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

Neurizon to present Q3 FY2025 Results to the Shareholders

06 May 2025 – Melbourne, Australia: Neurizon® Therapeutics Limited (ASX: NUZ & NUZOA) ("Neurizon" or "the Company"), a clinical-stage biotech company advancing treatments for neurodegenerative diseases, is pleased to announce an upcoming webinar presentation to provide shareholders with an update on the Company's Q3 FY2025 results and recent progress in advancing NUZ-001 toward participation in the HEALEY ALS Platform Trial.

The presentation will outline the following:

- Advancements made toward participation in the HEALEY ALS Platform Trial
- Regulatory engagement with the FDA and an update on the NUZ-001 IND clinical hold
- Participation in key industry events and advocacy initiatives, and expanding awareness of MND/ALS and Neurizon's mission
- Recent executive appointments and how Neurizon's growing leadership team is helping drive development and commercial strategy
- An outlook on upcoming milestones in advancing NUZ-001 through late-stage development

Presentation slides are available as an attachment to this announcement. The recording of the presentation will be made available on Neurizon's website at www.neurizon.com.

-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.

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This platform offers an opportunity to submit questions, share comments, and view video summaries of key announcements.

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Neurizon

Quarterly Shareholder Update - Q3 FY 2025

May 2025

ASX: NUZ



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Our mission is to lead the development of neurodegenerative treatments towards a promising new horizon for patients
Neurizon

Agenda

Quarterly Highlights

Team Overview

Financial Update

Regulatory Update

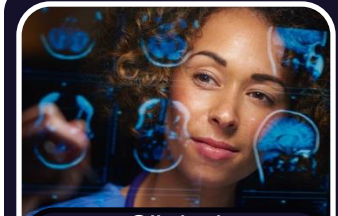
Clinical Developments

Preclinical Discovery

Upcoming Events and Milestones

Q&A Session

Quarterly Highlights



Clinical Development & HEALEY

- Updates to the HEALEY ALS Platform Trial's Master Protocol: slow vital capacity (SVC) as a valuable secondary endpoint
- 100kgs of NUZ-001 manufactured under Good Manufacturing Practice (GMP)
- GMP manufacturing campaign initiated with Catalent



Regulatory Engagement

- Our clinical strategy to address the hold is currently under FDA review
- Two short-term, low-cost pharmacokinetic (PK) studies initiated
- Clinical Hold expected to be lifted in Q3 CY2025



Corporate Developments

- NUZ-001 'method of use' patent for neurodegenerative diseases granted by the USPTO, extending patent protection to 2039
- Strengthened executive team with key leadership appointments in clinical, regulatory and finance functions



Market & Shareholder Engagement

- Participation in key global industry events
- Ncardia & FIERCE biotech global webinar
- Direct participation in MND Victoria's Great MND Relay, partnering with patient advocacy groups and with MND Australia to generate the new Economic Impact of MND Report

Meet Our
Executive Team



Dr. Michael Thurn

Managing Director & Chief Executive Officer

Michael has over 25 years of experience in technical, regulatory, commercial, and management roles in research organisations and industry, including early stage, fast growing, private and publicly listed biotechnology companies. Michael has led a variety of US IND applications across a range of therapeutic areas and evaluated drugs and vaccines for registration during his engagement at the TGA.



Dan O'Connell

Chief Finance Officer

Dan has over 20 years of experience working in multinational companies, with extensive experience in accounting and finance, research and development, M&A, procurement, shared services, investor relations and communications, government and industry relations, and tax. Dan was CFO of Kingsgate Consolidated, Interim CFO of Newcrest Mining, and has held other senior finance and commercial positions at Newcrest Mining, BHP, and Ernst & Young.



Kathryn Williams

Chief Regulatory Officer

Ms Williams is a distinguished regulatory affairs executive with over 20 years of industry experience. She has a proven track record developing and executing global regulatory strategies in major jurisdictions, including the US FDA, European EMA and Australian TGA. Most recently, Ms Williams held the position of Vice President of Regulatory Affairs at Clarity Pharmaceuticals Limited, as well as previous leadership positions at Merck, Sandoz, Sanofi and Genzyme.



Dr Jeffrey M. Brown

Chief Scientific Advisor

Dr Brown brings over two decades of drug development experience, scientific and commercial leadership, in the development of new treatments for neuropsychiatric and neurodegenerative diseases. He has overseen multiple neurology programs from early discovery through IND-enabling studies, including Huntington's disease, currently in clinical trials. He held executive roles in global biopharmaceutical companies such as Amgen, Pfizer, BMS, Alexion, Wave, Voyager, and Deep Genomics.



Dr Chris Freitag

Chief Medical Advisor

Dr Freitag has 20 years of experience in the pharmaceutical industry with positions in companies including Hoffmann La Roche, Shire, and BTG, where he led global clinical development projects. He held the position of Chief Medical Officer at Dynacure and Azafaros, where he was responsible for medical and regulatory strategy, including clinical development of a rare diseases compound. Dr Freitag was the Medical Monitor on NUZ's Phase 1 MEND study and oversaw medical and clinical activities.



John Clark

Chief Operating Officer

John has over 20 years of pharmaceutical industry experience in phase I – IV clinical trials across numerous therapeutic areas and multiple geographical regions. John has a thorough knowledge of ICH-GCP and regulatory requirements and held clinical operations leadership roles responsible for implementing global clinical programs.

Global Expertise

Backed by Industry Leaders from the World's Leading Companies



Financial Snapshot – Q3 FY2025

Continued progress on the strategy with a focus on HEALEY trial readiness and broadening NUZ-001's applicability to neurodegenerative diseases

Financial Snapshot - Q3 FY2025

- Cash balance of $8.6m at 31 March 2025
- Cash outflow of $5.5m, reflecting an increase on prior quarters.
- Increased cash outflow reflects one-off strategic investments focused on ensuring HEALEY trial and regulatory readiness as well as broadening NUZ-001's applicability to other neurodegenerative diseases

Strategic Investments

- Prepared for HEALEY ALS Platform Trial participation
- Secured 100 kg of GMP NUZ-001
- Initiated GMP tablet manufacturing campaign with Catalent
- Expanded mechanism of action research via Ncardia and other partners



FDA Review

Advancing Toward FDA Clearance: PK Studies in Progress, Submission on Track

Regulatory Support

The FDA continues to review our proposed strategy to address the clinical hold.

Neurizon remains engaged and responsive to agency requests.

PK Studies

Two pharmacokinetic studies initiated ahead of schedule.

Completion expected in Q3 CY2025.

Next Steps

FDA submission package to lift the clinical hold is progressing as planned.

Hold clearance anticipated following completion of PK studies.

Momentum

Maintaining momentum toward HEALEY ALS Platform Trial inclusion and broader clinical advancement.

Path to the HEALEY ALS Platform study

Neurizon is advancing toward participation in the HEALEY ALS Platform Trial, with the following key milestones anticipated in the Q3 CY2025:



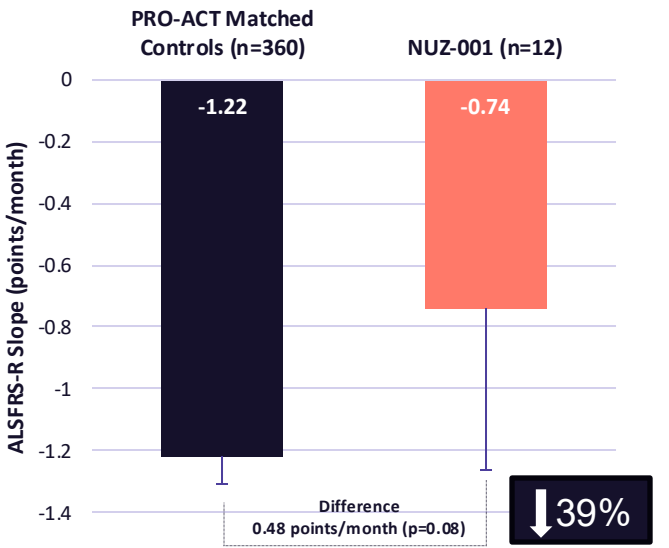
These milestones are expected to enable submission of the protocol amendment to the platform trial, paving the way for the inclusion of a dedicated NUZ-001 treatment arm.

Phase 1 MEND Study

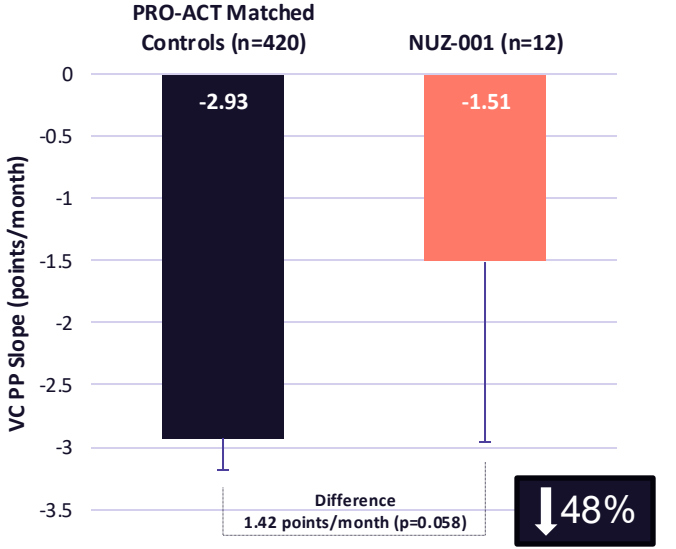
Preliminary Efficacy ALSFRS-R and SVC

Treatment with NUZ-001 for up to 12 months slowed the progression of ALS in all 12 patients by 39% for ALSFRS-R and 48% for SVC when compared to matched controls from the PRO-ACT historical database[1]

Motor Function – ALSFRS-R



Respiration – SVC[2]



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.

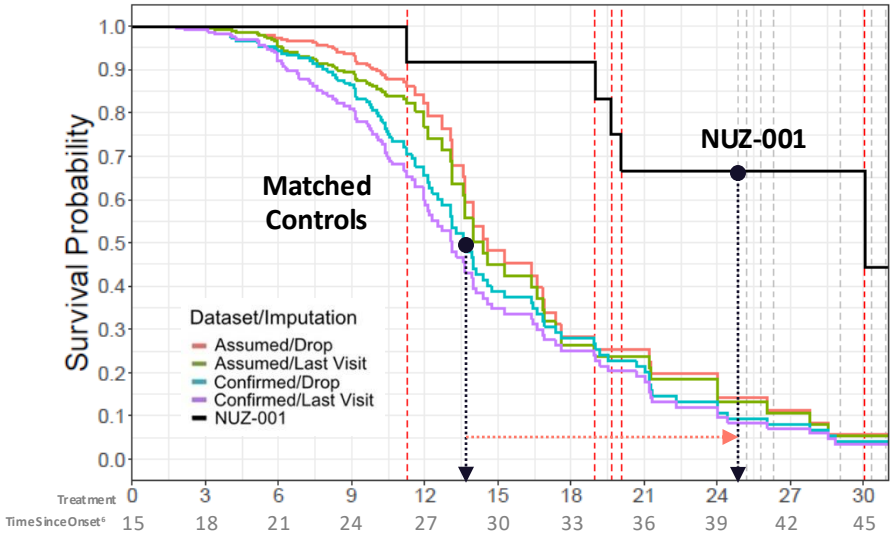
Preclinical Discovery

- The Strategic Objective of Preclinical Discovery is to identify, characterize, and optimize therapeutic molecules for clinical development, focusing on cellular effects in both simplified and complex biological systems.
- NUZ-001 is a small molecule therapeutic with positive effects on autophagy, a cellular process for removing toxic or unwanted proteins in a cell. Beyond autophagy, NUZ-001 is being evaluated for its effects on additional neuroprotective pathways that may shield neurons from toxic insults, offering a broader therapeutic potential.
- This work is being done using advanced disease modeling with collaborations leveraging 3D brain-like cell-based models, iPSC-derived neurons carrying disease-relevant mutations, and other neuronal systems which recapitulates aspects of the cellular pathways and phenotypes seen in neurodegenerative disorders. This includes collaborations with Tessara Therapeutics, University of Queensland and Ncardia.
- Using these cellular model systems, studies show NUZ-001 reduces TDP-43 protein aggregation, a hallmark pathology in ALS and related neurodegenerative conditions. This protection results in restoration of electrophysiological function in human iPSC-derived neurons.
- Based on these positive results, and the potential to positively affect multiple protective pathways, NUZ-001 is being evaluated for additional neurodegenerative indications to allow for expansion of the therapeutic options to bring hope to patients in need.

Phase 1
ALS Open Label Extension Study

Compared to matched controls from the PRO-ACT Historical Database[1], treatment with NUZ-001 results in a significantly (X^2=14.1, p=0.00017) longer survival of patients with ALS reducing the risk of death by 78.5%

Overall Survival Probability



Survival Statistics

- Median survival ~2 years from diagnosis[2]
- 20% live 5 years or more, and up to 10% survive for more than 10 years[3]
- Population-based prospective registries report 1-year mortality rates after diagnosis ranging from 22% to 34%[4]
- NUZ-001 may extend the median survival by ~11 months, with a possibility of a longer benefit
- Currently anchored to the patient with the shortest treatment duration (24.9 months) who remains alive

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. Cruz MP. Edaravone (Radicava): A Novel Neuroprotective Agent for the Treatment of Amyotrophic Lateral Sclerosis. P T. 2018 Jan;43(1):25-28. PMID: 29290672; PMCID: PMC5737249.
3. Karanevich, A.G., Statland, J.M., Gajewski, B.J. et al. Using an onset-anchored Bayesian hierarchical model to improve predictions for amyotrophic lateral sclerosis disease progression. BMC Med Res Methodol 18, 19 (2018). https://doi.org/10.1186/s12874-018-0479-92
4. Wolf, J., Safer, A., Wöhrle, J.C. et al. Factors predicting one-year mortality in amyotrophic lateral sclerosis patients - data from a population-based registry. BMC Neurol 14, 197 (2014). https://doi.org/10.1186/s12883-014-0197-9
6. Average time since onset

Current treatment landscape for ALS

There is no cure and MND/ALS is always fatal

Current Treatments

Riluzole
FDA approved in 1995

3

List price US$5,360
~US$40 mil in sales[1]



Edaravone
FDA approved in 2017

6

List price US$171,000
~US$1 billion in sales[2]



AMX0035
FDA approved in 2022

9

List price US$158,000
>US$400 mil in sales[3]



*Voluntary removal

12 LIFE EXTENSION 15

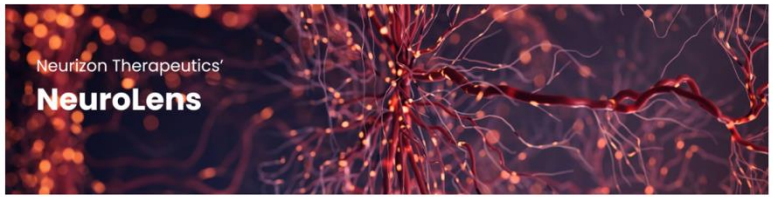
1. Verified Market Report 2025
2. Research Reports World 2024
3. Amylyx Pharmaceuticals 9 May 2024
* Amylyx Pharmaceuticals Announces Formal Intention to Remove Relyvrio from the Market, April 2024

Upcoming Events and Conferences

Confirmed Upcoming Events		
12-14 May	**ALS Drug Development**	Boston, MA, USA
May	**NeuroLens Ed2**	Online
16-19 June	**BIO International**	Boston, MA, USA
21 June	**International ALS Awareness**	Global
July	**Year in Review Update Webinar**	Online
7-9 September	**PACTALS**	Melbourne, AU
7-12 October	**NEALS**	Clearwater, FL, USA
5-7 December	**36th International Symposium on ALS/MND**	San Diego, CA, USA



Edition 2 of “NeuroLens” scheduled for end May

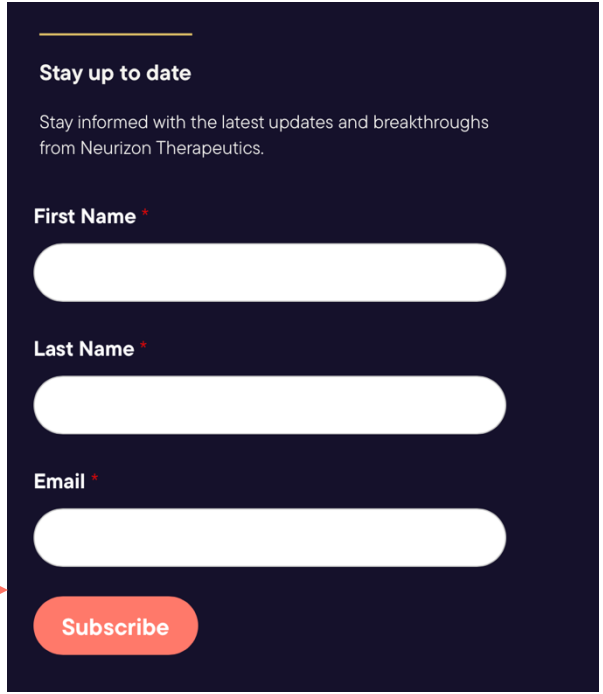


Welcome to NeuroLens
Your inside look at Neurizon Therapeutics

NeuroLens is our exclusive newsletter, delivering the latest **company milestones, upcoming events, and scientific breakthroughs** in ALS research. Stay informed with **insights from our CEO, key industry updates, and powerful NeuroFacts** that bring us closer to new hope for patients.

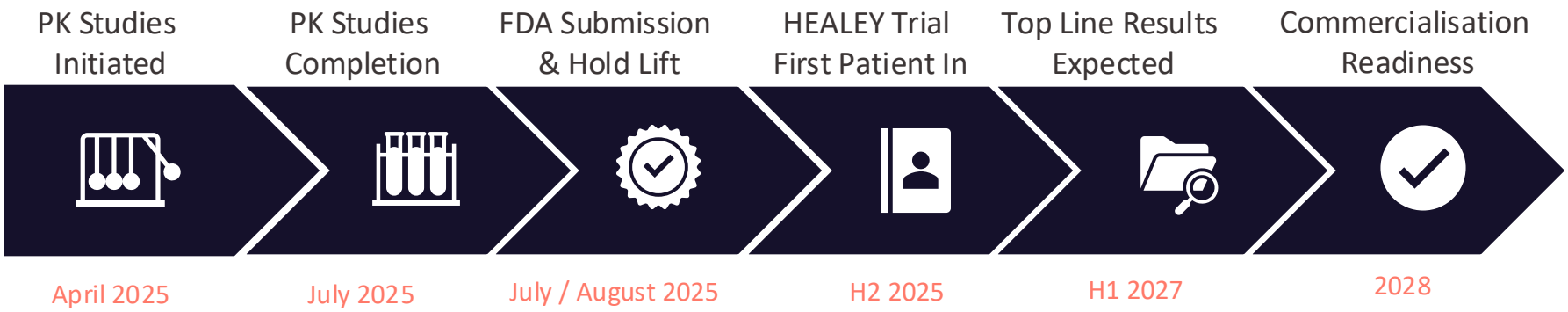
Sign up for the newsletter and other company updates at www.neurizon.com

(form can be found in the website footer)



NUZ-001 Development Milestones

Our accelerated timeline positions Neurizon for rapid clinical advancement. Each milestone brings us closer to delivering innovative ALS therapeutics.



Note: Dates are based on the calendar years

Development Milestones 2024/25

CY 2024 – Q3/Q4

- ✓Accepted into **HEALEY**
- ✓Positive 4- and 8-Month **Interim Results** from **OLE Study**
- ✓Positive **TDP-43 preclinical data** on NUZ-001
- ✓SME status granted by EMA
- ✓**OMPD granted** by EMA
- ✓**Name change** to Neurizon Therapeutics
- ✓Received 2 **R&D Tax-incentive** rebates totalling $1,537,836
- ✓Issue of **Tranche 2 Placement Shares** to Related Parties, raising $885,000

CY 2025 – Q1

- ✓Updates to the **HEALEY Master Protocol**
- ✓**Slow vital capacity** (SVC) as a valuable secondary endpoint
- ✓**100kgs of NUZ-001** successfully manufactured
- ✓**GMP manufacturing** campaign initiated
- ✓NUZ-001 **'method of use' patent** for neurodegenerative diseases granted by the USPTO
- ✓**FDA engagement** setting strong foundations for lifting the **IND Clinical Hold**
- ✓**Fierce Biotech Webinar** with Ncardia
- ✓**Strong global awareness** raised about NUZ-001 through leading **ALS conferences** and patient associations

Q2

- ✓Strengthened **NUZ's Leadership team** with the key appointments
- ✓ **Commencement of PK studies** to lift NUZ-001's IND clinical hold
- Results from **Tessara's ADBrain™ study** for sporadic **Alzheimer's disease**
- Results from **UQ's mouse model** of **Parkinson's disease**
- Participation at **global conferences** ALS Drug Development Summit and BIO International Convention

Q3

- Completion of PK studies to **lift NUZ-001's IND clinical hold**
- Submit request to US FDA to lift NUZ-001's IND clinical hold
- **Top-line results from OLE study**
- **US FDA lifts clinical hold**
- **HEALEY submits NUZ-001 protocol amendment** to US FDA for HEALEY ALS Platform Trial

ONGOING EFFORTS

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



Neurizon



Thank You

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