



Clene Reports Third Quarter 2023 Financial Results and Operating Highlights

November 7, 2023

- Reported statistically significant improved survival benefit of 19.3 months and significantly delayed clinical worsening in patients treated with CNM-Au8® in the RESCUE ALS open-label extension trial
- Reported statistically significant long-term survival benefit of 70% decreased risk of death associated with CNM-Au8 treatment in the HEALEY ALS Platform Trial compared to PRO-ACT historical controls
- Awarded \$45.1 million NINDS grant to support research and expanded access of CNM-Au8 in people living with ALS
- Announced peer-reviewed publication characterizing CNM-Au8 neuroprotective mechanism of action in the nanotechnology-focused journal, *Small*
- Cash and cash equivalents of \$42.1 million as of September 30, 2023, which includes gross proceeds of \$40 million from a public offering in June and that may provide additional capital of up to \$130 million through future warrant exercises based on regulatory milestones

SALT LAKE CITY, Nov. 07, 2023 (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 improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS), Parkinson's disease and multiple sclerosis (MS), today announced its third quarter 2023 financial results and provided recent operating highlights for its ALS clinical program.

"We are pleased to be approaching a meaningful regulatory discussion with the U.S. Food and Drug Administration (FDA) later in the fourth quarter to elucidate key next steps in our ALS regulatory submission of CNM-Au8," said Rob Etherington, President and CEO of Clene. "We are hopeful that the consistent survival, delayed time to clinical worsening and strong safety profile with CNM-Au8 treatment from two phase 2 independent trials is sufficiently compelling for FDA to consider an accelerated path forward. The unmet need remains high for treatments to improve and extend life for patients living with this highly debilitating and rapidly progressive condition."

Third Quarter 2023 and Recent Operating Highlights

CNM-Au8, a gold nanocrystal suspension, for the treatment of ALS

- In August, Clene reported 24-month data from the open-label extension of the Phase 2 RESCUE ALS study which showed a significant median survival benefit of 19.3 months, a 75% decreased risk of long-term all-cause mortality and a significant 52% decreased risk ($p=0.049$) of ALS clinical worsening events in patients originally randomized to CNM-Au8 treatment.
- In September, Clene announced long-term follow-up data for patients treated with CNM-Au8 for up to 133 weeks in the HEALEY ALS Platform Trial. These *post hoc* data demonstrate significantly improved survival with a 49% decreased risk of death compared to a group of historical controls, who were included in the largest U.S. clinical database of previous ALS trials (PRO-ACT).
- In October, Clene, in collaboration with Columbia University and Synapticure, was awarded a four-year grant totaling \$45.1 million from the National Institute of Neurological Disorders and Stroke (NINDS), a division of the National Institutes of Health (NIH), to support an Expanded Access Protocol (EAP) for the Company's investigational drug, CNM-Au8, in ALS.

Corporate Update

In September, the Company announced the publication of a scientific paper describing the catalytic mechanism of action (MOA) of its investigational drug, CNM-Au8 in the journal *Small*, a top nanotechnology-focused journal at the interface of materials science, chemistry, physics, engineering, medicine, and biology. The publication titled "A Mechanism Underpinning the Bioenergetic Metabolism-Regulating Function of Gold Nanocatalysts" characterizes the robust neuroprotective properties of CNM-Au8, which are related to the compound's therapeutic catalytic activity. Because of the unique MOA of CNM-Au8 and the wide applicability of its neuroprotective activities, the drug is being studied across multiple neurodegenerative diseases including ALS, MS and Parkinson's Disease.

The publication is available via Open Access at <https://onlinelibrary.wiley.com/doi/10.1002/sml.202304082>.

Third Quarter 2023 Financial Results

Clene's cash, cash equivalents and marketable securities totaled \$42.1 million as of September 30, 2023, compared to \$23.3 million as of December 31, 2022. Clene expects that its resources as of September 30, 2023, will be sufficient to fund its operations into the third quarter of 2024.

Research and development expenses were \$6.0 million for the quarter ended September 30, 2023, compared to \$6.4 million for the same period in 2022. The year-over-year decrease was primarily related to a decrease in expenses related to our lead drug candidate, CNM-Au8, due to a decrease in clinical trial expenses in our HEALEY ALS Platform Trial and our RESCUE-ALS, REPAIR-MS, REPAIR-PD, and VISIONARY-MS clinical trials due to the completion of the blinded period of each trial, partially offset by increased expenses related to our ongoing EAPs and increased facility costs related to our newly-leased facility in Elkton, Maryland.

General and administrative expenses were \$3.7 million for the quarter ended September 30, 2023, compared to \$3.6 million for the same period in 2022. General and administrative expenses have remained flat year over year although directors' and officers' insurance fees and legal fees have decreased year over year while finance and accounting expenses related to fees from auditors, consultants and other financial vendors have increased and personnel fees have increased.

Total other income was \$7.1 million for the quarter ended September 30, 2023, compared to total other expense of \$1.2 million for the same period in 2022. The year-over-year increase in other income was primarily attributable to the changes in the fair value of common stock warrant liabilities and contingent earn-out liabilities as well as an increase in interest income.

Clene reported a net loss of \$2.4 million, or \$0.02 per share, for the quarter ended September 30, 2023, compared to a net loss of \$11.0 million, or \$0.17 per share, for the same period in 2022.

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](#).

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 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 our ability to demonstrate the efficacy and safety 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		Nine Months Ended September	
	30,	30,	30,	30,
	2023	2022	2023	2022
Revenue:				
Product revenue	\$ 65	\$ 130	\$ 355	\$ 139
Royalty revenue	43	44	129	100
Total revenue	108	174	484	239
Operating expenses:				
Cost of revenue	12	19	83	19
Research and development	5,972	6,403	19,982	24,149
General and administrative	3,666	3,557	11,029	12,807
Total operating expenses	9,650	9,979	31,094	36,975

Loss from operations	(9,542)	(9,805)	(30,610)	(36,736)
Other income (expense), net:				
Interest income	546	59	931	144
Interest expense	(1,188)	(857)	(3,358)	(2,390)
Gain on termination of lease	—	—	—	420
Commitment share expense	—	—	(402)	—
Issuance costs for common stock warrant liability	—	—	(333)	—
Loss on initial issuance of equity	—	—	(14,840)	—
Change in fair value of common stock warrant liabilities	6,341	149	5,958	151
Change in fair value of Clene Nanomedicine contingent earn-out liability	1,004	(1,591)	2,114	6,662
Change in fair value of Initial Stockholders contingent earn-out liability	129	(205)	272	849
Research and development tax credits and unrestricted grants	247	1,346	902	2,001
Other income (expense), net	45	(72)	35	35
Total other income (expense), net	7,124	(1,171)	(8,721)	7,872
Net loss before income taxes	(2,418)	(10,976)	(39,331)	(28,864)
Income tax benefit	—	—	—	—
Net loss	(2,418)	(10,976)	(39,331)	(28,864)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	(4)	33	16	(54)
Foreign currency translation adjustments	(81)	(39)	(130)	(99)
Total other comprehensive loss	(85)	(6)	(114)	(153)
Comprehensive loss	<u>\$ (2,503)</u>	<u>\$ (10,982)</u>	<u>\$ (39,445)</u>	<u>\$ (29,017)</u>
Net loss per share – basic and diluted	\$ (0.02)	\$ (0.17)	\$ (0.41)	\$ (0.46)
Weighted average common shares used to compute basic and diluted net loss per share	128,405,483	63,508,928	97,026,964	63,234,757

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

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 42,113	\$ 18,332
Marketable securities	—	4,983
Accounts receivable	64	189
Inventory	104	43
Prepaid expenses and other current assets	4,165	5,648
Total current assets	46,446	29,195
Restricted cash	58	58
Operating lease right-of-use assets	4,287	4,602
Property and equipment, net	9,642	10,638
TOTAL ASSETS	<u>\$ 60,433</u>	<u>\$ 44,493</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,889	\$ 3,014
Accrued liabilities	3,194	3,863
Operating lease obligations, current portion	553	488
Finance lease obligations, current portion	44	74
Notes payable, current portion	9,588	6,418
Total current liabilities	15,268	13,857
Operating lease obligations, net of current portion	5,080	5,557
Finance lease obligations, net of current portion	—	34

Notes payable, net of current portion	6,675	9,483
Convertible notes payable	9,975	9,770
Common stock warrant liabilities	1,860	—
Clene Nanomedicine contingent earn-out liability	150	2,264
Initial Stockholders contingent earn-out liability	19	291
TOTAL LIABILITIES	<u>39,027</u>	<u>41,256</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value: 300,000,000 and 150,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 128,411,981 and 74,759,591 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	13	7
Additional paid-in capital	253,854	196,246
Accumulated deficit	(232,550)	(193,219)
Accumulated other comprehensive income	89	203
TOTAL STOCKHOLDERS' EQUITY	<u>21,406</u>	<u>3,237</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 60,433</u>	<u>\$ 44,493</u>