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

Webinar presentation - Regimen I expands to 240 participants

28 May 2026 – Melbourne Australia: Neurizon® Therapeutics Limited (ASX: NUZ & NUZOA; OTCQB: NUZTF) ("Neurizon" or "the Company"), a clinical-stage biotech company dedicated to advancing innovative treatments for neurodegenerative diseases, is pleased to provide the following presentation which will be used in the Company's webinar scheduled for 4:00pm AEST (2:00pm AWST) on Thursday, 28 May 2026.

The webinar will provide additional details regarding the recently announced expansion of Regimen I in the HEALEY ALS Platform Trial from 160 to 240 participants, including the strategic rationale for the expanded cohort, ongoing recruitment momentum across the HEALEY network, accelerated timelines to topline results, no change in financial implications and the broader strategic significance for the NUZ-001 program and Neurizon's future regulatory and commercial positioning.

Registration details are provided below. Participants are encouraged to submit questions in advance during the registration process or via company email to enquiries@neurizon.com.

- **Registration Link**: https://bit.ly/NUZ-001
- **Date**: 28 May 2026
- **Time**: 4:00pm AEST

-ENDS-

This announcement has been authorised for release by Sergio Duchini, Interim Executive Chair, on behalf of 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 the potential of NUZ-001 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. NUZ-001 is an investigational product and is not approved for commercial use in any jurisdiction.

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HEALEY ALS Platform Trial Regimen I Sample Size Expansion

MAY 2026

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Agenda

- Key takeaways
- Recruitment momentum and execution update
- HEALEY platform dynamics and rationale for expansion
- Regimen I Timeline
- Financial considerations
- Future milestones
- Q&A

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Key Takeaways

Neurizon announced an expansion to the size of Regimen I intended to support a larger and more informative dataset, with accelerated time to topline readout and no change in funding requirements.

Increase in Neurizon's Regimen I sample size driven by the enrolment rate exceeding original expectations and the absence of a concurrent regimen during the expected recruitment period.

Revised design preserves the original statistical assumptions underpinning the primary endpoint analysis and supports more robust subgroup and biomarker analysis.

Based on current enrolment momentum, Neurizon anticipates last participant dosing in Q2 CY2027 with topline results expected in early Q3 CY2027, ahead of previous expectations.

Funding requirements remain unchanged. A modest increase anticipated in total study completion costs to be offset by Philanthropic funding support from the Sean M. Healey & AMG Center for ALS.

Larger and more informative dataset generated under the same inclusion criteria strengthens future regulatory discussions, partnering opportunities and commercial positioning.

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Strong Phase 2/3 ALS Trial Recruitment Momentum

64

Activated Sites

193

Master Screening

113

Regimen Assignment

74

Dosed Participants

Numbers referred to above are as of 22 May 2026.

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Expansion of Regimen I sample from 160 to 240 participants

Expansion Driven by:

- Enrolment rates exceeding original expectations
- Rapid U.S. site activation and strong operational execution across the Sean M. Healey & AMG Center for ALS network
- Absence of a start of a concurrent regimen during the expected recruitment window
- Opportunity to generate a larger and more informative dataset under the same inclusion criteria
- Potential to strengthen future regulatory, partnering, and commercial positioning
- Ability to capitalise on current recruitment momentum while maintaining trial continuity and efficiency

Original Design:

- n=160 participants
- 3:1 Randomisation
- 120 Active
- 40 Placebo

Expanded Design:

- n=240 participants
- 3:1 Randomisation
- 180 Active
- 60 Placebo

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Why Expansion to 240 Matters?

Stronger Dataset

- Maintains statistical power aligned with the original assumptions
- Allows subgroups of lower prevalence to be studied
- Supports additional biomarker and translational insights relevant to ALS and broader neurodegenerative diseases

Improved Regulatory Credibility

- Clinically meaningful benefit with ability to detect effect size maintained
- Removes reliance on placebo data from concurrent regimens
- Strengthens interpretability of the primary endpoint analysis
- Supports future expedited regulatory pathway discussions, including Fast Track Designation, Breakthrough Designation, Priority Review and Accelerated Approval, where appropriate

Improves Commercial Positioning

- **Stronger Evidence**: Generates a larger, more informative dataset to support future regulatory interactions
- **Faster Execution**: Accelerates time-to-topline by delivering a fully powered dataset earlier through rapid enrolment rate
- **Commercial Advantage**: Optimises partnering and broader strategic positioning for NUZ-001

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‘Regimen-I’ Trial execution timelines exceed previous projections

Based on current enrolment rate, Neurizon anticipates accelerated trial timeline projection

Expanded cohort to 240 participants

Q4 2025	Q4 2025	Q1 2026	Q1 2026	Q3-Q4 2026	Q2-Q3 2027	Q3 2027	Q3 2027
				NOW Q3 2026	NOW Q2 2027	NOW Q2 2027	NOW EARLY Q3 2027
✓	✓	✓	✓	5	6	7	8
IND Amendment Submission	**FDA Clearance**	**First Patient Screened**	**First Patient Dosed**	**Enrollment Complete**	**Last Patient Dosed**	**Database Lock**	**Topline Data Released**
Platform Trial IND submitted to regulatory authorities	NUZ-001 entry accepted	First patient screened for eligibility	First participant dosed in Regimen I	160 patients enrolled in the trial	Last participant receives final dose	Clinical trial database locked for analysis	Topline results of the trial announced

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Financial Considerations

Accelerated time to topline readout with no change in funding requirements

Cost Management & Accelerated Trial Timeline

Focused cost management and fast enrolment support no change to expected costs to topline read out

Philanthropic Contribution from HEALEY

Additional cost being materially offset by meaningful contribution of philanthropic funds from the Sean M. Healey & AMG Center for ALS

R&D Tax Incentive

Modest increase in cost of full trial to be further offset by Australian Federal Government's R&D Tax Incentive cash rebate

Accelerating ALS research through collaboration and cost efficiency

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Key Progress and Upcoming Milestones

Key Progress in Q2

- Ethics Approval for Liquid Formulation PK Study
- EMA Scientific Advice preparation
- Data Strengthening MOA Understanding
- Shareholder events in NSW & WA
- HEALEY Regimen I update

Upcoming Milestones in Q2

- PMDA Regulatory Consultation
- Preclinical Updates
- Commercial Supply Agreement with Elanco

Upcoming Milestones Q3/Q4

- Preclinical updates
- HEALEY enrollment updates
- CEO Appointment
- VIC and QLD shareholder briefing events
- HEALEY tablet supply secured through completion
- Liquid Formulation PK Study
- EMA Protocol Advice opinion
- PMDA General Consultation
- HEALEY Trial enrollment complete
- Participation at partnering and scientific conferences

CY 2026

Q2

Q3-Q4

ONGOING EFFORTS

- ✓ Work to broaden pipeline to other neurodegenerative diseases
- ✓ Partnership expansion opportunities with patient associations
- ✓ Targeted engagement with potential strategic partners

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