Clene Reports First Quarter 2025 Financial Results and Recent Operating Highlights

May 7, 2025

- *Clene preparing for upcoming meeting in the second quarter with the U.S. Food and Drug Administration (FDA) to reach agreement on its statistical analysis plan (SAP) regarding analysis of neurofilament light chain (NfL) biomarker data*
- *Clene collecting NfL biomarker data from its large National Institute of Health (NIH)-sponsored Expanded Access Protocol (EAP), for evaluation in the third quarter to satisfy the FDA recommendation for additional NfL data*
- *Clene reported new data supporting the remyelination and neuronal repair associated with CNM-Au8® treatment in a late-breaking science session at the American Academy of Neurology (AAN) 2025 Annual Meeting*
- *Clene released new data from a cross-regimen analysis of HEALEY ALS Platform Trial, showing that CNM-Au8 significantly extends survival in patients with ALS*
- *Clene planning to submit a New Drug Application (NDA) in the fourth quarter of 2025 for potential Accelerated Approval of CNM-Au8 in ALS*
- *Cash and cash equivalents of $9.8 million as of March 31, 2025, providing cash runway into the third quarter of 2025*

SALT LAKE CITY, May 07, 2025 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, “Clene”) 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 first quarter 2025 financial results and provided recent updates on its CNM-Au8 programs.

“Prolonging survival for people living with ALS is the critical mission for Clene. Additionally, we continue to collect NfL biomarker data from our ongoing NIH-sponsored EAP in ALS patients, which we still plan to analyze in the third quarter of 2025, in alignment with FDA’s proposal, as announced in December 2024,” said Rob Etherington, President and CEO of Clene. “Using this data, alongside our data showing CNM-Au8 improved survival over time, we are in active preparations to potentially submit an NDA under the Accelerated Approval pathway for ALS in the fourth quarter of 2025. To discuss this possibility, we remain in active dialogue with the Division of Neurology at the FDA, who we believe also prioritizes alleviating the burden of neurodegenerative diseases for patients and their families.”

First Quarter 2025 and Recent Operating Highlights

CNM-Au8 for the treatment of ALS

Clene has a scheduled meeting in the second quarter of 2025 with the FDA to finalize its SAP for CNM-Au8 NfL biomarker data. This analysis of the NIH-sponsored EAP NfL biomarker data will occur in the third quarter of 2025 in order to support the planned submission of the ALS Accelerated Approval NDA in the fourth quarter of 2025.

Clene completed new analyses comparing survival in participants who received CNM-Au8 30 mg (Regimen C) to those of Regimen A in the HEALEY ALS Platform Trial. Regimen A provided a large concurrent control group versus CNM-Au8 treatment using the same randomization criteria established within the HEALEY master protocol. Long-term survival status, determined through public records and site reporting, was also evaluated over a follow-up period of up to 48 months. Overall survival improvement (all-cause mortality) was observed with the covariate-adjusted restricted mean survival time (RMST) improvement of 4.1 months (95% CI: 3 to 245 days, p=0.045). Further, enhanced survival benefit in more severe ALS seen in patients with baseline serum NfL > 33 pg/mL and TRICALS risk score range between –6.5 and –2.5 (i.e., filtering slow progressors where there was an imbalance between groups), where median survival improved by a 11.9 month gain and mortality risk in this subgroup decreased by 44% (Cox HR: 0.556, 95% CI: 0.367–0.842, p=0.006).

CNM-Au8 for the treatment of MS

In April, Clene presented new evidence of remyelination and neuronal repair with CNM-Au8 treatment at the AAN 2025 Annual Meeting Late-Breaking Science Session 2. The presentation, titled “Physiologic and Anatomical Evidence of Neuronal Repair and Remyelination from the Long-Term Open-Label Extension of the Phase 2 VISIONARY-MS Trial,” highlighted significant and clinically meaningful improvements in cognition and visual function, supported by corresponding objective biomarkers, including advanced MRI Diffusion Tensor Imaging (DTI) and multi-focal Visual Evoked Potential (mf-VEP) assessments which confirmed anatomical and physiological improvements, indicating remyelination and neuronal repair in the brains of MS patients treated with CNM-Au8 during the long-term extension of VISIONARY-MS. Clene plans to discuss the entire VISIONARY-MS trial, including this recently presented data at an end-of-Phase 2 meeting with the FDA in the third quarter of 2025.

First Quarter 2025 Financial Results

Clene’s cash and cash equivalents totaled $9.8 million as of March 31, 2025, compared to $12.2 million as of December 31, 2024. Clene expects that its resources as of March 31, 2025, will be sufficient to fund its operations into the third quarter of 2025.

Research and development expenses were $1.5 million for the quarter ended March 31, 2025, compared to $5.9 million for the same period in 2024. The year-over-year decrease was primarily related to grant revenue recognized related to Year 2 (September 2024 through March 2025) of our ongoing ALS EAP funded by the NIH, which reimbursements are recorded as an offset to research and development expense, as well as lower expenses related to regulatory, manufacturing and personnel costs due to the completion of several of our clinical trials, partially offset by an increase in expenses related to our three ongoing EAPs.

General and administrative expenses were $2.7 million for the quarter ended March 31, 2025, compared to $3.4 million for the same period in 2024. The year-over-year decrease was primarily related to decreases in public and investor relations expenses, decreases in personnel costs, and a decrease in stock-based compensation expense. Additionally, grant revenue increased related to Year 2 of our ongoing ALS EAP funded by the NIH, which is recorded as an offset to general and administrative expense.

Total other income was $3.3 million for the quarter ended March 31, 2025, compared to total other expense of $1.8 million for the same period in 2024. The year-over-year change was primarily related to non-cash gains recognized on the change in fair values of derivative liabilities separated from our senior secured convertible promissory notes, non-cash gains recognized on the change in fair values of common stock warrant liabilities, and decreases in interest expense primarily due to declining balances of notes payable following principal repayments, partially offset by a decrease in interest income primarily due to lower average balances of cash and cash equivalents and lower interest rates.

Clene reported a net loss of $0.8 million, or $0.09 per share, for the quarter ended March 31, 2025, compared to a net loss of $11.1 million, or $1.73 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 Company's expectations regarding the timing of its Phase 3 RESTORE-ALS study, the submission of its NDA, its meeting with the FDA and resulting statistical analyses, and the actual NfL biomarker collection and analyses; that it will be able to determine concordance of the NIH-sponsored EAP NfL data with NfL data from the HEALEY ALS Platform Trial; and that its resources will be sufficient to fund its operations into the third quarter of 2025. In addition, any statements that refer to 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. Some factors that could cause actual results to differ include the Company's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies; the Company's limited operating history and its ability to obtain additional funding for operations and to complete the development and commercialization of its 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,	
	2025	2024
Revenue:		
Product revenue	$ 64	$ 44

Royalty revenue	17	29
Total revenue	81	73
Operating expenses:		
Cost of revenue	20	16
Research and development	1,481	5,869
General and administrative	2,656	3,420
Total operating expenses	4,157	9,305
Loss from operations	(4,076)	(9,232)
Other income (expense), net:		
Interest income	81	359
Interest expense	(608)	(1,244)
Change in fair value of common stock warrant liabilities	2,510	(1,309)
Change in fair value of derivative liabilities	1,147	—
Change in fair value of Clene Nanomedicine contingent earn-out liability	—	53
Change in fair value of Initial Stockholders contingent earn-out liability	—	7
Research and development tax credits and unrestricted grants	195	286
Total other income (expense), net	3,325	(1,848)
Net loss before income taxes	(751)	(11,080)
Income tax expense	—	—
Net loss	$ (751)	$ (11,080)
Other comprehensive income (loss):		
Unrealized loss on available-for-sale securities	—	(4)
Foreign currency translation adjustments	15	(55)
Total other comprehensive income (loss)	15	(59)
Comprehensive loss	$ (736)	$ (11,139)
Net loss per share – basic and diluted	$ (0.09)	$ (1.73)
Weighted average common shares used to compute basic and diluted net loss per share	8,824,673	6,421,362

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

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,832	$ 12,155
Accounts receivable	—	64
Inventory	38	68
Prepaid expenses and other current assets	4,801	3,870
Total current assets	14,671	16,157
Restricted cash	58	58
Operating lease right-of-use assets	3,510	3,643
Property and equipment, net	7,075	7,479
TOTAL ASSETS	$ 25,314	$ 27,337
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,413	$ 1,240
Accrued liabilities	5,245	7,766
Operating lease obligations, current portion	985	926
Notes payable, current portion	3,121	359
Total current liabilities	10,764	10,291
Operating lease obligations, net of current portion	3,922	4,132
Notes payable, net of current portion	1,943	4,610
Convertible notes payable	10,970	10,816
Common stock warrant liabilities	2,031	4,541
Derivative liabilities	657	1,804

TOTAL LIABILITIES	30,287	36,194
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.0001 par value: 600,000,000 shares authorized; 8,667,770 and 8,089,565 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	1	1
Additional paid-in capital	277,814	273,194
Accumulated deficit	(282,874)	(282,123)
Accumulated other comprehensive income	86	71
TOTAL STOCKHOLDERS' DEFICIT	(4,973)	(8,857)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 25,314	$ 27,337