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): September 21, 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 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 September 21, 2022, Clene Inc. (the "Company") presented updated interim data from the RESCUE-ALS clinical trial long-term open label extension in a poster at the American Association of Neuromuscular & Electrodiagnostic Medicine ("AANEM") Annual Meeting, taking place September 21-24, 2022. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Poster presentation, dated September 21, 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: September 21, 2022

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

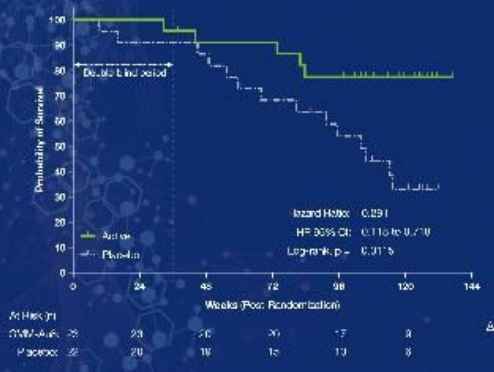
Evidence for A Survival Benefit with CNM-Au8 Treatment: Interim Results from the RESCUE-ALS Trial Long-Term Open Label Extension

RESCUEALS
Long-Term OLE

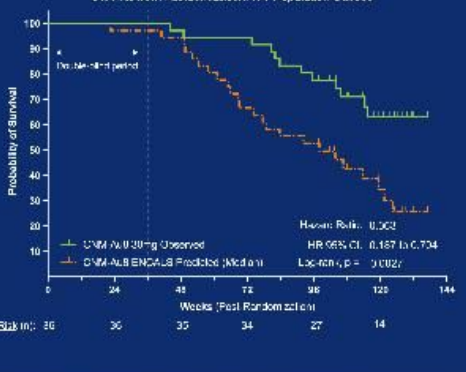
Steve Vucic PhD, DSc, FRACP, FAHMS, Parvathi Menon PhD, FRACP[1], William Huynh PhD, FRACP[2], Colin Mahoney, PhD, MB, MRCPP, Karen S. Ho, PhD MSc[3], Austin Rynders, RN[3], Jacob Evan[3], Jeremy Evan, PA-C, Robert Glanzman, MD FAAN[3], Michael T. Hotchkin[3], Matthew C. Kiernan PhD, DSc, MBBS, FRACP, 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 improved long-term survival with decreased mortality risk >70% vs. original placebo randomization, and compared to ENCALS predicted median survival

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



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



Study Design Scheme

- Early symptomatic ALS (within 2-years onset or 1-year diagnosis)
- Randomized (1:1, CNM-Au8 30 mg or placebo)

Participant Vital Status by Treatment Group

Notes: Time to all-cause mortality amongst participants originally randomized to CNM-Au8 compared to participants originally randomized to placebo through 31-Aug-2022. Vital status and date of death (as applicable) were 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). All OLE ex-placebo CNM-Au8 transitioned participants within the placebo group. All alive subjects are right censored as of 31-Aug-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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