

Neurizon to present Q4 Updates to the Shareholders

26 August 2025 – Melbourne, Australia: Neurizon® Therapeutics Limited (ASX: NUZ & NUZO) (“Neurizon” or “the Company”), a clinical-stage biotech company dedicated to advancing innovative treatments for neurodegenerative diseases, is pleased to announce an upcoming webinar presentation to provide shareholders with an update on the Company’s Q4 FY2025 results and recent developments.

The shareholder webinar will take place at 1:00 pm AEST (11:00am AWST) on Tuesday, 26 August 2025, and will outline the following:

- Ongoing efforts to expedite the FDA’s review of the Clinical Hold Complete Response for NUZ-001’s Investigational New Drug (IND) application
- Topline results from the 12-month Open Label Extension (OLE) Study using NUZ-001 for the treatment of amyotrophic lateral sclerosis (ALS)
- Continued preclinical initiatives
- Industry engagements
- Outlook on the Company’s near-term objectives

The briefing will be followed by a Q&A session. Questions can be submitted to enquiries@neurizon.com before the start of the webinar, during online registration, or in written form during the webinar. Anyone wishing to attend the webinar must register via the following:

- **Registration:** <https://bit.ly/26082025>
- **Date and time:** 1:00pm AEST (11:00am AWST) on Tuesday, 26 August 2025

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. For further information, please contact:

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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.

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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Shareholder Update Webinar

August 2025



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AGENDA

1. Welcome and Highlights
2. Regulatory Overview
3. Financial Snapshot
4. Topline Results – OLE
5. Preclinical Progress
6. Industry Engagement
7. Summary and Next Steps

Year in Reverse Highlights

From clinical and regulatory achievements to strategic partnerships and patient-focused innovations.



Inclusion in the HEALEY ALS Platform Trial

Lead asset, NUZ-001, selected for inclusion in the HEALEY ALS Platform Trial across +70 clinical sites in the US. Provides framework for independent validation of the potential of NUZ-001 as a treatment for ALS/MND and accelerates the path to FDA approval.



Completion of Phase 1 MEND and Open Label Extension Studies

The top line study results for 10-patient group - who all completed the earlier Phase 1 MEND Study - further demonstrate the long-term safety and efficacy signals of the treatment of ALS/MND with NUZ-001, building on interim findings that confirmed robust survival and functional benefits.



Grant of "Method of Use" Patent until 2041

Expedited grant of 'method of use' patent for NUZ-001 by the United States Patent & Trademark Office (USPTO). US patent protection for NUZ-001 and structurally related compounds for neurodegenerative diseases/cancer now extends to 2041.



Global Licence Agreement with Elanco

Exclusive global license agreement with Elanco Animal Health (NYSE:ELAN) for the rights to the active pharma ingredient in NUZ-001, aiding commercialisation pathway provides Neurizon with access to Elanco's comprehensive data set to support future regulatory submissions.



Development of Oral Liquid Formulation of NUZ-001

Successful development of a new oral liquid formulation of NUZ-001 for the treatment of ALS/MND, designed to support patients with all stages of ALS/MND, particularly those with swallowing. Developed as part of Neurizon's patient-centric innovation strategy, the liquid form enhances continuation of treatment, ease of administration, and overall treatment experience for patients with ALS.



Preclinical Advances Supporting Platform Potential

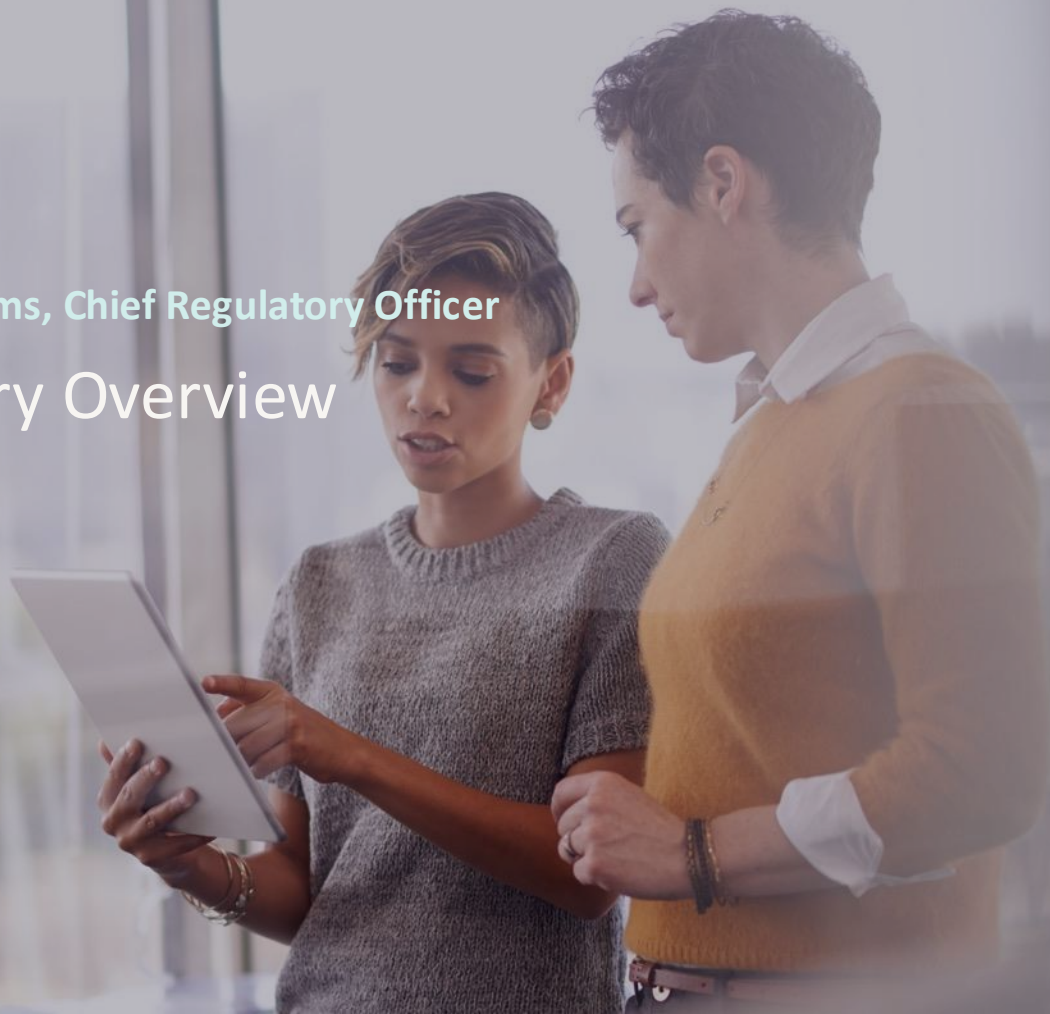
Preclinical studies strengthened the scientific foundation for NUZ-001 as a platform therapy beyond ALS/MND, demonstrating brain penetration, significant reduction of TDP-43 aggregation, restoration of neuronal survival factors, and protection against multiple pathways of neurodegeneration. These findings, showcased at leading international conferences, reinforce NUZ-001's potential to address a broad range of neurodegenerative diseases.

Together, we are moving closer to making treatments a reality for people living with ALS/MND and other neurodegenerative diseases.

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Kathryn Williams, Chief Regulatory Officer

Regulatory Overview



FDA Review Process: Navigating the Clinical Hold Resolution



Clinical Hold Complete Response (CHCR) Submitted

Our comprehensive response package addresses FDA feedback with robust scientific data:

PK Studies & Response Strategy

- Received positive feedback from FDA on our resolution strategy
- Completed two critical pharmacokinetic studies demonstrating >10-fold safety margin
- Submitted comprehensive CHCR package incorporating all requested data

Current Status & Next Steps

- FDA review timeline extended to 3 October 2025, due to agency delays impacting broader industry
- Actively engaging with Key Opinion Leaders and patient advocacy groups
- Preparing for HEALEY ALS Platform Trial inclusion in Q4 CY2025

📌 Note: Timelines indicative and subject to regulatory and operational variation

Clinical Development Timeline

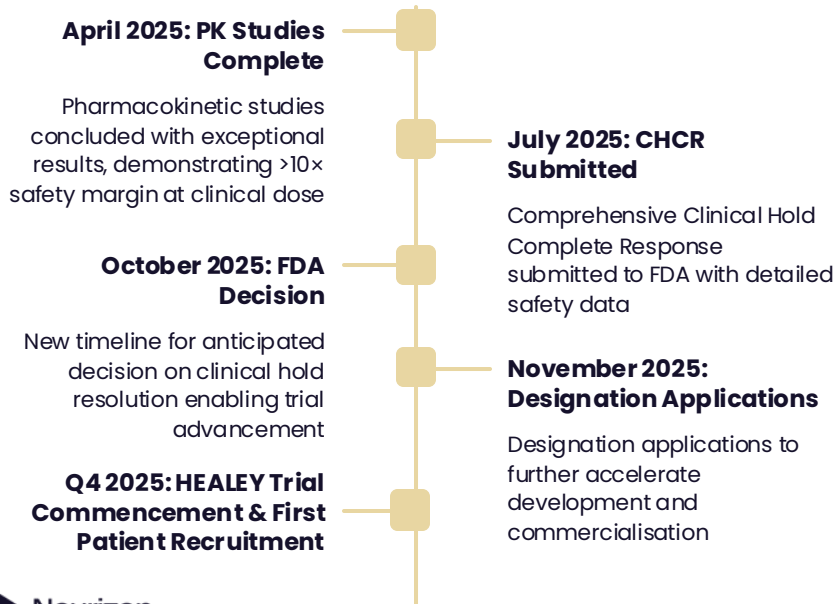


Our anticipated timeline shows progression from PK studies (April 2025) through clinical hold resolution (October 2025) to HEALEY trial commencement (Q4 CY2025), with top-line results expected in H1 CY2027 and commercialisation readiness by 2028.

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



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)

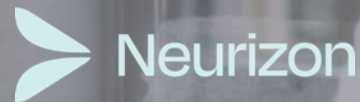
Japan consultation planned; Australia advancing Orphan Drug and Provisional Approval strategies

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

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Dan O'Connell, Chief Financial Officer

Financial Snapshot



Financial Snapshot

Significant strategic and commercial progress, with reduced spend compared to the prior quarter.

Financial Snapshot – Q4 FY2025

- Cash balance of \$4.2m at 30 June 2025.
- Cash outflow of \$4.4m, reflecting a 20% reduction on prior quarter.
- Neurizon executed a \$1.5 million loan from Radium Capital, secured against part of its 2025 R&D Tax Rebate, providing non-dilutive funding to maintain momentum.

Strategic Investments to strengthen the value proposition of NUZ-001

- Development of liquid formulation of NUZ-001 for patients with ALS.
- Significant pre-clinical progress expanding understanding of NUZ-001 mechanism of action, as well as its potential expansion to other neurodegenerative diseases, including Huntington's disease.
- Ongoing activities with the HEALEY ALS Platform Trial to develop a robust and cutting-edge regimen to support accelerated approval
- Executed the exclusive global license agreement with Elanco on 1 July 2025.

Annual Report 2025 Published



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John Clark, Chief Operating Officer

Topline Results Open Label Extension Study

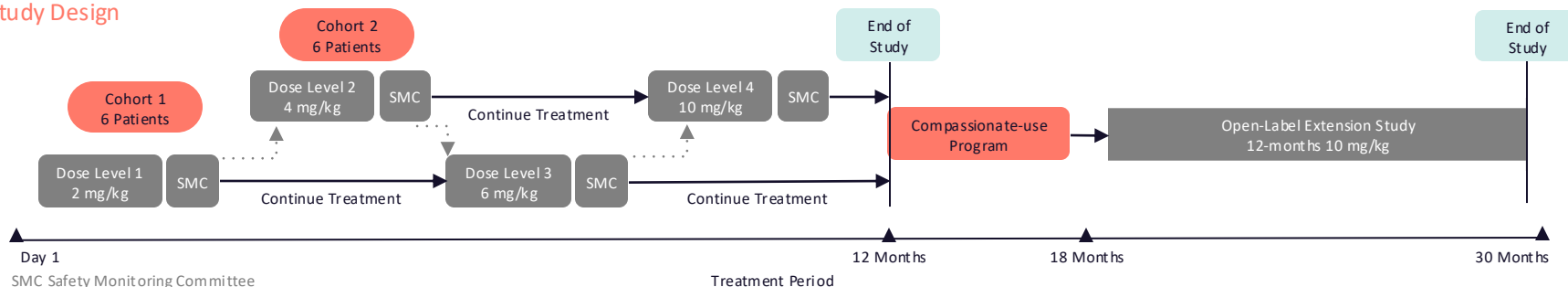


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Phase 1 ALS MEND and Open Label Extension (OLE) Study Design

The Phase 1 MEND Study was an open-label, multicentre study involving 12 patients with ALS that commenced in October 2022 and provided patients with ongoing access to NUZ-001 through a compassionate-use program and later a 12-month open-label extension study

Study Design



Study Update



- Positive Phase 1 MEND Study top-line results released in Q1 CY24
- 12 patients continued treatment with NUZ-001 under a compassionate-use program
- 10 patients rolled-over into a 12-month Open-Label Extension (OLE) Study. The final study patient completed the treatment period earlier this year
- Top-line results demonstrated long-term safety and efficacy signals of ALS treatment with NUZ-001
- NUZ-001 has been safely used for more than 2.5 years, with five patients still receiving treatment under the TGA's Special Access Scheme
- Phase 1 and baseline OLE data used to design pivotal registration adaptive Phase 2/3 Study, to commence in Q4 CY2025

Phase 1 Open Label Extension

Safety and Tolerability Summary

Study drug was well tolerated during long-term administration in the OLE, with no dose-limiting toxicities and no treatment-related deaths.

	Total (n)	Related to Treatment (n)
Adverse Events	25	3
Serious Adverse Events	5	0

- No participants withdrew from study
- No serious adverse events related to study drug
- Three (30%) participants reported TEAEs possibly related to study treatment, mild to moderate
 - Raised liver enzyme, Increased hair growth, Dry mouth at night
- Four (40%) participants experienced serious adverse events, all unrelated to study drug
 - Polymyalgia Rheumatica, Pneumonia, Respiratory Failure, Soft Tissue Injury, Suicide Attempt – Overdose
- Two (20%) deaths, both unrelated to study drug
 - Pneumonia, Respiratory Failure
- No unexpected safety findings observed in the OLE compared with Phase 1 MEND.
- 5 patients still receiving treatment under the TGA's Special Access Scheme.



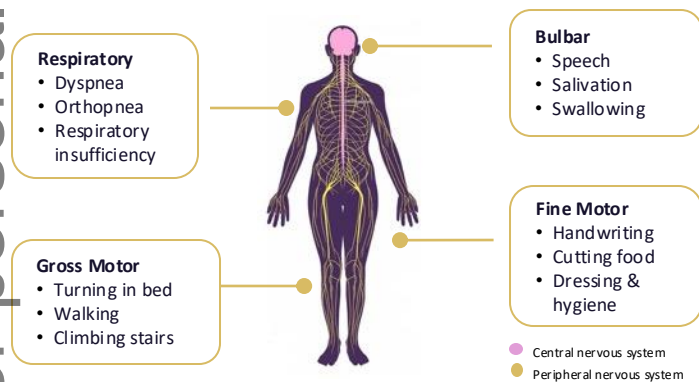
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Phase 1 Open Label Extension

Preliminary Efficacy Amyotrophic Lateral Sclerosis Function Rating Scale – Revised (ALSFRS-R)

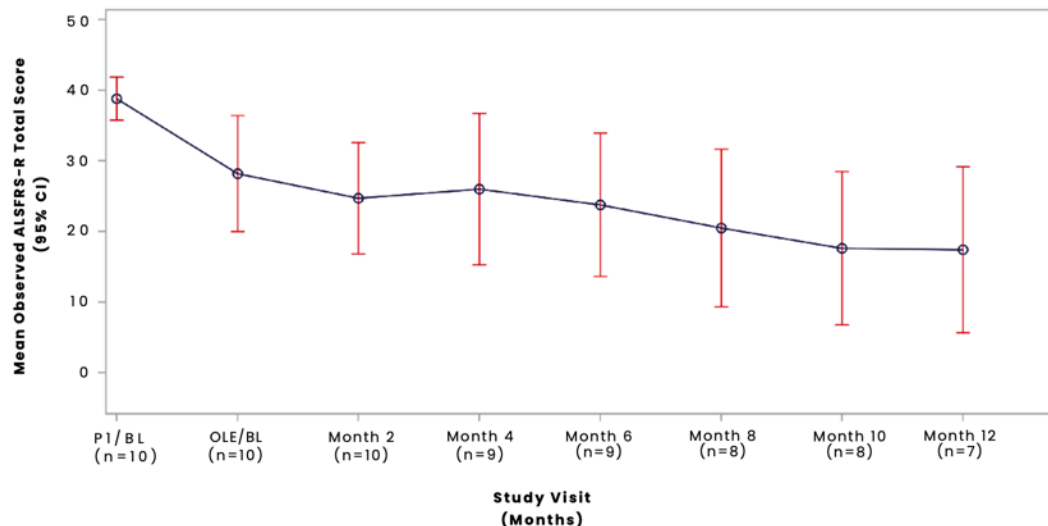
Estimated mean rate of decline was -0.88 pts/month (CI: -1.58, 0.10) in the OLE, compared with -0.74 pts/month (CI: -1.26, -0.23) in the MEND Study. These comparable results indicate a stable & durable treatment effect with long-term NUZ-001 therapy.

ALSFRS-R Domains Assessed



Each task is rated on a five-point scale from 0 = can't do, to 4 = normal ability.
Individual item scores are summed to produce a reported score of between 0=worst and 48=best.

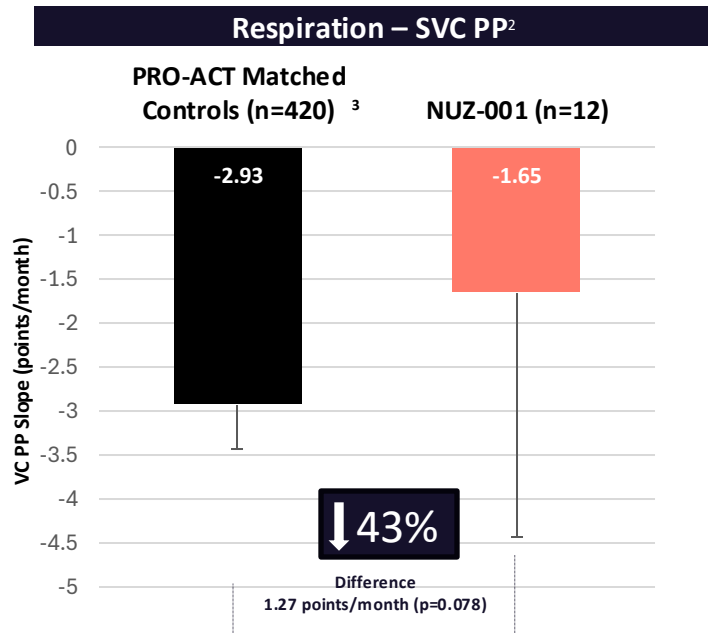
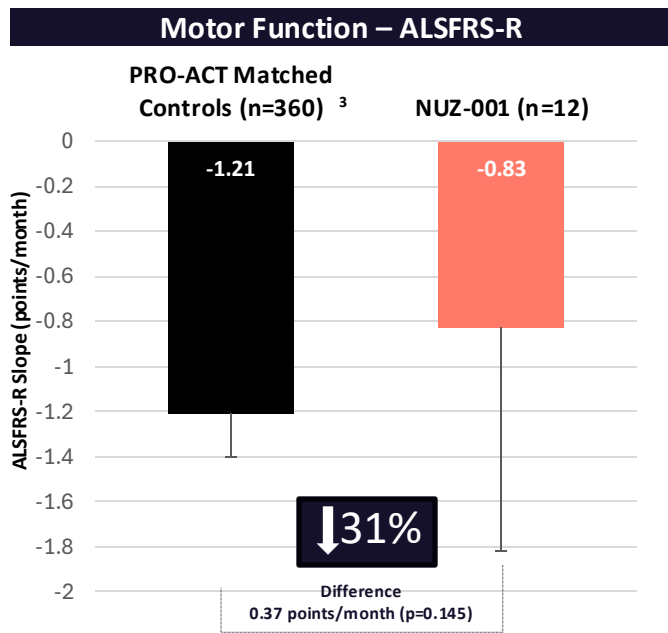
Observed ALSFRS-R Total Score



Phase 1 Open Label Extension

Preliminary Efficacy ALSFRS-R and SVC

Treatment with NUZ-001 across combined Phase 1 and OLE studies slowed the progression of ALS in all patients by 31% for ALSFRS-R and 43% for SVC percent predicted (PP) when compared to matched controls from the PRO-ACT historical database¹



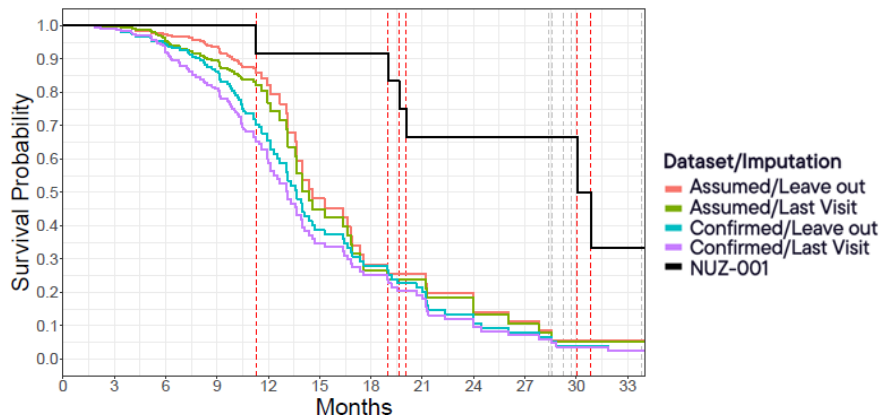
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Phase 1 Open Label Extension

Survival Probability Analysis

Compared to matched controls from the PRO-ACT, treatment with NUZ-001 results in a significantly ($\chi^2=13.75$, $p=0.00021$) longer survival of patients with ALS

Analysis Method		Log-Rank Test		Cox Proportional Hazards Model		
Dataset	Death Time Imputation	χ^2	p-value	Hazard Ratio	95% CI	p-value
Assumed Survival	Leave out	13.75	0.00021	0.233	(0.096, 0.566)	0.0013
	Last Visit	14.88	0.00011	0.225	(0.093, 0.544)	0.0009
Confirmed Survival	Leave out	20.87	0.00000	0.203	(0.087, 0.472)	0.0002
	Last Visit	22.79	0.00000	0.194	(0.083, 0.450)	0.0001



Hazard ratio of 0.233 (95% CI: (0.096, 0.566), $p = 0.0013$) indicating that treatment with NUZ-001 reduces the risk of death by 76.7%

Phase 1 Open Label Extension

Conclusion

These encouraging results support the potential of NUZ-001 as a disease-modifying therapy for ALS and provide strong justification for advancing the program into further clinical development

Highlights (Based on a small study population of 12 patients)



Primary Objectives

- Long-term treatment with NUZ-001 at the recommended Phase 2 dose was safe and well-tolerated



Slowed Functional Decline

- Sustained slowing in disease progression by 31% compared to PRO-ACT matched controls



Respiratory Stabilisation

- 43% reduction in VC PP compared to PRO-ACT matched controls



Survival*

- Reduction in the risk of death by 76.7% compared to PRO-ACT matched controls
- Estimated life extension of ~16 months



Biomarker Trends

- Stable plasma NfL and decreased (–17%) urinary p75^{ECD}



Patient Satisfaction

- No study discontinuations; 5 of the 6 remaining patients accessing NUZ-001 under the TGA's Special Access Scheme

* Data cut 15 Aug 2025

Dr Jeffrey M Brown, Chief Scientific Advisor

Preclinical Progress



Neurizon

Neurizon Discovery Pipeline: Driver of Continued Value Creation

Objective of preclinical research and development (RD) discovery engine is to drive future value creation through innovations in biology, chemistry and technology

Preclinical RD strategy

1. Drive deeper understanding of the mechanism of action of NUZ-001 to inform clinical studies and biomarker development.
2. Leverage biological understanding of NUZ-001 to drive expanded clinical opportunities and enhance overall value generation

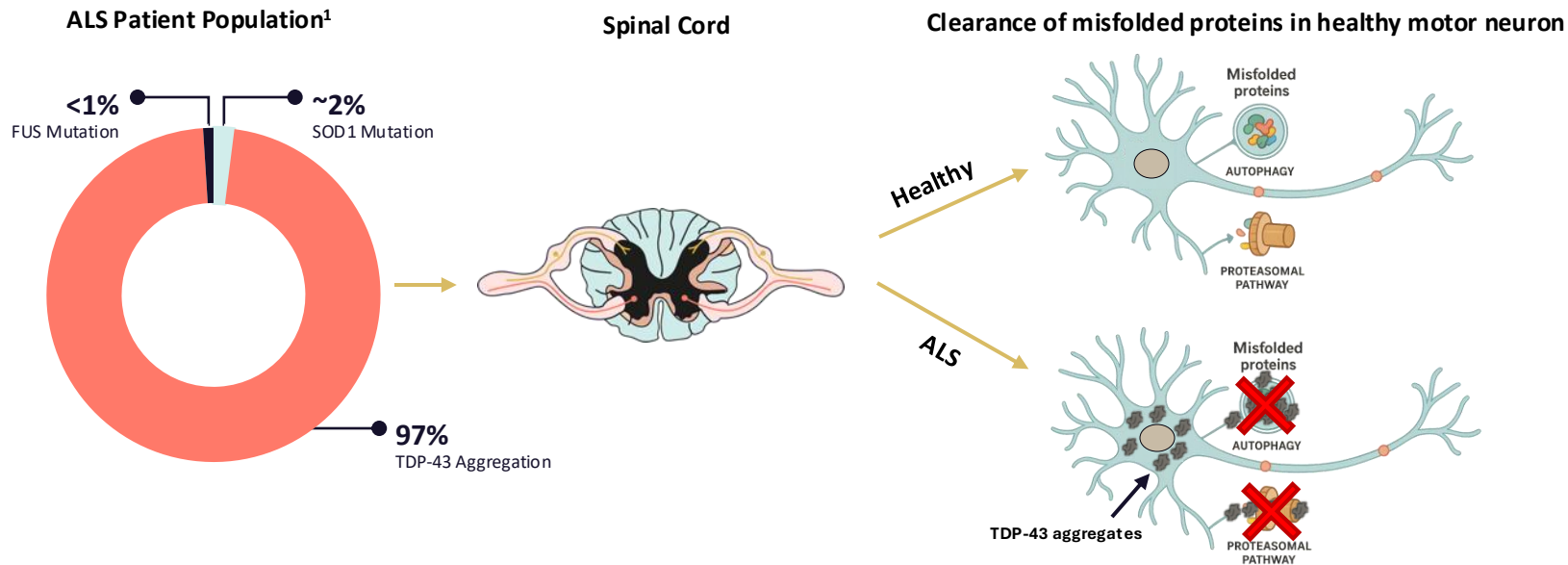
Key achievements in FY2025:

- ✓ Data demonstrate NUZ-001 reduces aggregation of TDP-43, a key driver of pathology in ALS
- ✓ Identified new biology pathways that represent a key driver of differentiation for NUZ-001
- ✓ New pharmacokinetic studies completed which demonstrate CNS exposure of both NUZ-001 and the active metabolite
- ✓ Positive studies in Huntington's disease support a new avenue for indication expansion



TDP-43 Aggregates are a Hallmark of ALS Pathology

Protein aggregates are cleared by multiple pathways including autophagy-lysosomal and ubiquitin-proteasome systems. Together these systems help to maintain proteostasis



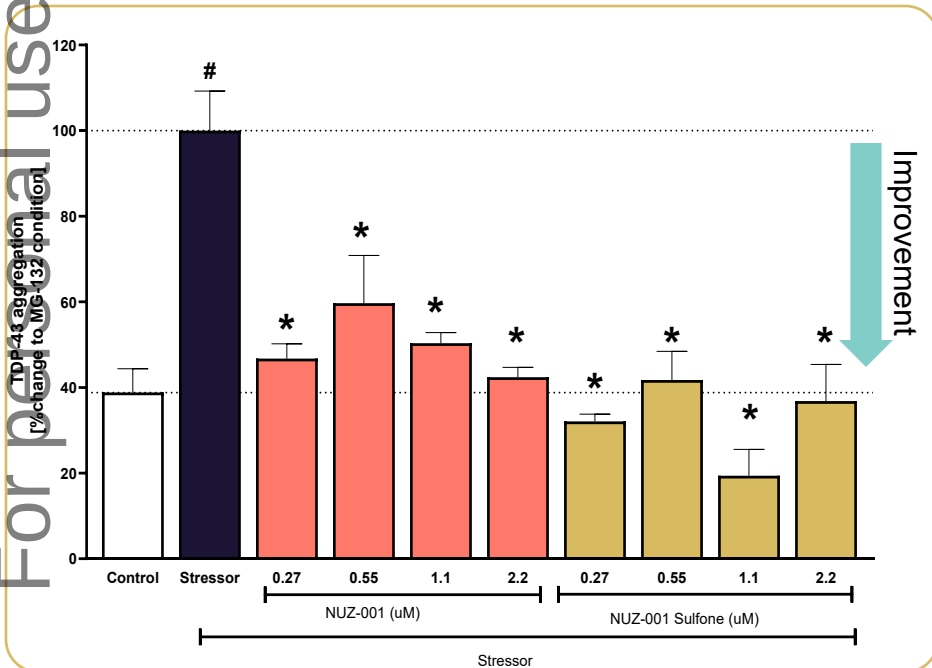
NUZ-001 enhances autophagy to maintain proteostasis

FUS = Fused in Sarcoma; SOD1 = Superoxide Dismutase 1; TDP-43 = Transactive response DNA-binding protein 43

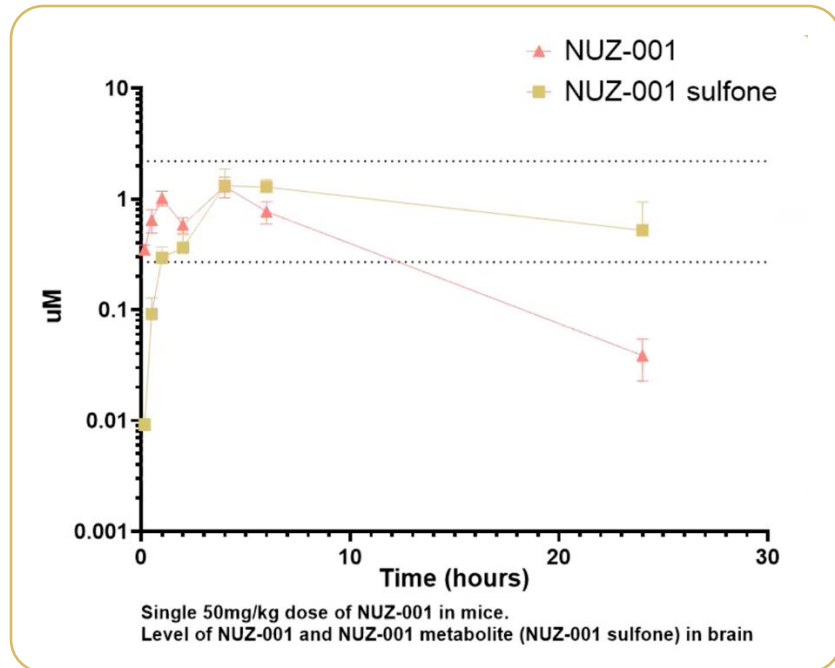
1. Ling SC, Polymenidou M, Cleveland DW. Converging mechanisms in ALS and FTD: disrupted RNA and protein homeostasis. Neuron. 2013 Aug 7;79(3):416-38. doi: 10.1016/j.neuron.2013.07.033. PMID: 23931993; PMCID: PMC4411085.

NUZ-001 and NUZ-001 Sulfone Achieve Brain Levels Required for Reversal of TDP-43 Aggregation Induced by Proteasome Inhibition (stressor) in ALS Neurons

Both NUZ-001 and NUZ-001 Sulfone reverse TDP-43 aggregation in iPSC-derived ALS neurons

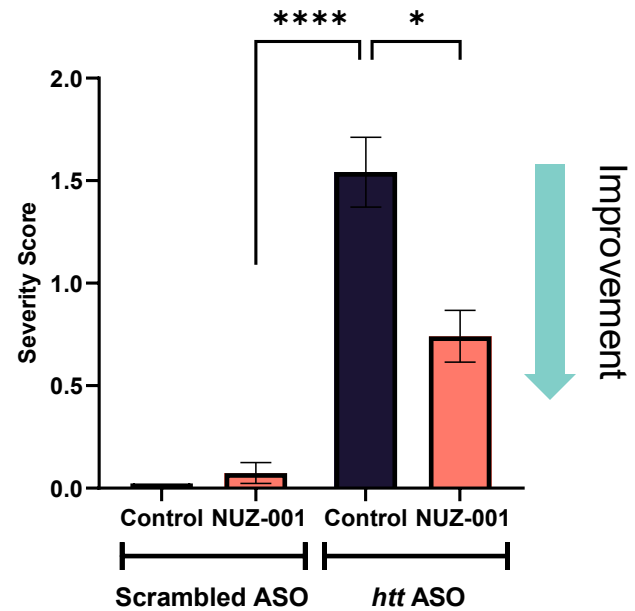


Both NUZ-001 and NUZ-001 achieve brain levels required for reduction in TDP43 aggregation

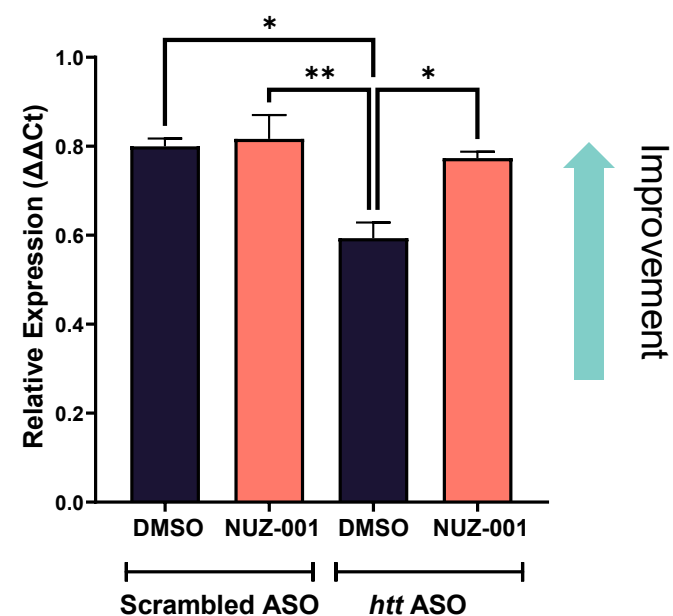


Protective Effects of NUZ-001 Seen Across Multiple Models of Neurodegeneration Including Huntingtons Disease (HD)

NUZ-001 reverses brain swelling induced by reduction of Huntington (*htt*) expression



NUZ-001 restores loss of BDNF expression induced by reduction of Huntington (*htt*) expression



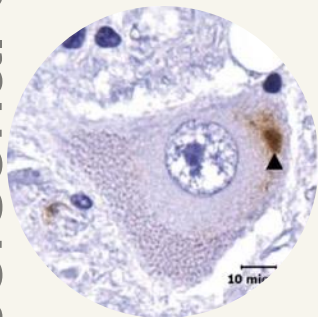
Zebrafish HD model: *Htt* expression was reduced by pretreatment with an antisense-oligonucleotide (ASO) targeting the *htt*.

NUZ-001: A Platform Molecule for Proteinopathy-Driven Diseases

Impaired proteostasis contributes to intracellular inclusion bodies of misfolded proteins is a hallmark of neurodegenerative diseases

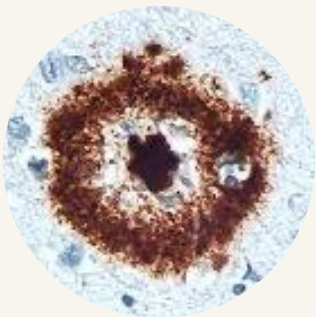
TDP-43

ALS/AD/PD/FTD/CTE



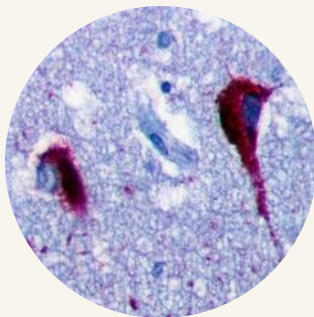
Amyloid beta

AD/PD



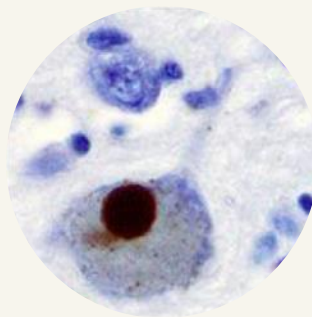
Tau

AD/PD/FTD/CTE/PSP



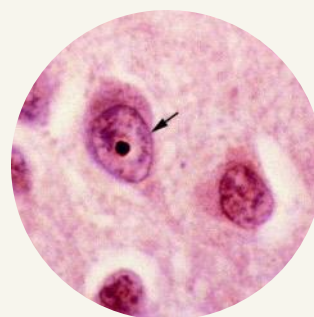
alpha Synuclein

AD/PD



mHTT

HD



NUZ-001 represents a mechanism-driven, disease-agnostic approach to treating neurodegeneration by rebalancing proteostasis and reversing core cellular dysfunction

AD = Alzheimer's Disease; ALS = Amyotrophic Lateral Sclerosis; CTE = Chronic Traumatic Encephalopathy; FTD = Frontotemporal Dementia; HD = Huntington Disease; PD = Parkinson's Disease; PSP = Progressive Supranuclear Palsy

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Stacie Seidel, Patient Advocacy

Industry Engagement



Connecting Minds, Accelerating Hope

We continue to connect with KOLs, Patients, Investors, and Biopharma leaders at global gatherings, broadening the network of experts, collaborators, and stakeholders connected to our mission.

Patient & Advocacy Partnerships

- Strengthened collaborations with leading ALS/MND patient associations, including **MND Australia, FightMND, I AM ALS, and ALS Association**
- **Participated in and led ALS awareness campaigns** (e.g., Lou Gehrig Day, #MoreThanADiagnosis, Big Freeze Gala), and volunteered in MND Victoria's "The Great MND Relay", supporting the community in raising funds for those impacted by MND
- Supported MND Australia's landmark economic burden report, "Every Moment Matters"
- **Ongoing dialogue with caregivers and patient communities** to embed patient voice into trial and access strategies

Scientific & Clinical Leadership

- **Ongoing participation in global ALS/MND research forums** and specialist workshops organized by key patient associations and specialised ALS Industry bodies
- **Presented at major international conferences**, including 2024 Annual NEALS Meeting, 7th Annual ALS ONE Research Symposium, International Symposium on ALS/MND, Bio-Neuroscience, AD/PD 2025 International Conference – showcasing preclinical data on TDP-43 and Huntington's models, Bio-International Convention, and ALS Drug Development Summit 2025

Upcoming Industry Engagements in 2025

We continue to engage with KOLs, Patients, Investors, and Biopharma leaders at global gatherings, broadening the network of experts, collaborators, and stakeholders connected to our mission.

- NEALS Annual Meeting (October 7-10, FL, USA)
- PACTALS (September 7-9, Melbourne, AU)
- FightMND's Global MND Research Roundtable (September 10-12, Melbourne, AU)
- BioJapan (October 8-10, Japan)
- Society for Neuroscience Annual Meeting (October 15, IL, USA)
- Ignite Investment Summit (October 15-16, Hong Kong)
- 14th Annual Australian Microcap Investment (October 21, Melbourne, AU)
- Walk to Defeat ALS Boston (October 26, 2025)
- Walk to Defeat MND, MND NSW (November 2, Sydney, AU)
- ALS Association Roundtable (November 14, 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 (January 12-15, CA, USA)



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Dr Michael Thurn, Managing Director and Chief Executive Officer

Summary & Next Steps

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Near Term Milestones

Significant near-term news flow drive value and growth

- ✓ Execute **License Agreement with Elanco**
- ✓ 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**
 - ✓ **First registration batch** of NUZ-001
 - ✓ **Preliminary R&D Funding received**
 - ✓ **Top-line results from OLE study**
 - **US FDA lifts clinical hold**
 - Additional **preclinical updates**
- **HEALEY submits NUZ-001 protocol amendment** to US FDA for Platform Trial
 - **PACTALS** conference and presentation
 - Supply Agreement **executed with Elanco**

Q3

- **HEALEY ALS Platform Trial– Initiation of site start-up activities**
 - **NEALS** Annual Conference Meeting
- **HEALEY ALS Platform Trial - Investigator Meeting**
 - **Australian R&D Refund** (net of R&D funding)
- **Second and Third registration batches** of NUZ-001
 - **36th International Symposium on ALS/MND**
 - Additional **preclinical updates**
 - **FDA Fast Track Designation for NUZ-001**
 - **EMA Scientific Advice** meeting
- **HEALEY ALS Platform Trial – First patient recruitment**

Q4

ONGOING EFFORTS

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

Investment credentials for NUZ-001

De-risked clinical program for a rare neurodegenerative disease positioned for near-term regulatory approval and launch



Well-characterized Drug

- Oral bioavailable
- Crosses the Blood Brain Barrier
- “Rediscovered” veterinary drug



Restores Proteostasis

- Targets the underlying pathology – protein aggregation
- Multiple indications possible



Clinical POC

- Promising Phase 1 data
- Long-term treatment with NUZ-001 was safe and well-tolerated
- Accepted into HEALEY ALS Platform Trial



Strategic Agreements

- Access to extensive data and IP
 - Supply Agreement



Near-term Regulatory Strategy

- FDA accelerated approval possible
- Multiple regulatory designations
- High deal flow for neurology assets



Strong IP Position

- Patent protection out to 2041
- World class team assembled to maximise IP



Comparison of Key Outcomes Across Approved ALS Treatments & NUZ-001

Cross-trial comparisons are descriptive only; differences in study design, patient populations, and endpoints limit direct comparability.

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			 ALSFRS-R (Improvement Compared to Placebo)	 FVC/SVC (Improvement Compared to Placebo)	 Survival (Improvement Compared to Placebo)	
01 (1995)	Riluzole¹ (Rilutek®)	52 weeks	Not evaluated	Not evaluated	~3 months	n=77
02 (2017)	Edaravone² (Radicava®)	24 weeks	33.20% (p=0.0013)	23.43% (FVC, p=0.0942)	~6 months	n=69
03 (2022)	Amx0035^{3,4} (Relyvrio®)	24 weeks	23.27% (p=0.030)	22.37% (SVC, p=0.080)	~6.5 months ⁵	n=89
04 (2023)	Tofersen⁶ (Qalsody®)	28 weeks	14.74% (p=0.970)	35.59% (SVC, p>0.05)	Not evaluated	n=72
Investigational	NUZ-001⁷	40 weeks ⁸	39% (p=0.080) ¹⁰	48% (SVC, p=0.058) ¹⁰	~16 months ¹⁰	n=12
		116 weeks ⁹	31% (p=0.145) ¹⁰	41% (SVC, p=0.078) ¹⁰		

¹ N Engl J Med. 1994 Mar 3;330(9):585-9; ² Lancet Neurol 2017;16: 505-12; ³ N Engl J Med 2020; 383:919-30; ⁴ Voluntary removal from the market; ⁵ Muscle Nerve. 2021 Apr;63(4): 31-39; ⁶ Engl J Med 2022;387:1099-110; ⁷ Neurizon data on file; ⁸ Median treatment period in Phase 1 MEND Study; ⁹ Median treatment period for combined Phase 1 MEND Study and OLE Study; ¹⁰ Comparison to matched untreated controls in PRO-ACT Database

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