Neurizon Therapeutics Limited
ABN 35 094 006 023
www.neurizon.com

Quarterly Report & Appendix 4C
Q2 FY25

Highlights:

- **Positive 8-Month interim results from OLE Study**
- **Positive Preclinical Data on NUZ-001**
- **IND submission to support HEALEY ALS Platform Trial**
- **Orphan Medicinal Product Designation granted by EMA**
- **Name change to Neurizon Therapeutics**
- **Received 2 Research & Development Tax-incentive rebates totaling $1,537,836**
- **Issue of Tranche 2 Placement Shares to Related Parties following shareholder approval, raising $885,000**
- **Cash at Bank position of $14m**

29 January 2025 – 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 31 December 2024.

During the period, Neurizon made significant strides in advancing NUZ-001 for neurodegenerative diseases, particularly Amyotrophic Lateral Sclerosis (ALS). The company achieved key regulatory milestones, reported encouraging clinical trial outcomes, and strengthened its corporate identity through strategic rebranding. These developments collectively position Neurizon for continued progress toward pivotal clinical trials and the advancement of innovative treatments for ALS.

Managing Director and Chief Executive Officer, Dr Michael Thurn commented: "The past quarter has been transformative for Neurizon Therapeutics. Our strategic rebranding has not only redefined our corporate identity but also reinforced our commitment to pioneering treatments for neurodegenerative diseases. The regulatory milestones in Orphan Drug Designation, IND submission to support HEALEY ALS Platform Trial and the positive interim data from our Open-Label Extension study underscore the therapeutic potential of NUZ-001. These milestones, coupled with our strengthened leadership team, and the strong support from our shareholders position us favorably as we advance toward pivotal clinical trials. We remain dedicated to delivering innovative therapies to patients in need and are enthusiastic about the progress we anticipate in the coming months."

Clincial Progress

Positive Interim 8-Month Results from Open-Label Extension (OLE) Study

In December 2024, Neurizon reported another set of promising interim results following 8 months of treatment in the OLE study which continued to demonstrate encouraging results in slowing disease progression and increasing the life expectancy of patients with ALS. At the time of the announcement, patients had entered their 27th month of continuous treatment with NUZ-001. Key findings compared to untreated matched controls from the PRO-ACT Historical Database[1] showed that NUZ-001 significantly increased survival ($\chi 2=11.67$, $p=0.00062$), and significantly reduced the risk of death by 78.1% (HR=0.219, p=0.0044). The mean rate of reduction in disease progression measured by ALSFRS-R from baseline was -0.77 points/month. There have been no serious adverse events related to treatment with NUZ-001 reported, and the treatment with NUZ-001 continued to be well-tolerated at the recommended 10 mg/kg daily dose, the same dose planned for the upcoming Phase 2/3 HEALEY ALS Platform Trial.

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Positive Preclinical Data on NUZ-001

In November 2024, Neurizon presented compelling preclinical data in human in vitro iPSC Motor Neuron models of ALS. These innovative studies reveal NUZ-001's unique mechanism of action in preventing the aggregation of TAR DNA-binding protein 43 (TDP-43), a key pathological feature of ALS. NUZ-001 and its major active metabolite significantly and dose-dependently prevented the aggregation of TDP-43 by ~50% and ~55% respectively, in M337V Motor Neurons in response to a stressor.

Data also demonstrated that treatment with NUZ-001 and its major metabolite significantly improved electrophysiological dysfunction of TDP-43 mutated M337V Motor Neurons.

This finding supports the therapeutic potential of NUZ-001 in targeting the underlying mechanisms of ALS and possibly other neurodegenerative diseases characterized by protein misfolding.

Regulatory MIlestones

Orphan Medicinal Product Designation

In December 2024, Neurizon Therapeutics received the official decision from the EMA granting Orphan Medicinal Product Designation (OMPD) for its lead drug candidate, NUZ-001, for the treatment of ALS.

OMPD provides a robust framework of benefits, including reduced regulatory fees, free protocol assistance, and market exclusivity for 10 years in the EU upon product approval. During this exclusivity period, similar medicinal products will not be eligible for marketing authorisation in the same indication, offering a substantial commercial advantage for NUZ-001. This designation compliments the Orphan Drug Designation previously granted by the U.S. Food and Drug Administration, providing global market exclusivity across key territories.

IND Submission to support inclusion in HEALEY ALS Platform Trial

In December 2024, Neurizon submitted an IND application to the U.S. Food and Drug Administration (FDA) to support the inclusion of NUZ-001 in the HEALEY ALS Platform Trial. This submission marks a significant regulatory milestone, facilitating the initiation of advanced clinical trials for NUZ-001 in patients with ALS.

Subsequent to the quarter's end, on January 17, 2024, the FDA placed the IND application for NUZ-001 on Clinical Hold. Detailed feedback from the FDA is anticipated within 30 days, which will outline the specific requirements needed to lift the Clinical Hold. We remain confident in NUZ-001's potential as a safe and effective therapy for patients with ALS and are fully committed to addressing the FDA's requests thoroughly and expeditiously.

Corporate & Financial Summary

Name Change to Neurizon Therapeutics

In October 2024, following shareholder approval at the Annual General Meeting, the company rebranded to Neurizon Therapeutics Limited. This strategic name change reflects our commitment to pioneering advancements in the treatment of neurodegenerative diseases.

Our new identity encapsulates Neurizon's mission to advance groundbreaking science, aiming to reach a new horizon in neurodegenerative disease treatments. We are dedicated to optimising the quality of life for patients and expediting the availability of innovative therapies.

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This rebranding reinforces our strategic priorities:

1. Advancing Patient Access to Innovative ALS Treatments: We are committed to addressing a critical unmet need in ALS by delivering transformative therapies to patients affected by this disease through programs such as a special access scheme and Open Label Extension.
2. Accelerating Progress through Strategic Partnerships: Collaborating with leading neurologists and participating in initiatives like the HEALEY ALS Platform Trial enables us to expedite the development and delivery of effective ALS treatment.
3. Unlocking the Potential of NUZ-001: Our focus is on harnessing the capabilities of NUZ-001 to treat a range of neurodegenerative diseases, including ALS, Alzheimer's, Parkinson's, and Huntington's diseases, thereby opening new possibilities for millions of patients worldwide.

Through these strategic initiatives, Neurizon Therapeutics is steadfast in its vision to create a promising horizon for patients facing complex neurodegenerative diseases, embodying our commitment to scientific excellence and patient-centric innovation.

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Research & Development Tax Incentive Rebates

During the quarter, Neurizon received two R&D tax rebates under the Federal Government's Research & Development (R&D) Tax Incentive scheme totaling $1,537,836. These funds provide non-dilutive financing, supporting the company's ongoing research and development activities and reinforcing its commitment to advancing innovative therapies for neurodegenerative diseases.

Issue of Tranche 2 Placement Shares to Related Parties

During the quarter, the Company issued 4,657,895 Tranche 2 Placement Shares to certain Related Parties of the Company, including Directors, which were approved by shareholders at the Annual General Meeting held on 9 October 2024, pursuant to Resolutions 14, 15, 16, 17 and 18. The Tranche 2 Placement Shares were issued at an issue price of $0.19 (19 cents) per share, raising $885,000.

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 $1.8 million during the quarter and held $11 million in cash and cash equivalents, plus an additional $3 million in term deposits, totaling $14 million as at 31 December 2024.

During the quarter, Neurizon invested $1.7 million in R&D activities, and had $0.9 million in net cash inflows from financing activities, relating to the issuance of Tranche 2 Placement Shares to certain related parties of the Company, including Directors, following shareholder approval at the Annual General Meeting held on 9 October 2024, and the exercise of options by optionholders during the quarter.

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 $372k. 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 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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[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.

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.

Neurizon Investor Hub

We encourage you to utilise our Investor Hub for any enquiries regarding this announcement or other aspects concerning Neurizon.
This platform offers an opportunity to submit questions, share comments, and view video summaries of key announcements.

To access Neurizon Investor Hub please scan the QR code or visit
https://investorhub.neurizon.com

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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	**Quarter ended ("current quarter")**
35 094 006 023	31 December 2024

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	(1,702)	(3,799)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(86)	(151)
	(d) leased assets	-	-
	(e) staff costs	(558)	(918)
	(f) administration and corporate costs	(1,124)	(1,975)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	144	178
1.5	Interest and other costs of finance paid	-	(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	1,531	1,531
1.9	**Net cash from / (used in) operating activities**	**(1,795)**	**(5,135)**

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	(20)	(6,020)
	(e) intellectual property	-	-

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) term deposits with maturities longer than 3 months at acquisition	3,000	3,000
	(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**	**2,980**	**(3,020)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	885	8,715
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	80	80
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	(6)	(163)
3.8	Dividends paid	-	-
3.9	Other	-	-
3.10	**Net cash from / (used in) financing activities**	**959**	**8,632**

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4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,992	10,660
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,795)	(5,135)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	2,980	(3,020)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	959	8,632
4.5	Effect of movement in exchange rates on cash held	(9)	(10)
4.6	**Cash and cash equivalents at end of period**	***11,127**	***11,127**

** In addition to the cash and cash equivalents balance above as at 31 December 2024, the Company holds an additional $3 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 a 30-day 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	11,127	2,992
5.2	Call deposits*	-	6,000
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)**	***11,127**	**8,992**

** In addition to the cash and cash equivalents balance above as at 31 December 2024, the Company holds an additional $3 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 a 30-day notice.*

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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	372
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 (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		

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8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,795)
8.2	Cash and cash equivalents at quarter end (item 4.6)	11,127
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	11,127
8.5	**Estimated quarters of funding available based on cash and cash equivalents under *AASB 107* (item 8.4 divided by item 8.1)**	6.19
	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.	

8.5.1	**Total funds held in bank**	**$A'000**
8.5.1(a)	Cash and cash equivalents (item 4.6)	11,127
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))	3,020
8.5.1(c)	**Total funds held in bank as at 31 December 2024**	**14,147**
8.5.1(d)	**Estimated quarters of total funding available (item 8.5.1(c) divided by item 8.1)**	**7.88**

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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
	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: 29 January 2025

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.

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