# 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 6, 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**<br>**Salt Lake City, Utah**<br>(Address of Principal Executive Offices) | **84121**<br>(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 6, 2023, Clene Inc. issued a press release announcing data from the open-label extension of the Phase 2 RESCUE-ALS clinical trial in amyotrophic lateral sclerosis. 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 6, 2022, announcing new data show CNM-Au8 preserved ALS patient function and slowed disease progression in the open-label extension of the Phase 2 RESCUE-ALS 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 6, 2023

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

**Exhibit 99.1**

**NEW DATA SHOW CNM-AU8® PRESERVED ALS PATIENT FUNCTION AND SLOWED DISEASE PROGRESSION IN THE OPEN-LABEL EXTENSION OF THE PHASE 2 RESCUE-ALS TRIAL**

- ***Significant preservation of function (ALSFRS-R) from randomization to 48 weeks (p=0.0159)***
- ***Significant preservation of function (ALSFRS-R) during the long-term open-label extension (OLE) week 24 to 120 weeks from randomization (p=0.0057)***
- ***Significantly reduced risk of ALS clinical worsening by 52% over 120 weeks (HR: 0.478, p=0.0494)***
- ***CNM-Au8 treatment was well-tolerated without long term safety concerns***

**SALT LAKE CITY, March 6, 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 showing preserved ALS patient functional score (ALSFRS-R) and delayed time to clinical worsening from the most recent 12-month data cut of the open-label extension (OLE) of the Phase 2 RESCUE ALS trial in people with early amyotrophic lateral sclerosis (ALS) treated with CNM-Au8®.

"Clene is pleased to report that CNM-Au8 preserved physical function in the long-term open-label portion of the Phase 2 RESCUE-ALS trial when given over 48-weeks as measured by the ALSFRS-R, a clinical assessment measuring activities such as walking, speaking, breathing, feeding, and dressing independently," said Rob Etherington, President and CEO of Clene. "Together with improved survival and slowing ALS clinical worsening, these functional changes are meaningful to people living with ALS."

Study participants in RESCUE-ALS were randomized 1:1 to receive 30 mg of CNM-Au8 or placebo daily for 36 weeks during the double-blind portion of the study, followed by an OLE period that extended treatment indefinitely. The trial randomized 45 participants (n=23 active treatment, n=22 placebo). Thirty-six participants continued into the OLE, including 20 of 21 eligible participants (95%) originally randomized to CNM-Au8, and 16 of 19 eligible (84%) participants originally randomized to placebo. The OLE analyses compared participants originally randomized to placebo who experienced a nine-month delay in treatment initiation with CNM-Au8 to participants treated daily with CNM-Au8 from randomization.

***New Findings from RESCUE-ALS OLE through 120 Weeks:***
The current data cut represents a 12-month minimum follow-up for OLE participants from the last-patient last-visit from the 36-week double-blind treatment period through July 14, 2022. The rates of change for ALSFRS-R were compared post hoc with a random slopes model.

- **Statistically significant difference in ALSFRS-R slope from day 1 (randomization) to week 48**: among participants originally randomized to active compared to participants originally randomized to placebo (**p=0.0159; 2.6-point difference in ALSFRS-R at week 48**). This represents an extension of the original double-blind period in which placebo-to-CNM-Au8 OLE participants had not yet reached effective drug concentrations.
- **Statistically significant difference in ALSFRS-R slope from week 60 to week 120** comparing participants originally randomized to active or placebo. Analyses were conducted starting at 24-weeks in open-label to ensure that ex-placebo participants who switched to CNM-Au8 in the OLE were at steady-state CNM-Au8 concentrations (**p=0.0057; 6.0-point difference in ALSFRS-R at week 120**).
- **Statistically significant delay in time to ALS clinical worsening** including death, tracheostomy, initiation of ventilatory support, or feeding tube insertion through 120 weeks (Cox **hazard ratio 0.478**, 95% CI: 0.225 to 1.015, log-rank **p=0.0494**). The risk of ALS progression was less than half for those originally receiving CNM-Au8 compared to those originally receiving placebo.

Professor Steve Vucic, PhD, DSc, Northcott Chair of Neurology, The University of Sydney, and a co-investigator of the RESCUE-ALS study, commented, "The totality of data generated from the CNM-Au8 ALS clinical program and the long-term patient benefits are highly encouraging. It is extraordinarily notable that a nine-month difference in treatment initiation with CNM-Au8 substantially preserved long-term function in patients originally receiving CNM-Au8 compared to patients originally receiving placebo during long-term follow-up. With its favorable tolerability profile and ability to be used alone or in combination with other ALS therapies, early treatment with CNM-Au8 may play an essential role in the treatment of ALS. We look forward to presenting these data at upcoming scientific congresses."

"The open-label data at 48 weeks and through 120 weeks from randomization suggests that CNM-Au8 has the ability to meaningfully improve patient daily functional status over longer periods of time, together with sustained treatment effects on ALS disease progression and survival," stated Professor Matthew Kiernan, PhD, DSc, Bushell Chair of Neurology, University of Sydney, and one of the trial's clinical advisors. "It is exciting to see such long-term data not only reinforcing the potential of CNM-Au8 as a therapy for ALS but also confirming its excellent safety profile."

These new data are summarized and posted at https://invest.clene.com/presentations/investor-presentation.

**About RESCUE-ALS**
RESCUE-ALS was a Phase 2 multi-center, randomized, double-blind, parallel-group, placebo-controlled trial, investigating the efficacy, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in 45 participants (73% limb onset, 27% bulbar onset) with early ALS over a 36-week treatment period. The primary endpoint was the percent change in the summated motor unit index (MUNIX) scores to week 36. The primary blinded comparative period was followed by an open-label extension (OLE) in which all participants received 30 mg of CNM-Au8 once-daily, with 90% (36 of 45 patients) entering the OLE. Clene announced topline results for RESCUE-ALS on November 2, 2021.

**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.

**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