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 18, 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 April 14, 2022, an article regarding plans of Clene Inc. (the "Company") to initiate a Phase 3 clinical trial, RESTORE-ALS, was published at the following link:

https://www.clinicaltrialsarena.com/news/als-clene-plans-300-patient-phase-iii-trial-of-cnm-au8/.

The Company is preparing preliminary concepts for a future Phase 3 trial in amyotrophic lateral sclerosis ("ALS") consistent with EMA and U.S. regulatory guidance, including the ongoing formation of a steering committee of ALS experts to guide study design. However, the Company has not filed a study protocol with the FDA or any other regulatory authority. The Company does not anticipate initiating a clinical trial in ALS until the results of the Phase 2/3 Healey ALS Platform Trial are available for its lead drug candidate, CNM-Au8®, which is anticipated in the second half of 2022. Additionally, there have been no commitments made with respect to such future clinical trial at this time.

The information furnished in this Item 7.01 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.

Forward-Looking Statements

This Current Report on Form 8-K may contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. The forward-looking statements include, but are not limited to, our expectations, hopes, beliefs, intentions, strategies, estimates and assumptions concerning events and financial trends that may affect our future results of operations or financial condition. 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," "could," "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. The forward-looking statements are based on information available as of the date of this report and our management's current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. As a result of a number of known and unknown risks and uncertainties, our actual results and the timing of events may differ materially from those expressed or implied by these forward-looking statements due to a number of factors. Applicable risks and uncertainties include those related to the possibility that any results of operations and financial condition of the Company are preliminary and subject to final audit, and the risks listed under the heading "Risk Factors" and elsewhere in our Annual Report on Form 10-K filed on March 11, 2022, and our subsequent filings with the U.S. Securities and Exchange Commission. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. We disclaim any 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 specifically required under applicable securities laws.

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 18, 2022

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

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