Clene Reports Full Year 2025 Financial Results and Recent Operating Highlights

March 12, 2026

- *In-person Type C FDA meeting scheduled by end of the first quarter of 2026 to discuss the latest CNM-Au8® data submitted; Clene expects formal written meeting minutes early in the second quarter 2026*
- *Oversubscribed registered direct offering of over $28 million priced above market*
  - *Initial financing tranche of over $6 million, which will provide cash runway to the end of the third quarter enabling funding through potential NDA acceptance decision by the FDA*
  - *Completion of this financing through its three tranches is expected to provide the Company with sufficient capital into 2027*

SALT LAKE CITY, March 12, 2026 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., a clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today announced its full year 2025 financial results and provided recent updates on its CNM-Au8 programs.

"Our next key milestone is the upcoming Type C face-to-face meeting with the U.S. Food and Drug Administration (FDA) on Clene's biomarker and survival data, which if positive, will facilitate filing of an new drug application (NDA) under an accelerated approval pathway for ALS by the end of the second quarter of 2026," said Rob Etherington, President and CEO of Clene. "In parallel, we continue to advance plans to initiate our confirmatory Phase 3 trial in ALS, which is required to be "underway" by CNM-Au8 approval in ALS, as well as to continue working with the FDA on the initiation of a Phase 3 clinical trial using cognition as an endpoint in MS. Based on our combined findings to date, we continue to believe that patients across multiple neurodegenerative conditions may benefit from the improved mitochondrial function plus energy metabolism associated with CNM-Au8 treatment."

Fourth Quarter 2025 and Recent Operating Highlights

CNM-Au8 for the treatment of ALS
Clene expects its Type-C meeting with the FDA will occur before the end of this month. Clene will then await formal written meeting minutes from the agency which are expected early in the second quarter of 2026, after which Clene will publicly announce the outcome of the FDA meeting. Clene plans to file an NDA for CNM-Au8 in ALS under an accelerated approval pathway by the end of June 2026.

Prolonged Survival and Associated Declines in Biomarkers of Neurodegeneration
In December 2025, the Company announced completion of the FDA-recommended biomarker analyses for CNM-Au8 in people living with ALS. The results demonstrated statistically significant reductions in both neurofilament light chain (NfL) and glial fibrillary acidic protein (GFAP) and provided compelling evidence linking biomarker decline to improved survival. The analyses followed FDA recommendations to support the persuasiveness of the Company's original NfL findings observed in the HEALEY ALS Platform Trial by extending the analyses to the NIH-sponsored Expanded Access Protocol (NIH-EAP) for CNM-Au8 in ALS. These biomarker findings correlated to survival findings and build on prior constructive FDA interactions in support of a planned NDA submission under an accelerated approval pathway for the treatment of ALS.

Favorable Safety and Benefit/Risk Profile
Across over 1,100 patient years of CNM-Au8 exposure data, with long-term treatment of people with ALS over 6 years, CNM-Au8's safety profile has no significant safety concerns nor safety trends identified. No serious adverse events (SAEs) have been identified as related to CNM-Au8 treatment by any investigator to date.

Corporate Update

In January, Clene announced an oversubscribed registered direct offering of over $28 million priced above market. The initial tranche of over $6 million is expected to provide operating runway to the end of the third quarter of 2026, sufficient funding through a potential NDA acceptance decision by the FDA. Two potential additional financing tranches totaling over $22 million are structured to align with NDA acceptance and FDA approval milestones and provide runway into 2027.

Full Year 2025 Financial Results

Clene's cash and cash equivalents totaled $5.2 million as of December 31, 2025, compared to $12.2 million as of December 31, 2024. Clene expects that its resources as of December 31, 2025, combined with the proceeds received from its January 2026 registered direct offering, will provide operating runway to the end of the third quarter of 2026 with potential additional tranches of financing from this offering extending its cash runway into 2027.

Research and development expenses were $14.0 million for the year ended December 31, 2025, compared to $20.1 million for the same period in 2024. The year-over-year decrease was primarily due to decreased expenses related to the HEALEY ALS Platform Trial and RESCUE-ALS due to their previous completion of the blinded portion and open-label extensions of each trial, a decrease in expenses for regulatory activities, and a decrease in pre-clinical, non-clinical and other general CNM-Au8 related expenses, partially offset by an increase in expenses related to the NIH-EAP due to higher enrollment in the EAP. Manufacturing related expenses, as well as expenses related to personnel and stock-based compensation, also decreased. Additionally, grant revenue, which is recorded as a reduction to research and development expense, significantly increased in 2025 as compared to 2024 primarily related to an increase in enrollment and study operations of the NIH-EAP.

General and administrative expenses were $9.2 million for the year ended December 31, 2025, compared to $13.3 million for the same period in 2024. The year-over-year decrease was primarily attributable to lower insurance fees, legal fees and public and investor relations fees, as well as decreased personnel and stock-based compensation expenses, partially offset by an increase in finance and accounting fees. Additionally, grant revenue, which is recorded as a reduction to general and administration expense, increased in 2025 as compared to 2024 primarily related to an increase in enrollment and study operations of the NIH- EAP.

Total other expense, net, was $3.1 million for the year ended December 31, 2025, compared to $6.3 million for the same period in 2024. The year-over-year decrease in other expense was primarily attributable to lower interest expense and smaller changes in warrant and derivative liabilities. Additionally, a one-time loss on extinguishment of notes payable and a loss on initial issuance of equity only occurred in 2024.

Clene reported a net loss of $26.2 million, or $2.65 per share, for the year ended December 31, 2025, compared to a net loss of $39.4 million, or $5.67 per share, for the same period in 2024.

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 Company's operating cash runway, the potential for additional tranches of financing and the timing of such financings, 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.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Audited)

	Year Ended December 31,	
	2025	**2024**
Revenue:		
Product revenue	$ 119	$ 237
Royalty revenue	81	105
Total revenue	200	342

Operating expenses:		
Cost of revenue	43	70
Research and development	14,011	20,058
General and administrative	9,229	13,307
Total operating expenses	23,283	33,435
Loss from operations	(23,083)	(33,093)
Other income (expense), net:		
Interest income	223	865
Interest expense	(2,682)	(4,064)
Loss on extinguishment of notes payable	—	(214)
Issuance costs for common stock warrant liabilities	—	(157)
Loss on initial issuance of equity	—	(2,097)
Change in fair value of common stock warrant liabilities	(522)	(702)
Change in fair value of derivative liabilities	(363)	(379)
Change in fair value of Clene Nanomedicine contingent earn-out liability	—	75
Change in fair value of Initial Stockholders contingent earn-out liability	—	10
Research and development tax credits and unrestricted grants	254	357
Other expense, net	—	(1)
Total other income (expense), net	(3,090)	(6,307)
Net loss before income taxes	(26,173)	(39,400)
Income tax expense	—	—
Net loss	$ (26,173)	$ (39,400)
Other comprehensive income (loss):		
Unrealized loss on available-for-sale securities	$ —	$ (1)
Foreign currency translation adjustments	101	(127)
Total other comprehensive income (loss)	101	(128)
Comprehensive loss	$ (26,072)	$ (39,528)
Net loss per share – basic and diluted	$ (2.65)	$ (5.67)
Weighted average common shares used to compute basic and diluted net loss per share	9,858,907	6,954,133

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

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,189	$ 12,155
Accounts receivable	—	64
Inventory	37	68
Prepaid expenses and other current assets	3,751	3,870
Total current assets	8,977	16,157
Restricted cash	58	58
Operating lease right-of-use assets	3,073	3,643
Property and equipment, net	6,023	7,479
TOTAL ASSETS	$ 18,131	$ 27,337
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 892	$ 1,240
Accrued liabilities	5,002	7,766
Operating lease obligations, current portion	808	926
Notes payable, current portion	1,696	359
Convertible notes payable, current portion	2,378	—
Total current liabilities	10,776	10,291

Operating lease obligations, net of current portion	3,250	4,132
Notes payable, net of current portion	3,741	4,610
Convertible notes payable	9,800	10,816
Common stock warrant liabilities	5,063	4,541
Derivative liabilities	3,093	1,804
TOTAL LIABILITIES	35,723	36,194
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.0001 par value: 600,000,000 shares authorized; 10,849,974 and 8,089,565 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	1	1
Additional paid-in capital	290,531	273,194
Accumulated deficit	(308,296)	(282,123)
Accumulated other comprehensive income	172	71
TOTAL STOCKHOLDERS' DEFICIT	(17,592)	(8,857)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 18,131	$ 27,337