Clene Reports First Quarter 2026 Financial Results and Recent Operating Highlights

May 14, 2026

- *After successful completion of FDA Type C meeting, Clene expects to submit an NDA for CNM-Au8® under the accelerated approval pathway in the third quarter of 2026*
- *In January 2026, Clene completed an oversubscribed registered direct offering totaling over $28 million, including an initial tranche of more than $6 million and two additional tranches totaling over $22 million tied to regulatory milestones*
- *In May 2026, Clene amended its existing $10 million convertible debt facility, extending maturity by six months to August 2027 and eliminating required monthly principal and interest payments before maturity*
- *In May 2026, Clene completed a $7 million underwritten registered direct offering with a single investor*

SALT LAKE CITY, May 14, 2026 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., a late-stage clinical biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today announced its first quarter 2026 financial results and provided recent updates on its CNM-Au8 programs.

"We were encouraged by the constructive dialogue during our recent Type C meeting with the FDA and appreciate the Agency's engagement as we advance toward a planned NDA submission for CNM-Au8 under the accelerated approval pathway for patients with ALS," said Rob Etherington, President and CEO of Clene. "People living with ALS continue to need additional treatment options, and we believe CNM-Au8 has the potential to restore and protect neuronal health and function, leading to improved survival. We look forward to continuing to work collaboratively with the FDA as the Agency reviews our extensive clinical efficacy and safety data."

First Quarter 2026 and Recent Operating Highlights

CNM-Au8 for the treatment of ALS
Clene had a successful Type C in-person meeting with the U.S. Food and Drug Administration (FDA) in the first quarter of 2026 to discuss the statistically significant reductions in neurofilament light (NfL), including the relationship between the magnitude of NfL reduction and clinical benefits, including longer survival in participants treated with CNM-Au8. During the meeting, and as confirmed in the final meeting minutes, the FDA stated that the "*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 also reminded the Company that the submission should demonstrate that CNM-Au8 has an effect on NfL and that the magnitude of change in NfL is reasonably likely to predict clinical benefits in patients with ALS.

Clene intends to submit the New Drug Application (NDA) in the third quarter of 2026. Also, Clene plans to commence the confirmatory Phase 3 trial in the first quarter of 2027. The RESTORE-ALS trial is designed to investigate the effects of CNM-Au8 on improved survival (primary endpoint) and delayed time to ALS clinical worsening events (secondary efficacy endpoint).

Corporate Update

In January, Clene announced an oversubscribed registered direct offering of over $28.0 million priced above market. The initial tranche was over $6.0 million with two potential additional financing tranches totaling over $22.0 million structured around CNM-Au8 NDA acceptance and FDA approval milestones.

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 convertible debt facility to extend the maturity date to August 2027 and to eliminate any required principal and interest payments prior to maturity in August 2027.

First Quarter 2026 Financial Results

Clene's cash and cash equivalents totaled $5.9 million as of March 31, 2026, compared to $5.2 million as of December 31, 2025. Clene expects that its resources as of March 31, 2026, including the $7.0 million in gross proceeds received from its May 2026 registered direct offering and the effects of its May 2026 amendment of its $10.0 convertible debt facility (requiring no principal or interest payments until August 2027), will provide operating runway into the fourth quarter of 2026. Additionally, with potential future warrant exercises tied to the acceptance of an NDA by the FDA of approximately $7.0 million, cash runway is expected to extend into 2027.

Research and development expenses were $0.3 million for the quarter ended March 31, 2026, compared to $1.5 million for the same period in 2025. The year-over-year decrease was primarily due to decreased expenses related to our ALS program including two of our ongoing expanded access programs (EAPs) and planning activities for the RESTORE-ALS clinical trial, partially offset by an increase in expenses for regulatory activities primarily related to the ongoing FDA discussions and NDA submission-related activities and increased expenses for our MS program related to an ongoing EAP. Additionally, manufacturing related expenses, as well as expenses related to personnel and stock-based compensation, also decreased.

General and administrative expenses were $1.7 million for the quarter ended March 31, 2026, compared to $2.7 million for the same period in 2025. The year-over-year decrease was primarily attributable to decreased personnel and stock-based compensation expenses, as well as lower legal fees and depreciation expense. Additionally, grant revenue, which is recorded as a reduction to general and administration expense, increased in 2026 as compared to 2025 primarily related to reimbursable general and administrative expenses in the National Institutes of Health (NIH) sponsored EAP.

Total other expense, net, was $6.0 million for the quarter ended March 31, 2026, compared to total other income, net, of $3.3 million for the same

period in 2025. The year-over-year change was primarily attributable to issuance costs for common stock warrant liabilities and a one-time loss on the initial issuance of equity related to our January 2026 financing, as well as fair value changes on existing warrant and derivative liabilities. In addition, during 2026 we had higher interest expense based on larger debt balances.

Clene reported a net loss of $8.1 million, or $0.69 per share, for the quarter ended March 31, 2026, compared to a net loss of $0.8 million, or $0.09 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 NDA submission, that the biomarker findings support an NDA submission, and the timing of the initiation of the Phase 3 trial and our cash runway. 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 March 31,	
	2026	**2025**
Revenue:		
Product revenue	$ 1	$ 64
Royalty revenue	14	17
Total revenue	15	81
Operating expenses:		
Cost of revenue	—	20
Research and development	329	1,481
General and administrative	1,747	2,656
Total operating expenses	2,076	4,157
Loss from operations	(2,061)	(4,076)

Other income (expense), net:		
Interest income	47	81
Interest expense	(791)	(608)
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	(1,060)	2,510
Change in fair value of derivative liabilities	713	1,147
Research and development tax credits and unrestricted grants	36	195
Total other income (expense), net	(6,030)	3,325
Net loss before income taxes	(8,091)	(751)
Income tax expense	—	—
Net loss	$ (8,091)	$ (751)
Other comprehensive income:		
Foreign currency translation adjustments	$ 44	$ 15
Total other comprehensive income	44	15
Comprehensive loss	$ (8,047)	$ (736)
Net loss per share – basic and diluted	$ (0.69)	$ (0.09)
Weighted average common shares used to compute basic and diluted net loss per share	11,644,214	8,824,673

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

	March 31, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,939	$ 5,189
Inventory	54	37
Prepaid expenses and other current assets	7,030	3,751
Total current assets	13,023	8,977
Restricted cash	58	58
Operating lease right-of-use assets	2,916	3,073
Property and equipment, net	5,668	6,023
TOTAL ASSETS	$ 21,665	$ 18,131
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,309	$ 892
Accrued liabilities	2,729	5,002
Operating lease obligations, current portion	826	808
Notes payable, current portion	990	1,696
Convertible notes payable, current portion	876	2,378
Total current liabilities	6,730	10,776
Operating lease obligations, net of current portion	3,017	3,250
Notes payable, net of current portion	4,633	3,741
Convertible notes payable, net of current portion	11,706	9,800
Common stock warrant liabilities	12,005	5,063
Derivative liabilities	2,380	3,093
TOTAL LIABILITIES	40,471	35,723
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.0001 par value: 600,000,000 shares authorized; 11,778,307 and 10,849,974 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	1	1
Additional paid-in capital	297,364	290,531
Accumulated deficit	(316,387)	(308,296)
Accumulated other comprehensive income	216	172

TOTAL STOCKHOLDERS' DEFICIT	(18,806)	(17,592)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 21,665	$ 18,131