Neuren (NEU) - ASX Announcement **27 July 2020**

Neuren Q2 2020 Activity Report

Q2 Highlights:

- **Enrolment in the LAVENDER Phase 3 trial of trofinetide in Rett syndrome re-initiated in June 2020 following pause of 3 months due to COVID-19**
- **Cash of $9.2 million at 30 June 2020, with $19 million net of costs received after 30 June from successful capital raise to fund the generation of valuable Phase 2 clinical trial data for NNZ-2591**
- **Phase 1 clinical trial of NNZ-2591 commenced in May 2020**
- **First patent in Israel granted for trofinetide to treat Rett syndrome, Fragile X syndrome and autism**
- **Jon Pilcher and Patrick Davies appointed as Chief Executive Officer and non-executive Chair**

Melbourne, Australia, 27 July 2020: Neuren Pharmaceuticals (ASX: NEU) today filed its Quarterly Activity Report and Cash Flow Report for Q2 2020.

Neuren CEO Jon Pilcher commented: "Neuren ended Q2 in a much stronger position after the re-initiation of enrolment in the trofinetide Phase 3 trial and securing the necessary funding to generate valuable Phase 2 clinical data for NNZ-2591. We now move forward with confidence to execute our plans for NNZ-2591, while ACADIA completes and funds the Phase 3 trial for trofinetide."

Events in the quarter:

- In June 2020 Neuren's US partner ACADIA re-initiated enrolment in the LAVENDER Phase 3 trial of trofinetide in Rett syndrome. Enrolment of new patients had been paused temporarily in March 2020, due to the measures taken in the US to combat the COVID-19 pandemic.
- In May 2020 Neuren commenced its first clinical trial of NNZ-2591. The Phase 1 trial, conducted in Australia is assessing safety, tolerability and pharmacokinetics in healthy adult volunteers. Based on its mechanism of action and positive results in animal models, NNZ-2591 has received Orphan Drug designation from the FDA for each of Phelan-McDermid, Angelman and Pitt Hopkins syndromes, three debilitating disorders that currently have no approved treatments.
- During the quarter Neuren continued to execute the non-clinical studies required for the planned Investigational New Drug Application (IND) to the FDA for NNZ-2591 in order to proceed with Phase 2 clinical trials.
- On 29 June 2020, Neuren announced the successful completion of a capital raise of $20 million, placing 14.3 million shares at $1.40 per share with institutional and sophisticated investors in Australia, New Zealand, Hong Kong and the UK in order to fund the NNZ-2591 Phase 2 trials.

- In April 2020 a new patent was granted by the Israel Patent Office covering trofinetide to treat Rett syndrome, Fragile X syndrome and autism. This first patent for trofinetide in Israel expires in 2032, with the potential for patent term extension of up to 5 years.
- In May 2020 Neuren announced the appointment of Jon Pilcher and Patrick Davies as Chief Executive Officer and non-executive Chair respectively.

Summary of Q2 cash flows

Cash at 30 June 2020 was $9.2 million, with additional cash of approximately $19 million net of costs received after 30 June from the placement of 14.3 million shares at $1.40. Net cash of $3.6 million was used in operating activities, with payments for R&D of $3.2 million mainly comprising the NNZ-2591 non-clinical studies and Phase 1 trial, including manufacture of the required drug. The carrying value of US dollar cash held to eliminate exchange rate risk for US dollar expenditure fell by $0.8 million due to the weakening of the US dollar against the Australian dollar, having previously increased by $1.1 million in Q1 2020.

Listing Rule 4.7C.3

In item 6 of the Appendix 4C cash flow report for the quarter, payments to Related Parties of approximately $121,000 comprised fees to executive and non-executive directors.

About Neuren

Neuren is developing new therapies for debilitating neurodevelopmental disorders that emerge in early childhood and are characterized by impaired connections and signalling between brain cells. The therapies utilize synthetic analogs of neurotrophic peptides that occur naturally in the brain. Trofinetide is currently in a Phase 3 clinical trial for Rett syndrome and has completed a Phase 2 clinical trial in Fragile X syndrome. The programs have each received Fast Track designation by the US Food and Drug Administration and Orphan Drug designation in both the United States and the European Union. Neuren has granted an exclusive license to ACADIA Pharmaceuticals Inc. for the development and commercialization of trofinetide in North America, whilst retaining all rights outside North America. Neuren is advancing the development of NNZ-2591 for Phelan-McDermid, Angelman and Pitt Hopkins syndromes, each of which has received Orphan Drug designation in the United States.

Contact:
Jon Pilcher, CEO
jpilcher@neurenpharma.com; +61 438 422 271

ASX Listing Rules information

This announcement was authorized to be given to the ASX by the board of directors of Neuren Pharmaceuticals Limited, Suite 201, 697 Burke Road, Camberwell, VIC 3124

Forward-looking Statements

This announcement contains forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Neuren to be materially different from the statements in this announcement.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Neuren Pharmaceuticals Limited	
ABN	**Quarter ended ("current quarter")**
72 111 496 130	30 June 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(3,212)	(4,121)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(374)	(757)
	(f) administration and corporate costs	(136)	(424)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	48	106
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	50	50
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,624)**	**(5,146)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(6)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**(6)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	144	144
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**144**	**144**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	13,427	13,844
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,624)	(5,146)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(6)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	144	144
4.5	Effect of movement in exchange rates on cash held	(775)	336
4.6	**Cash and cash equivalents at end of period**	**9,172**	**9,172**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	734	809
5.2	Call deposits	8,438	12,618
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**9,172**	**13,427**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	121
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,624)
8.2	Cash and cash equivalents at quarter end (item 4.6)	9,172
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	9,172
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.5

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: On 29 June 2020, Neuren announced the completion of a successful capital raise of $20 million, placing 14.3 million shares at $1.40 per share. Settlement occurred on 6 July 2020.

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 27 July 2020

Authorised by: The Board
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.