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 13, 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	**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 March 13, 2023, Clene Inc. (the "Company") issued a press release announcing its full year operating and financial results for its year ended December 31, 2022. 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 March 13, 2023, announcing the Company's operating and financial results for its year ended December 31, 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: March 13, 2023

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

Exhibit 99.1

CLENE REPORTS FULL YEAR 2022 FINANCIAL RESULTS AND RECENT OPERATING HIGHLIGHTS

- *Amyotrophic lateral sclerosis (ALS): Significant survival benefits demonstrated across two ALS clinical trials, along with clinical improvements as early as six months*
  - *CNM-Au8® associated with 74% lower risk of ALS clinical worsening events at six months supporting a survival benefit in the HEALEY ALS Platform Trial*
  - *CNM-Au8 significantly preserved physical function (ALSFRS-R) from randomization to 48 weeks in the RESCUE-ALS Trial OLE follow-up*
- *Multiple sclerosis (MS): Significant improvements in MS clinical outcomes including the visual system and global neurological function on top of immunomodulatory background standard-of-care in the VISIONARY-MS trial; significant paraclinical MRI and visual evoked potential (VEP) improvements reinforce clinical benefits:*
  - *CNM-Au8 significantly improved information signaling from the eye to the brain's visual cortex as shown by multifocal VEP*
  - *CNM-Au8 significantly improved brain neuronal structural integrity by MRI diffusion tensor imaging resulting in decreased brain deterioration*
- *Clinical and quantitative paraclinical outcomes support the potential neuroprotective and remyelinating effects of CNM-Au8 for treatment of multiple neurodegenerative disorders*
- *Cash, cash equivalents and marketable securities of $23.3 million as of December 31, 2022*

SALT LAKE CITY, March 13, 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 its full year 2022 financial results and provided recent operating highlights for the clinical programs in ALS and MS.

"We had an extremely productive year during which we generated consistent positive results from our clinical programs in ALS and MS that have helped advance both programs toward the next regulatory milestones. The initial placebo-controlled double-blinded Phase 2 RESCUE-ALS results were strengthened further with evidence of a survival benefit and preserved function at one year and beyond. The HEALEY ALS Platform Trial demonstrated consistent evidence of delayed time to ALS clinical worsening at six months in addition to a survival benefit," said Rob Etherington, President and CEO of Clene. "Results from our ALS clinical trials taken together along with significant Phase 2 findings of improvements in clinical outcomes, brain structure, and enhanced visual system signaling in stable MS patients from the VISIONARY-MS trial, have taught us of CNM-Au8's efficacy in multiple therapeutic areas. The totality of the clinical and paraclinical data are robust. In 2023, we will work to advance regulatory discussions with FDA on both ALS and MS and pursue partnering opportunities for the MS indication."

Fourth Quarter 2022 and Recent Operating Highlights

CNM-Au8, a gold nanocrystal suspension, for the treatment of ALS

New clinical improvement data from the HEALEY ALS Platform Trial (n=120 CNM-Au8 treated patients and 164 placebo-treated patients), led by the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital demonstrated a 74% decreased risk (lower hazard) of the composite endpoint of time to ALS clinical worsening ($p = 0.035$) as well as 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 ($p= 0.028$)
- 74% decreased risk of feeding tube placement ($p= 0.035$)
- 63% decreased risk of assisted ventilation ($p= 0.058$)

New clinical 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 OLE of the Phase 2 RESCUE ALS trial in people with early ALS, specifically:

- 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 ($p=0.0159$)
- Statistically significant difference in ALSFRS-R slope from week 60 to week 120 comparing participants originally randomized to active or placebo ($p=0.0057$).
- The risk of ALS progression was less than half for those originally receiving CNM-Au8 compared to those originally receiving placebo ($p=0.0494$).

Clene continues to support two expanded access programs providing CNM-Au8 treatment at four clinical sites to more than 50 participants with ALS and is presently expanding one EAP to include multiple centers across the U.S. and enroll up to 200 additional participants. The company plans to meet with the U.S. Food and Drug Administration (FDA) in an end of Phase 2 meeting during the third quarter of 2023 to discuss the regulatory path forward for CNM-Au8 in ALS.

CNM-Au8 for the treatment of MS

New data from the VISIONARY MS trial from MRI and VEP provide evidence of improved information signaling from the eye to the brain's visual cortex and improved brain neuronal structural integrity and decreased brain deterioration further supporting primary and secondary results shared in August 2022, including:

- Multi-focal Visual Evoked Potential (mf-VEP) findings provide evidence of improved information transmission in the visual system (from the eye to the visual cortex) with increased amplitude signal suggesting previously impaired neurons subsequently increase information transmission following CNM-Au8 treatment, supporting improved axonal integrity:
    - mf-VEP amplitude percent change in the least affected eye at baseline – Week 48 least squares [LS] mean difference: 9.7%, 95% CI: 3.1% to 16.3%, p=0.0047
    - mf-VEP amplitude percent change across both eyes – Week 48 LS mean difference: 7.9%, 95% CI: 1.4% to 14.4%, p=0.0184
- MRI findings provide evidence of brain neuronal structural integrity assessed by diffusion tensor imaging (DTI) that demonstrated statistically significant results for key metrics of axonal integrity and white matter integrity, independent of an immunomodulatory effect, with:
    - Fractional Anisotropy change within the whole brain (Cerebrum) – Week 48 Least-Squares (LS) Mean Difference: 0.0029, 95% CI: 0.0048 to 0.0054, p = 0.0199

Clene plans to meet with the FDA in an end of Phase 2 meeting during the third quarter of 2023 to discuss the regulatory path forward for CNM-Au8 in MS.

Corporate Updates

- In November 2022, Clene closed a registered direct offering of $10.8 million with certain existing stockholders, including existing stockholders affiliated with Clene's board of directors, for the purchase and sale of 10,723,926 shares of the Company's common stock at a purchase price per share of $1.01, priced at-the-market based on the October 28, 2022, closing stock price.

- In December 2022, Clene closed a debt facility with the Maryland Department of Housing and Community Development to borrow $5.0 million.

- On March 3, 2023, Clene entered into common stock purchase agreement for up to $25.0 million with Lincoln Park Capital Fund, LLC.

Full Year 2022 Financial Results

Clene's cash, cash equivalents and marketable securities totaled $23.3 million as of December 31, 2022, compared to $50.3 million as of December 31, 2021. Clene expects that its resources as of December 31, 2022, will be sufficient to fund its operations into the third quarter of 2023.

Research and development expenses were $31.9 million for the year ended December 31, 2022, compared to $28.4 million for the same period in 2021. The year-over-year increase was primarily related to the development of CNM-Au8 and CNM-ZnAg, rent expense for the newly-leased facility in Elkton, Maryland, and personnel, partially offset by decreased stock-based compensation and depreciation expense.

General and administrative expenses were $16.9 million for the year ended December 31, 2022, compared to $22.0 million for the same period in 2021. The year-over-year decrease was primarily attributable to lower finance and accounting fees, legal expenses and stock-based compensation, offset by increased personnel expenses.

Total other income (expense) was $18.5 million for the year ended December 31, 2022, compared to $39.8 million for the same period in 2021. The year-over-year decrease was primarily attributable to a decrease in the change in the fair value of the Clene and initial shareholder contingent earn-out liability, an increase in interest expense due to increasing interest rates during 2022, and a decrease in the change in the fair value of the common stock warrant liability; offset by an increase in research and development credits received in 2022.

Clene reported a net loss of $29.9 million, or $0.46 per share, for the year ended December 31, 2022, compared to a net loss of $9.7 million, or $0.16 per share, for the same period in 2021.

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.

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," "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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CLENE INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Audited)

	Year Ended December 31,	
	2022	2021
Revenue:		
Product revenue	$ 329	$ 570
Royalty revenue	144	153
Total revenue	473	723
Operating expenses:		
Cost of revenue	26	289
Research and development	31,920	28,416
General and administrative	16,936	21,996
Total operating expenses	48,882	50,701
Loss from operations	(48,409)	(49,978)
Other income (expense), net:		
Interest expense	(3,296)	(870)
Gain on extinguishment of notes payable	—	648
Gain on termination of lease	420	—
Change in fair value of common stock warrant liability	169	983
Change in fair value of Clene Nanomedicine contingent earn-out liability	15,836	33,953
Change in fair value of Initial Stockholders contingent earn-out liability	2,026	3,589
Research and development tax credits and unrestricted grants	3,079	1,519
Other income (expense), net	257	(12)
Total other income (expense), net	18,491	39,810
Net loss before income taxes	(29,918)	(10,168)
Income tax benefit	—	428
Net loss	(29,918)	(9,740)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities	(14)	—
Foreign currency translation adjustments	(16)	(92)
Total other comprehensive loss	(30)	(92)
Comprehensive loss	$ (29,948)	$ (9,832)
Net loss per share – basic and diluted	$ (0.46)	$ (0.16)
Weighted average common shares used to compute basic and diluted net loss per share	65,204,663	61,558,455

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,332	$ 50,288
Marketable securities	4,983	—
Accounts receivable	189	49
Inventory	43	41
Prepaid expenses and other current assets	5,648	4,205
Total current assets	29,195	54,583
Restricted cash	58	58
Right-of-use assets	4,602	3,250
Property and equipment, net	10,638	5,172
TOTAL ASSETS	$ 44,493	$ 63,063
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,014	$ 1,923
Accrued liabilities	3,863	3,610
Operating lease obligations, current portion	488	347
Finance lease obligations, current portion	74	146
Notes payable, current portion	6,418	—
Total current liabilities	13,857	6,026
Operating lease obligations, net of current portion	5,557	4,370
Finance lease obligations, net of current portion	34	97
Notes payable, net of current portion	9,483	14,484
Convertible notes payable	9,770	4,598
Common stock warrant liability	—	474
Clene Nanomedicine contingent earn-out liability	2,264	18,100
Initial Stockholders contingent earn-out liability	291	2,317
TOTAL LIABILITIES	41,256	50,466
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value: 150,000,000 shares authorized; 74,759,591 and 62,312,097 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	7	6
Additional paid-in capital	196,246	175,659
Accumulated deficit	(193,219)	(163,301)
Accumulated other comprehensive income	203	233
TOTAL STOCKHOLDERS' EQUITY	3,237	12,597
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 44,493	$ 63,063