

**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 23, 2023

CLENE INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39834
(Commission File Number)

85-2828339
(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 7.01 Regulation FD Disclosure.

On February 23, 2023, Clene Inc. (the “Company”) presented data from the VISIONARY-MS clinical trial in a poster at the Americas Committee for Treatment and Research in Multiple Sclerosis Forum 2023, taking place February 23-25, 2023. 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	Presentation, dated February 23, 2023.
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 23, 2023

By: /s/ Robert Etherington

Robert Etherington

President and Chief Executive Officer

CNM-Au8 Phase 2 VISIONARY-MS Trial Results



ACTRIMS 2023

Head: Bradual MBBS FRACP PhD¹, Alexander Kilian MD², Robert Sargin MD³, Benjamin Grossberg MD MSc FRAC-ORND⁴, Austin Rindler MD⁵, Karen S. Ho PhD⁶, Jacob Esau⁷, Jeremy Evan PA-C⁸, Ryan McEider⁹, Kyle McEider¹⁰, Alan Hartford PhD¹¹, Robert Gianman MD DABM¹², Michael Hochman¹³, Michael Bennett MBBS FRACP PhD¹⁴
¹Brain and Mind Centre, University of Sydney, Camperdown, NSW, Australia; ²Thomas Jefferson University Kennedy Krieger Center, Philadelphia, PA, USA; ³UT Southwestern Medical Center, Dallas, TX, USA; ⁴Clinic NeuroMedicine, Inc., Salt Lake City, UT, USA; ⁵Head Clinical Research, Chatham, New Jersey, USA

CONCLUSION | CNM-Au8 improved neurological function in stable RMS patients adjunctive to DMTs; Paraclinical MRI and VEP improvements support clinical benefits

Design Overview | Phase 2 Study: 48-Week Placebo-Control Treatment Period

- 2:1 Randomization (Active [15mg, 30 mg]: Placebo)
- Enrolled stable relapsing remitting MS participants with chronic optic neuropathy on background DMTs (45% treated with DMT, 55% immunosuppressant/active therapy, 12% none)
- ~1/3 of LSQ planned – study ended prematurely due to COVID pandemic-related enrollment challenges
- Prospective statistical threshold set at p<0.05, combined CNM-Au8 doses presented (15mg & 30mg)



Baseline Value (mean ± SD)	Age (SD)	Sex (% Female)	Race (% White)	Weight (SD)	DMT (SD)	Time From Onset (SD)	Months Since Relapse
144.8 ± 16.2	44.5 ± 10.5	68%	82%	76.8 ± 17.1	1.85 ± 0.35	6.5 ± 10.15	1.5
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1st EP

Change in Low Contrast Acuity (iCLA)

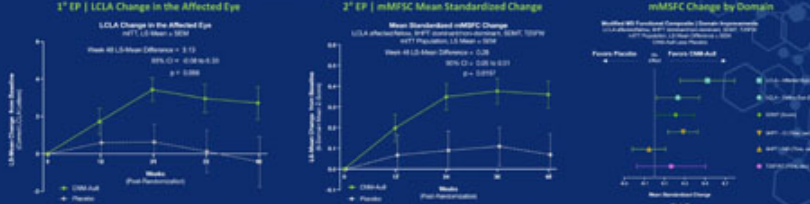
2nd EP

Change in modified MS Functional Composite (mMSFC, 6-domain)

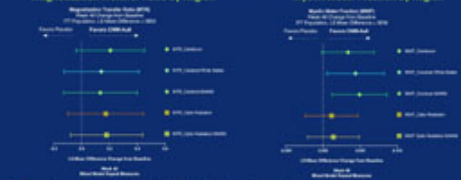
mMTT Population: unselected observations included

- Change in mobility assist device usage (to walking) for T25FW (only)
- Invalid data from 1 of 11 sites (only with iCLA, testing association across)

Results | Primary and Secondary Efficacy Clinical Outcomes at Week 48



Exploratory MRI | Week 48 Myelin Imaging Results

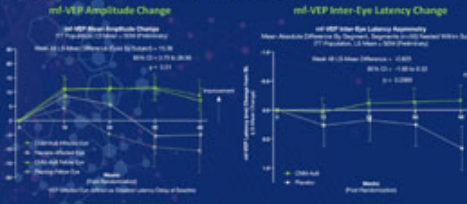


Safety

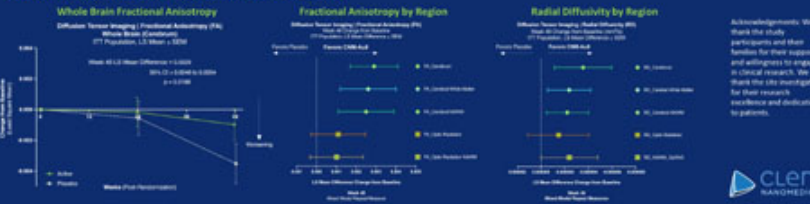
- CNM-Au8 treatment was safe and well-tolerated
- Treatment emergent adverse events (TEAEs) were transient and predominantly mild to moderate
- No dose-limiting adverse events; no related serious adverse events

Treatment Emergent Adverse Events (TEAEs)	CNM-Au8 15 mg (n=103)	CNM-Au8 30 mg (n=69)	Placebo (n=45)
Subjects with any TEAE	23 (22%)	25 (36%)	22 (49%)
Subjects with SAE	1 (1%)	2 (3%)	2 (4%)
Subjects with Related TEAE	2 (2%)	3 (4%)	2 (4%)
Subjects Discontinued Due to TEAE	0	1 (1%)	2 (4%)

Exploratory Visual Evoked Potentials | Week 48 mf-VEP Results



Exploratory MRI | Week 48 Diffusion Tensor Imaging Results



Acknowledgments: We thank the study participants 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.

