Neuren Pharmaceuticals Limited

Appendix 4D Half-Year Financial Report

30 June 2023

Name of entity

Neuren Pharmaceuticals Limited

ABN

72 111 496 130

Half-year ended

30 June 2023

1. Reporting Period

Neuren Pharmaceuticals Limited ("Neuren" or the "Company") presents this financial report, including the interim consolidated financial statements, for the six months ended 30 June 2023, with the six months ended 30 June 2022 as the comparative period.

2. Results for announcement to the market

	30 June 2023 $'000	30 June 2022 $'000	Movement %
2.1 Total income	64,405	283	22658%
2.2 Profit/(loss) after tax from ordinary activities	47,805	(7,054)	778%
2.3 Net profit/(loss) attributable to members	47,805	(7,054)	778%
2.4 Dividends and franked amount per security	nil	nil	n/a
2.5 Dividend record date	n/a	n/a	n/a

2.6 Explanation of results:

The Group's net profit after income tax for the half-year ended 30 June 2023 was $47.8 million, compared with a net loss after tax of $7.0 million for the half-year ended 30 June 2022. Neuren recognised revenue from licence agreements of $59.4 million following the first commercial sale of DAYBUE by Acadia in April 2023. Royalty income of $3.5 million has been recognised in relation to the Q2 2023 net sales reported by Acadia.

Research and development costs increased by $6.5 million, with the higher expenditure in 2023 due to the NNZ-2591 Phase 2 clinical trials and the foundational work to prepare for Phase 3 development of NNZ-2591 across multiple indications. The net income tax expense recognised for the half-year ended 30 June 2023 was $1.8 million (30 June 2022: nil). There was no income tax payable at 30 June 2023, due to the utilisation of carried forward tax losses and the expectation of offsetting the 5% withholding tax paid to the US Internal Revenue Service in relation to the milestone payment earned following the first commercial sale of DAYBUE by Acadia in April 2023.

The basic earnings per share for the half-year to 30 June 2023 was $0.378 (half-year to 30 June 2022: loss per share $0.056). Total cash and short-term investments at 30 June 2023 were $85.7 million (31 December 2022: $40.2 million). Net cash generated from operating activities was $44.9 million (half-year to 30 June 2022: net cash used $5.8 million).

A more detailed discussion of the activities undertaken in the period is set out in the Directors' Report contained in the attached Interim Report.

3. Net Tangible Assets per Security

	June 2023	June 2022
Net tangible assets per share	$ 0.7157	$ 0.2659

4. Entities over which control has been gained or lost during the period:

None.

5. Details of dividends

Not applicable.

6. Details of dividend reinvestment plans

Not applicable.

7. Details of associates and joint venture entities

None.

8. Accounting standards

The interim financial statements have been prepared in accordance with *International Accounting Standard 34* and NZ IAS 34 *Interim Financial Reporting*.

9. Auditors review

The interim financial statements have been subject to independent review by the Company's auditors. The unqualified review report is included in the attached Interim Report.

Neuren Pharmaceuticals Limited

ABN 72 111 496 130

Incorporated in New Zealand

Consolidated Interim Financial Report for the Half-Year ended 30 June 2023

Directors' Report

The Directors submit the interim financial report of Neuren Pharmaceuticals Limited for the half-year ended 30 June 2023.

Directors' details

The names of Directors who held office during or since the end of the half-year are:

Patrick Davies (Non-Executive Chair)
Dr Trevor Scott (Non-Executive Director)
Dianne Angus (Non-Executive Director)
Dr Jenny Harry (Non-Executive Director)
Joe Basile (Non-Executive Director) (Appointed 2 March 2023)
Jonathan Pilcher (Managing Director)

Review of Operations

Neuren Pharmaceuticals Limited ("Neuren" or the "Company"), and its subsidiaries (collectively the "Group") is a biopharmaceutical company, incorporated in New Zealand and listed on the Australian Securities Exchange (ASX: NEU). Neuren is developing two new drug therapies to treat multiple serious neurological disorders that emerge in early childhood.

In March 2023, Neuren's partner 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 or older. DAYBUE is the first and only approved treatment for Rett syndrome. In April, Acadia announced the commercial launch of DAYBUE in the United States. The first commercial sale earned Neuren a milestone payment of US$40 million (A$59.4).

Neuren receives ongoing quarterly royalties of between 10% and 15% of DAYBUE net sales in North America, plus milestone payments of up to US$350 million on achievement of a series of four thresholds of total annual net sales. Acadia announced net sales of DAYBUE for the first partial quarter (Q2 2023) of US$23.2 million and provided guidance for net sales in Q3 2023 of US$45 to US$55 million.

Upon FDA approval of the New Drug Application (NDA) with Rare Pediatric Disease designation, Acadia was awarded a Priority Review Voucher (PRV) by the FDA, which can be used to obtain FDA review of a NDA for another product in an expedited period of six months. The voucher may also be sold for use by another company. When Acadia use or sell the PRV, they must pay Neuren one third of the value. In July 2023, a voucher was sold for US$102 million.

Neuren is also eligible to receive development and first commercial sales milestone payments of up to US$55 million if Acadia develops trofinetide for Fragile X syndrome.

In July 2023, Neuren announced the expansion of its partnership with Acadia, with Acadia's exclusive licence for trofinetide in North America expanded to a worldwide exclusive licence. This leverages Acadia's unique knowledge and expertise from the successful development and commercialisation of DAYBUE in the United States. The existing milestone payments and royalties for trofinetide in North America remained unchanged, with additional payments related to the development and commercialisation outside North America. An up-front payment of US$100 million (A$145.7) was received by Neuren on 27 July 2023. Further development milestone payments of up to US$64 million in total may be received on the first commercial sale in Europe and Japan for each of Rett syndrome and a second indication. There are potential sales milestone payments of up to US$363 million on achievement of escalating annual net sales thresholds as well as mid-teen to low twenties per cent tiered royalties on net sales.

Neuren is developing a second drug NNZ-2591 for four other seriously debilitating disorders that have no or limited approved treatment options. Phase 2 clinical trials are currently ongoing in children with each of Angelman, Phelan-McDermid, Pitt Hopkins and Prader-Willi syndrome. All four programs have been granted Orphan Drug designation by the FDA. The estimated number of patients being targeted across these four indications is more than five times larger than Rett syndrome. Neuren retains all global rights to these programs.

In July and August 2022, Neuren announced the commencement of Phase 2 clinical trials of NNZ-2591 for Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome, after receiving in March 2022 approval from the FDA for Investigational New Drug (IND) applications to conduct the trials. In June 2023, Neuren announced the commencement of its Phase 2 clinical trial of NNZ-2591 in Prader-Willi syndrome, after receiving approval for its IND application from the FDA in January 2023.

In June 2023, Neuren announced that enrolment of subjects in the Phase 2 clinical trial of NNZ-2591 in Phelan-McDermid syndrome had been completed. Top-line results from the trial are expected to be available in December 2023.

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

In order to expedite the overall development plan for NNZ-2591, 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.

The consolidated interim financial statements for the half-year are presented on pages 4 to 12. All amounts in the Financial Statements are shown in Australian dollars unless otherwise stated.

The Group's net profit after income tax for the half-year ended 30 June 2023 was A$47.8 million, compared with a net loss after tax of A$7.0 million for the half-year ended 30 June 2022. Neuren recognised revenue from licence agreements of A$59.4 million following the first commercial sale of DAYBUE by Acadia in April 2023. Royalty income of A$3.5 million was recognised in relation to the Q2 2023 net sales reported by Acadia.

Research and development costs increased by A$6.5 million, with the higher expenditure in 2023 due to the NNZ-2591 Phase 2 clinical trials and the foundational work to prepare for Phase 3 development of NNZ-2591 across multiple indications. Corporate and administrative costs increased by A$1.1 million, mostly due to one-time bonus payments following the receipt of the first commercial sale milestone payment from Acadia.

The net income tax expense recognised for the half-year ended 30 June 2023 was A$1.8 million (30 June 2022: nil). There was no income tax payable at 30 June 2023, due to the utilisation of carried forward tax losses and the expectation of offsetting the 5% withholding tax paid to the US Internal Revenue Service in relation to the milestone payment earned following the first commercial sale of DAYBUE by Acadia in April 2023.

The basic earnings per share for the half-year to 30 June 2023 was A$0.378 (half-year to 30 June 2022: loss per share A$0.056) based on a weighted average number of shares outstanding of approximately 126.3 million (half-year to 30 June 2022: 126.0 million).

Total cash and short-term investments at 30 June 2023 were A$85.7 million (31 December 2022: A$40.2 million). Net cash generated from operating activities was A$44.9 million (half-year to 30 June 2022: net cash used A$5.8 million). Following the receipt of the first commercial sale milestone payment from Acadia, the Company is holding more funds than are required to meet currently forecast short-term cash commitments. As a result, the Company has classified A$47.3 million of cash held in short-term deposits as Short-term Investments.

Directors' Report

Directors' declaration

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

The accompanying condensed consolidated financial statements of Neuren and its subsidiaries for the half-year ended 30 June 2023 and the notes to those condensed consolidated financial statements:

- comply with International Accounting Standard 34 and NZ IAS 34 *Interim Financial Reporting*; and
- present fairly, in all material respects, the financial position as at 30 June 2023 and of the performance for the half-year ended on that date of Neuren and its subsidiaries.

In the Directors' opinion there are reasonable grounds to believe that Neuren will be able to pay its debts as and when they become due and payable.

This report is signed and the declaration is made in accordance with a resolution of the Board of Directors dated 25 August 2023.

On behalf of the Board

Patrick Davies
Non-Executive Chair

Dr Trevor Scott
Director

Neuren Pharmaceuticals Limited

Consolidated Interim Statement of Comprehensive Income
For the half-year ended 30 June 2023

	Note	Half-year ended Jun 2023 $'000	Jun 2022 $'000
Revenue from contracts with customers	4	62,926	-
Other income	4	1,479	283
Total income		64,405	283
Research and development costs		(11,089)	(4,610)
Corporate and administrative costs		(2,659)	(1,577)
Share based payment expense		(1,035)	(1,150)
Profit/(loss) before income tax		49,622	(7,054)
Income tax expense		(1,817)	-
Profit/(loss) after income tax for the period		47,805	(7,054)
Other comprehensive expense, net of tax			
Amounts which may be reclassified to profit or loss:			
Exchange differences on translation of foreign operations		(13)	(17)
Total comprehensive income/(loss) for the period		47,792	(7,071)
Profit/(loss) after tax attributable to Equity holders of the Company		47,805	(7,054)
Total comprehensive income/(loss) attributable to Equity holders of the Company		47,792	(7,071)
Basic earnings/(loss) per share	3	$0.378	($0.056)
Diluted earnings/(loss) per share	3	$0.368	($0.056)

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Statement of Financial Position
As at 30 June 2023

	As at 30 Jun 2023 $'000	As at 31 Dec 2022 $'000
ASSETS		
Current Assets:		
Cash and cash equivalents	38,389	40,180
Short-term investments	47,286	-
Trade and other receivables	10,592	3,066
Derivative assets	131	-
Total current assets	96,398	43,246
Non-current assets:		
Property, plant and equipment	32	21
Deferred tax asset	1,093	-
Total non-current assets	1,125	21
TOTAL ASSETS	97,523	43,267
LIABILITIES AND EQUITY		
Current liabilities:		
Trade and other payables	3,100	978
Derivative liabilities	-	700
Income tax payable	2,910	-
Total current liabilities	6,010	1,678
Total liabilities	6,010	1,678
EQUITY		
Share capital	169,258	167,740
Share option reserve	3,836	3,222
Currency translation reserve	(10,693)	(10,680)
Accumulated deficit	(70,888)	(118,693)
Total equity attributable to equity holders	91,513	41,589
TOTAL LIABILITIES AND EQUITY	97,523	43,267

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Statement of Changes in Equity
For the half-year ended 30 June 2023

	Share Capital $'000	Share Option Reserve $'000	Currency Translation Reserve $'000	Accumulated Deficit $'000	Total $'000
Equity as at 1 January 2022	167,578	1,234	(10,682)	(118,877)	39,253
Reversal of share issue costs	162	-	-	-	162
Share based payments	-	1,150	-	-	1,150
Transactions with owners	162	1,150	-	-	1,312
Loss after income tax	-	-	-	(7,054)	(7,054)
Other comprehensive expense	-	-	(17)	-	(17)
Total comprehensive income/(loss) for the period	-	-	(17)	(7,054)	(7,071)
Equity as at 30 June 2022	167,740	2,384	(10,699)	(125,931)	33,494
Equity as at 1 January 2023	167,740	3,222	(10,680)	(118,693)	41,589
Loan funded shares converted	1,104	-	-	-	1,104
Issue costs on conversion of loan funded shares	(7)	-	-	-	(7)
Share based payments	-	1,035	-	-	1,035
Transfer on conversion of loan funded shares	421	(421)	-	-	-
Transactions with owners	1,518	614	-	-	2,132
Profit after income tax	-	-	-	47,805	47,805
Other comprehensive expense	-	-	(13)	-	(13)
Total comprehensive income/(loss) for the period	-	-	(13)	47,805	47,792
Equity as at 30 June 2023	169,258	3,836	(10,693)	(70,888)	91,513

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Cash Flow Statement
For the half-year ended 30 June 2023

		Half-year ended	
		Jun 2023	Jun 2022
		$'000	$'000
Cash flows from operating activities:			
Receipts from licence agreement		59,810	-
Withholding tax paid		(2,910)	-
Interest received		766	33
GST refunded		130	132
Payments for employees and directors		(2,993)	(1,275)
Payments to other suppliers		(9,925)	(4,706)
Net cash from/(used in) operating activities		**44,878**	**(5,816)**
Cash flows from investing activities:			
Purchase of property, plant and equipment		(18)	(10)
Net cash used in investing activities		**(18)**	**(10)**
Cash flows from financing activities:			
Proceeds from the issue of shares		1,104	-
Payment of share issue expenses		(7)	(2)
Net cash provided from/(used in) financing activities		**1,097**	**(2)**
Net increase/(decrease) in cash		**45,957**	**(5,828)**
Effect of exchange rate changes on cash balances		(462)	133
Cash and cash equivalents at the beginning of the period		40,180	36,783
Less cash transferred to short-term investments	(i)	(47,286)	-
Cash and cash equivalents at the end of the period		**38,389**	**31,088**
Reconciliation with profit/(loss) after income tax:			
Profit/(loss) after income tax		47,805	(7,054)
Non-cash items requiring adjustment:			
Depreciation of property, plant and equipment		6	4
Share based payments expense		1,035	1,150
Foreign exchange loss		(250)	(149)
Unrealised gain on financial assets		(131)	-
Movements in working capital		(3,587)	233
Net cash from/(used in) operating activities		**44,878**	**(5,816)**

(i) Following the receipt of the first commercial sale milestone payment from Acadia, the Company is holding more funds than are required to meet currently forecast short-term cash commitments. As a result, the Company has reclassified cash held in short-term deposits from Cash and Cash Equivalents to Short-term Investments.

The accompanying notes form part of this financial statement.

Notes to the Consolidated Interim Financial Statements
For the half-year ended 30 June 2023

1. Nature of the business

Neuren Pharmaceuticals Limited ("Neuren" or the "Company"), and its subsidiaries (collectively the "Group") is a biopharmaceutical company developing new drug therapies to treat multiple serious neurodevelopmental disorders with high unmet need.

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 operates in Australia and its ordinary shares are listed on the Australian Securities Exchange (ASX code: NEU).

These consolidated interim financial statements were approved for issue by the Board of Directors on 25 August 2023.

2. Summary of significant accounting policies

Basis of preparation

These condensed consolidated interim financial statements are for the half-year ended 30 June 2023 and have been prepared in accordance with, and comply with International Accounting Standard 34 and NZ IAS 34 *Interim Financial Reporting*.

The Group is a Tier 1 for-profit entity under the External Reporting Board Accounting Standards Framework in New Zealand.

No new Standards were adopted in the current year.

There have been no significant changes in accounting policies during the current period. The accounting policies that materially affect the measurement of the Consolidated Statement of Comprehensive Income, Consolidated Statement of Financial Position, Consolidated Statement of Changes in Equity and the Consolidated Statement of Cash Flows have been applied on a basis consistent with those used in the audited financial statements for the year ended 31 December 2022 and the unaudited interim financial statements for the half-year ended 30 June 2022. There is no cyclical seasonality of interim operations.

The functional and presentation currency of the Group is Australian dollars.

These interim financial statements do not include all the notes of the type normally included in an annual financial report. Accordingly, this interim report is to be read in conjunction with the annual report for the year ended 31 December 2022.

Going concern assumption

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 $47.8 million for the period ended 30 June 2023 and had positive operating cash flows for the period of $44.9 million. The Group had cash of $38.4 million and short-term investments (term deposits) of $47.3 million at 30 June 2023.

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

3. Earnings per share

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

Diluted earnings per share is calculated by dividing the profit attributable to ordinary equity holders of the company 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.

	Jun-23	Jun-22
Consolidated		
Earnings/(loss) after income tax attributable to equity holders (basic) ($'000)	47,805	(7,054)
Weighted average shares outstanding (basic) - (No.)	126,336,947	125,965,676
Basic earnings/(loss) per share	$0.378	($0.056)
Earnings/(loss) after income tax attributable to equity holders (diluted) ($'000)	47,805	(7,054)
Weighted average shares outstanding (diluted) - (No.)	130,049,131	125,965,676
Diluted earnings/(loss) per share	$0.368	($0.056)

4. Revenue

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

	Jun 2023 $'000	Jun 2022 $'000
Revenue from contracts with customers		
Licences of intellectual property - at a point in time	59,434	-
Royalty income	3,492	-

All revenue from licences of intellectual property is from the United States. The revenue from licences of intellectual property was earned by Neuren on the first commercial sale of DAYBUE by Acadia in the United States.

Neuren is eligible to receive quarterly royalty income, calculated as a percentage of net sales of DAYBUE in North America and is recognised in the period the Acadia makes the sales of DAYBUE. The royalty rate for ≤US$250 million of annual net sales is 10%.

Other income		
Interest income	684	55
Net foreign currency gains	664	228
Gain on financial derivatives measured at fair value through profit or loss	131	-
Total other income	1,479	283

5. Income tax

Income tax expense is recognised based on management's estimate of the weighted average effective annual income tax rate expected for the full financial year. The estimated average annual tax rate used for the half-year ended 30 June 2023 is 30%, compared with 25% for the year ended 31 December 2022. The tax rate was lower in 2022 as the Group was a base rate entity however will exceed the aggregated turnover thresholds in 2023.

Current tax expense was $2.9 million, offset by a deferred tax benefit of $1.1 million, resulting in a net income tax expense recognised for the half-year ended 30 June 2023 of $1.8 million (30 June 2022: nil). There is no income tax payable at 30 June 2023, due to the utilisation of carried forward tax losses and the expectation of offsetting the 5% withholding tax paid to the US Internal Revenue Service in relation to the milestone payment earned following the first commercial sale of DAYBUE by Acadia in April 2023.

At 30 June 2023, a $1.1 million deferred tax asset has been recognised in relation to the future income tax benefit of remaining Australian tax losses ($0.55 million) and other deferred tax assets ($0.55 million) in relation to temporary timing differences, on the basis there is probable realisation through future profits. The deferred tax asset recognised in relation to remaining tax losses is the tax effect amount of carried forward tax losses of $1.8 million.

6. Share capital

Consolidated	Half-year Jun-23 Shares	Year Dec-22 Shares
Issued share capital		
Ordinary shares on issue at beginning of period	128,965,676	128,965,676
Ordinary shares on issue at end of period	128,965,676	128,965,676

At 30 June 2023, 126,565,676 shares (31 December 2022: 125,965,676) are quoted on the ASX, and 2,400,000 unquoted ordinary shares (31 December 2022: 3,000,000) were held as treasury stock in respect of the Loan Funded Share plan.

Share based payments
During the half-year to 30 June 2023 $1.0 million (30 June 2022: $1.2 million) was recognised in share-based payments expense.

Loan funded shares
At 30 June 2023 2.4 million Loan Funded Shares are held in trust for Key Management Personnel (KMP), of which 0.6 million were vested and 1.8 million were unvested. During the half-year ended 30 June 2023, 600,000 vested loan funded shares were converted to issued ordinary shares upon repayment of the loan.

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 2022	3,000,000	$1.84	1,200,000	$1.84
Loan repaid and shares transferred to participant	(600,000)	$1.84	(600,000)	$1.84
Outstanding at 30 June 2023	2,400,000	$1.84	600,000	$1.84

The exercise price for the 2.4 million Loan Funded Shares is $1.84 per share.

Options to acquire ordinary shares
At 30 June 2023, there are 2,200,000 options to acquire ordinary shares on issue to employees and consultants. There were no movements in the options to acquire ordinary shares on issue for the period ended 30 June 2023.

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 2022	2,200,000	$3.59	200,000	$3.46
Outstanding at 30 June 2023	2,200,000	$3.59	200,000	$3.46

The weighted average exercise price for the options to acquire ordinary shares is $3.59.

7. Commitments and contingencies

(a) Legal claims
The Group had no significant legal matter contingencies at 30 June 2023 (30 June 2022: nil).

(b) Commitments
The Group was not committed to the purchase of any property, plant or equipment or intangible assets as at 30 June 2023 (30 June 2022: nil).

As at 30 June 2023, the Group had commitments under product development contracts at the end of the reporting period but not recognised as liabilities amounting to approximately $11.1 million, comprising approximately US $7.0 million, £0.1 million and AU $0.3 million.

(c) Contingent liabilities
The Group had no contingent liabilities at 30 June 2023 (30 June 2022: nil) that require disclosure.

8. Key management personnel
Key management personnel remuneration is disclosed in the annual financial report.

During the half-year ended 30 June 2023, 600,000 vested loan funded shares were converted to issued ordinary shares upon repayment of the loan. There were no loan funded shares or share options issued to key management personnel in the half-year ended 30 June 2023.

9. Segment information
The Group has a single reportable segment and internal management reporting systems present financial information as a single segment. The segment is involved in the development of pharmaceutical products. The Board of the Company has been identified as the chief operation decision maker. The Board assesses the financial performance and position of the Group and makes strategic decisions.

10. Events after balance date

On 14 July 2023, the Group announced the expansion of its partnership with Acadia Pharmaceuticals for trofinetide (marketed in US as DAYBUE™). Acadia's exclusive licence for trofinetide in North America was expanded to a worldwide exclusive licence. The existing milestone payments and royalties to Neuren for trofinetide in North America were unchanged, with additional payments related to development and commercialisation outside North America. Neuren received an up-front payment of US$100 million from Acadia on 27 July 2023. Further development milestone payments of up to US$64 million in total may be received on the first commercial sale in Europe and Japan for each of Rett syndrome and a second indication. There are potential sales milestones payments of up to US$363 million on achievement of escalating annual net sales thresholds as well as mid-teen to low twenties per cent tiered royalties on net sales.

If Acadia sub-licenses trofinetide for any region outside North America within the first two years, Neuren is entitled to a share of any upfront and development milestones received by Acadia. Any such payment to Neuren will be credited against any future milestone and royalty payments payable to Neuren in the relevant region.

Under the new agreement, Neuren also granted to Acadia an exclusive worldwide licence to develop and commercialise NNZ-2591 for Rett syndrome and Fragile X syndrome only. This replaced the restrictions in the existing agreement on use by Neuren in those two indications. Potential milestone payments and royalties payable to Neuren for NNZ-2591 in Rett and Fragile X are identical to the trofinetide milestone payments and royalties in each of North America and other regions. Neuren retains worldwide rights to NNZ-2591 in all other indications. Acadia is responsible for all costs of development and commercialization globally for trofinetide in all indications and for NNZ-2591 in Rett and Fragile X only.

Neuren has an obligation not to develop NNZ-2591 or any other product for North America in an indication for which Acadia develops trofinetide, except for Phelan-McDermid, Pitt Hopkins, Angelman and Prader-Willi syndromes.

The non-market performance vesting condition relating to the execution of a partnering transaction for trofinetide outside North America was met when Acadia's licence was expanded to a worldwide exclusive licence, with 600,000 Loan Funded Shares and 780,000 options to acquire ordinary shares vesting.

As at the date of approving these consolidated interim financial statements there are no other events arising since 30 June 2023 that require disclosure.

Independent Auditor's Review Report

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To the Shareholders of Neuren Pharmaceuticals Limited

Report on the Review of the Condensed Consolidated Interim Financial Statements

Conclusion

We reviewed the condensed consolidated interim financial statements (the "financial statements") of Neuren Pharmaceuticals Limited and its subsidiaries (the 'Group'), which comprise the consolidated interim statement of financial position as at 30 June 2023, and the consolidated interim statement of comprehensive income, consolidated interim statement of changes in equity and consolidated interim cash flow statement for the period ended on that date, and a summary of significant accounting policies and other explanatory information.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying financial statements on pages 4 to 12 do not present fairly, in all material respects, the consolidated interim financial position of Neuren Pharmaceuticals Limited as at 30 June 2023, and of its consolidated interim financial performance and consolidated interim cash flows for the six month period ended on that date, in accordance with *New Zealand equivalents to International Accounting Standard 34 Interim Financial Reporting ('NZ IAS 34')* issued in New Zealand by the New Zealand Accounting Standards Board.

Basis for Conclusion

We conducted our review in accordance with NZ SRE 2410 (Revised) *Review of Financial Statements Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the *Auditor's Responsibilities for the Review of the Financial Statements* section of our report. We are independent of the Neuren Pharmaceuticals Limited in accordance with the relevant ethical requirements in New Zealand relating to the audit of the annual financial statements, and we have fulfilled our other ethical responsibilities in accordance with these ethical requirements.

Other than in our capacity as assurance practitioner we have no relationship with, or interests in, Neuren Pharmaceuticals Limited.

Director's Responsibility for the Financial Statements

The Directors are responsible, on behalf of the Group, for the preparation and fair presentation of the financial statements in accordance with NZ IAS 34 issued in New Zealand by the New Zealand Accounting Standards Board, and for such internal control as the Directors determine is necessary to enable the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibilities for the Review of the Financial Statements

Our responsibility is to express a conclusion on the financial statements based on our review. NZ SRE 2410 (Revised) requires us to conclude whether anything has come to our attention that causes us to believe that the financial statements, taken as a whole, are not prepared in all material respects, in accordance with NZ IAS 34 issued in New Zealand by the New Zealand Accounting Standards Board.

A review of the financial statements in accordance with NZ SRE 2410 (Revised) is a limited assurance engagement. We perform procedures, consisting of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. The procedures performed in a review are substantially less than those performed in an audit conducted in accordance with International Standards on Auditing (New Zealand) and consequently

does not enable us to obtain assurance that we might identify in an audit. Accordingly, we do not express an audit opinion on those financial statements.

Restriction on use of our review report

This review report on the financial statements is made solely to the shareholders, as a body. Our limited assurance work has been undertaken so that we might state to the shareholders, as a body, those matters which we are required to state to them in an independent review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than Neuren Pharmaceuticals Limited and the shareholders, as a body, for our work, for this review report or for the conclusion we have formed.

Grant Thornton New Zealand Audit Limited

Grant Thornton

R Campbell

Partner

Auckland

25th August 2023