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 14, 2026

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

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 14, 2026, Clene Inc. (the "Company") issued a press release announcing its second quarter 2026 financial results and recent operating highlights for its quarter ended June 30, 2026. 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	by Exhibit Description
99.1	Press Release, dated August 14, 2026, announcing the Company's second quarter 2026 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 14, 2026

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

Exhibit 99.1

CLENE REPORTS SECOND QUARTER 2026 FINANCIAL RESULTS AND RECENT OPERATING HIGHLIGHTS

- *Clene expects to submit a New Drug Application for CNM-Au8® in ALS under the accelerated approval pathway in early fourth quarter of 2026*
- *Clene announces survival and functional benefit in CNM-Au8-treated patients whose NfL declined or stabilized*

SALT LAKE CITY, August 14, 2026 -- Clene Inc. (Nasdaq: CLNN) today announced its second quarter 2026 financial results and provided recent updates on its CNM-Au8 programs.

"We plan to submit our new drug application (NDA) for CNM-Au8 under the accelerated approval pathway for patients with ALS and believe the evidence connecting the magnitude of NfL reduction to clinical benefit data we have generated since our last FDA meeting will be critical for a successful review," said Rob Etherington, President and CEO of Clene. "Patients with ALS are in desperate need of additional treatment options, and we believe that CNM-Au8 may restore and protect neuronal health and function, leading to improved survival."

Second Quarter 2026 and Recent Operating Highlights

CNM-Au8 for the treatment of ALS

Clene announced receipt of formal meeting minutes in May, confirming the Company's ability to file an NDA for CNM-Au8 for the treatment of ALS under the accelerated approval pathway. In its final meeting minutes, the U.S. Food and Drug Administration (FDA), stated that Clene's "*proposed data may be capable of supporting the submission and review of an NDA under the accelerated approval pathway for the treatment of ALS*." The FDA reminded the Company that the submission should demonstrate the effectiveness of and effect of CNM-Au8 on neurofilament light (NfL) and show that the magnitude of change in NfL is reasonably likely to predict clinical benefits in patents with ALS.

New biomarker analyses of the Company's two completed Phase 2 ALS trials revealed additional evidence that CNM-Au8-treated patients whose NfL declined or stabilized lived significantly longer than concurrently randomized controls and performed significantly better on combined measures of survival and function, including the ALS Functional Rating Scale-Revised (ALSFRS-R) and breathing capacity (Slow Vital Capacity; SVC). These new data intend to show the FDA that the "magnitude of change in NfL is reasonably likely to predict clinical benefits in patients with ALS," as noted from the FDA minutes.

These findings were derived from multiple lines of analysis: clinical benefit versus concurrently randomized controls; the relationship between the size of the NfL reduction and clinical outcome; a causal analysis that identified likely NfL responders from pre-treatment characteristics alone, preserving the randomized comparison; and replication of the association between NfL change and survival across independent datasets.

The NDA submission is expected to be made under the accelerated approval pathway and will be supported by NfL biomarker and clinical data from the Phase 2 HEALEY ALS Platform Trial and its open-label extension, the Phase 2 RESCUE-ALS Trial, and the NIH-sponsored Expanded Access Protocol for CNM-Au8.

Corporate Update

In May, the Company closed an underwritten registered direct common stock offering to a single investor totaling $7.0 million in gross proceeds.

Also in May, the Company amended its existing $10.0 million senior secured convertible debt facility and its $1.5 million senior secured convertible debt facility to extend the maturity date of both senior secured convertible debt facilities to August 2027 and to eliminate any required principal and interest payments prior to maturity in August 2027.

Second Quarter 2026 Financial Results

Clene's cash and cash equivalents totaled $9.7 million as of June 30, 2026, compared to $5.2 million as of December 31, 2025. Net cash used in operating activities was $7.1 million for the six months ended June 30, 2026, compared to $9.8 million for the same period in 2025. Clene expects that its resources as of June 30, 2026, will provide operating runway through late fourth quarter 2026.

Research and development expenses were $3.5 million for the quarter ended June 30, 2026, compared to $3.5 million for the same period in 2025. The changes were primarily attributable to lower expenses related to the Company's ALS expanded access programs (EAPs) and planning activities for the RESTORE-ALS clinical trial, and lower expenses related to our REPAIR-MS clinical trial program due to its conclusion, partially offset by an increase in expenses for regulatory activities related to the Company's ongoing FDA discussions and preparation of its planned NDA submission and expenses related to our MS EAP, as well as higher pre-clinical, manufacturing and personnel related expenses.

General and administrative expenses were $1.9 million for the quarter ended June 30, 2026, compared to $2.4 million for the same period in 2025. The decrease was primarily attributable to lower legal fees and finance and accounting fees, as well as decreased stock-based compensation expenses and an increase in grant revenue recorded as a reduction to general and administrative expense.

Total other expense, net, was $8.1 million for the quarter ended June 30, 2026, compared to $1.6 million for the same period in 2025. The year-over-year increase was primarily attributable to a change in fair value of common stock warrant liabilities and derivative liabilities and higher interest expense related to the Company's outstanding $1.5 million senior secured convertible note issued in August 2025.

Clene reported a net loss of $13.4 million, or $1.08 per share, for the quarter ended June 30, 2026, compared to a net loss of $7.4 million, or $0.78 per share, for the same period in 2025.

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 (formerly Twitter) 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 the timing of the Company's meeting with the FDA, the timing of the Company's NDA submission, and that the biomarker findings support an NDA submission. 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 general market conditions, whether clinical trials demonstrate the efficacy and safety of our drug candidates 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; 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.
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,	
	2026	2025	2026	2025
Revenue:				
Product revenue	$ 74	$ 1	$ 75	$ 65
Royalty revenue	16	26	30	43
Total revenue	90	27	105	108
Operating expenses:				
Cost of revenue	36	—	36	20
Research and development	3,471	3,514	3,800	4,995
General and administrative	1,930	2,377	3,677	5,033
Total operating expenses	5,437	5,891	7,513	10,048
Loss from operations	(5,347)	(5,864)	(7,408)	(9,940)
Other income (expense), net:				
Interest income	55	62	102	143
Interest expense	(695)	(679)	(1,486)	(1,287)
Issuance costs for common stock warrant liabilities	—	—	(393)	—
Loss on initial issuance of equity	—	—	(4,582)	—
Change in fair value of common stock warrant liabilities	(4,132)	(515)	(5,192)	1,995
Change in fair value of derivative liabilities	(3,333)	(439)	(2,620)	708
Research and development tax credits and unrestricted grants	28	16	64	211
Total other income (expense), net	(8,077)	(1,555)	(14,107)	1,770
Net loss before income taxes	(13,424)	(7,419)	(21,515)	(8,170)
Income tax expense	—	—	—	—
Net loss	$ (13,424)	$ (7,419)	$ (21,515)	$ (8,170)
Other comprehensive income (loss):				
Foreign currency translation adjustments	$ (8)	$ 63	$ 36	$ 78
Total other comprehensive income (loss)	(8)	63	36	78
Comprehensive loss	$ (13,432)	$ (7,356)	$ (21,479)	$ (8,092)
Net loss per share – basic and diluted	$ (1.08)	$ (0.78)	$ (1.79)	$ (0.89)
Weighted average common shares used to compute basic and diluted net loss per share	12,382,702	9,523,592	12,015,498	9,176,063

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

	June 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,671	$ 5,189
Accounts receivable	43	—
Inventory	37	37
Prepaid expenses and other current assets	5,163	3,751
Total current assets	14,914	8,977
Restricted cash	58	58
Operating lease right-of-use assets	2,753	3,073
Property and equipment, net	5,316	6,023
TOTAL ASSETS	$ 23,041	$ 18,131
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,142	$ 892
Accrued liabilities	2,482	5,002
Operating lease obligations, current portion	815	808
Notes payable, current portion	413	1,696
Convertible notes payable, current portion	—	2,378
Total current liabilities	4,852	10,776
Operating lease obligations, net of current portion	2,805	3,250
Notes payable, net of current portion	5,374	3,741
Convertible notes payable, net of current portion	12,937	9,800
Common stock warrant liabilities	16,137	5,063
Derivative liabilities	5,713	3,093
TOTAL LIABILITIES	47,818	35,723
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.0001 par value: 600,000,000 shares authorized; 12,778,307 and 10,849,974 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	1	1
Additional paid-in capital	304,825	290,531
Accumulated deficit	(329,811)	(308,296)
Accumulated other comprehensive income	208	172
TOTAL STOCKHOLDERS' DEFICIT	(24,777)	(17,592)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 23,041	$ 18,131