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): May 8, 2024

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)

(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 2.02 Results of Operations and Financial Condition.

On May 8, 2024, Clene Inc. (the "Company") issued a press release announcing its first quarter 2024 financial results and operating highlights for its quarter ended March 31, 2024. A copy of the press release 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 2.02, 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	Press Release, dated May 8, 2024, announcing the Company's first quarter 2024 financial results and operating highlights.
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: May 8, 2024

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

Exhibit 99.1

CLENE REPORTS FIRST QUARTER 2024 FINANCIAL RESULTS AND RECENT OPERATING HIGHLIGHTS

- *Data from long-term extension of Phase 2 VISIONARY-MS clinical trial of CNM-Au8® demonstrated significant evidence of repair and remyelination across multiple paraclinical endpoints (change from original baseline, p<0.05)*
- *Peer-reviewed publication characterized the protein corona of CNM-Au8*
- *Company received sub-award of $7.3 million from NIH grant for ALS Expanded Access Program*
- *Cash, cash equivalents and marketable securities of $27.9 million as of March 31, 2024*

SALT LAKE CITY, May 8, 2024 -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine, Inc., a late clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today announced its first quarter 2024 financial results and provided recent operating highlights for the CNM-Au8 clinical program for MS.

"In the first quarter our team worked diligently to advance our FDA discussions in ALS while continuing to generate more data supporting the neurological benefits and mechanism of action of CNM-Au8," said Rob Etherington, President and CEO of Clene. "We look forward to a productive and collaborative FDA meeting by mid-2024 and laying the groundwork towards filing of a New Drug Application in the second half of the year. Additionally, we are very pleased to see the recent data from our long-term extension of the VISIONARY-MS study. These data represent significant evidence of repair and remyelination across multiple paraclinical endpoints and provide us with greater support for the continued clinical evaluation of CNM-Au8 for this important indication."

First Quarter 2024 and Recent Operating Highlights

CNM-Au8 for the treatment of MS

- In April, the Company announced at the 2024 American Academy of Neurology (AAN) Annual Meeting clinical data demonstrating that long-term CNM-Au8 treatment produced significant evidence of repair and remyelination across multiple paraclinical endpoints. Participants originally randomized to CNM-Au8 treatment experienced continued significant improvement in vision as measured by low contrast letter acuity. More than half of participants improved by 10 or more letters on a low-contrast Sloan eye chart, with increases of up to 38 letters (mixed model repeat measures, or MMRM vs. original baseline, $p < 0.001$). Study participants treated with CNM-Au8 also experienced up to 29 points of significant improvement (max score =110) in cognition and working memory as measured by the Symbol Digit Modality Test (SDMT) (MMRM vs. original baseline, $p < 0.001$). Study participants treated with CNM-Au8 also demonstrated functional and structural evidence of repair and remyelination.

The presentation of Visionary-MS long-term extension results presented at the 2024 AAN Annual Meeting is available here.

Corporate Updates

- In April, the Company entered into a grant sub-award agreement with Columbia University pursuant to the National Institute of Health (NIH) Grant that includes reimbursement of Company expenses for the NIH Expanded Access Program (EAP) in an amount up to $7.3 million during the period from September 25, 2023 to August 31, 2024. In October 2023, the Company announced a four-year, $45.1 million grant from the NIH in collaboration with Columbia University and Synapticure, a neurology specialty health clinic, that is intended to support an EAP for CNM-Au8 treatment of ALS. Disbursement of funds will be paid to Clene based on invoice submissions for reimbursement on a monthly or quarterly basis.

- In March, Clene announced the publication "Protein Corona Composition of Gold Nanocatalysts" in the journal *ACS Pharmacology & Translational Science*, a journal of the American Chemical Society that publishes innovative and impactful research with translational relevance across a broad spectrum of biological sciences. This corona is an important feature of CNM-Au8's neuroprotective mechanism of action and enables the drug's longevity in circulation without provoking an inflammatory response.

The full publication can be accessed here: https://pubs.acs.org/doi/10.1021/acsptsci.4c00028

First Quarter 2024 Financial Results

Clene's cash, cash equivalents and marketable securities totaled $27.9 million as of March 31, 2024, compared to $35.0 million as of December 31, 2023. Clene expects that its resources as of March 31, 2024, will be sufficient to fund its operations into the fourth quarter of 2024.

Research and development expenses were $5.9 million for the quarter ended March 31, 2024, compared to $7.4 million for the same period in 2023. The year-over-year decrease was primarily related to lower expenses related the HEALEY ALS Platform Trial and the RESCUE-ALS, REPAIR-MS, REPAIR-PD, VISIONARY-MS and its long-term extension, and COVID-19 clinical trials, partially offset by an increase in expenses related to the two ongoing EAPs.

General and administrative expenses were $3.4 million for the quarter ended March 31, 2024, compared to $3.4 million for the same period in 2023.

Total other expense was $1.8 million for the quarter ended March 31, 2024, compared to total other expense of $1.0 million for the same period in 2023. The year-over-year increase in expense was primarily attributable to the change in the fair value of our common stock warrant liabilities associated with warrants issued in our financing in June 2023 and warrants issued to Avenue Capital related to our debt facility amendment in June 2023.

Clene reported a net loss of $11.1 million, or $0.09 per share, for the quarter ended March 31, 2024, compared to a net loss of $11.8 million, or $0.15 per share, for the same period in 2023.

About Clene
Clene Inc., (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine, Inc., is a late clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis, Parkinson's disease and multiple sclerosis. CNM-Au8® is an investigational first-in-class therapy that improves central nervous system cells' survival and function via a mechanism that targets mitochondrial function and the NAD pathway while reducing oxidative stress. CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc. 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 X and LinkedIn.

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.

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," "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. 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 whether clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or do not otherwise produce positive results, which may cause us to incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates; changes in government regulation or in practices relating to the pharmaceutical and biotechnology industries, including potential healthcare reform, which could decrease the need for our drug candidates, or make it more difficult to obtain regulatory approvals for our drug candidates and commercialize them; our substantial dependence on the successful commercialization of our drug candidates in the future, which may fail to materialize or may experience significant delays; our limited operating history, which may make it difficult to evaluate our current business and predict our future performance; and our ability to continue as a going concern, which requires that we obtain sufficient funding to finance our operations, which financing may not be available on acceptable terms, or at all, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce, or terminate our drug development or commercialization efforts; 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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CLENE INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Revenue:		
Product revenue	$ 44	$ 64
Royalty revenue	29	43
Total revenue	73	107
Operating expenses:		
Cost of revenue	16	5
Research and development	5,869	7,395
General and administrative	3,420	3,439
Total operating expenses	9,305	10,839
Loss from operations	(9,232)	(10,732)
Other income (expense), net:		
Interest income	359	172
Interest expense	(1,244)	(1,066)
Commitment share expense	—	(399)
Change in fair value of common stock warrant liabilities	(1,309)	—
Change in fair value of Clene Nanomedicine contingent earn-out liability	53	(55)
Change in fair value of Initial Stockholders contingent earn-out liability	7	(7)
Research and development tax credits and unrestricted grants	286	314
Other income, net	—	3
Total other income (expense), net	(1,848)	(1,038)
Net loss before income taxes	(11,080)	(11,770)
Income tax benefit	—	—
Net loss	(11,080)	(11,770)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities	(4)	14
Foreign currency translation adjustments	(55)	4
Total other comprehensive income (loss)	(59)	18
Comprehensive loss	$ (11,139)	$ (11,752)
Net loss per share – basic and diluted	$ (0.09)	$ (0.15)
Weighted average common shares used to compute basic and diluted net loss per share	128,427,231	76,049,665

CLENE INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,732	$ 28,821
Marketable securities	6,178	6,179
Accounts receivable	64	143
Inventory	37	37
Prepaid expenses and other current assets	4,100	3,672
Total current assets	32,111	38,852
Restricted cash	58	58
Operating lease right-of-use assets	4,046	4,168
Property and equipment, net	8,854	9,263
TOTAL ASSETS	$ 45,069	$ 52,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,645	$ 1,504
Accrued liabilities	3,905	3,720
Operating lease obligations, current portion	599	576
Finance lease obligations, current portion	7	27
Notes payable, current portion	14,987	14,627
Convertible notes payable, current portion	5,042	4,876
Total current liabilities	26,185	25,330
Operating lease obligations, net of current portion	4,720	4,903
Notes payable, net of current portion	1,820	1,894
Convertible notes payable, net of current portion	5,265	5,258
Common stock warrant liabilities	2,790	1,481
Clene Nanomedicine contingent earn-out liability	22	75
Initial Stockholders contingent earn-out liability	3	10
TOTAL LIABILITIES	40,805	38,951
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value: 300,000,000 and 300,000,000 shares authorized at March 31, 2024 and December 31, 2023, respectively; 128,433,721 and 128,422,851 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	13	13
Additional paid-in capital	257,914	255,901
Accumulated deficit	(253,803)	(242,723)
Accumulated other comprehensive income	140	199
TOTAL STOCKHOLDERS' EQUITY	4,264	13,390
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 45,069	$ 52,341