



Clene Reports Third Quarter 2024 Financial Results and Recent Operating Highlights

November 13, 2024

- *Clene met with the U.S. Food and Drug Administration (FDA) on November 1, 2024, in a Type C meeting to discuss the potential for an accelerated approval pathway in ALS and are awaiting meeting minutes*
- *Cash, cash equivalents and marketable securities of \$14.6 million as of September 30, 2024*
- *Amended debt agreement with Avenue Capital to defer principal payments and extend maturity of facility to second quarter of 2025*
- *Completed registered direct offering and concurrent private placements to raise \$7.3 million in gross proceeds on October 1, 2024*

SALT LAKE CITY, Nov. 13, 2024 (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 third quarter 2024 financial results and provided recent updates on its CNM-Au8 programs.

Third Quarter 2024 and Recent Operating Highlights

CNM-Au8 for the treatment of ALS

On November 1, 2024, the Company met with the FDA in a Type C meeting to discuss the potential for an accelerated approval pathway in ALS for CNM-Au8, including biomarker and related clinical and survival data, and are currently awaiting meeting minutes from this meeting.

Corporate Update

In July, Clene announced a 1-for-20 reverse stock split. Clene's common stock now trades on the Nasdaq Capital Market on a split-adjusted basis under a new CUSIP number 185634201 and the Company's existing trading symbol "CLNN." The reverse stock split enabled Clene to regain compliance with the \$1.00 minimum closing bid price required for continued listing on the Nasdaq Capital Market. All outstanding stock options, warrants, rights to restricted stock awards, convertible debt, and contingent earn-out shares entitling their holders to purchase or receive shares of Common Stock were adjusted as a result of the reverse stock split as required by the terms of each security.

In September, Clene amended its existing debt facility with Avenue Venture Opportunities Fund, L.P. in which the parties agreed to reduce or defer future monthly principal payments and extend the principal amortization period and maturity date into the second quarter of 2025.

In October, Clene announced the closing of a registered direct offering and concurrent private placements of common stock and warrants with a healthcare-focused institutional investor and existing shareholders, including insiders, with total gross proceeds of \$7.3 million and the potential for additional capital in the future through the exercise of warrants. The offering was led by a healthcare-focused institutional investor with participation from SymBiosis; founding investor Kensington Capital Holdings; Clene's Chairman of the Board of Directors, Chief Executive Officer and Chief Scientific Officer and Founder; along with support from several other previously existing shareholders.

The October offering, combined with the amendment to the debt facility with Avenue, is expected to enable the Company to fund its operations into the first quarter of 2025. We believe that this funding enables runway for key inflection points.

In October, Clene presented the design for RESTORE-ALS, its potentially confirmatory international Phase 3 clinical trial of CNMAu8 30 mg, at the 2024 Annual Northeast Amyotrophic Lateral Sclerosis Consortium.

Third Quarter 2024 Financial Results

Clene's cash, cash equivalents and marketable securities totaled \$14.6 million as of September 30, 2024, compared to \$35.0 million as of December 31, 2023. Clene expects that its resources as of September 30, 2024 combined with gross proceeds raised in the October offering, will be sufficient to fund its operations into the first quarter of 2025.

Research and development expenses were \$4.5 million for the quarter ended September 30, 2024, compared to \$6.0 million for the same period in 2023. The year-over-year decrease was primarily related to a decrease in expenses in the HEALEY ALS Platform Trial, RESCUE-ALS, REPAIR-MS, and VISIONARY-MS clinical trials due to the previous completion of the blinded period of each trial; a decrease in expenses for the VISIONARY-MS LTE due to its completion; and a decrease in non-clinical and pre-clinical activities; partially offset by an increase in expenses related to our two ALS EAPs with Massachusetts General Hospital due to increased enrollment and expansion of one EAP.

General and administrative expenses were \$3.4 million for the quarter ended September 30, 2024, compared to \$3.7 million for the same period in 2023. The year-over-year decrease was primarily related to decreases in directors' and officers' insurance premiums, decreases in finance and accounting fees, primarily due to a decrease in fees from consultants, advisors, and other financial vendors, and decreases in stock-based compensation expense; partially offset by an increase in legal fees, primarily related to regulatory activities, and an increase in other general and administrative fees associated primarily with lobbying activities.

Total other expense was \$0.2 million for the quarter ended September 30, 2024, compared to total other income of \$7.1 million for the same period in 2023. During 2023, Clene recorded significant non-cash gains from the change in the fair value of the common stock warrant liability related to the 2023 Avenue Warrants and Tranche A Warrants as well as significant non-cash gains from the change in fair value of the Clene Nanomedicine

Contingent Earn-out liability and the Initial Stockholders Contingent Earn-out liability. Similar large non-cash gains were not recorded in 2024. Additionally, interest expense was less in 2024 due to reduced interest rates and outstanding principal balances.

Clene reported a net loss of \$8.0 million, or \$1.22 per share, for the quarter ended September 30, 2024, compared to a net loss of \$2.4 million, or \$0.38 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.

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 Clene's expectations that its resources are sufficient to fund operations into the first quarter of 2025 and the availability of an accelerated approval regulatory pathway. 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. As a result of a number of known and unknown risks and uncertainties, Clene's expectations that its resources are sufficient to fund operations into the first quarter of 2025, and the availability of an accelerated approval regulatory pathway 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 of our drug candidates fail to demonstrate safety and efficacy 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; Clene'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, which may affect the initiation, timing and progress of clinical trials and marketing approval; Clene's ability to achieve commercial success for its drug candidates, if approved; Clene'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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue	\$ 65	\$ 65	\$ 173	\$ 355
Royalty revenue	22	43	78	129
Total revenue	87	108	251	484
Operating expenses:				
Cost of revenue	18	12	52	83

Research and development	4,471	5,972	14,490	19,982
General and administrative	3,413	3,666	10,147	11,029
Total operating expenses	7,902	9,650	24,689	31,094
Loss from operations	(7,815)	(9,542)	(24,438)	(30,610)
Other income (expense), net:				
Interest income	127	546	755	931
Interest expense	(1,022)	(1,188)	(3,548)	(3,358)
Commitment share expense	—	—	—	(402)
Issuance costs for common stock warrant liabilities	—	—	—	(333)
Loss on initial issuance of equity	—	—	—	(14,840)
Change in fair value of common stock warrant liabilities	697	6,341	956	5,958
Change in fair value of Clene Nanomedicine contingent earn-out liability	—	1,004	75	2,114
Change in fair value of Initial Stockholders contingent earn-out liability	—	129	10	272
Research and development tax credits and unrestricted grants	27	247	339	902
Other income, net	—	45	—	35
Total other income (expense), net	(171)	7,124	(1,413)	(8,721)
Net loss before income taxes	(7,986)	(2,418)	(25,851)	(39,331)
Income tax expense	—	—	—	—
Net loss	(7,986)	(2,418)	(25,851)	(39,331)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	1	(4)	(1)	16
Foreign currency translation adjustments	52	(81)	25	(130)
Total other comprehensive income (loss)	53	(85)	24	(114)
Comprehensive loss	<u>\$ (7,933)</u>	<u>\$ (2,503)</u>	<u>\$ (25,827)</u>	<u>\$ (39,445)</u>
Net loss per share – basic and diluted	\$ (1.22)	\$ (0.38)	\$ (4.00)	\$ (8.11)
Weighted average common shares used to compute basic and diluted net loss per share	6,557,839	6,420,274	6,467,771	4,851,348

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

	<u>September 30,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,645	\$ 28,821
Marketable securities	—	6,179
Accounts receivable	—	143
Inventory	128	37
Prepaid expenses and other current assets	4,925	3,672
Total current assets	<u>19,698</u>	<u>38,852</u>
Restricted cash	58	58
Operating lease right-of-use assets	3,776	4,168
Property and equipment, net	8,037	9,263
TOTAL ASSETS	<u>\$ 31,569</u>	<u>\$ 52,341</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 1,678	\$ 1,504
Accrued liabilities	6,733	3,720
Share subscriptions payable	3,810	—
Operating lease obligations, current portion	732	576
Finance lease obligations, current portion	—	27
Notes payable, current portion	10,875	14,627
Convertible notes payable, current portion	—	4,876

Total current liabilities	23,828	25,330
Operating lease obligations, net of current portion	4,335	4,903
Notes payable, net of current portion	1,668	1,894
Convertible notes payable, net of current portion	5,271	5,258
Common stock warrant liabilities	592	1,481
Clene Nanomedicine contingent earn-out liability	—	75
Initial Stockholders contingent earn-out liability	—	10
TOTAL LIABILITIES	<u>35,694</u>	<u>38,951</u>
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value: 600,000,000 and 300,000,000 shares authorized at September 30, 2024 and December 31, 2023, respectively; 6,857,170 and 6,421,084 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	264,225	255,913
Accumulated deficit	(268,574)	(242,723)
Accumulated other comprehensive income	223	199
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>(4,125)</u>	<u>13,390</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 31,569</u>	<u>\$ 52,341</u>