) per share	\$0.001	(\$0.066)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

8. CASH AND CASH EQUIVALENTS

	2022 \$'000	2021 \$'000
Cash	2,304	6,912
Demand and short-term deposits	37,876	29,871
	40,180	36,783

9. TRADE AND OTHER RECEIVABLES

	2022 \$'000	2021 \$'000
Trade receivables	-	7
Other receivables	17	21
Interest receivables	207	3
Prepayments	1,977	1,837
Australian R&D tax incentive	865	1,393
	3,066	3,261

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 including historical experience, external indicators and forward-looking information to calculate the expected credit losses.

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 (2021: nil).

10. TRADE AND OTHER PAYABLES

	2022 \$'000	2021 \$'000
Trade payables	258	245
Accruals	267	209
Employee benefits	453	349
	978	803

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 goods or services received but not invoiced at each reporting date.

11. DERIVATIVES

	2022 \$'000	2021 \$'000
<i>Current derivative liabilities</i>		
Forward exchange contracts	700	-

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

12. SHARE CAPITAL

	2022 Shares	2021 Shares	2022 \$'000	2021 \$'000
Issued Share Capital				
Ordinary shares on issue at beginning of year	128,965,676	117,608,108	167,578	145,567
Shares issued in private placement	–	9,756,098	–	20,000
Share issued in Share Purchase Plan	–	1,601,470	–	3,281
Share issue expenses - issue costs	–	–	162	(1,270)
	128,965,676	128,965,676	167,740	167,578

At 31 December 2022 125,965,676 ordinary shares are quoted on the ASX, and 3,000,000 unquoted ordinary shares (31 December 2021: 3,000,000 ordinary shares) were held as treasury stock in respect of the Loan Funded Share Plan described 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

During the year ended 31 December 2022 \$2.0 million (31 December 2021: \$0.8 million) was recognised in share-based payments expense.

Loan funded shares

The Company has a Loan Funded Share Plan to support the achievement of the Company's business strategy by linking executive reward to improvements in the financial performance of the Company and aligning the interests of executives with shareholders. Under the Loan Funded Share Plan, loan funded shares may be offered to employees or consultants ("Participants"). 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 loan funded shares under the plan during the year ended 31 December 2022 are subject to the following vesting conditions:

- i. 40% of the Loan Funded Shares shall vest on acceptance by the US Food and Drug Administration of the filing of a New Drug Application for Trofinetide; and
- ii. 40% of the Loan Funded Shares shall vest when the Company determines to progress NNZ-2591 to a Phase 2b or Phase 3 clinical trial following a positive Phase 2 clinical trial outcome, or executes a partnering transaction for NNZ-2591;
- iii. 20% of the Loan Funded Shares shall vest when the Company executes a partnering transaction for trofinetide outside North America, or submits a Marketing Authorisation Application for trofinetide in the European Union, the United Kingdom, or Japan.

Each of these vesting conditions shall be tested separately from the other vesting conditions. The first vesting condition (i) was met in September 2022.

The estimated fair value of the shares has been determined using the Black-Scholes valuation model. The significant inputs into the model were the share price on date of valuation, the estimated future volatility of the share price, a dividend yield of 0%, an expected life of 5 years, and an annual risk-free interest rate of 0.4%. The estimated future volatility of the share price was derived by analysing the historic volatility of the share price during the relevant period.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

12. SHARE CAPITAL (CONTINUED)

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

	Loan Funded Shares	Weighted Average Exercise Price	Exercisable	Weighted Average Exercise Price
Outstanding at 31 December 2021	3,000,000	\$1.84	–	–
Outstanding at 31 December 2022	3,000,000	\$1.84	1,200,000	\$1.84

The exercise price for 3.0 million Loan Funded Shares is \$1.84 per share.

Options to acquire ordinary shares

During the year ended 31 December 2022, options to acquire 2,200,000 ordinary shares were issued to employees and consultants. Options to acquire ordinary shares vest subject to remaining an employee or consultant if and when the following non-market performance vesting conditions are met:

	950,000 share options	500,000 share options	750,000 share options
i. on acceptance by the US Food and Drug Administration of the filing of a New Drug Application for trofinetide	–	40%	–
ii. when the Company determines to progress NNZ-2591 to a Phase 2b or Phase 3 clinical trial following a positive Phase 2 clinical trial outcome, or executes a partnering transaction for NNZ-2591	60%	40%	60%
iii. when the Company executes a partnering transaction for trofinetide outside North America, or submits a Marketing Authorisation Application for trofinetide in the European Union, the United Kingdom, or Japan	40%	20%	40%

Each of these vesting conditions shall be tested separately from the other vesting conditions. The first vesting condition (i) was met in September 2022.

The estimated fair value of the options to acquire ordinary shares has been determined using the Black-Scholes valuation model. The significant inputs into the model were the share price on date of valuation, the estimated future volatility of the share price, the risk-free interest rate, a dividend yield of 0% and an expected life of 2.75 years. The estimated future volatility of the share price was derived by analysing the historic volatility of the share price on a daily basis during the two years prior to the issue date, as this period is reflective of the anticipated volatility in the future.

Details of the options to acquire ordinary shares issued during the year ended 31 December 2022, the estimated fair value and variable inputs into the valuation model are shown in the table below. The exercise price for the options to acquire ordinary shares is the 5-day weighted average price at which the shares were traded on the ASX in the 5 days preceding the issue of the options.

Number of shares under option	1,450,000	750,000
Issue date	3 February 2022	8 July 2022
Exercise price per share option	\$3.46	\$3.83
Share price on date of valuation	\$3.90	\$3.90
Fair value per share option	\$2.03	\$1.79
Estimated future volatility	77.58%	68.20%
Annual risk-free interest rate	1.40%	3.09%

Movements in the number of Share Options were as follows:

	Share Options	Weighted Average Exercise Price	Exercisable	Weighted Average Exercise Price
Outstanding at 31 December 2021	–	–	–	–
Issued	2,200,000	\$3.59	–	–
Outstanding at 31 December 2022	2,200,000	\$3.59	200,000	\$3.46

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

13. SUBSIDIARIES

(a) Investment in subsidiaries

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

Name of entity	Date of incorporation	Principle activities	Interest held	Domicile
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.

14. COMMITMENTS AND CONTINGENCIES

(a) Legal claims

The Group had no significant legal matter contingencies as at 31 December 2022 or at 31 December 2021.

(b) Commitments

The Group was not committed to the purchase of any property, plant or equipment or intangible assets as at 31 December 2022 (2021: nil).

At 31 December 2022, the Group had commitments under product development contracts amounting to approximately \$6.0 million, comprising approximately US\$3.9 million, GBP 0.1 million, EUR 0.1 million and AU \$0.2 million. At 31 December 2021, the Group had commitments under product development contracts amounting to approximately \$6.1 million, comprising approximately US\$3.3 million, GBP 0.3 million and AU \$0.9 million.

(c) Contingent liabilities

The Group had no contingent liabilities at 31 December 2022 or at 31 December 2021.

15. RELATED PARTY TRANSACTIONS

(a) Key Management Personnel

The Key Management Personnel of the Group (KMP) include the directors of the Company and employees who reporting directly to the Managing Director. Compensation for KMP was as follows:

	2022 \$'000	2021 \$'000
Short-term benefits	1,682	1,340
Post-employment benefits	112	83
Other long-term benefits	34	26
Share based payment compensation	837	840
	2,665	2,289

(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. All amounts due between entities are payable on demand and bear no interest.

16. EVENTS AFTER REPORTING DATE

As at the date of these consolidated financial statements authorised for issue, there are no events arising since 31 December 2022 that require disclosure.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

17. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

(a) Categories of financial instruments

		At amortised cost		At fair value through profit or loss	Total \$'000
		Floating Interest Rate \$'000	Non-Interest Bearing \$'000	Non-Interest Bearing \$'000	
2022					
Financial assets					
Cash and cash equivalents	8	40,180	-	-	40,180
Trade and other receivables	9	-	207	-	207
Total financial assets		40,180	207	-	40,387
Financial liabilities					
Trade and other payables	10	-	525	-	525
Derivative financial instruments - forward exchange contracts	11	-	-	700	700
		-	525	700	1,225
2021					
Financial assets					
Cash and cash equivalents	8	36,783	-	-	36,783
Trade and other receivables	9	-	10	-	10
Total financial assets		36,783	10	-	36,793
Financial liabilities					
Trade and other payables	10	-	454	-	454
Total financial liabilities		-	454	-	454

At 31 December 2022, the carrying value of all financial instruments approximated their 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 the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises three types of risk: currency risk, interest rate risk and other price risk.

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 2021, there were no forward contracts outstanding.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

17. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT (CONTINUED)

At 31 December 2022, there were two forward contracts to convert Australian dollars to US dollars outstanding. Adjustment of these financial instruments to fair value as measured at 31 December 2022 resulted in a loss of \$0.7 million. This fair value measurement is categorised within Level 2 of the fair value hierarchy. A summary of the forward contracts outstanding at 31 December 2022 is as follows:

	Buy USD \$'000	Sell AUD \$'000	Term	Weighted average exchange rate
Buy US dollar / sell AU dollar	7,873	12,323	3 months or less	0.6389

During the year, the US dollar fluctuated against the Australian dollar. A net foreign exchange gain of \$1.2 million is included in results for the year ended 31 December 2022 (2021: \$0.4 million), this includes a \$1.4 million gain on the milestone revenue from Acadia, offset by a loss on the translation for reporting purposes of the Group's US dollar cash balances into Australian dollars.

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

	2022 \$'000	2021 \$'000
Assets		
US dollars	2,104	6,905
Liabilities		
US dollars	803	38

An increase of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have increased the consolidated loss after income tax by \$1,238,107 (2021: \$624,255). A decrease of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have decreased the consolidated loss after income tax by \$1,514,242 (2021: \$762,978). An increase of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have decreased equity by \$12,419 (2021: increase of \$2,109). A decrease of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have increased equity by \$15,179 (2021: decrease of \$2,578).

Interest rate risk

The Group is exposed to changes in market interest rates as entities in the Group hold cash and cash equivalents.

The effective interest rates on financial assets are as follows:

	2022 \$'000	2021 \$'000
Financial Assets		
Cash and cash equivalents		
Australian dollar cash deposits	38,076	29,885
Australian dollar interest rate	3.58%	0.17%
US dollar cash deposits	2,104	6,898
US dollar interest rate	-%	-%

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 5% change in average market interest rates would have changed reported loss after tax by approximately \$68,200 (2021: \$2,580). A 5% increase/decrease in the average market interest rates would have no impact on other components of equity.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

CONTINUED

17. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT (CONTINUED)

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 Primis bank.

Liquidity risk

The Group's financial liabilities, comprising trade and other payables and derivatives, are generally repayable within 1 – 3 months. The maturity and availability of financial assets, comprising cash and cash equivalents and trade and other receivables, are monitored and managed to ensure financial liabilities can be repaid when due.

Capital management

The Group monitors capital including share capital, retained earnings and reserves and the cash and cash equivalents presented in the consolidated statement of financial position. The Group has no debt. The key objective of the Group when managing its capital is to safeguard its ability to continue as a going concern, so that the Group can sustain the future development of the research and development activities being performed by the Group.

18. 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 2022 the Group has recorded other revenue of \$0.9 million (2021: \$3.2 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.

Cash and cash equivalents include term deposits of \$37.9 million with 3-month or less maturities which are held to meet short-term cash commitments, rather than for investment or other purposes.

The Group measures the fair value of loan funded shares and options to acquire ordinary shares with employees and consultants by reference to the fair value of the equity instruments at the date at which they are granted. The estimated fair value of the shares is determined using the Black-Scholes valuation model, taking into account the terms and conditions upon which the instruments were granted. Some judgements are made on the inputs into the valuation model, including the expected life and volatility.



Independent Auditor's Report

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To the Shareholders of Neuren Pharmaceuticals Limited

Report on the Audit of the Consolidated Financial Statements

Opinion

We have audited the consolidated financial statements of Neuren Pharmaceuticals Limited (the "Company") and its subsidiaries (the "Group") on pages 26 to 44 which comprise the consolidated statement of financial position as at 31 December 2022, 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 consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the financial position of the Group as at 31 December 2022 and of its financial performance and cash flows for the year then ended in accordance with the 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 Auditing 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 *International Code of Ethics for Assurance Practitioners (including International Independence Standards) (New Zealand)* issued by the New Zealand Auditing and Assurance Standards Board and the International Ethics Standards Board for Accountants' *International Code of Ethics for Professional Accountants (including International Independence Standards) (IESBA Code)*, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code. 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 year. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Why the audit matter is significant	How our audit addressed the key audit matter
<p>Share Based Payments</p> <p>During the year ended 31 December 2022, the Group issued share options to key employees and contractors, which have been accounted for as share based payments under IFRS 2: <i>Share-Based Payments</i>.</p> <p>Share-based payments are a complex accounting area including assumptions utilised in the fair value calculations</p>	<p>Our procedures in relation to management's valuation include:</p> <ul style="list-style-type: none"> Evaluating management's assessment of the valuation and recognition of the options. Obtaining an understanding of the key terms and conditions of the share options by review relevant agreements.

Chartered Accountants and Business Advisers
 Member of Grant Thornton International Ltd.



Why the audit matter is significant	How our audit addressed the key audit matter
<p>and judgements regarding the options issued during the year.</p> <p>The fair value was determined using the Grant-Date Method via a Black-Scholes Model as described in Note 12 in the financial statements.</p> <p>The valuation involved significant judgements and estimates from management, including the estimated future volatility of the share price, and an annual risk-free interest rate.</p> <p>We included the valuation of the share options as a key audit matter, due to the high estimation uncertainty within the assumptions and the impact these have on the fair value of the shares.</p>	<ul style="list-style-type: none"> Engaged auditor's valuation expert to assess reasonability of key assumptions and methodology used in the estimation of fair value of the share options. Recalculating the estimated fair value of the share options using the valuation methodology selected. Performed a sensitivity analysis on key inputs on the model and reviewed the impact on the fair value. Reviewing the adequacy of the Company's disclosures in respect of the accounting treatment of share-based payments in the financial statements, including significant judgments involved and the accounting policies adopted.

Information Other than the Consolidated Financial Statements and Auditor's Report thereon

The Directors are responsible for the other information. The other information comprises the annual report. The annual report is expected to be made available to us after the date of this report.

Our opinion on the consolidated financial statements does not cover the other information and we do 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 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. When we read the annual report, if we conclude that there is a material misstatement therein, we are required to report that fact.

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 the Company's shareholders, as a body, for our audit work, for this report or for the opinion we have formed.

Grant Thornton New Zealand Audit Limited

Grant Thornton

Ryan Campbell

Partner

Auckland

23 February 2023

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ADDITIONAL INFORMATION

BOARD AND COMMITTEE ATTENDANCE

The table below shows the number of Board and Committee meetings each Director was eligible to attend and attended during the financial year ended 31 December 2022:

Director	Board		Audit and Risk		Remuneration	
	Held ⁽ⁱ⁾	Attended	Held ⁽ⁱ⁾	Attended	Held ⁽ⁱ⁾	Attended
Patrick Davies	10	10	2	2	2	2
Dr Trevor Scott	10	10	2	2	2	2
Dianne Angus	10	10	2	2	2	2
Dr Jenny Harry	10	10	2	2	2	2
Jonathan Pilcher	10	10	-	-	-	-

(i) Number of meetings held during the time the Director was a member of the Board or Committee

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 in this register during and since the end of 2022.

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 (2021: \$nil).

REMUNERATION OF DIRECTORS

2022	Salary/fees \$	Bonus \$	Super- annuation \$	Share based payments \$	Total \$
Non-Executive Directors					
Patrick Davies	125,000	-	-	-	125,000
Dr Trevor Scott	75,000	-	-	-	75,000
Dianne Angus	68,028	-	6,972	-	75,000
Dr Jenny Harry	68,028	-	6,972	-	75,000
	336,056	-	13,944	-	350,000
Executive Directors					
Jonathan Pilcher	396,403	-	24,430	125,505	546,338
Total	732,459	-	38,374	125,505	896,338

ADDITIONAL INFORMATION

CONTINUED

2021	Salary/fees \$	Bonus \$	Super- annuation \$	Share based payments \$	Total \$
Non-Executive Directors					
Patrick Davies	120,000	-	-	-	120,000
Dr Trevor Scott	72,000	-	-	-	72,000
Dianne Angus	54,670	-	5,330	-	60,000
Dr Jenny Harry	60,094	-	5,906	-	66,000
	306,764	-	11,236	-	318,000
Executive Directors					
Jonathan Pilcher ¹	190,437	-	12,688	229,123	432,248
Total	497,201	-	23,924	229,123	750,248

1 The table for the year ended 31 December 2021 shows the total remuneration for Jon Pilcher since his appointment to Managing Director on 14 June 2021.

Loan Funded Shares

Jon Pilcher has an interest in 1,500,000 Loan Funded Shares held by Neuren Trustee Limited. As detailed in Note 12 to the Financial Statements, the Loan Funded Shares are subject to vesting conditions and repayment of a loan amounting to \$1.84 per share before they can be transferred to Jon.

EMPLOYEE REMUNERATION

The number of employees, not being directors of the Company, who received remuneration and benefits in their capacity as employees totalling NZ \$100,000 or more during the year, shown in bands denominated in Australian dollars, was as follows:

Excluding share based payments

	2022 \$'000	2021 \$'000
\$150,000 - \$159,999	1	-
\$160,000 - \$169,999	-	1
\$170,000 - \$179,999	-	2
\$190,000 - \$199,999	1	-
\$240,000 - \$249,999	2	-
\$270,000 - \$279,999	1	1
\$290,000 - \$299,999	-	1
\$300,000 - \$309,999	1	-

Including share based payments

	2022 \$'000	2021 \$'000
\$150,000 - \$159,999	1	-
\$160,000 - \$169,999	-	1
\$170,000 - \$179,999	-	1
\$340,000 - \$349,999	1	-
\$360,000 - \$369,999	1	1
\$390,000 - \$399,999	1	-
\$400,000 - \$409,999	1	-
\$480,000 - \$489,999	-	1
\$500,000 - \$509,999	-	1
\$640,000 - \$649,999	1	-

ADDITIONAL INFORMATION

CONTINUED

AUDITORS

Grant Thornton New Zealand Audit Limited ('Grant Thornton') is the independent auditor of the Company. Audit fees in relation to the annual and interim financial statements were \$70,214 (2021: \$65,921). Grant Thornton did not receive any other fees in relation to other financial advice and services. No amounts were payable to an auditor by subsidiary companies in 2022 or 2021.

EQUITY SECURITIES HELD BY DIRECTORS AS AT 24 MARCH 2023

Director	Interests in Ordinary Shares		Interests in Loan Funded Shares
	Direct	Indirect	Indirect
Dr Trevor Scott	1,000,000	2,589,784	-
Dianne Angus	30,000	-	-
Patrick Davies	-	264,634	-
Jenny Harry	-	29,663	-
Jonathan Pilcher ¹	-	398,207	1,500,000

¹ Jon Pilcher has an interest in 1.5 million Loan Funded Shares held by Neuren Trustee Limited. As detailed in Note 12 to the Financial Statements, the Loan Funded Shares are subject to vesting conditions and repayment of a loan amounting to \$1.84 per share before they can be transferred to Jon.

DIRECTORS OF SUBSIDIARY COMPANIES AT 31 DECEMBER 2022

	Jon Pilcher	Larry Glass	Dr 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:

- 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.
- 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.
- 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 24 March 2023.

The number of ordinary shareholdings held in less than marketable parcels at 24 March 2023 was 381, holding 1,941 ordinary shares.

DISTRIBUTION OF SECURITY HOLDERS

Listed ordinary shares

Size of holding	Number of ordinary shares	%	Number of holders	%
100,001 and Over	91,443,978	72.42	128	2.04
10,001 to 100,000	24,371,857	19.30	814	12.96
5,001 to 10,000	4,449,073	3.52	591	9.41
1,001 to 5,000	4,862,294	3.85	1,885	30.01
1 to 1,000	1,138,474	0.90	2,864	45.59
Total	126,265,676	100.00	6,282	100.00

UNLISTED SECURITIES

2,700,000 Loan Funded Shares, held as treasury stock, with a weighted average exercise price of \$1.84, have an expiry date of 13 July 2025. There are 3 holders of 100,001 and over.

2,200,000 Employee Share Scheme options, with a weighted average exercise price of \$3.59, of which 1,450,000 have an expiry date of 3 February 2026 and 750,000 have an expiry date of 8 July 2026. There are 5 holders of 100,001 and over.

SUBSTANTIAL SECURITY HOLDERS

The following have filed substantial holding notifications:

	Number held	Percentage
Milford Asset Management Limited	6,561,977	5.088%

Substantial holdings are based on the last notice lodged on the ASX.

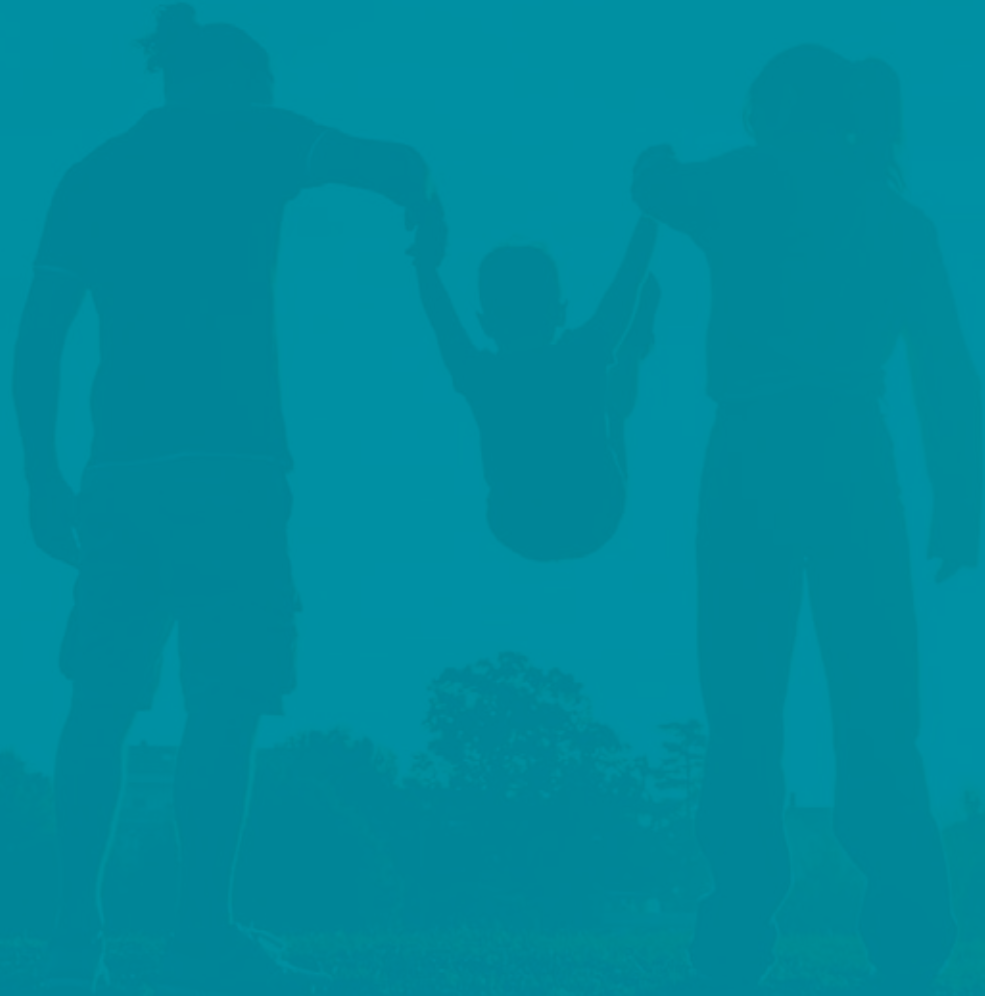
ADDITIONAL INFORMATION

CONTINUED

Twenty largest holders of quoted ordinary shares

	Number of ordinary shares	% of issued share capital
1 NATIONAL NOMINEES LIMITED	11,810,223	9.35
2 CITICORP NOMINEES PTY LIMITED	10,759,990	8.52
3 HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	9,174,182	7.27
4 J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	8,875,428	7.03
5 HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	6,639,176	5.26
6 CAMERON RICHARD PTY LTD	4,206,313	3.33
7 BNP PARIBAS NOMS PTY LTD	2,710,864	2.15
8 STUART ANDREW PTY LTD	2,460,000	1.95
9 ESSEX CASTLE LIMITED	2,367,144	1.87
10 SMITHLEY SUPER PTY LTD	2,010,000	1.59
11 LINWIERIK SUPER PTY LTD	1,885,000	1.49
12 SHARESIES NOMINEE LIMITED	1,385,966	1.10
13 MXB INVESTMENTS LLC	1,330,000	1.05
14 DR TREVOR SCOTT	1,000,000	0.79
15 FIRST COLBYCO PTY LTD	790,000	0.63
16 MJHFT PTY LTD	750,000	0.59
17 DR ROBIN LANCE CONGREVE	671,637	0.53
18 HOBSON WEALTH CUSTODIANS LTD	589,337	0.47
19 EMANCIPAYTE PTY LTD	476,607	0.38
20 BNP PARIBAS NOMINEES PTY LTD ACF CLEARSTREAM	465,450	0.37
Total	70,357,317	55.72
Balance of share register	55,908,359	44.28
Total ordinary shares quoted on ASX	126,265,676	100.00

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pharmaceuticals

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