Clene Reports Third Quarter 2025 Financial Results and Recent Operating Highlights

November 13, 2025

- *As the U.S. Food and Drug Administration (FDA) proposed, Clene is concluding analyses of its ALS biomarker data with completion planned shortly*
- *The FDA advised Clene to request a Type C meeting to review these further ALS biomarker data analyses*
- *The Company plans to submit a New Drug Application (NDA) in the first quarter of 2026 under an accelerated approval pathway*
- *The Company expects to have the first patient dosed in the confirmatory Phase 3 RESTORE-ALS trial of CNM-Au8 in the first half of 2026*
- *The FDA and Clene participated in a Type B end of Phase 2 meeting in the third quarter of 2025 to discuss the Company's MS clinical development program and ongoing plans for MS development of CNM-Au8*
- *Cash and cash equivalents of $7.9 million as of September 30, 2025*
- *Cash runway extended into the second quarter of 2026, including $1.2 million additionally raised following the third quarter close*

SALT LAKE CITY, Nov. 13, 2025 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene" or the "Company") 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 third quarter 2025 financial results and provided recent updates on its CNM-Au8 programs.

"The three potential biomarker paths that could be leveraged to increase the persuasiveness of our ALS data, as outlined by the FDA, include: a) the NfL analysis of our ongoing NIH-sponsored Expanded Access Program (EAP); b) additional ALS disease-specific biomarker changes (in addition to NfL) from the HEALEY ALS Platform Trial; and c) NfL analysis of subjects in the open-label extension (OLE) of the HEALEY ALS Platform Trial who were initially treated with placebo during the placebo-controlled portion of the trial and then received CNM-Au8 during the OLE," said Rob Etherington, President and CEO of Clene. "The Company anticipates completing these data analyses shortly which could support the filing of an NDA using the accelerated approval pathway."

Third Quarter 2025 and Recent Operating Highlights

CNM-Au8 for the treatment of ALS

Clene held a second Type C meeting with the FDA to review the long-term survival benefit from CNM-Au8 30 mg treatment compared to concurrently randomized controls from another HEALEY ALS Platform Trial regimen in the third quarter. Consistent with prior interactions, the FDA remains focused on demonstrated improvements in ALS disease-specific biomarkers to support a regulatory filing under the accelerated approval path, with analyses of overall survival potentially serving as confirmatory evidence.

The FDA recommended three potential paths that could be leveraged to increase the persuasiveness of the Company's data, including analyses of other ALS disease-specific biomarkers and the effect of CNM-Au8 on NfL decline in various studies (NIH-sponsored EAP and HEALEY ALS Platform trial).

Further, as recommended by the FDA, Clene plans to request a Type C meeting with the FDA to review its data from these analyses, which meeting is expected to occur in the first quarter of 2026. Assuming the further ALS data analyses are consistent with previous results and incorporating FDA feedback, the Company plans to submit an NDA under an accelerated approval pathway.

Clene also anticipates having the first patient dosed in its confirmatory Phase 3 RESTORE-ALS trial of CNM-Au8 in the first half of 2026.

CNM-Au8 for the treatment of MS

In September 2025, the Company held a Type B end-of-Phase 2 meeting with the FDA, during which Clene and the FDA reviewed results from the Phase 2 VISIONARY-MS trial and explored proposed endpoints for the planned Phase 3 study focusing on cognition improvement as an adjunct to standard-of-care MS therapies. The FDA aligned with Clene acknowledging the limitations of the Expanded Disability Status Scale and expressed openness to considering other potential primary endpoints, including cognition, to evaluate broader treatment effects.

In September 2025, Clene presented the combined Phase 2 REPAIR-MS trial results across relapsing MS and non-active progressive MS during the 41st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). CNM-Au8 improved the brain's energy metabolism as evidenced by improvements to the NAD+/NADH ratio.

CNM-Au8 for the treatment of PD

In September 2025, Clene announced new preclinical data showing that CNM-Au8 improved key measures of cellular health in a novel dopaminergic neuron model of Parkinson's disease (PD). This novel model for PD demonstrated CNM-Au8's ability to improve mitochondrial health, restore cellular metabolism, reduce inflammation, and normalize dysregulated gene expression in both familial and sporadic PD. These new data support the continued development of CNM-Au8 as a treatment for PD.

Third Quarter 2025 Financial Results

Clene's cash and cash equivalents totaled $7.9 million as of September 30, 2025, compared to $12.2 million as of December 31, 2024. Clene expects that its cash and cash equivalents as of September 30, 2025, together with $1.2 million raised subsequent to September 30, 2025, will be sufficient to fund its operations into the second quarter of 2026.

Research and development expenses were $3.5 million for the quarter ended September 30, 2025, compared to $4.5 million for the same period in 2024. The year-over-year decrease was primarily related to decreased personnel expenses, primarily due to cost-saving initiatives, and a reduction in manufacturing expenses due to the conclusion of various clinical programs; a decrease in stock-based compensation expenses due to the timing of award grants, vesting and forfeitures; a decrease in expenses related to MS clinical programs; a decrease in expenses for regulatory activities related to ongoing FDA discussions and NDA submission-related activities; and an increase in grant revenue, recorded as a reduction in research and development expense, due to an increase in the enrollment and study operations in the NIH-sponsored EAP; partially offset by an increase in expenses related to the Company's ongoing EAPs and planning activities for the Phase 3 RESTORE-ALS clinical trial.

General and administrative expenses were $2.2 million for the quarter ended September 30, 2025, compared to $3.4 million for the same period in 2024. The year-over-year decrease was primarily related to decreases in legal fees, public and investor relations expenses, personnel expenses, and stock-based compensation expenses.

Total other expense was $3.1 million for the quarter ended September 30, 2025, compared to total other expense of $0.2 million for the same period in 2024. The increase in other expense was primarily related to losses from the changes in fair value of common stock warrant liabilities and derivative liabilities, partially offset by decreases in interest expense.

Clene reported a net loss of $8.8 million, or $0.85 per share, for the quarter ended September 30, 2025, compared to a net loss of $8.0 million, or $1.22 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 our analyses of potential biomarker paths, our plans to submit an NDA and the related timing, our expectations regarding the timing of the first patient dosing in the confirmatory Phase 3 RESTORE-ALS trial of CNM-Au8, the timing of our data collection and analyses, and our or our management team's expectations, hopes, beliefs, intentions or strategies regarding our future operations. 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue	$ —	$ 65	$ 65	$ 173
Royalty revenue	15	22	58	78
Total revenue	15	87	123	251
Operating expenses:				
Cost of revenue	—	18	20	52
Research and development	3,513	4,471	8,508	14,490
General and administrative	2,150	3,413	7,183	10,147
Total operating expenses	5,663	7,902	15,711	24,689
Loss from operations	(5,648)	(7,815)	(15,588)	(24,438)
Other income (expense), net:				
Interest income	40	127	183	755
Interest expense	(649)	(1,022)	(1,936)	(3,548)
Change in fair value of common stock warrant liabilities	(1,728)	697	267	956
Change in fair value of derivative liabilities	(797)	—	(89)	—
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	5	27	216	339
Total other income (expense), net	(3,129)	(171)	(1,359)	(1,413)
Net loss before income taxes	(8,777)	(7,986)	(16,947)	(25,851)
Income tax expense	—	—	—	—
Net loss	$ (8,777)	$ (7,986)	$ (16,947)	$ (25,851)
Other comprehensive income:				
Unrealized loss on available-for-sale securities	$ —	$ 1	$ —	$ (1)
Foreign currency translation adjustments	1	52	79	25
Total other comprehensive income	1	53	79	24
Comprehensive loss	$ (8,776)	$ (7,933)	$ (16,868)	$ (25,827)
Net loss per share – basic and diluted	$ (0.85)	$ (1.22)	$ (1.77)	$ (4.00)
Weighted average common shares used to compute basic and diluted net loss per share	10,284,674	6,557,839	9,549,661	6,467,771

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

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,925	$ 12,155
Accounts receivable	—	64
Inventory	61	68
Prepaid expenses and other current assets	4,687	3,870
Total current assets	12,673	16,157
Restricted cash	58	58
Operating lease right-of-use assets	3,225	3,643
Property and equipment, net	6,355	7,479
TOTAL ASSETS	$ 22,311	$ 27,337
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		

Accounts payable	$ 1,369	$ 1,240
Accrued liabilities	4,894	7,766
Operating lease obligations, current portion	783	926
Notes payable, current portion	690	359
Convertible notes payable, current portion	570	—
Total current liabilities	8,306	10,291
Operating lease obligations, net of current portion	3,484	4,132
Notes payable, net of current portion	4,567	4,610
Convertible notes payable	11,218	10,816
Common stock warrant liabilities	4,274	4,541
Derivative liabilities	2,819	1,804
TOTAL LIABILITIES	34,668	36,194
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.0001 par value: 600,000,000 shares authorized; 10,219,946 and 8,089,565 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	1	1
Additional paid-in capital	286,562	273,194
Accumulated deficit	(299,070)	(282,123)
Accumulated other comprehensive income	150	71
TOTAL STOCKHOLDERS' DEFICIT	(12,357)	(8,857)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 22,311	$ 27,337