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): October 23, 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-fortieth of one share of Common Stock for $230.00 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 October 23, 2024, Clene Inc. (the "Company") presented the preliminary design for RESTORE-ALS, an international Phase 3 clinical trial of CNM-Au8 30 mg, at the 2024 Annual Northeast Amyotrophic Lateral Sclerosis Consortium ("NEALS") Meeting. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report") 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	RESTORE-ALS Presentation.
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: October 23, 2024

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

RESTORE-ALS
Phase 3 Trial Design

RestoreALS

Steve Vucic PhD, DSc, FRACP[1], Benjamin Greenberg MD MHS FANA FAAN CRND[2], Austin Rynders RN[2], Marjan Sepassi PharmD[2], Karen S. Ho PhD[2], Jeremy Evan PA-C[2], Jacob Evan[2], Kyle McBride[3], Alan Hartford PhD[2], Michael Hotchkin[2], Merit Cudkowicz MD MPH[4].
[1]Concord Repatriation General Hospital, University of Sydney; [2]Clene Nanomedicine; [3] Veristat Clinical Research; [4]Chief, Neurology Department Director, Sean M. Healey & AMG Center for ALS, Director and the Julieanne Dorn Professor of Neurology at Harvard Medical School

Objective: to investigate the effects of CNM-Au8 on survival and delayed clinical worsening events in ALS

Participant criteria: ALS diagnosis per Gold Coast criteria; symptom onset within 36 months of the Screening visit; ≥ 60% predicted vital capacity; TRICALS Risk Score: -2.5 to -6.5

Investigational Product **CNM-Au8 30 mg** randomized 2:1 (or matched placebo)

Study Center(s): Expert ALS centers

- ❑ North America
- ❑ Europe
- ❑ Australia
- ❑ Asia/Pacific

Design Scheme

- Interim Futility analysis at 50% and 75% of events
- Interim efficacy at 75% of events

Screening (~6 weeks)

Event Driven Trial
Double-blind Treatment Period Until 190 Events Accrue
CNM-Au8 30mg or Placebo
(Planned: n=561; n=374 active, n=187 placebo)

Open Label Extension
Continued until study is terminated or study drug is approved

End of Study Safety Follow-up
(4-weeks)

Enrollment Criteria

Key Inclusion Criteria:

1. Aged ≥ 18 years at the Screening
2. Confirmed diagnosis of ALS per Gold Coast criteria
3. Time since onset of ALS symptoms ≤ 36 months
4. Upright forced vital capacity (FVC) ≥ 60% of predicted
5. TRICALS risk score (6-factor model) range: -2.5 to -6.5
6. Screening biofluid (plasma) NfL ≥ 45 pg/mL
7. Stable background treatment (e.g., riluzole, edaravone, both)

Key Exclusion Criteria:

1. Presently use or at risk of needing: (i) Feeding tube, (ii) NIV, or (iii) Tracheostomy
2. Clinically significant findings on standard renal, hepatic, hematologic panels
3. Nonstable background treatment; treatment with antisense oligonucleotides
4. Allergy to gold

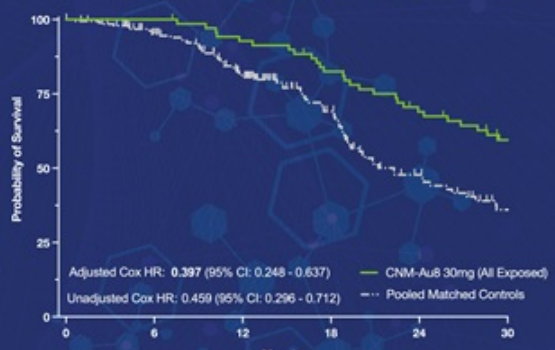
Methods, Statistics, and Powering

- Enrollment plan: approximately 561 randomized participants
  - 2:1 treatment allocation (CNM-Au8 30 mg: Placebo)
- Primary endpoint: delayed time to death (all-cause mortality)
  - Assumed hazard ratio (HR) of 0.625
  - One-sided alpha < 0.025; Power = 87% with 190 events
- Statistical model: Covariate adjusted cox proportional hazard
- Randomization Stratification factors:
  - Screening biofluid (plasma) NfL level: < 110 pg/mL versus ≥ 110 pg/mL
  - Symptom onset age: < 50 years versus ≥ 50 years
  - BMI < 25 kg/m² versus ≥ 25 kg/m²
- Secondary endpoints:

  (i) Time to death or death equivalent (PAV), (ii) Composite ALS clinical worsening hierarchy, (iii) joint-rank of time to death or PAV and ALSSQOL-SF change to Week 72, (iv) joint-rank of time to death or PAV and ALSFRS-R change to Week 72, (v) joint-rank of time to death or PAV and ROADs change to Week 72, (vi) joint-rank of time to death or PAV and SVC% change to Week 72

Survival Effect Planning Considerations

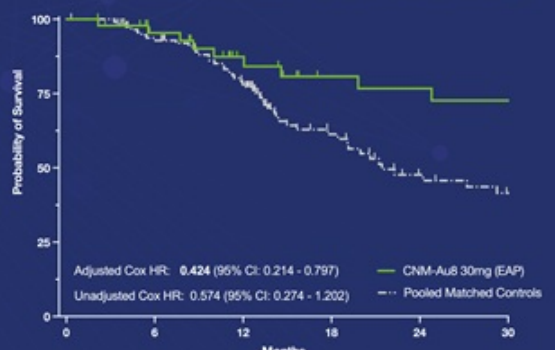
RESTORE-ALS Treatment Effect Scenario (Clinical)
Pooled CNM-Au8 30 mg (RESCUE-ALS & HEALEY ALS Platform Trial)
All CNM-Au8 30 mg Exposed and Meeting Key* RESTORE Inclusion Criteria vs.
Propensity Matched Controls (Pooled PRO-ACT, ALS NHC, ANSWER-ALS)



At Risk						
CNM-Au8:	70	70	64	56	45	34
Matched Controls:	194	166	128	68	40	24

*Key Inclusion Criteria: VC% predicted > 60%, TRICALS: -2.5 to -6.5, Onset ≤ 36 months; 1:3 Match

RESTORE-ALS Treatment Effect Scenario (Expanded Access Programs)
Pooled EAP01 and EAP02 That Met Key* RESTORE Inclusion Criteria vs.
Propensity Matched Controls (Pooled PRO-ACT, ALS NHC, ANSWER-ALS)



At Risk						
CNM-Au8:	47	37	27	20	19	18
Matched Controls:	117	102	79	39	24	19

*Key Inclusion Criteria: VC% predicted > 60%, TRICALS: -2.5 to -6.5, Onset ≤ 36 months; 1:3 Match

Acknowledgements: We thank the RESTORE-ALS Steering Committee and key ALS advisors who have contributed to the planning and design of the RESTORE-ALS trial. We are indebted to the participants and investigators of the HEALEY ALS Platform Trial and the RESCUE-ALS trial whose contributions have led to the design of the RESTORE-ALS trial.

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