

Quarterly Report & Appendix 4C Q1 FY25

Highlights:

- Lead product candidate accepted into prestigious HEALEY ALS Platform Trial
- Positive interim results from OLE Study
- SME status granted by European Medicines Agency (EMA)
- EMA Pre-submission Meeting for Orphan Designation
- Investor engagement at the TechKnow Invest Roadshow and Spark Plus Aussie Equities Day
- Name change to Neurizon Therapeutics approved by shareholders, post Quarter end
- Cash at Bank position of \$15m, following successful Share Purchase Plan (SPP) raising \$7.8m, in excess of the initial \$2m sought

Planned activity for Q2 FY25:

- Finalise Specific Regimen Protocol with the HEALEY ALS Platform Trial
- Open Investigational New Drug (IND) application with United States (US) Food and Drug Administration (FDA)
- EMA Orphan Medicinal Product Designation Grant outcome
- Preclinical data readouts in models of neurodegenerative diseases

31 October 2024 – Melbourne, Australia: Neurizon Therapeutics Limited (ASX: NUZ & NUZOA) (“Neurizon” or “the Company”), a clinical-stage biotech company dedicated to advancing treatments for neurodegenerative diseases, is pleased to provide its Appendix 4C and Quarterly Activities Report for the period ended 30 September 2024.

During this period, Neurizon has made significant progress in advancing its clinical-stage development of monepantel, now known as NUZ-001, for neurodegenerative diseases, with a focus on Amyotrophic Lateral Sclerosis (ALS). The company has achieved key milestones, including regulatory advancements, positive clinical trial updates, and a successful capital raise, all of which position Neurizon for continued growth and success as it progresses towards pivotal clinical trials.

Managing Director and Chief Executive Officer, Dr Michael Thurn commented: “This quarter was truly transformational as our Company continued to strengthen our position to lead the development of treatments for neurodegenerative diseases. The selection of our lead product candidate, NUZ-001, for inclusion in the prestigious HEALEY ALS Platform Trial and positive regulatory engagement, combined with the strong support from our shareholders through the SPP, has solidified our momentum. We are making significant strides towards bringing NUZ-001 to patients with ALS, with encouraging clinical results and ongoing regulatory progress. Our focus remains on advancing these critical programs, and we look forward to the continued development of NUZ-001 in the months ahead.”

Operational Progress

Selection for the HEALEY ALS Platform Trial

In July 2024, NUZ-001 was selected for inclusion in the HEALEY ALS Platform Trial due to previously announced positive results from Neurizon's Phase 1 MEND study. The HEALEY platform is a multi-drug evaluation across 70+ clinical sites in the United States. This prestigious trial offers independent validation of NUZ-001's potential as a treatment for ALS, accelerating its path toward FDA approval. Trial enrolment is expected to begin in Q1 2025.

Positive Interim Results from Open-Label Extension (OLE) Study

In August, Neurizon reported promising interim results following 4 months of treatment for participants in the OLE study which showed NUZ-001 continues to be well-tolerated at a daily dose of 10 mg/kg. The first patients enrolled in the Phase 1 MEND study (now in the OLE study) had now entered their 23rd month of continuous treatment with NUZ-001. The interim results demonstrated that NUZ-001 reduced the rate of ALS functional decline by 43.2% (ALSF_{RS}-R was -0.41 points/month) significantly increased survival ($p=0.00034$) and significantly reduced risk of death by 80.3% ($HR=0.197$, $p=0.0059$) when compared to the external historical control PRO-ACT database¹. Clinical studies² have shown that rates of decline in ALSF_{RS}-R scores between -0.25 to -0.45 points/month translate to a median survival of 3.7 years. This study will provide further long-term safety and efficacy data as Neurizon prepares for the Phase 2/3 HEALEY ALS Platform Trial.

EMA Pre-submission Meeting for Orphan Designation

Neurizon has submitted a request for Orphan Medicinal Product Designation (OMPD) with the EMA for NUZ-001 in ALS. If granted, this designation would provide 10 years of market exclusivity following approval in the European Union, along with additional regulatory and commercial benefits. A decision is expected in December 2024.

EMA Small and Medium-Sized Enterprise (SME) Status

Neurizon was granted SME status by the EMA in July 2024. This status entitles the company to regulatory fee reductions and enhanced support, significantly streamlining its regulatory engagement as NUZ-001 progresses through clinical development for neurodegenerative diseases, particularly ALS.

Corporate & Financial Summary

Name Change to Neurizon Therapeutics

Following the end of the quarter, the Company formally changed its name to Neurizon Therapeutics Limited. The name change was approved by shareholders at the Company's Annual General Meeting in October and aligns with the Company's focus on creating a promising horizon for patients facing complex neurodegenerative diseases.

The Company's new identity reinforces its key strategic priorities:

- (1) Advancing patient access to innovative ALS treatments
- (2) Accelerating hope by partnering with the world's leading neurologists and HEALEY ALS Platform Trial, and
- (3) Unlocking the potential of NUZ-001 to treat a range of neurodegenerative diseases

Investor Engagement

During the quarter the Company presented to institutional, sophisticated and retail investors at the TechKnow Invest Roadshow held in Sydney and Melbourne in July 2024 and at the Spark Plus Aussie Equities Day in Singapore on 20 September 2024.

Successful Share Purchase Plan

Neurizon successfully completed its SPP in July 2024, raising \$7.8 million before costs. Demand for the SPP was significantly in excess of the initial target of \$2.0 million, reflecting strong shareholder support for Neurizon's refreshed strategy to focus on neurodegenerative disease. The proceeds further strengthen the Company's balance sheet, enabling it to advance its clinical development program for NUZ-001, including trial preparations and regulatory engagement.

Cash Flow Summary

During the quarter, Neurizon continued to fund the advancement of its clinical development program for NUZ-001.

Neurizon had net cash outflows from operating activities of \$3.3 million during the quarter and held \$9 million in cash and cash equivalents, plus an additional \$6 million in term deposits, totalling \$15 million as at 30 September 2024.

During the quarter, Neurizon invested \$2.1 million in R&D activities, and had \$7.7 million in net cash inflows from financing activities, following the completion of the Company's \$7.8 million SPP.

Payments to related parties and their associates during the quarter, which are outlined in Section 6 of the accompanying Appendix 4C to this quarterly activity report, were \$331k. These payments included non-executive director fees and consulting fees as well as salary (including superannuation) for the CEO and Managing Director.

A copy of the Appendix 4C - Quarterly Cash Flow Report for the quarter is attached.

-ENDS-

This announcement has been authorized for release by the Board of Neurizon Therapeutics Limited.

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About Neurizon Therapeutics Limited

Neurizon Therapeutics Limited (ASX: NUZ) is a clinical-stage biotechnology company dedicated to advancing treatments for neurodegenerative diseases. Neurizon is developing its lead drug candidate, NUZ-001, for the treatment of ALS, which is the most common form of motor neurone disease. Neurizon's strategy is to accelerate access to effective ALS treatments for patients, while exploring NUZ-001's potential for broader neurodegenerative applications. Through international collaborations and rigorous clinical programs, Neurizon is dedicated to creating new horizons for patients and families impacted by complex neural disorders.

¹ Atassi N, Berry J, Shui A, Zach N, Sherman A, Sinani E, Walker J, Katsovskiy I, Schoenfeld D, Cudkowicz M, Leitner M. The PRO-ACT database: design, initial analyses, and predictive features. *Neurology*. 2014 Nov 4;83(19):1719-25. doi: 10.1212/WNL.0000000000000951. Epub 2014 Oct 8. PMID: 25298304; PMCID: PMC4239834.

² Elamin M, Bede P, Montuschi A, Pender N, Chio A, Hardiman O. Predicting prognosis in amyotrophic lateral sclerosis: a simple algorithm. *J Neurol*. 2015 Jun;262(6):1447-54. doi: 10.1007/s00415-015-7731-6. Epub 2015 Apr 11. PMID: 25860344; PMCID: PMC4469087.

Appendix 4C

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

Name of entity

Neurizon Therapeutics Limited (Formerly known as PharmAust Limited)

ABN

35 094 006 023

Quarter ended ("current quarter")

30 September 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(2,097)	(2,097)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(65)	(65)
(d) leased assets	-	-
(e) staff costs	(360)	(360)
(f) administration and corporate costs	(851)	(851)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	34	34
1.5 Interest and other costs of finance paid	(1)	(1)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(3,340)	(3,340)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) term deposits with maturities longer than 3 months at acquisition	(6,000)	(6,000)
(e) intellectual property	-	-

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
	(f) other non-current assets	-	-
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	(6,000)	(6,000)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	7,830	7,830
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	(157)	(157)
3.8	Dividends paid	-	-
3.9	Other	-	-
3.10	Net cash from / (used in) financing activities	7,673	7,673

Appendix 4C

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

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	10,660	10,660
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,340)	(3,340)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6,000)	(6,000)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,673	7,673
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
4.6	Cash and cash equivalents at end of period	*8,992	*8,992

** In addition to the cash and cash equivalents balance disclosed above as at 30 September 2024, the Company holds an additional \$6 million in term deposits with maturity terms greater than 3 months, classified in the statement of financial position as short-term investments in accordance with AASB 107 Statement of Cash Flows. The term deposits can be withdrawn with 30-days notice.*

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	2,992	9,648
5.2	Call deposits*	6,000	1,012
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)	*8,992	10,660

** In addition to the cash and cash equivalents balance above as at 30 September 2024, the Company holds an additional \$6 million in term deposits with maturity terms greater than 3 months, classified in the statement of financial position as short-term investments in accordance with AASB 107 Statement of Cash Flows. The term deposits can be withdrawn with 30-days notice.*

Appendix 4C

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

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	331
6.2 Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>	

7. Financing facilities <i>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.</i>	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 (Premium financing)	-	-
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.		
N/A		

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,340)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,992
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,992
8.5	Estimated quarters of funding available based on cash and cash equivalents under AASB 107 (item 8.4 divided by item 8.1)	2.69
<i>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.</i>		
8.5.1	Total funds held in bank	\$A'000
8.5.1(a)	Cash and cash equivalents (item 4.6)	8,992
8.5.1(b)	Term deposits with maturity terms greater than 3 months that can be withdrawn with 30-day notice (item 2.1(d))	6,000
8.5.1(c)	Total funds held in bank as at 30 September 2024	14,992
8.5.1(d)	Estimated quarters of total funding available (item 8.5.1(c) divided by item 8.1)	4.5
8.5.2	Events subsequent to 30 September 2024	\$A'000
8.5.2(a)	Tranche 2 equity placement as approved at AGM (yet to be issued)	885
8.5.2(b)	Research and development tax incentives received	887
8.5.2(c)	Successful Advance Overseas Finding application to AusIndustry in respect of eligible overseas expenditure (yet to be received)	655
8.5.2(d)	Pro-forma bank balance at the date of appendix 4C (item 8.5.1(c) + 8.5.2(a)-(c))	17,419
8.5.2(e)	Estimated quarters of total funding available based on pro-forma bank balances adjusted for events subsequent to 30 September 2024 (item 8.5.2(d) divided by item 8.1)	5.2

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions: N/A
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?
	N/A
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?
	N/A
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?
	N/A
<i>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.</i>	

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: 31 October 2024

Authorised by: 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 – e.g. 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.