# 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): February 24, 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**<br>**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 February 24, 2022, Clene Inc. (the "Company") issued a press release announcing presentation of data from two multiple sclerosis clinical trials at the Americas Committee for Treatment and Research in Multiple Sclerosis ("ACTRIMS") Forum 2022, taking place February 24-26, 2022. A copy of the press release and poster presentations are furnished as Exhibit 99.1, Exhibit 99.2, and Exhibit 99.3 to this Current Report on Form 8-K and are incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibit 99.1, Exhibit 99.2, and Exhibit 99.3, 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 | Press Release, dated February 24, 2022, announcing the presentation of data from two Phase 2 multiple sclerosis trials at ACTRIMS Forum 2022. |
| 99.2 | VISIONARY-MS poster, dated February 24, 2022. |
| 99.3 | REPAIR-MS poster, dated February 24, 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: February 24, 2022

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

**Exhibit 99.1**

# Clene Nanomedicine Presents Data from Two Phase 2 Multiple Sclerosis Trials at ACTRIMS Forum 2022

- *VISIONARY-MS Phase 2 blinded interim data suggest clinically relevant improvements in the modified MS Functional Composite for the study population through 48 weeks of treatment*
- *REPAIR-MS Phase 2 clinical trial demonstrated improved brain energetic metabolism following CNM-Au8® treatment*

SALT LAKE CITY, Feb. 24, 2022 – 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 disease, today announced the presentation of updated blinded interim data from its VISIONARY-MS study and results from its REPAIR-MS study in poster presentations at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2022, taking place Feb. 24-26, 2022, in West Palm Beach, Fla. These data further support Clene's lead drug candidate, CNM-Au8®, a catalytically active gold nanocrystal suspension, as a potential disease-modifying therapy for Multiple Sclerosis (MS).

The first poster, titled "***VISIONARY-MS: Update to a Phase 2 Clinical Trial of CNM-Au8, Catalytically Active Gold Nanocrystal Suspension, for the Treatment of Chronic Optic Neuropathy***," includes updated blinded data from the ongoing VISIONARY-MS Phase 2 clinical trial evaluating the efficacy and safety of CNM-Au8 as a remyelinating and neuro-reparative treatment in MS patients. In this Phase 2 study, the efficacy and safety of CNM-Au8 (15 mg or 30 mg daily) versus placebo is being evaluated in stable relapsing MS patients with chronic optic neuropathy who are currently receiving disease-modifying therapy (DMT).

Blinded analyses presented compared changes in the overall study population's modified Multiple Sclerosis Functional Composite (mod-MSFC) values over the 48-week treatment period to the baseline values of study participants with mild disease as defined by pre-treatment Expanded Disability Status Scale (EDSS) scores of 1.5 or less. Changes in the four mod-MSFC domains (low contrast letter acuity (LCLA), symbol digit modalities test (SDMT), 9-hole peg test (9HPT) and timed 25-foot walk test (T25FWT) were compared to baseline scores of the mild disease comparator group at Weeks 12, 24, 36, and 48. At each visit, the overall study population (randomized 2:1, active CNM-Au8 to placebo) mean standardized change showed increasing improvements for LCLA (primary endpoint, mixed-effects model; $p<0.0001$ vs. baseline); averaged MSFC scores (secondary endpoint, mixed-effects model; $p<0.0001$ vs. baseline); and individual MSFC domains, including SDMT ($p<0.0001$ vs. baseline), 9HPT dominant-hand ($p<0.001$ vs. baseline), and 9HPT non-dominant hand ($p<0.002$). These data support CNM-Au8's potential to drive meaningful neurological improvements in stable relapsing MS patients.

The second poster, titled "***Improvement of Brain Energy Metabolism in Relapsing Multiple Sclerosis Patients: Results from Phase 2 REPAIR-MS Clinical Trial With CNM-Au8***," demonstrated that, utilizing high-resolution magnetic resonance spectroscopy ($^{31}$P-MRS) in stable relapsing MS patients, CNM-Au8 showed CNS target engagement resulting in improved brain energetic metabolism.

In the pre-specified integrated analysis across two identical clinical trials (REPAIR-MS and REPAIR-PD), the results for the primary endpoint, mean change in brain $NAD^+$/NADH ratio (the ratio of the oxidized to reduced form of nicotinamide adenine dinucleotide), demonstrated a statistically significant increase of 10.4% (0.589 units) following 12-weeks of treatment with CNM-Au8 ($p=0.037$, paired t-test), with the REPAIR-MS trial itself demonstrating a 14.3% (0.8296 units) improvement ($p=0.14$, paired t-test). REPAIR-MS incorporated a third $^{31}$P-MRS scan following a six-week treatment washout, which demonstrated a return to baseline in mean NAD+/NADH ratio levels following withdrawal of CNM-Au8. Exploratory endpoints showed that CNM-Au8 administration resulted in normalization of several critical markers of brain energy production capacity, including beta-ATP levels ($r^2 = 0.71$, $p = 0.001$) and phosphorylation potential ($r^2 = 0.68$, $p = 0.002$).

"The results of the REPAIR-MS trial demonstrate the ability of CNM-Au8 to enter the brain and address energetic failure, a key driver in the pathophysiology of MS and other neurodegenerative diseases," said Dr. Robert Glanzman, FAAN, Chief Medical Officer at Clene. "These mechanistic results support the blinded interim VISIONARY-MS data, which we believe suggest that CNM-Au8 has the potential to drive clinically meaningful improvements in recognized MS functional endpoints when administered in addition to standard of care. We look forward to sharing the unblinded data from VISIONARY-MS in the second half of 2022 that will help inform the design of our next clinical trial in MS patients."

The posters are available on the Posters & Presentations section of the Clene website.

**About VISIONARY-MS**
VISIONARY-MS is a Phase 2 multi-center, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of CNM-Au8 for remyelination and neurorepair in stable relapsing multiple sclerosis (MS) patients with chronic visual impairment who are allowed disease-modifying therapy (DMT). The primary endpoint is improvement in Low Contrast Letter Acuity (LCLA) from baseline to week-24. Key secondary endpoints include improvements from baseline to week-24 in the remaining modified-Multiple Sclerosis Functional Composite (MSFC) subscales (Symbol Digit Modalities Test, 9-Hole Peg Test, and Timed 25-Foot Walk). Unblinded top-line data are targeted for the second half of 2022. For more information, see ClinicalTrials.gov Identifier: NCT03536559.

**About REPAIR-MS**
REPAIR-MS is a Phase 2 single-center, active-only, sequential group study examining the brain metabolic effects, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in patients diagnosed with multiple sclerosis (MS) within 15 years of screening. Investigators and participants are blinded to dose. Participants undergo 31P-MRS brain imaging scans to semi-quantitatively measure central nervous system (CNS) energetic metabolites at baseline, prior to administration of CNM-Au8, and following at least 12 weeks of exposure. The objective of the study is to demonstrate target engagement for CNM-Au8 on CNS biomarkers related to energetics and neuronal membrane stability in patients with MS. The study is conducted at the University of Texas Southwestern Medical Center with a team of internationally recognized experts in brain imaging and treatment of disorders of the CNS. For more information see ClinicalTrials.gov Identifier: NCT03815916.

**About CNM-Au8®, a gold nanocrystal suspension**
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” which are intended to be covered by the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Clene’s actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as “expect,” “estimate,” “project,” “budget,” “forecast,” “anticipate,” “intend,” “plan,” “may,” “will,” “could,” “should,” “believes,” “predicts,” “potential,” “might” and “continues,” and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant known and unknown risks and uncertainties, many of which are beyond Clene’s control and could cause actual results to differ materially and adversely from expected results. Factors that may cause such differences include Clene’s ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its 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; Clene’s ability to achieve commercial success for its marketed products and drug candidates, if approved; Clene’s ability to obtain and maintain protection of intellectual property for its technology and drugs; Clene’s reliance on third parties to conduct drug development, manufacturing and other services; Clene’s limited operating history and its ability to obtain additional funding for operations and to complete the licensing or development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on Clene’s clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled “Risk Factors” in Clene’s Annual Report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in Clene’s subsequent filings with the U.S. Securities and Exchange Commission. Clene undertakes no obligation to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, subject to applicable law. 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**
Erica Fiorini, Ph.D., or David Schull
Russo Partners, LLC
Erica.fiorini@russopartnersllc.com
David.schull@russopartnersllc.com
+1-212-845-4253

**Investor Contact**
John Woolford
Managing Director, Westwicke
clene@westwicke.com
+1-443-213-0506

# VISIONARY-MS Blinded Interim Data Update

VISIONARY-MS STUDY

P113

## Treatment of Visual Pathway Deficits In Chronic Optic Neuropathy for Assessment of Remyelination in Stable RMS

H. Beadnall[1], A. Klistorner[3], M. Barnett[3], R. Sergott[4], A. Rynders[2], K.S. Ho[2], M. Mortenson[5], R. Glanzman[2], M. Hotchkin[2]

[1]Sydney Brain Mind Centre and Royal Prince Alfred Hospital, University of Sydney, Australia. [2]Clene Nanomedicine, Salt Lake City, UT. [3]Sydney Neuroimaging Analysis Centre, Sydney, Australia. [4]Annesley EyeBrain Center at Thomas Jefferson University Partnered with Wills Eye Hospital, Philadelphia, PA. [5]Clene Nanomedicine, North East, MD.

**Best Corrected Low Contrast Letter Acuity (OD/OS)**

Scale 2.5% Contrast (2 meter)

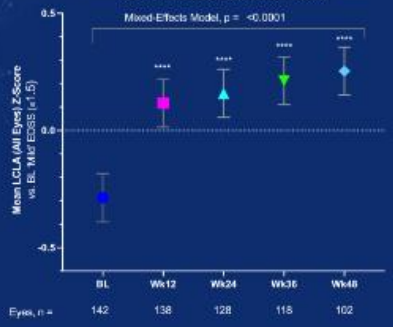
**Symbol Digit Modalities Test** (Cognition)

**9-Hole Peg Test (D/ND)**

**Timed 25-Foot Walk**

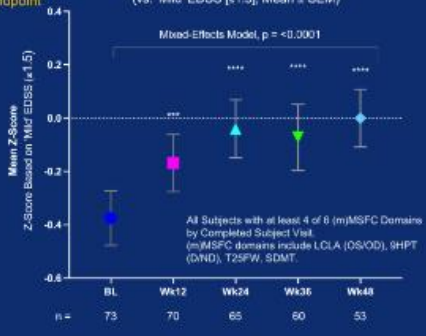

LCLA (Primary Endpoint)

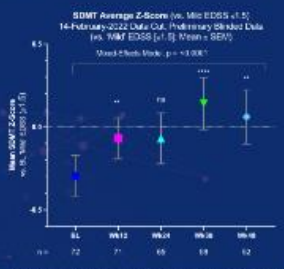
**LCLA (All Eyes) Average Z-Score**
14-February-2022 Data Cut, Preliminary Blinded Data
(vs. 'Mild' EDSS [≤1.5]; Mean ± SEM)

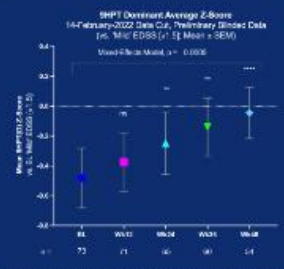


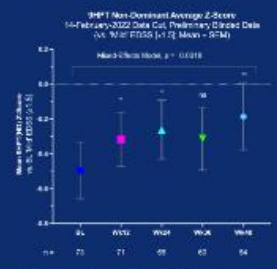

(m)MSFC Secondary Endpoint

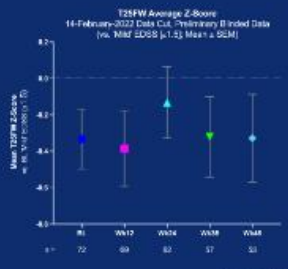
**(m)MSFC 6-Component Average Z-Score**
14-February-2022 Data Cut, Preliminary Blinded Data
(vs. 'Mild' EDSS [≤1.5]; Mean ± SEM)




- Design: Randomized Double-Blind Placebo Controlled Trial (1:1:1, 30mg, 15mg, Placebo)
- Safety: No treatment related SAEs, TEAEs predominantly mild-to-moderate and transient
- Conclusion: Blinded data show clinically relevant improvements across LCLA & modified-MSFC domains

Notes: Mixed Effects Model, Dunnett's test for multiplicity: * p<0.05, ** p<0.01, *** p<0.001, **** p<0.0001. Z-Score based on Baseline value for EDSS with 'Mild' Severity (e.g., BL Low EDSS [≤1.5]) for each domain. (m)MSFC is the modified MS Functional composite (Low contrast letter acuity (LCLA), 9-hole peg test (9HPT), Timed 25-foot walk (T25FW), and Symbol digit modalities test (SDMT)). All available data in EDC.

clene NANOMEDICINE

# Improvement of Brain Energy Metabolism in Relapsing MS Results from Phase 2 REPAIR-MS Clinical Trial With CNM-Au8

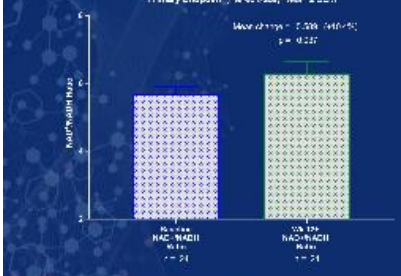
RepairMS P100

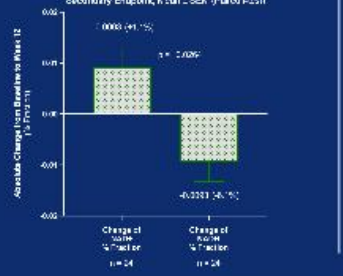
Robert Glanzman[1], Jimin Ren[2], Austin Rynders[1], Karen S. Ho[1], Michael T. Hotchkin[1] Benjamin Greenberg[2]

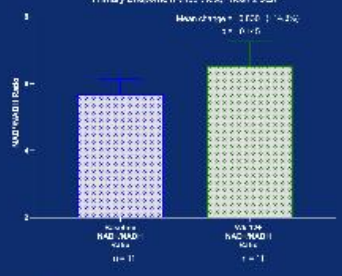
*[1]Cleine Nanomedicine, Inc. Holladay, UT/United States of America, [2]UT Southwestern, Dallas, TX/United States of America*

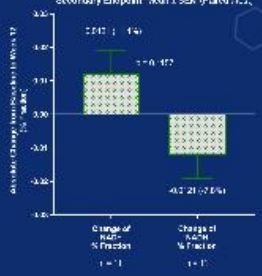
Improved NAD+/NADH Ratio

Primary Endpoint

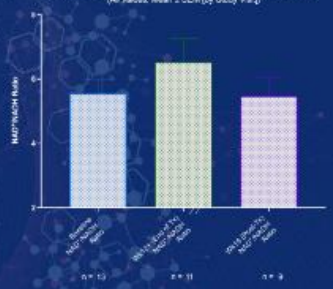


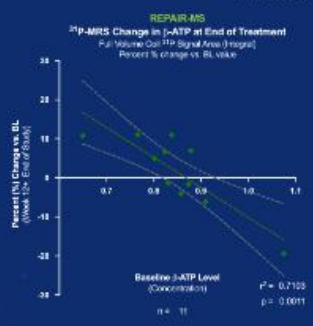



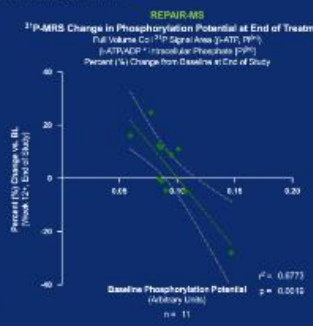




Post-Treatment Washout Returned NAD+/NADH to Baseline Levels




Improved Key Indices of Energetic Potential




Design: Open-label, dose blinded 12-week treatment (n=13)

Safety: No SAEs; TEAEs were all mild-to-moderate severity and transient

Results:

- Statistically significant increase in NAD⁺/NADH ratio based on pre-specified integrated analyses of PD & MS cohorts
- MS population trend in brain NAD⁺/NADH ratio improvement driven by increased NAD⁺ and decreased NADH
- CNM-Au8 treatment equilibrated key markers of brain metabolism
- Demonstration of CNS target engagement