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): November 4, 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 November 4, 2026, Clene Inc. (the "Company") issued a press release announcing its third quarter 2026 financial results and recent operating highlights for its quarter ended September 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 November 4 2026, announcing the Company's third 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: November 4, 2026

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

Exhibit 99.1

CLENE REPORTS THIRD QUARTER 2026 FINANCIAL RESULTS AND RECENT OPERATING HIGHLIGHTS

- *Submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in October 2026 seeking accelerated approval for CNM-Au8® in amyotrophic lateral sclerosis (ALS)*
- *Completed a $4.0 million registered direct offering in September that is expected to fund operations through mid-first quarter 2027*
- *Plans to initiate the Phase 3 RESTORE-ALS confirmatory trial of CNM-Au8 in ALS in the second quarter of 2027*

SALT LAKE CITY, November 4, 2026 -- Clene Inc. (Nasdaq: CLNN), a late clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative diseases, today announced its third quarter 2026 financial results and provided updates on its CNM-Au8 programs.

"Clene's submission of the NDA for CNM-Au8 is a pivotal achievement for the company and, more importantly, a meaningful step toward bringing new treatment options to people living with ALS," said Rob Etherington, President and CEO of Clene. "People living with ALS urgently need additional treatment options, and we appreciate the FDA's constructive engagement throughout this process. We look forward to working closely with the Agency during its pending review. We believe CNM-Au8 has the capacity to restore and protect neuronal health and function and improve survival."

Third Quarter 2026 and Recent Operating Highlights

CNM-Au8 for the treatment of ALS

In October, Clene submitted an NDA to the FDA seeking accelerated approval of CNM-Au8 for ALS. The NDA is 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.

Clene plans to randomize the first participants for the Phase 3 RESTORE-ALS trial in the second quarter of 2027. The trial will evaluate the effect of CNM-Au8 on survival (primary endpoint) and time to ALS clinical worsening events (secondary efficacy endpoint).

Corporate Update

In September, the Company closed a $4.0 million registered direct offering of common stock to existing stockholders, including insiders, priced at $3.28 per share. The offering was led by Clene's Chairman, David Matlin, with founding investor Kensington Capital Holdings, Clene's CEO and other existing stockholders.

The Company expects the proceeds from the offering to fund operations through mid-first quarter 2027. Subject to FDA acceptance of the NDA for review, the Company could receive $6.7 million to $7.8 million in proceeds from common stock warrants issued in its January 2026 financing.

Third Quarter 2026 Financial Results

Clene's cash and cash equivalents totaled $9.9 million as of September 30, 2026, compared to $5.2 million as of December 31, 2025. Net cash used in operating activities was $11.7 million for the nine months ended September 30, 2026, compared to $13.7 million for the same period in 2025. Clene expects that its resources as of September 30, 2026, will provide operating runway through mid-first quarter 2027.

Research and development expenses were $4.4 million for the quarter ended September 30, 2026, compared to $3.5 million for the same period in 2025, an increase of approximately 27%. The increase was primarily due to higher regulatory expenses for the NDA submission, as well as higher manufacturing and personnel expenses. Personnel expenses rose due to non-executive salary increases and the reinstatement of previously reduced executive compensation. Additionally, lower grant revenue was recorded in 2026, which is recorded as a reduction to research and development expense. These increases were partially offset by lower clinical expenses related to Clene's lead drug candidate, CNM-Au8, for both its ALS and MS clinical programs and lower stock-based compensation expense.

General and administrative expenses were $1.9 million for the quarter ended September 30, 2026, compared to $2.2 million for the same period in 2025, a decrease of approximately 10%. The decrease was primarily due to lower insurance costs, legal fees, finance and accounting fees and stock-based compensation expenses, partially offset by higher personnel expenses, as described above.

Total other income, net, was $10.3 million for the quarter ended September 30, 2026, compared to total other expense, net, of $3.1 million for the same period in 2025. The change was primarily due to a change in fair value of common stock warrant liabilities and derivative liabilities.

Clene reported net income of $3.9 million, or $0.30 per basic share and $0.05 per diluted share, for the quarter ended September 30, 2026, compared to a net loss of $8.8 million, or $0.85 per basic and diluted 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 FDA's review and potential acceptance of the Company's NDA for CNM-Au8, the potential for accelerated approval of CNM-Au8, the timing of the Company's confirmatory Phase 3 RESTORE-ALS trial, the sufficiency of the Company's cash runway, the potential receipt of proceeds from the exercise of warrants, and the potential benefits of CNM-Au8. 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.

Investor Contact: Kevin Gardner, LifeSci Advisors; kgardner@lifesciadvisors.com; 617-283-2856
Media Contact: Caroline Wagner, FTP; CWagner@ftpadvocacy.com; 267-294-6563

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue	$ 43	$ —	$ 118	$ 65
Royalty revenue	13	15	43	58
Total revenue	56	15	161	123
Operating expenses:				
Cost of revenue	16	—	52	20
Research and development	4,447	3,513	8,247	8,508
General and administrative	1,940	2,150	5,617	7,183
Total operating expenses	6,403	5,663	13,916	15,711
Loss from operations	(6,347)	(5,648)	(13,755)	(15,588)
Other income (expense), net:				
Interest income	50	40	152	183
Interest expense	(665)	(649)	(2,151)	(1,936)
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	7,493	(1,728)	2,301	267
Change in fair value of derivative liabilities	3,368	(797)	748	(89)
Research and development tax credits and unrestricted grants	16	5	80	216
Total other income (expense), net	10,262	(3,129)	(3,845)	(1,359)
Net income (loss) before income taxes	3,915	(8,777)	(17,600)	(16,947)
Income tax expense	—	—	—	—
Net income (loss)	$ 3,915	$ (8,777)	$ (17,600)	$ (16,947)
Other comprehensive income:				
Foreign currency translation adjustments	$ 19	$ 1	$ 55	$ 79
Total other comprehensive income	19	1	55	79
Comprehensive income (loss)	$ 3,934	$ (8,776)	$ (17,545)	$ (16,868)
Net income (loss) per share – basic and diluted				
Basic	$ 0.30	$ (0.85)	$ (1.42)	$ (1.77)
Diluted	$ 0.05	$ (0.85)	$ (1.42)	$ (1.77)
Weighted average common shares used to compute basic and diluted net income (loss) per share				
Basic	13,079,599	10,284,674	12,374,096	9,549,661
Diluted	14,668,742	10,284,674	12,374,096	9,549,661

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

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,887	$ 5,189
Accounts receivable	43	—
Inventory	41	37
Prepaid expenses and other current assets	4,523	3,751
Total current assets	14,494	8,977
Restricted cash	58	58
Operating lease right-of-use assets	2,587	3,073
Property and equipment, net	5,018	6,023
TOTAL ASSETS	$ 22,157	$ 18,131
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 862	$ 892
Accrued liabilities	2,510	5,002
Operating lease obligations, current portion	788	808
Notes payable, current portion	4,974	1,696
Convertible notes payable, current portion	7,980	2,378
Total current liabilities	17,114	10,776
Operating lease obligations, net of current portion	2,603	3,250
Notes payable, net of current portion	964	3,741
Convertible notes payable, net of current portion	5,295	9,800
Common stock warrant liabilities	8,644	5,063
Derivative liabilities	2,345	3,093
TOTAL LIABILITIES	36,965	35,723
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.0001 par value: 600,000,000 shares authorized; 14,213,981 and 10,849,974 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	1	1
Additional paid-in capital	310,860	290,531
Accumulated deficit	(325,896)	(308,296)
Accumulated other comprehensive income	227	172
TOTAL STOCKHOLDERS' DEFICIT	(14,808)	(17,592)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 22,157	$ 18,131