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 17, 2024

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 Salt Lake City, Utah	**84121**
(Address of principal executive offices)	(Zip Code)

(801) 676-9695

(Registrant's telephone number, including area code)

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 the evening of June 17, 2024, Clene Inc. (the "Company") presented a poster (the "Poster") at the 2024 ENCALS Meeting. The Poster discusses clinical results of CNM-Au8® treatment in the HEALEY ALS Platform Trial open label extension ("OLE") for amyotrophic lateral sclerosis ("ALS"). A copy of the Poster 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 8.01 Other Events.

On June 18, 2024, the Company issued a press release announcing presentation of extended survival data through 3.5 years and new neurofilament light ("NfL") responder results with CNM-Au8 30 mg treatment from the HEALEY ALS Platform Trial OLE at the 2024 ENCALS Meeting. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	HEALEY ALS Platform Trial OLE Poster.
99.2	Press release, dated June 18, 2024, announcing Clene presents extended survival data through 3.5 years and new NfL responder results with CNM-Au8 30 mg treatment from the HEALEY ALS Platform Trial open label extension at the 2024 ENCALS Meeting.
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 18, 2024

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

Long-Term CNM-Au8 Treatment Reduces Neurofilament Light Levels and Improves Survival: Results from the HEALEY ALS Platform Trial

HEALEY ALS Platform Trial

Marjan Sepassi, PharmD; James D. Berry, MD, MPH; Nicholas Maragakis, MD; Sabrina Paganoni, MD, PhD; Melanie Quintana, PhD; Eric A. Macklin, PhD; Benjamin R. Saville, PhD; Jinsy Andrews, MD; Jeremy Shefner, MD, PhD; Elijah Stommel MD, Meghan Hall; Mariah Connolly; Gale Kittle; Marianne Chase; Alex Sherman; Hong Yu; Lindsay Pothier; Kristin Drake, MBA; Lori Chibnik, PhD, MPH; Austin Rynders, RN; Jacob Evan, PA-C, Jeremy Evan, Karen S. Ho, PhD; Kyle McBride, MS; Alan Hartford, PhD; Robert Glanzman, MD FAAN; Benjamin Greenberg, MD; Merit E. Cudkowicz, MD; Michael T. Hotchkin; for the HEALEY ALS Platform Trial Study Group

CONCLUSIONS: Long-Term CNM-Au8 30mg Treatment Resulted in 1) Improved Survival vs. PRO-ACT Matched Controls, and 2) Decreased Plasma NfL Levels; NfL Decreases Were Greatest In Participants With Higher Baseline Levels (≥ Median)

NfL Analysis Methods

Plasma NfL was tested by the Quanterix Simoa Neurology 4-PLEX A assay. Change from baseline by treatment group was analyzed as the least-squares mean (LS mean) change of the natural logarithm (Ln) of the plasma NfL values (delta-Ln units).

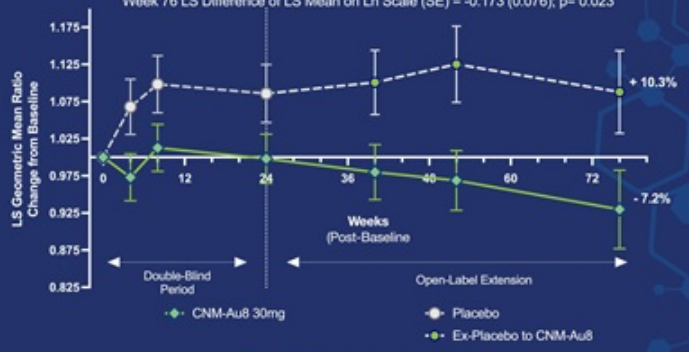
Analyses by mixed model repeated measures (MMRM) with prespecified covariates including: (i) pre-treatment ALSFRS-R slope (delta-FS), (ii) months from symptom onset, (iii) use of riluzole, (iv) use of edaravone; (v) treatment by visit interaction. All visits graphed with n ≥ 10 participant data.

Survival Analysis Methods

Propensity score matching methods were prespecified and matching was conducted by an independent statistician blinded to survival outcomes. Nearest neighbor matching with a caliper of 0.2 was used based on the following pre-treatment (baseline) covariates: (i) age at onset, (ii) site of onset (bulbar or limb), (iii) TRICALS risk score, (iv) sex, (v) ALSFRS-R pre-treatment slope (delta-FS), (vi) body mass index (BMI), and (vii) diagnostic delay (in months). All participants exposed to CNM-Au8 30mg, including ex-placebo to OLE, with complete evaluable baseline covariates, were included (n=70).

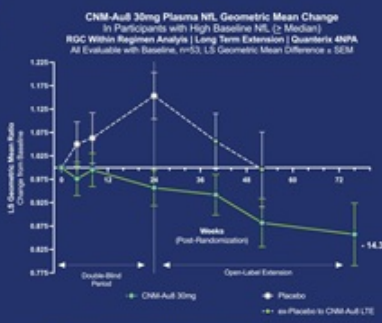
Pre-specified covariates associated with survival risk were included in the cox model: (i) age at disease onset, (ii) sex, (iii) BMI, (iv) delta-FS, (v) ALSFRS-R Total Score, (vi) diagnostic delay (in months), (v) vital capacity (% predicted), (vi) vital capacity slope, and (vii) TRICALS risk score. Participants were right censored at last observed value (PRO-ACT) or through March/April 2024 (HEALEY).

Long-Term NfL Decline (All Evaluable)

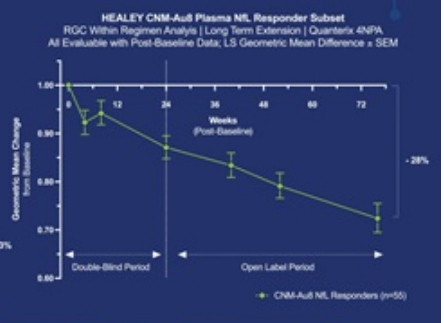


Long-Term NfL Decline by Subset

Baseline NfL ≥ Median



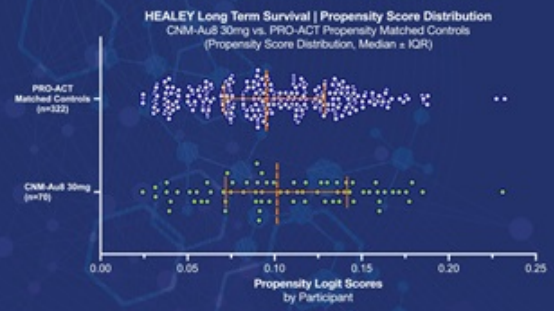
CNM-Au8 NfL Responder Subset[2]



2. NfL responders were defined all participants with consistent repeated post-baseline declines of at least 10 pg/mL, or with all post-baseline values declined

Propensity Match Logit Scores Were Balanced

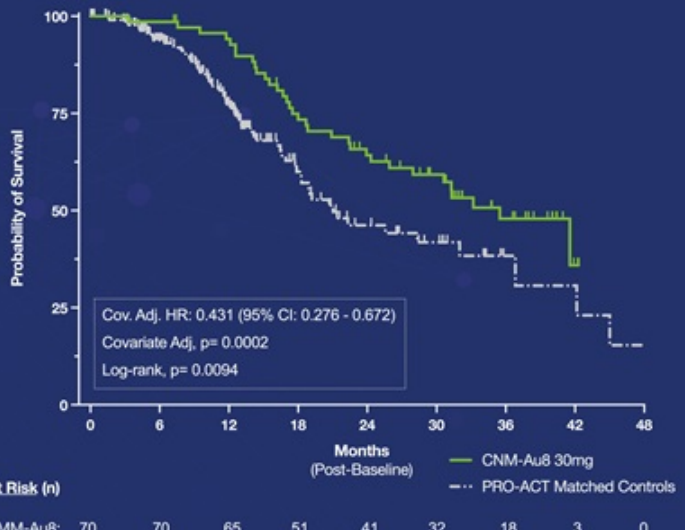
Supporting the validity of the matched set for survival analyses



Sensitivity Analyses Demonstrated Consistent Evidence Supporting a Survival Benefit

Sensitivity Analyses: With Additional Matching Covariates	Primary Covariate Model [1]	Added Matching Covariate: Time from Symptom Onset	Added Matching Covariates: Both Time from Symptom Onset and Observation Time
Covariate Adjusted HR (95% Wald CI)	0.431 (0.276 -0.672)	0.399 (0.252 -0.631)	0.551 (0.359 – 0847)
Covariate-adjusted p-value	p= 0.0002	p <0.0001	p= 0.007
Unadjusted Cox HR (95% Wald CI)	0.574 (0.376 - 0.876)	0.542 (0.352 -0.833)	0.692 (0.461 – 1.039)
Log-rank, p-value	p = 0.0094	p = 0.0048	p = 0.074

CNM-Au8 30 mg Treatment vs. PRO-ACT Matched Controls



At Risk (n)

CMM-Au8:	70	70	65	51	41	32	18	3	0
Matched Controls:	322	259	174	43	25	16	6	5	3

1. Primary covariate model: (i) age at disease onset (p<0.0001), (ii) sex (p=0.276), (iii) BMI (p=0.01), (iv) delta-FS (p=0.185), (v) ALSFRS-R Total Score (p=0.344), (vi) diagnostic delay (p=0.698), (v) vital capacity (% predicted) (p=0.005), (vi) vital capacity slope (p=0.808), and (vii) TRICALS risk score (p=0.778)

Acknowledgements: We acknowledge the altruism of the participants and the contributions of the participating sites of the NEALS Consortium. The HEALEY ALS Platform Trial was funded by the Sean M. Healey and AMG Center for ALS, the AMG Charitable Foundation, Tackle ALS, The ALS Association, ALS Finding a Cure®, Muscular Dystrophy Association, ALS One, Arthur M. Blank Family Foundation, I AM ALS, Tambourine and many other community fundraising initiatives and donors. Partial funding was also provided by UCB Pharma, Biohaven Pharmaceuticals, Clene Nanomedicine Inc., and Prilenia Therapeutics.

Clene NANOMEDICINE

Exhibit 99.2

Clene Presents Extended Survival Data Through 3.5 Years and New NfL Responder Results with CNM-Au8® 30 mg Treatment from the HEALEY ALS Platform Trial Open Label Extension at the 2024 ENCALS Meeting

- *Survival analyses with CNM-Au8 30 mg treatment compared to matched PRO-ACT controls demonstrated* ***improved survival up to 3.5 years post-baseline (hazard ratio: 0.431, p=0.0002)***
- ***Average of 28% NfL reduction observed in an NfL responder subset*** *(geometric mean ratio, change at Week 76 post-baseline: 0.72, p<0.0001)*
- *More than 650 patient years of CNM-Au8 treatment exposure without any identified safety signals*

SALT LAKE CITY, June 18, 2024 -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., a clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today presented new long-term CNM-Au8 treatment results for survival and neurofilament light (NfL) levels from the HEALEY ALS Platform Trial open label extension (OLE) at the European Network for the Cure of ALS (ENCALS) meeting in Stockholm, Sweden.

The data presentation, titled ***"Long-Term CNM-Au8 Treatment Reduces Neurofilament Light Levels and Improves Survival: Results from the HEALEY ALS Platform Trial,"*** highlights up to 42 months (3.5 years) of survival follow-up and 76 weeks of long-term NfL biomarker results, including a responder subset from the HEALEY ALS Platform Trial in participants with ALS. All participants treated with CNM-Au8 30 mg, including ex-placebo participants who transitioned to CNM-Au8 in the OLE, with complete baseline co-variates were included in the survival analysis.

Improved Survival Compared to Matched PRO-ACT Controls:

Survival analyses of participants originally randomized to CNM-Au8 30 mg treatment (n=59) and ex-placebo to CNM-Au8 (n=11) compared to matched PRO-ACT controls up to 3.5 years post-baseline.

- **Approximately 60% decreased risk of death in CNM-Au8 30 mg treated patients compared to matched PRO-ACT controls** up to 3.5 years of follow-up; covariate-adjusted hazard ratio: 0.431 (95% CI: 0.276-0.672), **p-value = 0.0002**

Reduced Neurofilament Light Biomarker Levels (NfL) in NfL Responders:

NfL Responder Subset: The NfL responder analysis was completed to identify NfL decreases in participants who showed consistent NfL declines (n=55). Responders were defined as participants who had all post-baseline measures with an NfL decrease or repeated declines of at least 10 pg/mL following the start of CNM-Au8 treatment:

- **Responders demonstrated an average NfL reduction of 28%, which is suggestive of decreased axonal loss on an ongoing basis**; GMR at Week 76 change vs. baseline: 0.72, (95% CI: 0.67 – 0.79), p<0.0001

The NfL results are based on earlier announced analyses of plasma NfL collected from participants (n=99) in the HEALEY OLE who were treated with CNM-Au8 30 mg through week 76 compared to participants treated with placebo for 24 weeks prior to crossing over to active treatment for up to 52 weeks. Long-term treatment with CNM-Au8 30 mg resulted in continued significant decline of plasma NfL levels. The geometric mean ratio (GMR) vs. placebo at week 76 was 0.841, 95% CI: 0.73 – 0.98, p=0.023.

CNM-Au8 was safe and well-tolerated during the OLE.

Benjamin Greenberg, M.D., Head of Medical at Clene, said, "The clinical evidence of plasma neurofilament reduction, as well as the long-term improved survival results up to 3.5 years compared to an established multi-study ALS dataset of more than 12,000 patients across multiple clinical centers provides further evidence to strongly support CNM-Au8 as a potential treatment for ALS."

The poster is now available in the Scientific Posters & Presentations section of the Clene website.

About Clene

Clene Inc., (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., is a late clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis, Parkinson's disease and multiple sclerosis. CNM-Au8® is an investigational first-in-class therapy that improves central nervous system cells' survival and function via a mechanism that targets mitochondrial function and the NAD pathway while reducing oxidative stress. CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc. The company is based in Salt Lake City, Utah, with R&D and manufacturing operations in Maryland. For more information, please visit www.clene.com or follow us on X (formerly Twitter) and LinkedIn.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, which are intended to be covered by the "safe harbor" provisions created by those laws. Clene's forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements represent our views as of the date of this press release and involve a number of judgments, risks and uncertainties. We anticipate that subsequent events and developments will cause our views to change. We undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include our ability to demonstrate the efficacy and safety of our drug candidates; the clinical results for our drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; our ability to achieve commercial success for our drug candidates, if approved; our limited operating history and our ability to obtain additional funding for operations and to complete the development and commercialization of our drug candidates; and other risks and uncertainties set forth in "Risk Factors" in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements. All information in this press release is as of the date of this press release. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this press release.

Contacts:

Media Contact
Ignacio Guerrero-Ros, Ph.D., or David Schull
Russo Partners, LLC
Ignacio.guerrero-ros@russopartnersllc.com
David.schull@russopartnersllc.com
(858) 717-2310

Investor Contact
Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com
617-283-2856