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

Neurizon to present Q1 FY2026 Results to the Shareholders

31 October 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 Q1 FY2026 results and recent progress in advancing NUZ-001 toward participation in the HEALEY ALS Platform Trial.

The presentation will outline the following:

- Advancing NUZ-001 towards the HEALEY ALS Platform trial: successful submission and acceptance by the U.S. FDA to lift the clinical hold, clearing the pathway for Neurizon's entry into the trial.
- Overview of synchronized regulatory strategy: continued execution of Neurizon's regulatory strategy designed to align U.S. FDA approval with global access across key markets.
- Strengthened financial position: completion of a $5.2 million share placement with new and existing investors, and receipt of $1.5 million from a secured loan against the FY2025 R&D Tax Incentive rebate.
- Expanding global engagement: participation in leading industry conferences and scientific events to deepen relationships with potential commercial partners, researchers, and the ALS patient community.

Anyone wishing to attend the webinar should register via the following link:

Registration: https://bit.ly/NUZ1025
Date and time: 1:00pm AEDT (10:00am AWST) on Friday, 31 October

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 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.

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
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Neurizon

Shareholder Update Webinar Q1 FY 2026



31 October 2025

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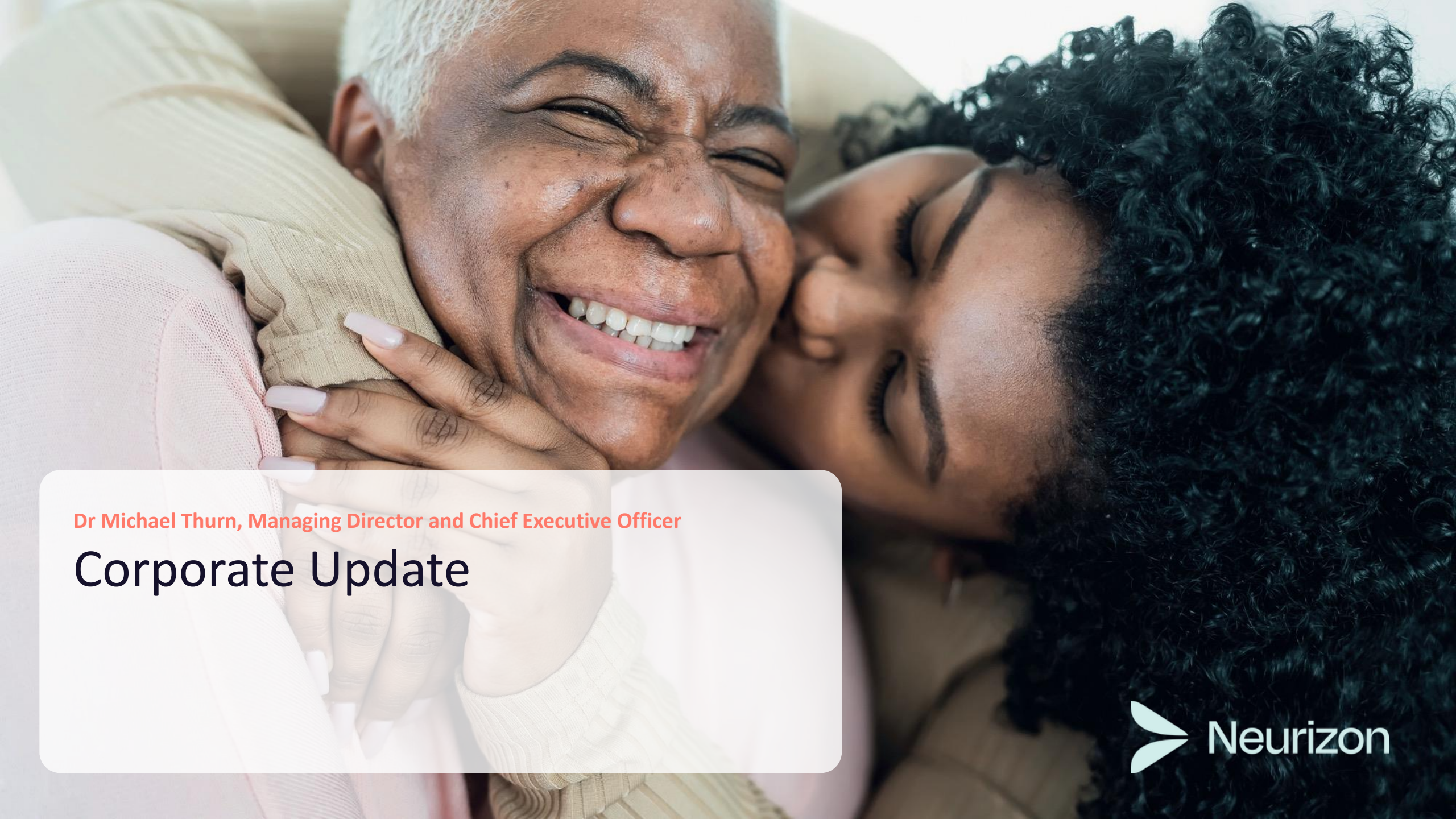
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AGENDA

1. Corporate Updates
2. Financial Snapshot
3. HEALEY ALS Platform Trial Update
4. Preclinical Development
5. Industry Engagement & Upcoming Milestones



Dr Michael Thurn, Managing Director and Chief Executive Officer

Corporate Update

Neurizon

Q1 FY 2026 Highlights

Executed Global License Agreement with Elanco

Submitted Clinical Hold Complete Response to FDA

First registration batch of NUZ-001

Preliminary R&D Funding received

Top-line results from OLE study

R&D Tax Incentive Advance & Overseas Finding Approval

PACTALS conference and presentation

Successfully raised $5.2m through a share placement

Company Post-Quarter Milestones:

- FDA opens IND for NUZ-001, clearing the path to inclusion in HEALEY ALS Platform Trial
- Common shares approved for trading on the OTCQB®
- Australian patent granted for NUZ-001
- Appointment of Integrous Communications to strengthen North American investor engagement

Global Regulatory Strategy: Synchronised Approvals for Maximum Impact

Our regulatory strategy synchronises FDA approval with global market access, maximising commercial potential while addressing the urgent needs of ALS patients worldwide.

FDA Accelerated Pathway

April 2025: PK Studies Complete

Pharmacokinetic studies concluded with exceptional results, demonstrating >10× safety margin at clinical dose

July 2025: CHCR Submitted

Comprehensive Clinical Hold Complete Response submitted to FDA with detailed safety data

October 2025: IND Opened

FDA's decision to lift the clinical hold received, clearing the path to the inclusion into the HEALEY Trial

November 2025: Designation Applications

Designation applications to further accelerate development and commercialisation

Q4 2025: HEALEY Trial Entry

Synchronized Global Strategy

European Medicines Agency (EMA)

Orphan Drug Designation secured; regulatory consultation aligned with FDA strategy for parallel review

Health Canada / Swissmedic

Regulatory timelines synchronized with FDA/EMA processes; accelerated review pathways identified

PMDA (Japan) & TGA (Australia)

Japan consultation planned; Australia advancing Orphan Drug and Provisional Approval strategies

Commercial readiness and new indication development (2027-2028) will leverage our platform technology's potential across multiple neurodegenerative diseases



Dan O’Connell, Chief Financial Officer

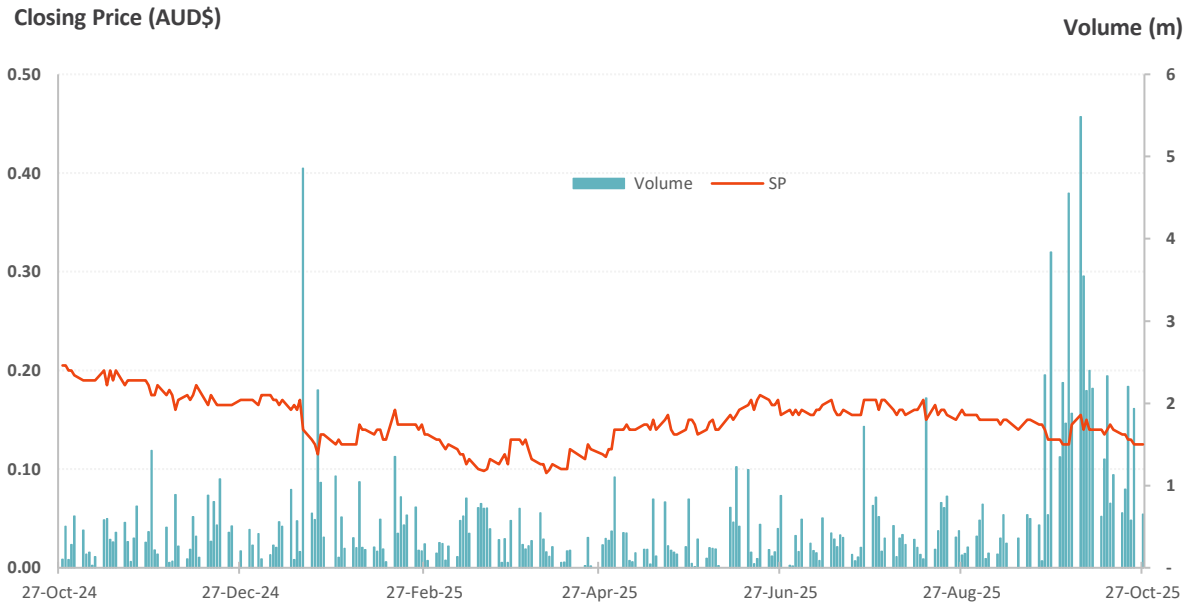
Financial Snapshot

Neurizon

Corporate Overview

Mid-stage biotechnology company targeting human neurodegenerative diseases

Share Price Performance



Capital Structure (AUD$)	27 October 2025
Current Share Price (NUZ/NUZOA)	$0.125/ $0.07
52 Week Low / High (NUZ)	$0. 096/ $0.205
No. of Shares (NUZ) [1]	534,555,765
Listed Options (NUZOA)	116,315,955
Market Capitalisation	**$66.8m**
Cash (as at 30-Sep-25)	$6.6m
Debt (as at 30-Sep-25) [2]	($1.5m)
Net Cash	**$5.1m**
Enterprise Value	**$61.7m**
Unlisted Options (10c/15c/17.5c/20c/26c/33.25c)	29.65m
Enterprise Value (fully diluted)	**$80.0m**

Board & Management

Mr Sergio Duchini	Chairman & Non-Executive Director
Dr Michael Thurn	Chief Executive Officer & Managing Director
Mr Marcus Hughes	Non-Executive Director
Dr Katie MacFarlane	Non-Executive Director
Mr Dan O'Connell	Chief Financial Officer
Mr Stefan Ross	Company Secretary

Top Shareholders (as at 10 October 2025)

Hybrid Holdings Pty Ltd <Darcy Family Super Fund A/C>	4.16%
Mr GJ & Mrs G Van Blommestein <Van Blommestein S/F A/C>	3.48%
Mr Chek Loon Tan	2.81%
Dr Roger Aston	2.53%
Board & Management	3.89%

[1] Excludes 1,083,335 shares allocated to Directors but subject to shareholder approval. Shareholder approval is being sought at the Annual General Meeting on 26 November 2025
[2] Debt is a A$1.5m loan from Radium Capital secured against Australian R&D Rebate. See ASX:NUZ "R&D Tax Incentive Advance & Overseas Finding Approval" 18 September 2025

Commercial & Financial Update

Continued spend reduction with additional funding to support strategic progress of Neurizon's strategy

Financial Snapshot

- Cash balance of $6.6m at 30 September 2025
- Operating cash outflow of $3.7m - 17.5% reduction on prior quarter.
- Executed a $1.5 million loan from Radium Capital, secured against R&D Tax Rebate - an important source of non-dilutive funding.

R&D Advance & Overseas Finding

- Advance and Overseas Finding awarded by AusIndustry meaning eligible overseas R&D expenditure with qualify for the rebate.
- Covers all NUZ-001 development activities - manufacturing, regulatory and clinical - including HEALEY ALS Platform Trial
- Binding on AusIndustry and the Australia Taxation Office for 2025, 2026 and 2027 financial years.
- Supports Australian R&D Tax Rebate of approximately $5.6m for FY2025.

Institutional Placement - $5m

- Raised $5.0m through a placement of at $0.12 per share
- Strong demand from new & existing investors, with significant support from institutions
- Board and management committed a further $0.2m in subscriptions, demonstrating support for strategy
- Proceeds directed to advancing participation in the HEALEY ALS Platform Trial, pre-clinical programs, GMP manufacturing, regulatory submissions, and working capital requirements.



Dr Michael Thurn, Managing Director and Chief Executive Officer
Sharon Tamir, Clinical Development
Stacie Seidel, Translational Science & Patient Engagement
Josie Hayes, Translational Science

HEALEY ALS Platform Trial Update

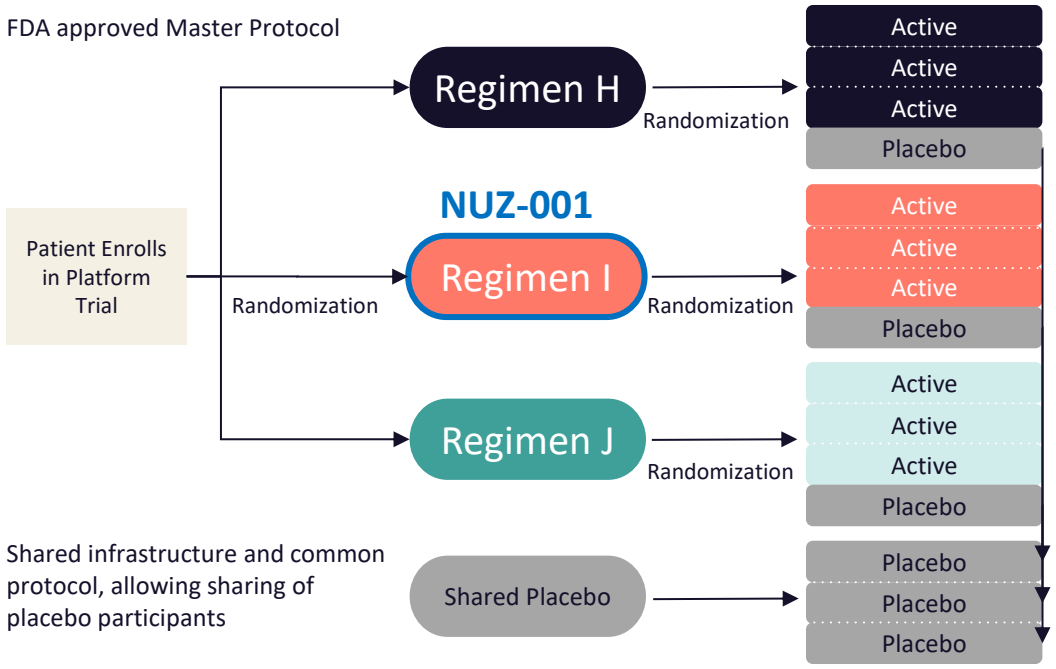
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HEALEY ALS Platform Trial

NUZ-001 selected for entry into the HEALEY ALS Platform Trial

The HEALEY ALS Platform Trial is a competitive process led by a group of expert ALS scientists and members of the Healey & AMG Center Science Advisory Committee

HEALEY ALS Platform Trial Design[1]



Innovative Trial Structure

Design

- Shared master protocol
- >70 clinical sites across the US
- 3:1 active drug to placebo ratio
- 160 participants per regimen
- 7 regimens completed
- 2 regimens progressing to Phase 3

Primary Endpoint
Change from baseline through Week 36 in disease severity, measured by the ALS Functional Rating Scale -Revised (ALSFRS-R) total score and survival.

Secondary Endpoints
Change from baseline through Week 36 in secondary efficacy measures (e.g., respiratory function via slow vital capacity [SVC]

Survival through Week 36 (death or equivalent endpoint)

1. HEALEY ALS Platform Trial (https://www.massgeneral.org/neurology/als/research/platform-trial).

“Regimen-I” HEALEY ALS Platform Key Milestones

Neurizon’s clinical hold was lifted by the FDA on October 3, 2025, clearing the path to entry into the HEALEY ALS Platform Trial

- ✓ 30% reduction in research costs
- ✓ 50% Faster
- ✓ 67% More Participants
- ✓ 160 participants

Q4 2025	1	**IND Amendment Submission** Platform Trial IND submitted to regulatory authorities	
FDA Clearance NUZ-001 entry confirmed	2	Q4 2025	
Q1 2026	3	**First Patient Screened** First patient screened for eligibility	
First Patient Randomized First participant randomized into treatment regimen	4	Q1 2026	
Q3-Q4 2026	5	**Enrollment Complete** 160 patients enrolled in the trial	
Last Patient Dosed Last participant receives final dose	6	Q2-Q3 2027	
Q3 2027	7	**Database Lock** Clinical trial database locked for analysis	
Topline Data Released Topline results of the trial announced	8	Q3 2027	

Advancing Biomarker Strategy for in Ph2 HEALEY ALS Platform Trial

Unlock clinical and regulatory value to help accelerate approval and patient access

Priority Assays: Focus on Key Proteins in ALS

Biomarker	What it Measures	Rationale
NfL	Axonal injury / neuronal degeneration	Sensitive, robust, validated in CSF & blood; strong prognostic & pharmacodynamic value
p75^{ECD}	Ongoing axonal damage, higher levels may correlate with disease progression	Ph1 MEND + OLE data suggest positive trends for patients on NUZ-001, non-invasive urine testing

- **Working alongside KOLs and clinical experts to develop and utilize additional assays:**
  - Protein assays testing key proteins in CSF and blood are being explored
  - RNA Expression and Whole Genome Sequencing (WGS) are also options to dive in deeper to understand gene expression changes

We are developing a regimen-specific biomarker plan, using cutting-edge single-molecule and spatial multi-omics technologies, to identify novel predictive and pharmacodynamic biomarkers beyond the HEALEY platform plan, ensuring the most sensitive and relevant measures of clinical impact.

- **Innovative Digital Biomarker Strategy in Partnership with Redenlab**
  - Speech intelligibility in ALS is both a functional outcome (how well a person communicates) and a biological signal of disease progression, making it highly relevant for patient care, prognosis, and clinical research.



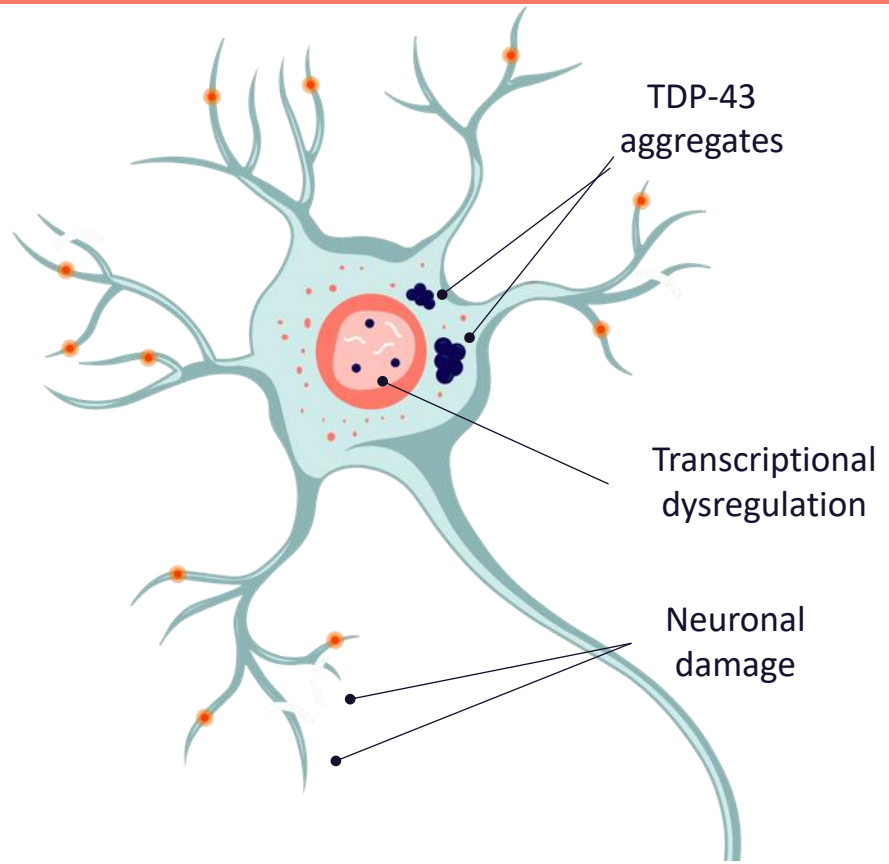
Dr Jeffrey M Brown, Chief Scientific Advisor

Preclinical Development

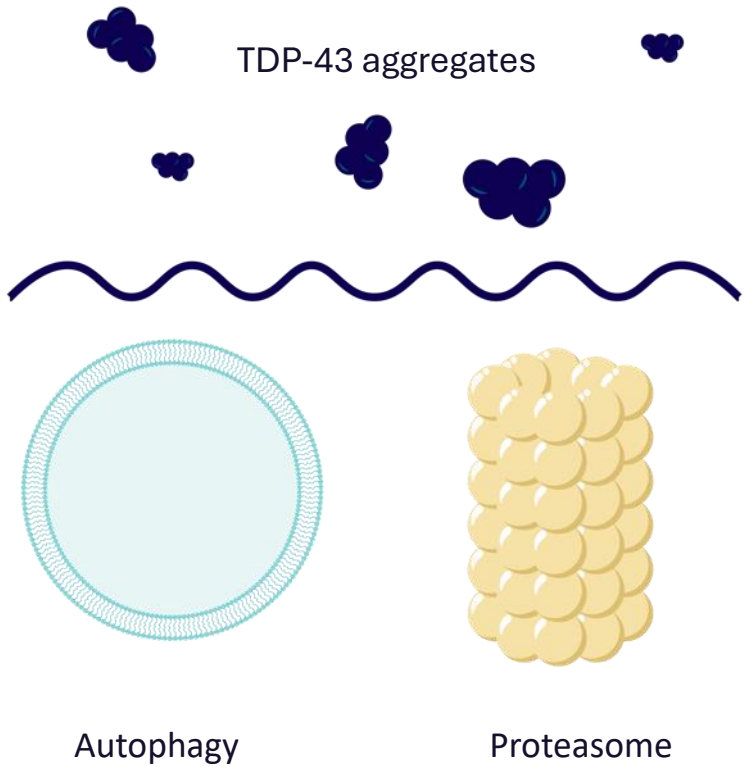
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Protein Aggregation and Reduced Protein Clearence are Drivers of Neuronal Pathology in ALS

TDP-43 protein aggregation is a major driver of neuronal damage in ALS

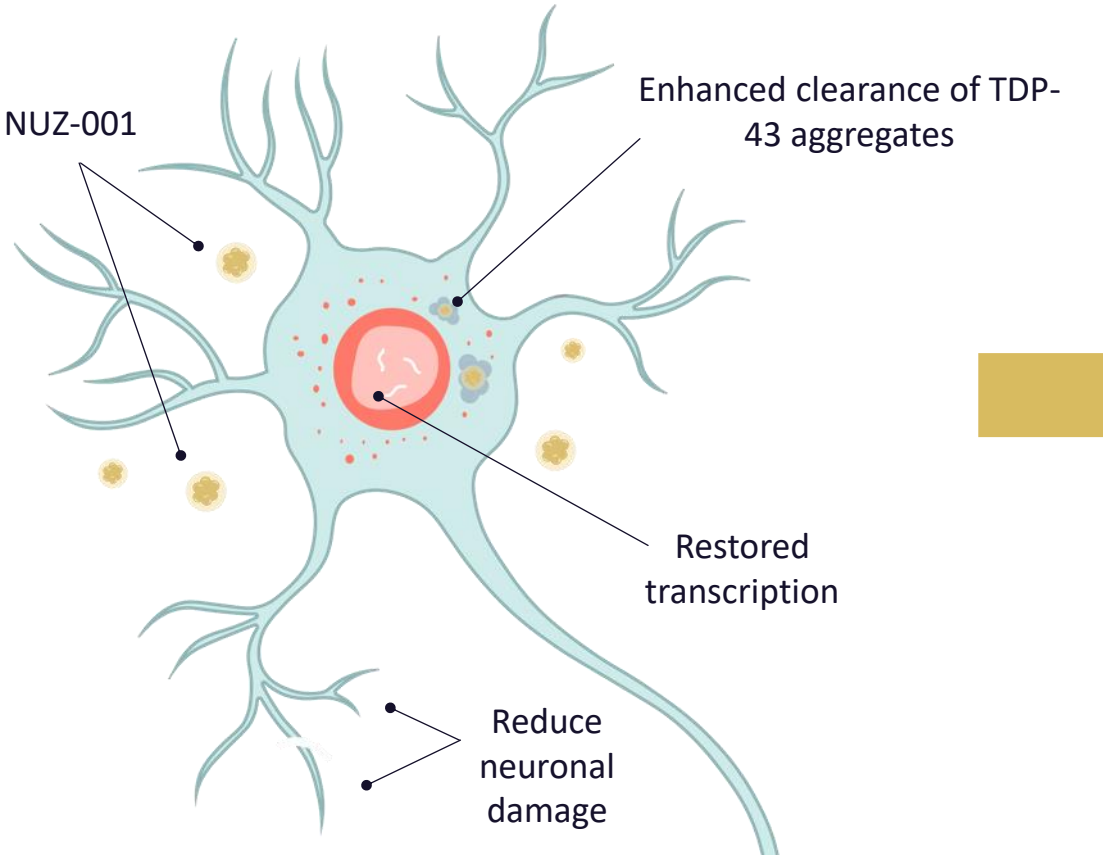


Protein aggregates block endogenous protein clearance pathways

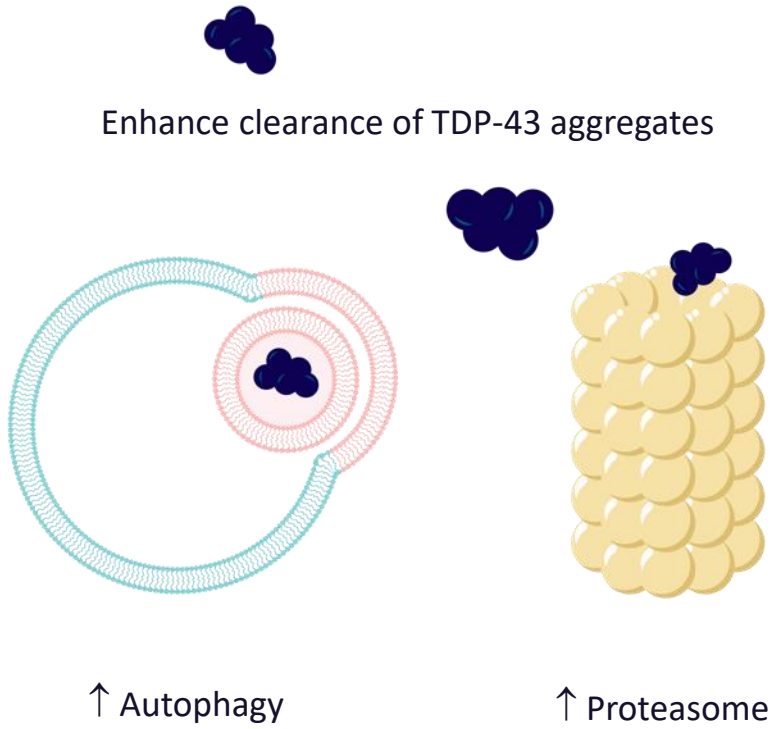


NUZ-001 Enhances Endogenous Protein Clearance Pathways to Remove Toxic Protein Aggregates

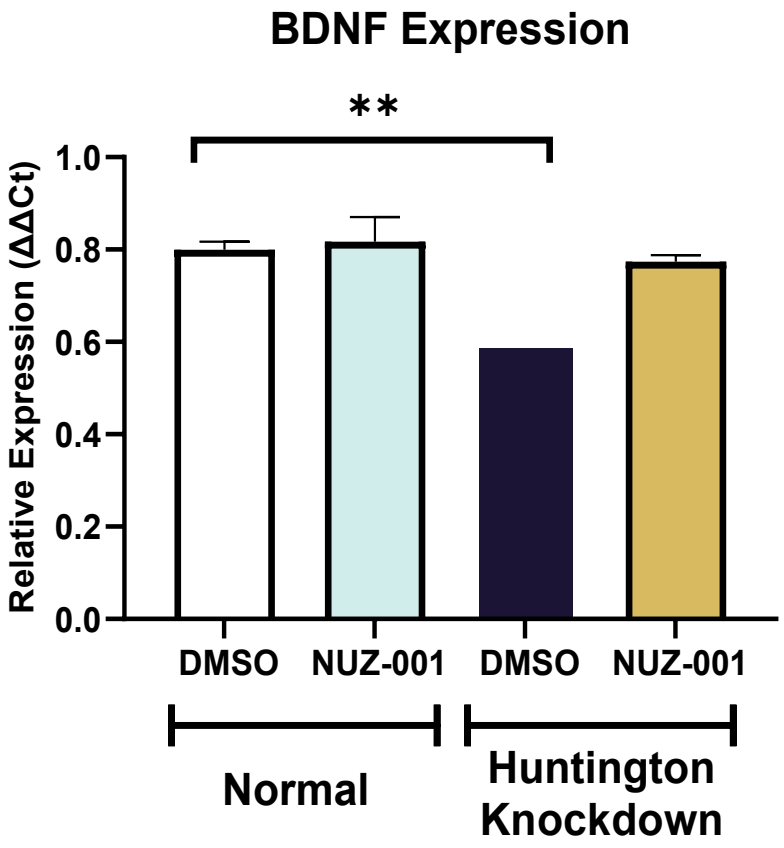
NUZ-001 enters neuron and binds molecular target

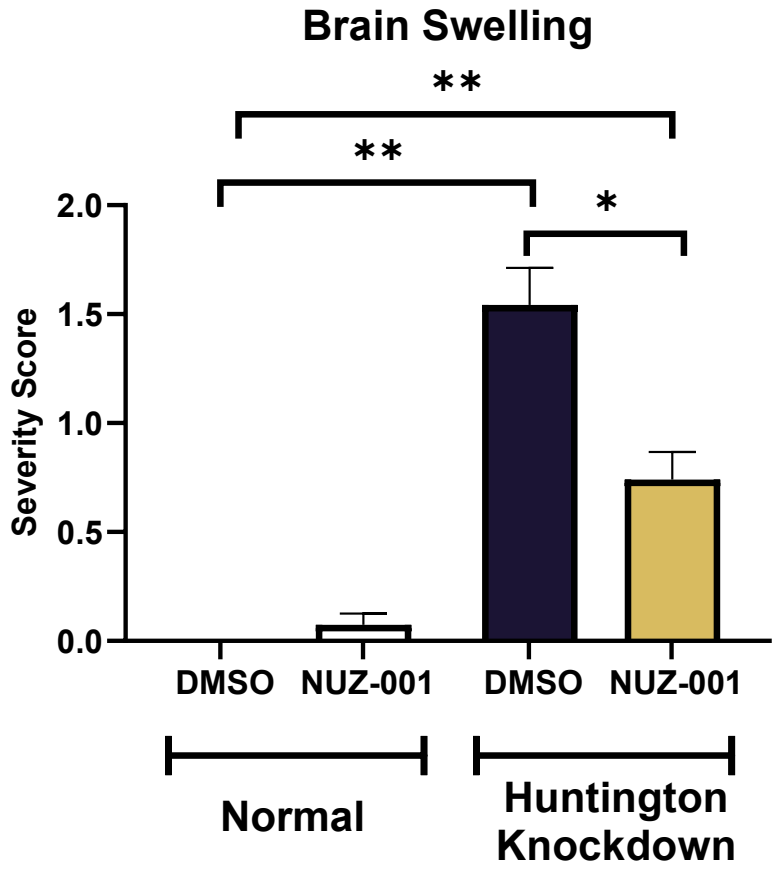


NUZ-001 enhances endogenous protein clearance pathways



NUZ-001 Restored Brain-Derived Neurotrophic Factor (BDNF) Expression and Reduced Brain Pathology in a Huntington's Disease Model





Preclinical Data Continues to Inform Biology of NUZ-001 for ALS and Other Neurodegenerative Diseases

NUZ-001:

- Reduces TDP-43 aggregation in a human neuronal model of ALS
- Crosses the the blood brain barrier
- Achieves brain levels that are physiologically relevant based on preclinical studies
- Restores expression of a critical neurotrophic factor (Brain Derived Neurotrophic Factor) in a Zebra Fish model of Huntington's disease
- Reverse deficits-induced by loss of the huntingtin protein in a Zerba fish model of Huntington's Disease.
- Decreases p62 levels, consistent with activation of autophagy in normal and Huntington's disease human neuronal models



Dr Michael Thurn, Managing Director and Chief Executive Officer

Industry and Patient Engagement & Upcoming Milestones

Neurizon

Driving Impact Through Global Collaboration and Engagement

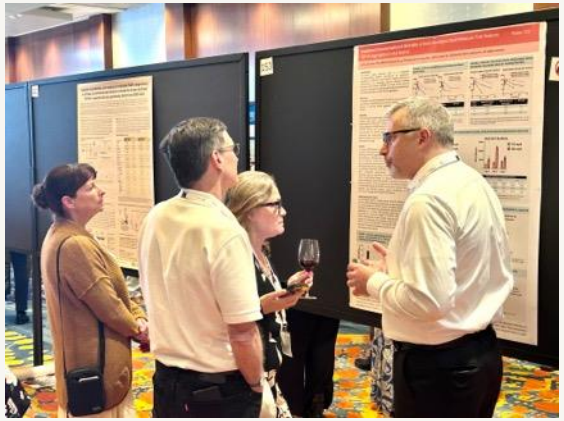
Engaging with investors through global roadshows and strategic summits, including HealthInvest, BioJapan and Ignite Summit.





Represented at leading ALS and neurodegenerative research conferences, including NEALS and PACTALS.





Championing a patient-driven mission that keeps people living with ALS at the centre of everything we do.







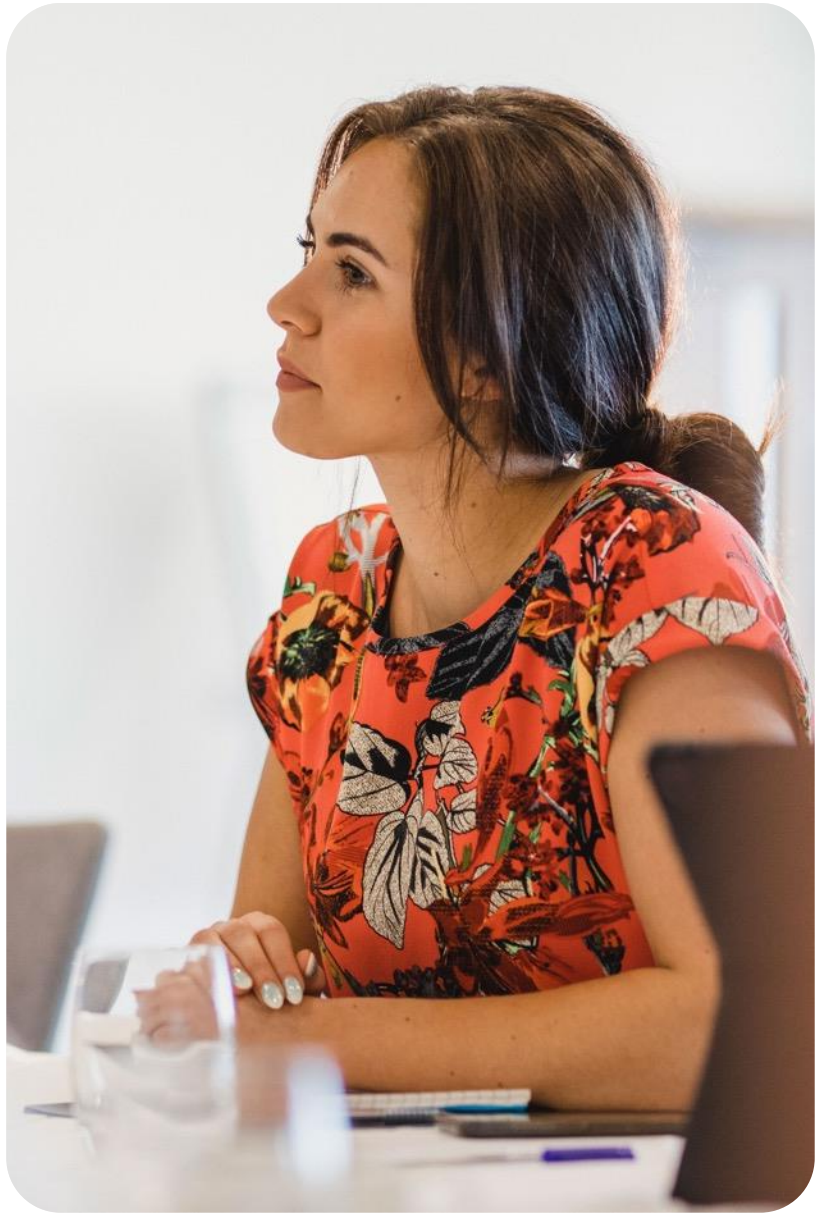


Upcoming Industry Engagements

Neurizon remains focused on expanding its global presence

Advancing awareness, forging strategic partnerships, and engaging with the broader scientific and patient communities.

- USA Investor Roadshow (October 29-31)
- ALS Association Roundtable (November 13, DC, USA)
- The Annual Society of Neuroscience Conference (November 15-19, CA, USA)
- 36th International Symposium on ALS/MND (December 5-7, CA, USA)
- JP Morgan Healthcare Conference (January 12-15, CA, USA)



Near Term Milestones

Significant near-term news flow drive value and growth

FY 2026

Q2

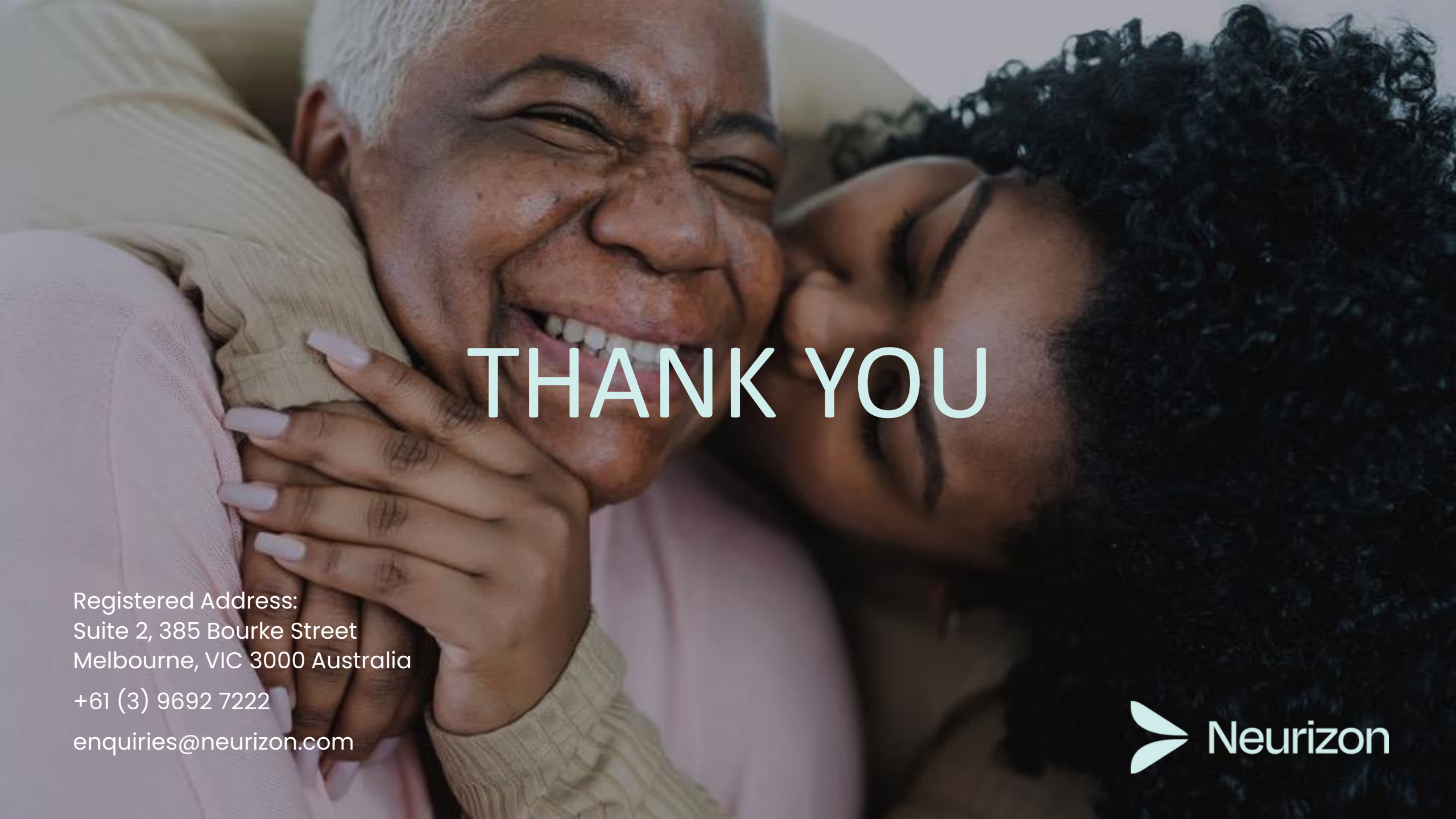
- ✓**US FDA lifts clinical hold**
- ✓**NEALS** Annual Conference Meeting Presentations
- ✓Commenced **trading on OTCQB**
- ✓**Australian Patent** granted for NUZ-001
- Additional **Preclinical Updates**
- **Completion of Second and Third registration batches** of NUZ-001
- Supply Agreement **with Elanco**
- Australian **R&D Refund** (net of R&D funding)
- **HEALEY Submits NUZ-001 Protocol Amendment** to US FDA for Platform Trial
- **FDA's Confirmation of Entry into HEALEY ALS Platform Trial**
- 36th **International Symposium on ALS/MND**
- FDA **Fast Track Designation for NUZ-001**

Q3

- 43rd **J.P. Morgan Annual Healthcare Conference**
- HEALEY ALS Platform Trial– **Site Activation**
- Additional **Preclinical Updates**
- **EMA Scientific Advice** meeting
- Ethics Approval for **Liquid Formulation PK Study**
- HEALEY ALS Platform Trial – **First Patient Dosed**

ONGOING EFFORTS

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



THANK YOU

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