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): March 9, 2023

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** (Address of Principal Executive Offices)	**84121** (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 8.01 Other Events.

On March 9, 2023, Clene Inc. (the "Company") issued a press release announcing new results for CNM-Au8® in the HEALEY ALS Platform Trial. A copy of the press release is filed as Exhibit 99.1 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	Press release, dated March 9, 2023, announcing CNM-Au8 associated with delayed time to key clinical progression events at six months supporting a survival benefit in the HEALEY ALS Platform Trial.
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: March 9, 2023

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

Exhibit 99.1

CNM-Au8® ASSOCIATED WITH DELAYED TIME TO KEY CLINICAL PROGRESSION EVENTS AT SIX MONTHS SUPPORTING A SURVIVAL BENEFIT IN THE HEALEY ALS PLATFORM TRIAL

- ***CNM-Au8 associated with a 74% lower risk (lower hazard ratio) of ALS clinical worsening, which included death, non-invasive ventilation >22 hours per day, tracheostomy, or feeding tube placement (p = 0.035)***
- ***CNM-Au8 associated with a 98% lower risk of death or permanent assisted ventilation (p= 0.028)***
- ***CNM-Au8 associated with a 74% lower risk of feeding tube placement (p= 0.035)***
- ***CNM-Au8 associated with a 63% lower risk of initiation of assisted ventilation (p= 0.058)***
- ***CNM-Au8 treatment was well-tolerated without significant safety concerns***

Clene will host a live audio webcast at 7:30 a.m. EST today to review these new clinical results.

SALT LAKE CITY, March 9, 2023 -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative diseases, today announced new results from exploratory analyses including delayed time to key clinical progression events in people living with amyotrophic lateral sclerosis (ALS) who were treated with CNM-Au8® in the HEALEY ALS Platform Trial over the 6-months of the double-blind period.

"Analyses of prespecified exploratory endpoints from the HEALEY ALS Platform Trial suggest that treatment with CNM-Au8 delayed time to ALS clinical worsening events across all of the domains, including the need for assisted breathing and placement of stomach feeding tubes. When supported by a confirmatory trial, this would give people living with ALS longer periods of independence, which are precious to them and their families. The consistent nature of the efficacy signal for delayed clinical worsening is highly encouraging and provides new insights supporting the survival benefit seen with the 30mg dose of CNM-Au8. We plan to discuss these findings with the FDA in an end of Phase 2 meeting in order to seek a regulatory pathway towards approval for this significant unmet need," said Rob Etherington, Clene's CEO.

New Six-Month Findings from HEALEY ALS Platform Trial Regimen C (CNM-Au8):
Results are based on prespecified risk adjusted Cox proportional hazards analyses within the population for Regimen C, where treatment with CNM-Au8 30mg over 24-weeks was associated with:

- **A 74% decreased risk (lower hazard) of the composite endpoint of time to ALS clinical worsening**, which included the first instance of death, tracheostomy, initiation of permanent assisted ventilation (>22-hours per day of non-invasive ventilatory support), or placement of a feeding tube **(p = 0.035)**. Living longer, being independent of breathing support, and eating and drinking without a stomach feeding tube is important for ALS patients to lead more independent lives.

- **Treatment with CNM-Au8 was also associated with statistically significant and directional trends** across all prespecified time to clinical worsening event analyses:

    - 98% decreased risk (lower hazard) of death or permanently assisted ventilation **(p= 0.028)**
    - 95% decreased risk of death **(p= 0.053)**
    - 74% decreased risk of feeding tube placement **(p= 0.035)**
    - 63% decreased risk of assisted ventilation **(p= 0.058)**
    - 84% decreased risk of ALS-related hospitalization **(p= 0.107)**
    - 69% decreased risk of all-cause hospitalization **(p= 0.065)**

The reported p-values were not adjusted for multiple comparisons. Supportive sensitivity analyses incorporating baseline neurofilament light chain (NfL) levels were similarly robust and resulted in increased effect sizes and smaller nominal p-values in the same 'within regimen' analyses.

"These meaningful delays in clinical worsening, coupled with the previously suggested benefit in ALS patient survival and favorable tolerability profile of CNM-Au8 could prove to be profoundly beneficial to people living with ALS and their families," stated Merit Cudkowicz, M.D., Chief Neurology Department, Director, Sean M Healey & AMG Center for ALS, and the Principal Investigator of the HEALEY ALS Platform Trial. "We hope to see these results persist and strengthen over an even longer-term follow-up period for patients who have entered the open-label portion of the trial, and for those individuals who will participate in Clene's next ALS clinical trial."

“The results from the HEALEY Platform Trial suggesting an association of CNM-Au8 with delays in time to clinical decline, particularly at the 30mg dosage, provide ample rationale to continue its development in a Phase 3 ALS trial. We would like to thank the hundreds of people living with ALS and their loved ones and caregivers, who have dedicated themselves to participation in this trial, and we look forward to learning more about the impact of CNM-Au8 on ALS progression in the future,” stated James Berry, M.D., the co-lead investigator for Regimen C, which evaluated CNM-Au8.

Robert Glanzman, M.D. FAAN, Clene’s Chief Medical Officer, noted, “In addition to these highly encouraging delayed time to clinical worsening results, we will be analyzing disease progression based on validated biomarkers from both the double-blind and open label periods of the HEALEY ALS Platform Trial. We also plan to perform similar analyses of clinical worsening and survival beyond the six-month double-blind period. These data will inform the design of the planned Phase 3 trial with CNM-Au8, RESTORE-ALS. We sincerely thank the people living with ALS, as well as their families, for their willingness to engage in clinical research and participate in the HEALEY ALS Platform Trial.”

The HEALEY ALS Platform Trial is a perpetual multi-center, randomized, double-blind, placebo-controlled program designed to evaluate the efficacy and safety of multiple investigational products utilizing a shared placebo group in people living with ALS.

Clene will host a live audio webcast at 7:30 a.m. EST today, Thursday, March 9, to review these new clinical results.

Webcast Information
Title: Clene’s HEALEY ALS Platform Trial Data Update
Presenters: Clene and Merit Cudkowicz, M.D., Chief Neurology Department, Director, Sean M Healey & AMG Center for ALS
Date: March 9, 2023
Start Time: 7:30 a.m. ET
Webcast link: https://edge.media-server.com/mmc/p/e8xezoye

The archived webcast will be available on the Company's website beginning approximately two hours after the event.

About CNM-Au8®
CNM-Au8 is an oral suspension of gold nanocrystals developed to restore neuronal health and function by increasing energy production and utilization. The catalytically active nanocrystals of CNM-Au8 drive critical cellular energy producing reactions that enable neuroprotection and remyelination by increasing neuronal and glial resilience to disease-relevant stressors. CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc.

About Clene
Clene is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease by targeting energetic failure, an underlying cause of many neurological diseases. 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 Twitter, LinkedIn and Facebook.

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.

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