

**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): April 5, 2022

Clene Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39834
(Commission File Number)

85-2828339
(IRS Employer
Identification No.)

6550 South Millrock Drive, Suite G50
Salt Lake City, Utah
(Address of Principal Executive Offices)

84121
(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 April 5, 2022, Clene Inc. (the “Company”) presented updated interim data from the RESCUE-ALS open-label extension study in the Emerging Science Program at 2022 AAN Annual Meeting. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibit 99.1, 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 presentation, dated April 5, 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: April 5, 2022

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



Cutting edge research into
Frontotemporal Dementia and Motor
Neurodegenerative Syndromes



**Randomized, Double-Blind, Placebo-Controlled Study in
Early Symptomatic Amyotrophic Lateral Sclerosis Patients
on Stable Background Therapy to Assess Bioenergetic
Catalysis with CNM-Au8 to Slow Disease Progression in ALS**

Matthew Kiernan



THE UNIVERSITY OF
SYDNEY

matthew.kiernan@sydney.edu.au



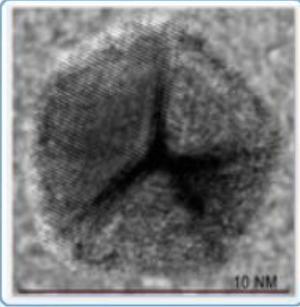
Disclosures & Acknowledgements

- MCK and the University of Sydney have received research funding from Clene to undertake Rescue-ALS
- We thank FightMND for its philanthropic support of the RESCUE-ALS study
- We thank the study participants and their families for their willingness to support clinical research



CNM-Au8[®] | Catalytically Active Au Nanocrystals Improve Cellular Energy Production

CNM-Au8[®]
Nanocrystal



Clean Surfaced, Highly Faceted Shape Enhances Catalytic Activity

Electrons (e⁻)
Move Freely Across
Nanocrystal Surface

Vertices, Edges, & Facets
Key to Catalytic Activity

Mechanistic Effects

↑ Increased NAD

↑ Increased ATP

↓ Decreased reactive oxygen species

↑ Increased proteostasis

Increased Energy Production & Utilization

↑ Increased energetic potential

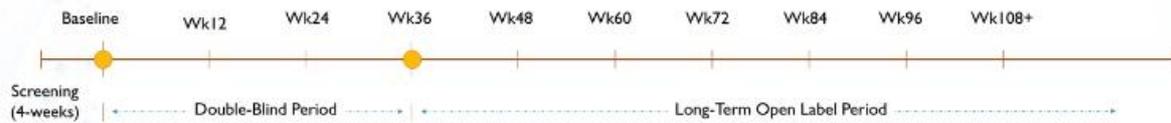


↑ Improved resistance to oxidative, mitochondrial, and excitotoxic stressors

↓ Reduction in levels of misfolded proteins

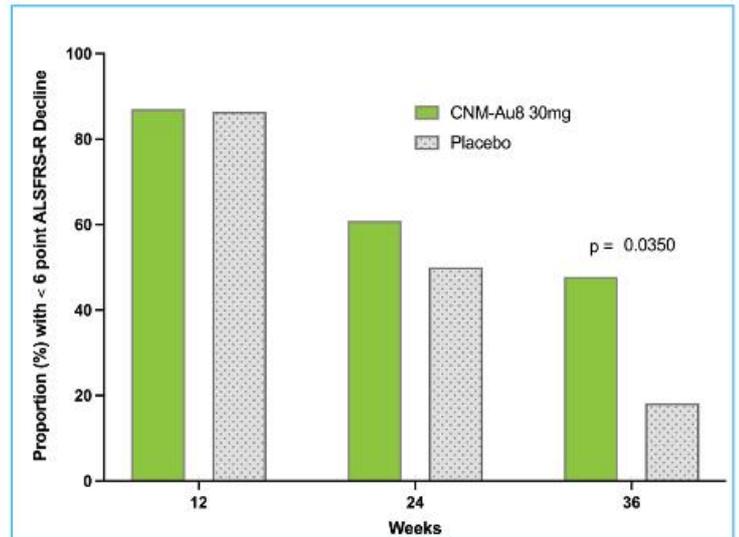
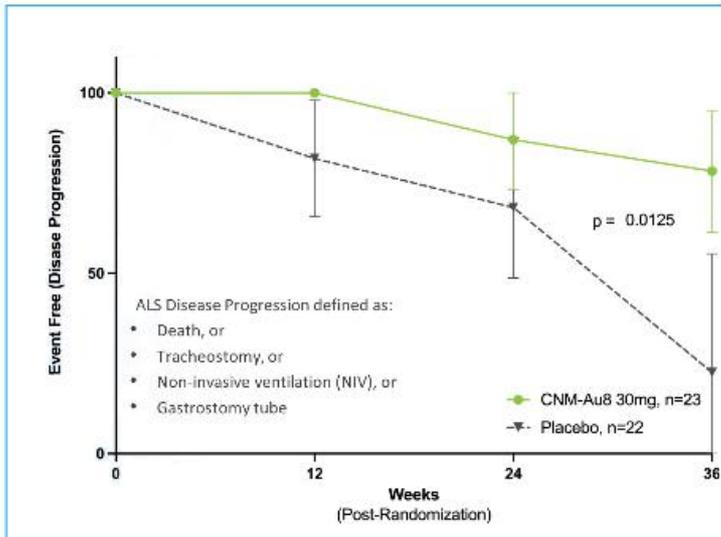
Design & Baseline Characteristics

36-Week Treatment Blinded Treatment with Long-Term Open-Label Follow-Up

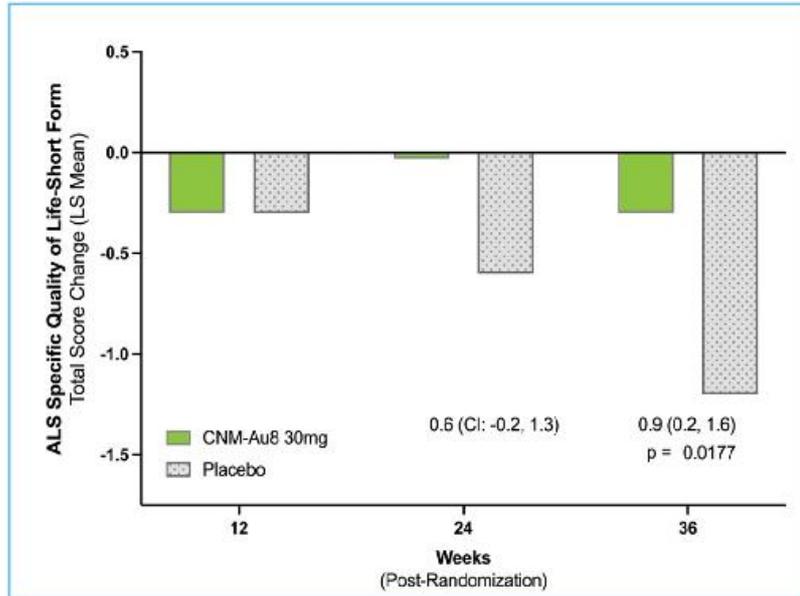


Baseline Value mean (sd)	Age (yrs)	Sex n, (%) Male Female	Onset Site n, (%) Limb Bulbar	Months from Onset	FVC (% pred.)	ALSFRS-R Score	ENCALS Risk Score	MUNIX Sum
All (n=45)	59.1 (12.3)	M: 26 (58%) F: 19 (42%)	L: 33 (73%) B: 12 (27%)	15.8 (9.3)	81.5 (16.7)	38.7 (6.0)	-4.4 (1.8)	378.2 (175.3)
CNM-Au8 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)

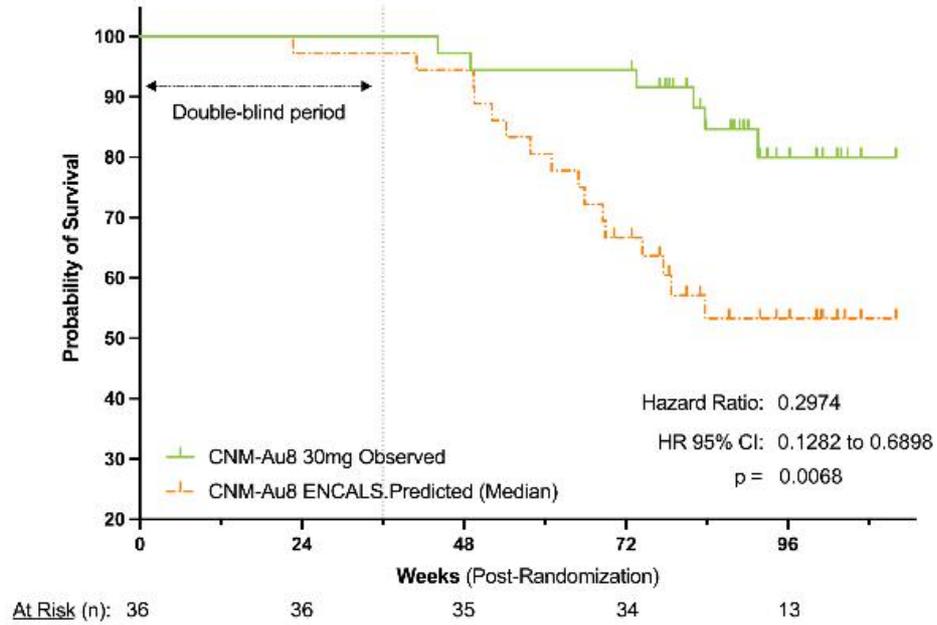
Significant slowing in disease progression & ALSFRS-R 6-point decline



Significant improvement in quality of life

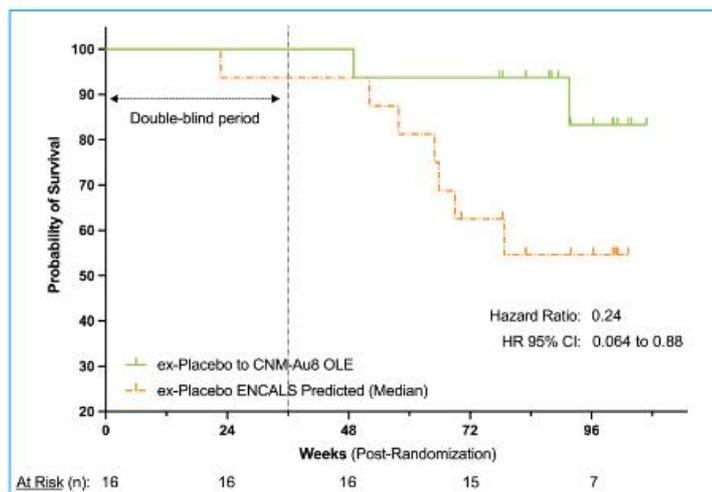
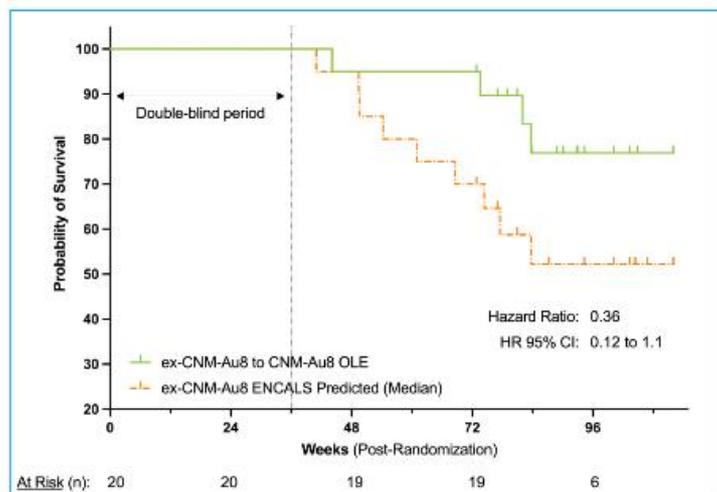


Long-Term Survival in OLE Participants: 70% Improvement vs. Predicted Survival



- All OLE participants. Data censored as of 10-March-2022. Vital status and date of death (as applicable) captured for all subjects withdrawn from the study. ENCALS median survival estimate from baseline characteristics.

Consistent Survival Effect in ex-Placebo Participants



- All OLE participants. Data censored as of 10-March-2022. Vital status and date of death (as applicable) captured for all subjects withdrawn from the study. ENCALS median survival estimate from baseline characteristics.

Conclusions

- Well tolerated and safe in ALS
- Evidence of CNM-Au8 therapeutic activity:
 - Evidence for improved survival
 - Significant reduction in functional decline
 - Significant slowing in disease progression
 - Improvement in quality of life