# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 OR 15(d)**
**of The Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): June 1, 2022**

# Clene Inc.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39834** | **85-2828339** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| **6550 South Millrock Drive, Suite G50**<br>**Salt Lake City, Utah** | **84121** |
|---|---|
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (801) 676-9695**

**N/A**
**(Former Name or Former Address, if Changed Since Last Report.)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.0001 par value | CLNN | The Nasdaq Capital Market |
| Warrants, to acquire one-half of one share of Common Stock for $11.50 per share | CLNNW | The Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01 Regulation FD Disclosure.**

On June 1, 2022, Clene Inc. (the "Company") presented new data from the RESCUE-ALS clinical trial and long-term open-label extension study in three posters in the Emerging Science Program at European Network to Cure ALS ("ENCALS") Meeting 2022, taking place June 1-3, 2022. A copy of the posters are furnished as Exhibit 99.1, Exhibit 99.2, and Exhibit 99.3 to this Current Report on Form 8-K and are incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibit 99.1, Exhibit 99.2, and Exhibit 99.3, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in any such filings, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit Number | Exhibit Description |
|---|---|
| 99.1 | RESCUE-ALS poster, "Evidence for an ALS Survival Benefit with CNM-Au8 Treatment: Interim Results from the RESCUE-ALS Trial Long-Term Open Label Extension," dated June 1, 2022. |
| 99.2 | RESCUE-ALS poster, "Evidence for Continuing Quality of Life Benefit Following CNM-Au8 ALS Treatment: Preliminary Analyses of the RESCUE-ALS Long Term OLE," dated June 1, 2022. |
| 99.3 | RESCUE-ALS poster, "Preliminary Biomarker Findings from the RESCUE-ALS Trial: A Phase 2 Double-Blind, Placebo-Controlled Study of CNM-Au8 to Slow Disease Progression in ALS," dated June 1, 2022. |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL). |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CLENE INC.

Date: June 1, 2022

By: /s/ Robert Etherington
Robert Etherington
President and Chief Executive Officer

# Evidence for an ALS Survival Benefit with CNM-Au8 Treatment: Interim Results from the RESCUE-ALS Trial Long-Term Open Label Extension

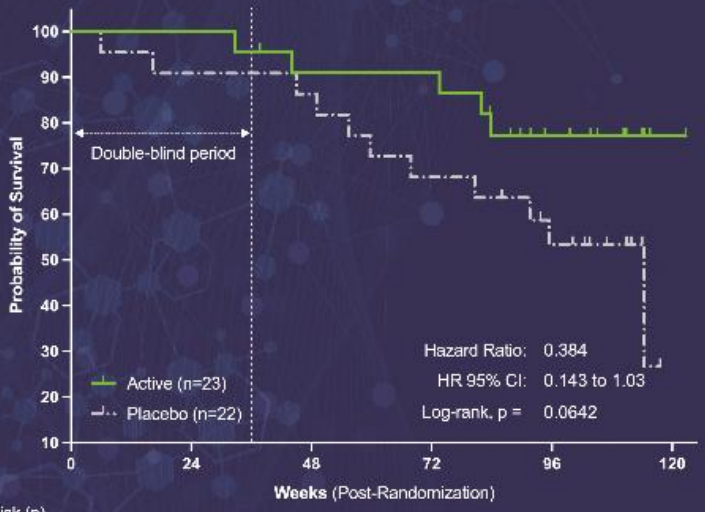
RESCUEALS Long-Term OLE

Steve Vucic PhD, DSc, FRACP, FAHMS, Parvathi Menon PhD, FRACP[1], William Huynh PhD, FRACP[2], Colin Mahoney, PhD, MB, MRCPI, Karen S. Ho, PhD MSc[3], Austin Rynders, RN[3], Jacob Evan[3], Jeremy Evan, PA-C[3], Robert Glanzman, MD FAAN[3], Michael T. Hotchkin[3], Matthew C. Kiernan PhD, DSc, MBBS, FRACP, FAHMS
[1]Concord Repatriation General Hospital, University of Sydney, Australia;[2]Brain and Mind Centre, University of Sydney, Australia;[3]Clene Nanomedicine, Salt Lake City, UT, USA

## CONCLUSION: CNM-Au8 treatment impacts long-term survival with decreased mortality risk >60% vs. original placebo randomization, and compared to ENCALS predicted median survival

### Long Term Vital Status
### All Randomized | Active vs. Placebo
### Original Treatment vs. No OLE or OLE Delayed Start

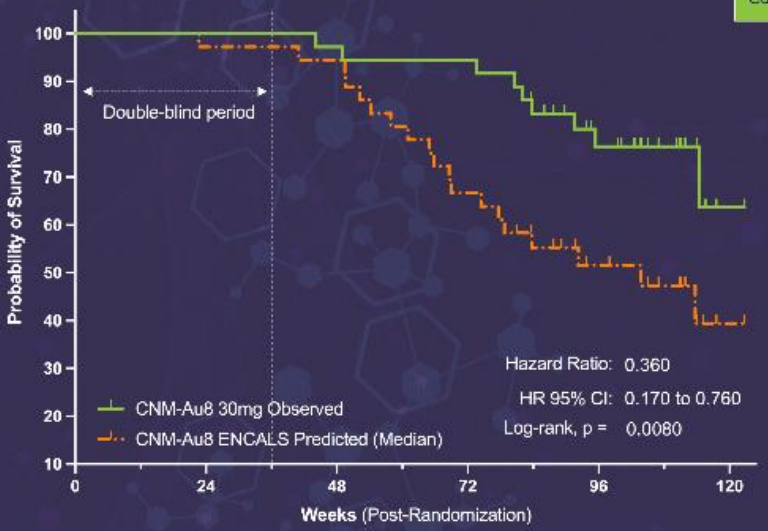
**Long-Term Survival: Originally Randomized Active vs. Original Placebo**
ITT Population, All Subjects from Randomization
(Long-term vital status including all study withdrawals)




| At Risk (n) | | | | | |
|---|---|---|---|---|---|
| CMM-Au8: | 23 | 23 | 20 | 20 | 13 |
| Placebo: | 22 | 20 | 19 | 15 | 11 |

### All OLE Participants
### Observed vs. ENCALS Predicted Median Survival

**All Open-Label Participants Long-Term Observed Survival vs. ENCALS Predicted Median Survival**
All CNM-Au8 + Placebo Subjects Entering OLE
Survival from Randomization, ITT Population Subset

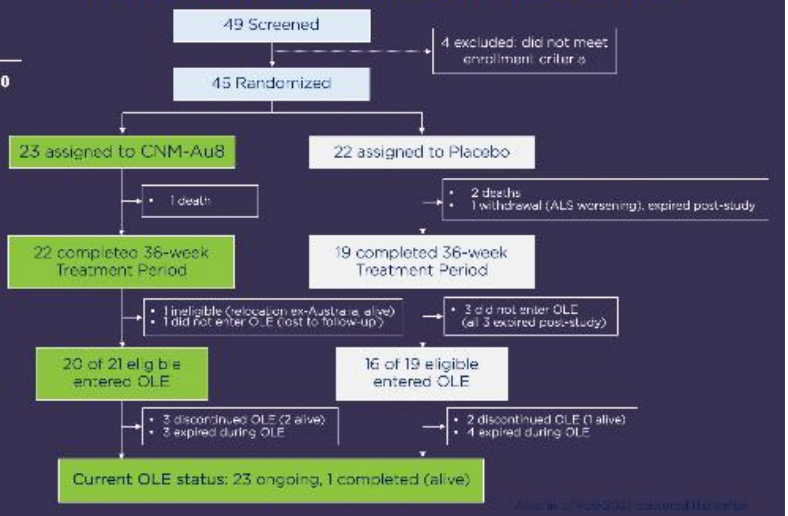



| At Risk (n): | 36 | 36 | 35 | 34 | 22 |
|---|---|---|---|---|---|

### Study Design Scheme


- Early symptomatic ALS (within 2-years onset or 1-year diagnosis)
- Randomized (1:1, CNM-Au8 30 mg or placebo)
- 36-week treatment period with long-term open label extension
- 1st EP: MUNIX(4) summed %change of 4-spinal cord innervated muscles
- 2nd EPs: absolute MUNIX change, % FVC
- Exploratory EPs: disease progression, 6-pt decline in ALSFRS-R, ALSSQOL-SF, & other neurophysiology endpoints

### Participant Vital Status by Treatment Group




Notes: Interim data cut as of 24-May-2022. All current active OLE subjects are censored as of 24-May-2022. Vital status and date of death (as applicable) captured for all subjects withdrawn from the study. Lost-to-follow-up (active, n=1; placebo, n=1) censored as of the date of last study contact (Active: Feb-2021; Placebo: Feb-2022).

Acknowledgements: We thank the ALS study patients and their families for their support and willingness to engage in clinical research. We thank the site investigators for their research excellence and dedication to patients. We thank FightMND of Australia for substantially funding the RESCUE-ALS trial.

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# Evidence for Continuing Quality of Life Benefit Following CNM-Au8 ALS Treatment

*Preliminary Analyses of the RESCUE-ALS Long Term OLE*

RESCUEALS Long-Term OLE

Steve Vucic PhD, DSc, FRACP, FAHMS, Parvathi Menon PhD, FRACP[1], William Huynh PhD, FRACP[2], Colin Mahoney, PhD, MB, MRCPI, Karen S. Ho, PhD MSc[3], Austin Rynders, RN[3], Jacob Evan[3], Jeremy Evan, PA-C[3], Robert Glanzman, MD FAAN[3], Michael T. Hotchkin[3], Matthew C. Kiernan PhD, DSc, MBBS, FRACP, FAHMS
[1]Concord Repatriation General Hospital, University of Sydney, Australia;[2]Brain and Mind Centre, University of Sydney, Australia;[3]Clene Nanomedicine, Salt Lake City, UT, USA

**CONCLUSION: In RESCUE-ALS, CNM-Au8 treatment stabilised ALS-Specific QoL decline during the double-blind period, which was maintained for up to 84 weeks post-randomisation**

## Design Scheme

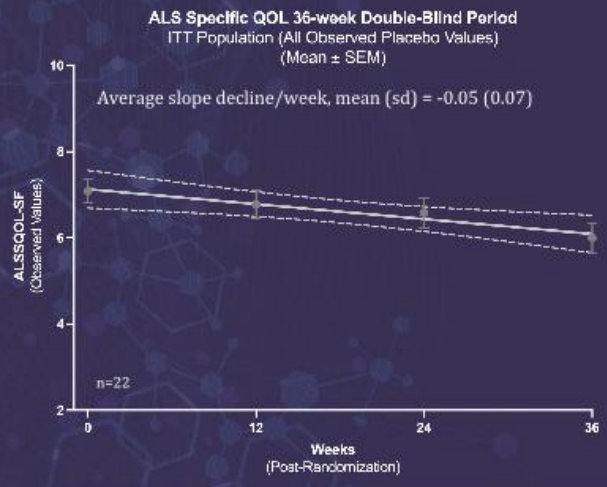

- Early symptomatic ALS (within 2-years onset or 1-year diagnosis)
- Randomized (1:1, CNM-Au8 30 mg or placebo)
- 36-week treatment period with long-term open label extension
- 1st EP: MUNIX(4) summed %change of 4-spinal cord innervated muscles
- 2nd EPs: absolute MUNIX change, % FVC
- Exploratory EPs: disease progression, 6-pt decline in ALSFRS-R, ALSSQOL-SF, & other neurophysiology endpoints

## Week 36 Unblinded ALSSQOL Results

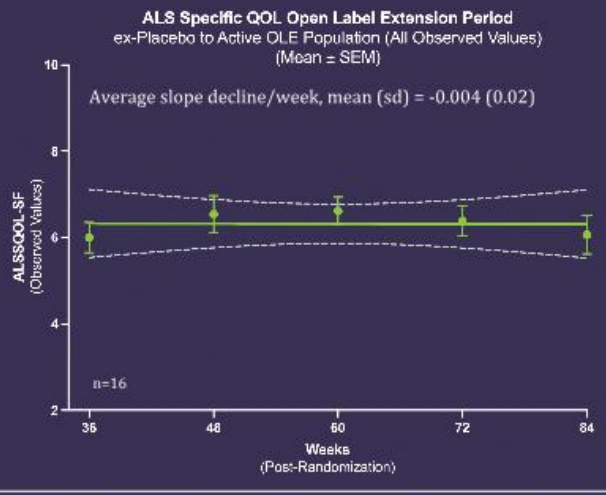

P value is based on MMRM model with treatment, visit, treatment by visit interaction as fixed effects and baseline value and ENCALS score as covariates. An unstructured covariance matrix was used.

## Ex-Placebo OLE CNM-Au8 treated participants stabilized ALS Specific QOL decline during OLE

### Original Placebo | 36-Week Randomized Period

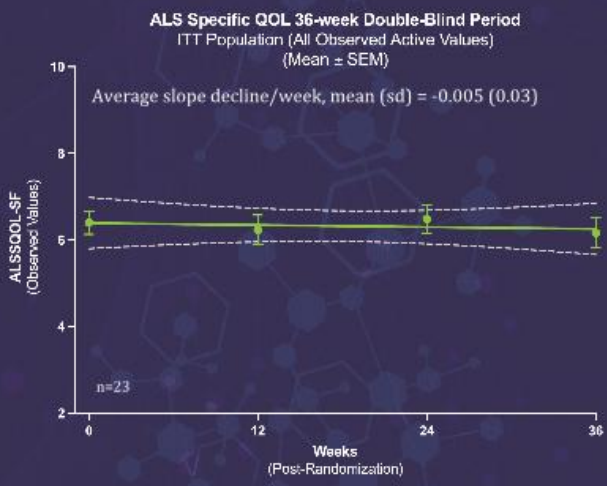



### Original Placebo to OLE CNM-Au8 Treatment

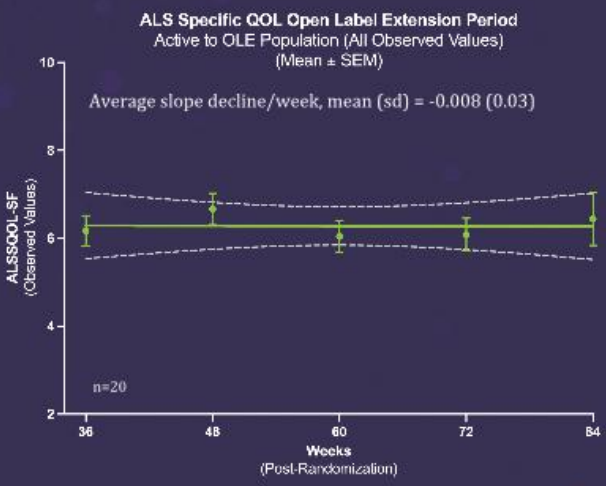



## Original CNM-Au8 treated participants maintained ALS Specific QOL values during OLE treatment

### Original Active | 36-Week Randomized Period




### Original Active to OLE CNM-Au8 Treatment




**Notes**: Interim data cut as of 15-March-2022. Data include all reported values without imputation for missing data. **Acknowledgements**: We thank the ALS study patients and their families for their support and willingness to engage in clinical research. We thank the site investigators for their research excellence and dedication to patients. We thank FightMND of Australia for substantially funding the RESCUE-ALS trial.

clene NANOMEDICINE

# Preliminary Biomarker Findings from the RESCUE-ALS Trial | A Phase 2 Double-Blind, Placebo-Controlled Study of CNM-Au8 to Slow Disease Progression in ALS

Steve Vucic PhD, DSc, FRACP, FAHMS, Parvathi Menon PhD, FRACP[1], William Huynh PhD, FRACP[2], Colin Mahoney, PhD, MB, MRCPI[2], Karen S. Ho, PhD MSc[1], Austin Rynders, RN[3], Jacob Evan[3], Jeremy Evan, PA-C[3], Robert Glanzman, MD FAAN[3], Michael T. Hotchkin[3], Matthew C. Kiernan PhD, DSc, MBBS, FRACP, FAHMS
[1]Concord Repatriation General Hospital, University of Sydney, Australia;[2]Brain and Mind Centre, University of Sydney, Australia;[3]Clene Nanomedicine, Salt Lake City, UT, USA

**CONCLUSION: CNM-Au8 treatment decreased urinary p75 and plasma UCHL1 levels during the double-blind period; plasma NfL levels were predominantly stable in this early ALS population**

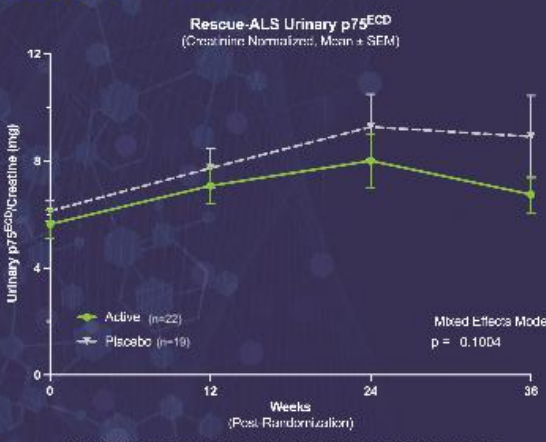
## Baseline Demographics

| Baseline Value mean (sd) | Age (yrs) | Sex n, (%) Male \| Female | Onset Site n, (%) Limb \| Bulbar | Months from Onset | FVC (% pred.) | ALSFRS-R Score | ENCALS Risk Profile[1] | MUNIX Sum |
|---|---|---|---|---|---|---|---|---|
| **All** (n=45) | 59.1 (12.3) | M: 26 (58%) F: 19 (42%) | L: 33 (73%) B: 12 (27%) | 15.8 (9.3) | 81.5 (16.7) | 38.7 (6.0) | -4.4 (1.8) | 378.2 (175.3) |
| **CNM-Au8 30mg** (n=23) | 57.0 (13.3) | M: 13 (57%) F: 10 (43%) | L: 16 (70%) B: 7 (30%) | 15.5 (7.6) | 84.5 (18.3) | 38.6 (6.6) | -4.6 (1.7) | 380.2 (198.0) |
| **Placebo** (n=22) | 61.3 (10.9) | M: 13 (59%) F: 9 (41%) | L: 17 (77%) B: 5 (23%) | 16.1 (10.9) | 78.2 (14.5) | 38.8 (5.4) | -4.2 (1.8) | 376.2 (152.7) |

## Design Summary

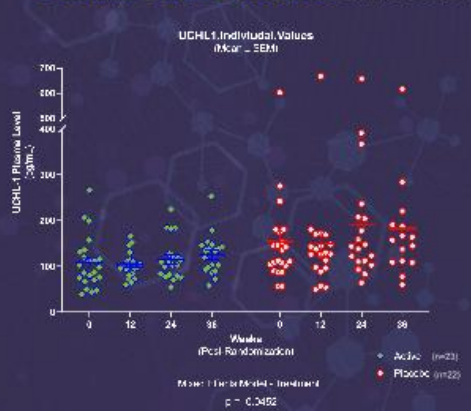
- Early symptomatic ALS
- Randomized (1:1, CNM-Au8 30 mg or placebo)
- 36-week treatment period with open label extension
- 1st EP: MUNIX(4) summed %change of ADM, APB, BB, & TA
- Exploratory pharmacodynamic markers: p75$^{ECD}$, NfL, UCHL1, GFAP, untargeted proteomics, untargeted metabolomics

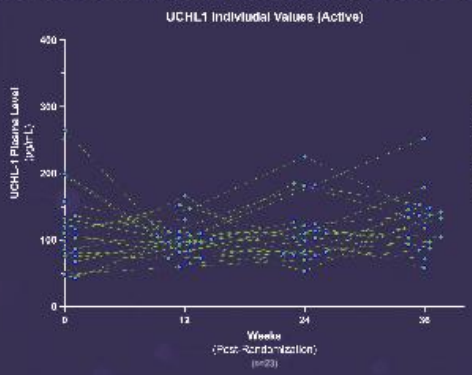
## [1]Urinary p75$^{ECD}$ Results: CNM-Au8 treatment demonstrated trend for decreased p75$^{ECD}$ (ELISA, M. Rodgers, U. Flinders)

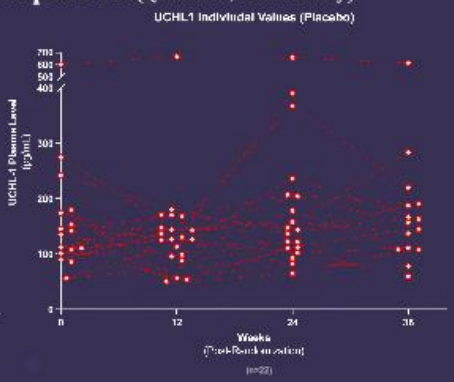



All available data; samples with low creatinine <0.3 mg/ml urinary creatinine.

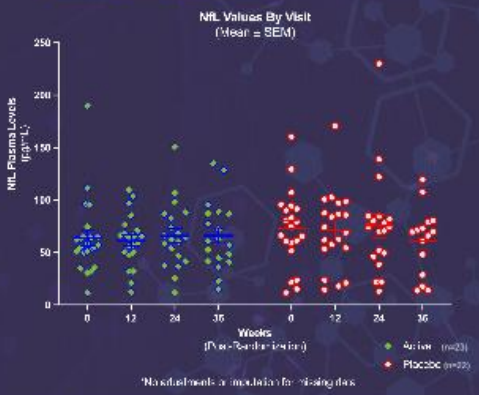

## [2]Plasma UCHL1 Results: CNM-Au8 treatment blunted increased UCHL1 vs. placebo (Quanterix, Simoa Assay)



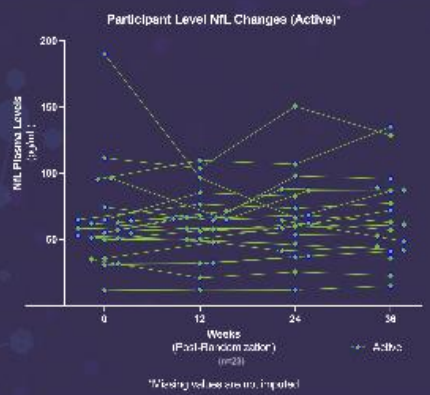



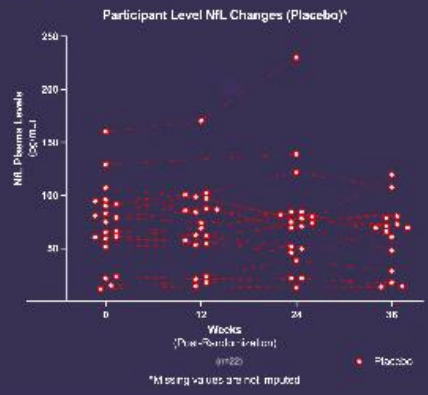

## Plasma NfL Results: Levels were predominantly stable across both treatment groups (Quanterix, Simoa Assay)




*No adjustments or imputation for missing data




*Missing values are not imputed




*Missing values are not imputed

**Acknowledgements:** We thank the ALS study patients and their families for their support and willingness to engage in clinical research. We thank the site investigators for their research excellence and dedication to patients. We thank FightMND of Australia for substantially funding the RESCUE-ALS trial.
1. Sheapheard et al. 2020 Neurology 2017, 88 (12), 1137–1143. 2. Li et al. 2020 Ann. Clin. Transl. Neurol. 2020, 7 (8), 1420–1428.