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): August 7, 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-fortieth of one share of Common Stock for $230.00 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 August 7, 2024, Clene Inc. (the "Company") issued a press release announcing its second quarter 2024 financial results and recent operating highlights for its quarter ended June 30, 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 August 7, 2024, announcing the Company's second quarter 2024 financial results and recent 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: August 7, 2024

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

Exhibit 99.1

CLENE REPORTS SECOND QUARTER 2024 FINANCIAL RESULTS AND RECENT OPERATING HIGHLIGHTS

- *Survival analyses with CNM-Au8® 30 mg treatment compared to matched PRO-ACT controls demonstrated improved survival up to 3.5 years post-baseline*
- *CNM-Au8 treated participants in the HEALEY ALS Platform Trial with substantial neurofilament light (NfL) declines (CNM-Au8 NfL Responders) demonstrated significant clinical improvements in survival, functional status (slowed ALSFRS-R decline), and combined function and survival (CAFS scores) compared to CNM-Au8 NfL non-responders*
- *CNM-Au8 demonstrated neuroprotective effects in an in vitro model of Rett Syndrome, a rare pediatric neurodevelopmental disease*
- *Enrolled first ALS patient in NIH-funded Expanded Access Program (EAP) in June*
- *Regained compliance with Nasdaq Listing Rule 5550(a)(2) for continued listing on Nasdaq*
- *Submitted briefing book to the U.S. Food and Drug Administration (FDA) in advance of granted Type C interaction to occur in the third quarter of 2024*
- *Cash and cash equivalents of $21.7 million as of June 30, 2024*

SALT LAKE CITY, August 7, 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 second quarter 2024 financial results and provided recent updates on its CNM-Au8® programs.

"We are approaching our next FDA interaction focused on the regulatory path forward to potentially bring CNM-Au8 to people living with ALS," said Rob Etherington, President and CEO of Clene. "With this imminent timing, we are optimistic about the possibility of submitting a new drug application later this year. Our utmost priority is to help patients and their families for whom time is critical."

Second Quarter 2024 and Recent Operating Highlights

CNM-Au8 for the treatment of ALS

In June, the Company presented new long-term CNM-Au8 treatment results for survival and neurofilament light (NfL) levels from the HEALEY ALS Platform Trial open label extension (OLE) at the European Network for the Cure of ALS (ENCALS) meeting in Stockholm, Sweden. The data highlights up to 42 months of survival follow-up and 76 weeks of long-term NfL biomarker results, including a NfL responder subset (CNM-Au8 NfL Responders) from the HEALEY ALS Platform Trial who had consistent and sustained NfL reductions, comprising nearly half of all CNM-Au8 patients.

The data demonstrated improved survival compared to matched PRO-ACT controls as well as continued significant decline in plasma NfL levels in CNM-Au8 treated patients.

Improved Survival Compared to Matched PRO-ACT Controls: Survival analyses of participants originally randomized to CNM-Au8 30 mg treatment (n=59) and ex-placebo to CNM-Au8 (n=11) compared to matched PRO-ACT controls up to 3.5 years post-baseline.

- Approximately 60% decreased risk of death in CNM-Au8 30 mg treated patients compared to matched PRO-ACT controls up to 3.5 years of follow-up; covariate-adjusted hazard ratio (HR): 0.431 (95% CI: 0.276-0.672), p-value = 0.0002.

Reduced NfL Biomarker Levels in CNM-Au8 NfL Responders: CNM-Au8 NfL Responder Subset: The CNM-Au8 NfL Responder analysis was completed to identify NfL decreases in participants who showed consistent NfL declines (n=55). CNM-Au8 NfL Responders were defined as participants who had all post-baseline measures with an NfL decrease or repeated declines of at least 10 pg/mL following the start of CNM-Au8 treatment.

- CNM-Au8 NfL Responders demonstrated an average NfL reduction of 28%, which is suggestive of decreased axonal loss on an ongoing basis; geometric mean ratio (GMR) at week 76 change vs. baseline: 0.72, (95% CI: 0.67 – 0.79), $p < 0.0001$.
- The NfL results are based on earlier announced analyses of plasma NfL collected from participants (n=99) in the OLE who were treated with CNM-Au8 30 mg through week 76 compared to participants treated with placebo for 24 weeks prior to crossing over to active treatment for up to 52 weeks. Long-term treatment with CNM-Au8 30 mg resulted in continued significant decline of plasma NfL levels. The GMR vs. placebo at week 76 was 0.841, 95% CI: 0.73 – 0.98, $p = 0.023$.

On July 13, 2024, the Company submitted a briefing book to FDA in advance of a granted Type C interaction expected to occur in the third quarter of 2024. The briefing book contains new post-hoc analyses from two independently conducted Phase 2 clinical trials of CNM-Au8 for the treatment for ALS. This new information supplements the original data previously discussed with the FDA in late 2023 and is intended to guide the planned FDA Type C interaction to discuss an accelerated approval regulatory pathway. The Company plans to publicly announce the topline FDA feedback following the conclusion of the Type C interaction. CNM-Au8 NfL Responders demonstrated a 28% mean reduction in NfL levels compared to baseline, while NfL levels continued to increase in CNM-Au8 NfL non-responders (all doses; GMR difference at week 76 post-baseline: 0.57, 95% CI: 0.50 – 0.64, $p < 0.00001$). The analyses of the CNM-Au8 NfL Responders demonstrated efficacy in all-cause mortality, function, and combined assessment of function and survival (CAFS).

Late last year, Clene, in collaboration with Columbia University and Synapticure, announced the award of a four-year grant from the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH), to support an EAP for the Company's investigational drug, CNM-Au8 in ALS. The Company enrolled its first EAP patient in June.

CNM-Au8 for the treatment of Rett Syndrome

In June, Clene presented new, preliminary data demonstrating the potential of CNM-Au8 as a treatment for Rett Syndrome. at the International Rett Syndrome Foundation 2024 Annual Meeting. The presentation was titled, "CNM-Au8, a Candidate First-in-Class Nanotherapeutic for Treatment of Rett Syndrome." Key findings included:

- Statistically significant improvement in neuronal health ($p<0.01$), neuron survival ($p<0.0001$), and neurite lengths ($p<0.05$) in an in vitro model of Rett Syndrome, and;
- Improvements in the mitochondrial respiration deficits associated with Rett patient-derived astrocytes with CNM-Au8 treatment in vitro, with full rescue ($p<0.0001$) of both basal and ATP-linked respiration observed in one Rett line, and partial rescue observed in a second Rett line (ns change in basal respiration; $p<0.001$ improvement in ATP-linked respiration) at one concentration of CNM-Au8 treatment for 24 hours.

Corporate Update

In July, Clene completed a 1-for-20 reverse stock split. Clene's common stock now trades on the Nasdaq Capital Market on a split-adjusted basis under a new CUSIP number 185634201 and the Company's existing trading symbol "CLNN." The reverse stock split enabled Clene to regain compliance with the $1.00 minimum closing bid price required for continued listing on the Nasdaq Capital Market. The number of shares of common stock issued and outstanding has been reduced from approximately 128.7 million shares to approximately 6.4 million shares. All outstanding stock options, warrants, rights to restricted stock awards, convertible debt, and contingent earn-out shares entitling their holders to purchase or receive shares of Common Stock were adjusted as a result of the reverse stock split as required by the terms of each security. In addition, the number of shares reserved for issuance pursuant to the Company's Amended 2020 Stock Plan were also adjusted.

Second Quarter 2024 Financial Results

Clene's cash, cash equivalents and marketable securities totaled $21.7 million as of June 30, 2024, compared to $35.0 million as of December 31, 2023. Clene expects that its resources as of June 30, 2024, will be sufficient to fund its operations into the fourth quarter of 2024.

Research and development expenses were $4.2 million for the quarter ended June 30, 2024, compared to $6.6 million for the same period in 2023. The year-over-year decrease was primarily related to reimbursements for expenses incurred since September 2023 from our ongoing ALS EAP funded by a NIH grant for which reimbursements are recorded as an offset to research and development expense, as well as lower expenses related the HEALEY ALS Platform Trial and the RESCUE-ALS, REPAIR-MS, and VISIONARY-MS clinical trials, partially offset by an increase in expenses related to the two ongoing EAPs and planning activities for the RESTORE-ALS Phase 3 clinical trial.

General and administrative expenses were $3.3 million for the quarter ended June 30, 2024, compared to $3.9 million for the same period in 2023. The year-over-year decrease was primarily related to decreases in directors' and officers' insurance premiums, decreases in finance and accounting fees, primarily due to a decrease in fees from consultants, advisors, and other financial vendors, and decreases in stock-based compensation expense.

Total other income was $0.6 million for the quarter ended June 30, 2024, compared to total other expense of $14.8 million for the same period in 2023. The year-over-year decrease in expense was primarily attributable to a decline in the fair value of common stock warrant liabilities. Additionally, there was a $14.8 million charge during 2023 from the fair value of a public equity offering in excess of proceeds that did not occur in 2024.

Clene reported a net loss of $6.8 million, or $1.06 per share, for the quarter ended June 30, 2024, compared to a net loss of $25.1 million, or $5.84 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 Clene's expectations that its resources are sufficient to fund operations into the fourth quarter of 2024, the timing of Clene's public announcement of topline FDA feedback, the timing of Clene's submission of a new drug application and the availability of an accelerated approval regulatory pathway. In addition, any statements that refer to 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, Clene's expectations that its resources are sufficient to fund operations into the fourth quarter of 2024, the timing of Clene's public announcement of topline FDA feedback, the timing of Clene's submission of a new drug application and the availability of an accelerated approval regulatory pathway may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include general market conditions, 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 drug candidates, if approved; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the development and commercialization of its 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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue	$ 64	$ 226	$ 108	$ 290
Royalty revenue	27	43	56	86
Total revenue	91	269	164	376
Operating expenses:				
Cost of revenue	18	66	34	71
Research and development	4,150	6,615	10,019	14,010
General and administrative	3,314	3,924	6,734	7,363
Total operating expenses	7,482	10,605	16,787	21,444
Loss from operations	(7,391)	(10,336)	(16,623)	(21,068)
Other income (expense), net:				
Interest income	269	213	628	385
Interest expense	(1,282)	(1,104)	(2,526)	(2,170)
Commitment share expense	—	(3)	—	(402)
Issuance costs for common stock warrant liabilities	—	(333)	—	(333)
Loss on initial issuance of equity	—	(14,840)	—	(14,840)
Change in fair value of common stock warrant liabilities	1,568	(383)	259	(383)
Change in fair value of Clene Nanomedicine contingent earn-out liability	22	1,165	75	1,110
Change in fair value of Initial Stockholders contingent earn-out liability	3	150	10	143
Research and development tax credits and unrestricted grants	26	341	312	655
Other expense, net	—	(13)	—	(10)
Total other income (expense), net	606	(14,807)	(1,242)	(15,845)
Net loss before income taxes	(6,785)	(25,143)	(17,865)	(36,913)
Income tax expense	—	—	—	—
Net loss	(6,785)	(25,143)	(17,865)	(36,913)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	2	6	(2)	20
Foreign currency translation adjustments	28	(53)	(27)	(49)
Total other comprehensive income (loss)	30	(47)	(29)	(29)
Comprehensive loss	$ (6,755)	$ (25,190)	$ (17,894)	$ (36,942)
Net loss per share – basic and diluted	$ (1.06)	$ (5.84)	$ (2.78)	$ (9.11)
Weighted average common shares used to compute basic and diluted net loss per share	6,423,182	4,302,520	6,422,242	4,053,883

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

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,682	$ 28,821
Marketable securities	—	6,179
Accounts receivable	—	143
Inventory	37	37
Prepaid expenses and other current assets	6,191	3,672
Total current assets	27,910	38,852
Restricted cash	58	58
Operating lease right-of-use assets	3,920	4,168
Property and equipment, net	8,442	9,263
TOTAL ASSETS	$ 40,330	$ 52,341
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,066	$ 1,504
Accrued liabilities	5,927	3,720
Operating lease obligations, current portion	623	576
Finance lease obligations, current portion	—	27
Notes payable, current portion	20,453	14,627
Convertible notes payable, current portion	—	4,876
Total current liabilities	28,069	25,330
Operating lease obligations, net of current portion	4,530	4,903
Notes payable, net of current portion	1,745	1,894
Convertible notes payable, net of current portion	5,268	5,258
Common stock warrant liabilities	1,222	1,481
Clene Nanomedicine contingent earn-out liability	—	75
Initial Stockholders contingent earn-out liability	—	10
TOTAL LIABILITIES	40,834	38,951
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 600,000,000 and 300,000,000 shares authorized at June 30, 2024 and December 31, 2023, respectively; 6,433,628 and 6,421,084 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	259,913	255,913
Accumulated deficit	(260,588)	(242,723)
Accumulated other comprehensive income	170	199
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(504)	13,390
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 40,330	$ 52,341