Clene Reports Full Year 2024 Financial Results and Recent Operating Highlights

March 24, 2025

- *Clene planning to submit a New Drug Application (NDA) in the second half of 2025 for potential Accelerated Approval of CNM-Au8® in ALS*
- *Clene planning to initiate the confirmatory Phase 3 RESTORE-ALS trial in subjects with ALS in mid-2025*
- *Secured new $10.0 million debt facility at a lower interest rate to replace remaining outstanding $7.85 million debt balance with Avenue Capital*
- *Cash, cash equivalents and marketable securities of $12.2 million as of December 31, 2024, includes $7.3 million in gross proceeds raised on October 1, 2024*
- *Clene collecting and analyzing biomarker NfL data from its large NIH-sponsored Early Access Protocol (EAP), for evaluation in the third quarter to satisfy the U.S. Food and Drug Administration (FDA) recommendation for additional neurofilament light chain (NfL) data*

SALT LAKE CITY, March 24, 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 full year 2024 financial results and provided recent operating highlights for the clinical programs in ALS and MS.

“We expect further regulatory guidance in 2025 on the critical next steps required to advance our CNM-Au8 NDA submission for the treatment of ALS under the accelerated approval pathway. We plan to meet with the agency in the second quarter of 2025 to align on our statistical analysis plan for our NfL biomarker data being collected from the ongoing NIH-sponsored EAP in ALS patients and then conduct the resulting analyses in the third quarter,” said Rob Etherington, President and CEO of Clene. “Our goal from these additional analyses is to determine concordance of the NIH-sponsored EAP NfL data with NfL results in our HEALEY Platform Trial. We intend to use this NfL surrogate biomarker data as a basis to file our NDA in the second half of 2025 for potential Accelerated Approval. In addition, Clene continues analyzing the long-term effect of CNM-Au8 on vision and cognition improvements seen in our VISIONARY-MS trial in MS. As always, we are incredibly motivated by our mission to help people suffering from ALS and other neurodegenerative diseases prolong their lifespan and improve their quality of life.”

Fourth Quarter 2024 and Recent Operating Highlights
CNM-Au8, a gold nanocrystal suspension, for the treatment of ALS

In December, Clene announced that it recently received written guidance from the Division of Neurology 1 (DN1), of the FDA regarding a potential accelerated approval pathway for CNM-Au8 in ALS.

- Following Clene’s November 1, 2024 meeting with DN1 and presentation of additional data and analyses, the FDA has provided guidance on a potential path to meet the regulatory standard for substantial evidence of effectiveness supporting accelerated approval. The FDA recommended that Clene investigate whether additional data from the ongoing EAPs could be leveraged to substantiate the effect of CNM-Au8 on NfL decline.

- Clene intends to follow the FDA’s recommendation to provide data from the ongoing EAPs and believes that it can address the FDA’s requests. Clene will meet with the FDA in the second quarter of 2025 to review and finalize its statistical analysis plan for the EAP NfL biomarker analyses followed by the actual NfL biomarker collection and analyses in the third quarter to support NDA submission. NDA submission is anticipated to occur in the second half of 2025. Additionally, the FDA indicated that the decision as to whether NfL can serve as a reasonably likely surrogate endpoint for the effects of CNM-Au8 in ALS and whether the magnitude of change observed on NfL in patients treated with CNM-Au8 is reasonably likely to predict clinical benefit for ALS would be a matter of FDA review.

- 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 vs. 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 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).

- Clene plans to commence the confirmatory Phase 3 RESTORE-ALS trial with participant enrollment beginning in mid-2025 which is prior to the submission of the NDA. The study 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).

In over 800 patient years of use of CNM-Au8, no significant safety concerns or safety trends have been identified. No serious adverse events (SAEs) have been identified as related to CNM-Au8 treatment by any investigator to date.

Corporate Update

In December, Clene secured a new $10.0 million debt facility (Note) to replace its outstanding remaining $7.85 million debt balance with Avenue Capital. As part of this transaction, the three lenders provided the aggregate principal amount of $10 million for the secured, partially convertible Note with a maturity of eighteen months after closing bearing a fixed interest rate of 12%. The first twelve months of the Note are interest-only. Sixty-five percent of the Note is convertible into shares of Clene's common stock at a fixed conversion price of $5.67, a 30% premium to Clene's closing stock price on the day of signing.

Full Year 2024 Financial Results

Clene's cash, cash equivalents and marketable securities totaled $12.2 million as of December 31, 2024, compared to $35.0 million as of December 31, 2023. Clene expects that its resources as of December 31, 2024, will be sufficient to fund its operations into the second quarter of 2025.

Research and development expenses were $20.1 million for the year ended December 31, 2024, compared to $26.7 million for the same period in 2023. The year-over-year decrease was primarily due to lower expenses related to the HEALEY ALS Platform Trial and the RESCUE-ALS and VISIONARY-MS clinical trials, and corresponding decreases in manufacturing costs needed to support ongoing trials; partially offset by an increase in expenses related to the REPAIR-MS clinical trial, due to the ongoing second dosing cohort, an increase in expenses related our two ongoing ALS EAPs sponsored by Massachusetts General Hospital and our ongoing MS EAP, and an increase in personnel expenses, primarily due to an increase in personnel supporting our NIH-sponsored EAP and regulatory activities in advance of a potential NDA submission. Additionally, grant revenue, which is recorded as a reduction to research and development expense, significantly increased in 2024 as compared to 2023 primarily related to our NIH-sponsored EAP.

General and administrative expenses were $13.3 million for the year ended December 31, 2024, compared to $14.4 million for the same period in 2023. The year-over-year decrease was primarily attributable to lower insurance fees, financing and accounting fees, and stock-based compensation; partially offset by an increase in legal fees related to regulatory activities and intellectual property, as well as an increase in other expenses.

Total other expense was $6.3 million for the year ended December 31, 2024, compared to $9.0 million for the same period in 2023. The year-over-year decrease in expense was primarily attributable to lower interest expense and a smaller loss on initial issuance of equity from our public equity offerings in 2024; offset partially by smaller gains from the change in the fair value of contingent earn-out liabilities and losses from the change in fair value of common stock warrant liabilities in 2024 compared to gains in 2023, less interest income earned in 2024 and less revenues from research and development tax credits and unrestricted grants received in 2024.

Clene reported a net loss of $39.4 million, or $5.67 per share, for the year ended December 31, 2024, compared to a net loss of $49.5 million, or $9.43 per share, for the same period in 2023.

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.

About RESTORE-ALS
RESTORE-ALS is a Phase 3 (RESTORE-ALS) confirmatory global, multi-center, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy, safety, pharmacodynamics, and pharmacokinetics of CNM-Au8 in participants diagnosed with ALS on stable background therapy. The study 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). Participants will be randomized in a 2:1 ratio to receive either active treatment with CNM-Au8 30 mg or matched placebo daily during the 108-week double-blind treatment period.

The Phase 3 RESTORE-ALS clinical trial, due to launch in mid-2025, is planned to serve as the confirmatory clinical trial required to meet the FDA's guidance for an "underway" clinical trial when a New Drug Application requesting Accelerated Approval is submitted.

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 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 second 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.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Audited)

	Year Ended December 31,	
	2024	**2023**
Revenue:		
Product revenue	$ 237	$ 498
Royalty revenue	105	156
Total revenue	342	654
Operating expenses:		
Cost of revenue	70	121
Research and development	20,058	26,655
General and administrative	13,307	14,418
Total operating expenses	33,435	41,194
Loss from operations	(33,093)	(40,540)
Other income (expense), net:		
Interest income	865	1,389
Interest expense	(4,064)	(4,558)
Loss on extinguishment of notes payable	(214)	—
Commitment share expense	—	(402)
Issuance costs for common stock warrant liabilities	(157)	(333)
Loss on initial issuance of equity	(2,097)	(14,840)
Change in fair value of common stock warrant liabilities	(702)	6,337
Change in fair value of derivative liabilities	(379)	—
Change in fair value of Clene Nanomedicine contingent earn-out liability	75	2,189
Change in fair value of Initial Stockholders contingent earn-out liability	10	281
Research and development tax credits and unrestricted grants	357	963
Other income (expense), net	(1)	10
Total other income (expense), net	(6,307)	(8,964)
Net loss before income taxes	(39,400)	(49,504)
Income tax expense	—	—
Net loss	(39,400)	(49,504)
Other comprehensive loss:		
Unrealized gain (loss) on available-for-sale securities	(1)	16
Foreign currency translation adjustments	(127)	(20)
Total other comprehensive loss	(128)	(4)
Comprehensive loss	$ (39,528)	$ (49,508)

Net loss per share – basic and diluted	$ (5.67)	$ (9.43)
Weighted average common shares used to compute basic and diluted net loss per share	6,954,133	5,246,941

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

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,155	$ 28,821
Marketable securities	—	6,179
Accounts receivable	64	143
Inventory	68	37
Prepaid expenses and other current assets	3,870	3,672
Total current assets	16,157	38,852
Restricted cash	58	58
Operating lease right-of-use assets	3,643	4,168
Property and equipment, net	7,479	9,263
TOTAL ASSETS	$ 27,337	$ 52,341
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,240	$ 1,504
Accrued liabilities	7,766	3,720
Operating lease obligations, current portion	926	576
Finance lease obligations, current portion	—	27
Notes payable, current portion	359	14,627
Convertible notes payable, current portion	—	4,876
Total current liabilities	10,291	25,330
Operating lease obligations, net of current portion	4,132	4,903
Notes payable, net of current portion	4,610	1,894
Convertible notes payable, net of current portion	10,816	5,258
Common stock warrant liabilities	4,541	1,481
Derivative liabilities	1,804	—
Clene Nanomedicine contingent earn-out liability	—	75
Initial Stockholders contingent earn-out liability	—	10
TOTAL LIABILITIES	36,194	38,951
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 600,000,000 and 300,000,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; 8,089,565 and 6,421,084 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	273,194	255,913
Accumulated deficit	(282,123)	(242,723)
Accumulated other comprehensive income	71	199
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(8,857)	13,390
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 27,337	$ 52,341