Clene Reports First Quarter 2023 Financial Results and Recent Operating Highlights

May 12, 2023

- *ALS biomarker and long-term clinical data expected mid-year*
- *Neurology expert Ben Greenberg, M.D., M.H.S., joined as Head of Medical*

SALT LAKE CITY, May 12, 2023 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, “Clene”) and its wholly owned subsidiary Clene Nanomedicine Inc., a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative diseases, today announced its first quarter 2023 financial results and provided recent operating highlights for the clinical programs in amyotrophic lateral sclerosis (“ALS”) and multiple sclerosis (“MS”).

“Clene is approaching several important data milestones in ALS,” said Rob Etherington, President and CEO of Clene. “These include key biomarker data that may support accelerated FDA approval as well as additional long-term survival data from both the HEALEY ALS Platform trial and our RESCUE ALS open-label extension trial. These data will inform our regulatory strategy as we plan ahead for our end-of-Phase 2 meeting with the FDA in the third quarter. In parallel, we are planning to advance regulatory discussions about MS anticipated in the fourth quarter and continue our pursuit of opportunities to establish a partnership for this program.”

First Quarter 2023 and Recent Operating Highlights

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

A poster entitled “Evidence for Survival Benefit in ALS with CNM-Au8 Treatment Across Three Study Populations” was presented on April 25 th by Dr. James Berry at the American Academy of Neurology conference and included the following highlights:

- Survival in Early-to-Mid Stage ALS: CNM-Au8 30 mg demonstrated a statistically significant survival benefit of 60% and decreased risk of death through 120 weeks versus original placebo randomization in during follow-up of participants in the RESCUE-ALS trial .
- Survival in Mid-to-late stage ALS: CNM-Au8 30mg was associated with risk adjusted survival benefit of >90% and decreased risk of death through 24 weeks versus placebo in participants with mid-to-late stage ALS in the HEALEY ALS Platform trial.
- Survival from real world experience in ALS: CNM-Au8 30mg demonstrated observed median survival of more than three years in analyses of two compassionate use expanded access protocols.

CNM-Au8 for the treatment of MS

A platform presentation entitled “VISIONARY MS Top-line Results: A Phase 2, Randomized, Double-Blind, Parallel Group, Placebo-controlled Study to Assess the Safety and Efficacy of CNM-Au8, a Catalytically Active Gold Nanocrystal Suspension in Relapsing Multiple Sclerosis” was presented on April 25th by Dr. Michael Barnett at the American Academy of Neurology and included the following highlights:

- The primary and secondary endpoints demonstrated improved clinical outcomes in the mITT population, independent of an immunomodulatory effect.
- The prespecified exploratory MRI findings provide evidence of brain neuronal structural integrity assessed by diffusion tensor imaging (DTI) that demonstrated statistically significant results for key metrics of axonal integrity and white matter integrity. Preservation of white matter integrity is generally associated with decreased cognitive and functional decline in MS patients.
- CNM-Au8 was well-tolerated, and no significant safety findings were observed.

Corporate Updates

- On March 3, Clene entered into a purchase agreement with Lincoln Park Capital Fund, LLC (“Lincoln Park”) pursuant to which Lincoln Park has committed to purchase up to $25 million of shares of the Company's common stock at the Company's sole discretion, from time to time over a 36-month period.
- On March 16, Clene appointed neurology expert Benjamin Greenberg, M.D., M.H.S., as Head of Medical.

First Quarter 2023 Financial Results

Clene’s cash, cash equivalents and marketable securities totaled $18.4 million as of March 31, 2023, compared to $23.3 million as of December 31, 2022. Clene expects that its resources as of March 31, 2023, will be sufficient to fund its operations into the third quarter of 2023.

Research and development expenses were $7.4 million for the quarter ended March 31, 2023, compared to $8.6 million for the same period in 2022. The year-over-year decrease was primarily related to decreases in development costs of CNM-Au8 in the HEALEY ALS Platform Trial and the REPAIR-PD and VISIONARY-MS trials due to completion of the blinded period of each trial, a decrease in development costs of CNM-ZnAg due to the completion of our COVID-19 trial in 2022, and a decrease in personnel expenses due to a reduction in headcount during the fourth quarter of 2022, partially offset by increases in rent expense for the newly-leased facility in Elkton, Maryland, and increases in stock-based compensation primarily due to the timing of award grants, vesting, and forfeitures.

General and administrative expenses were $3.4 million for the quarter ended March 31, 2023, compared to $4.8 million for the same period in 2022. The year-over-year decrease was primarily attributable to lower finance and accounting fees, insurance costs, legal expenses, personnel expenses and stock-based compensation.

Total other income (expense) was ($1.0) million for the quarter ended March 31, 2023, compared to ($18,000) for the same period in 2022. The year-over-year increase in other expense was primarily attributable to an increase in interest expense due to increasing interest rates and an increase in our overall debt balances, a gain on termination of an operating lease in 2022 that did not repeat in 2023, the expense for shares issued to Lincoln Park as an initial fee for their commitment under a purchase agreement in 2023, and a decrease in realized gains on foreign currency transactions and other miscellaneous income, offset by increased interest income primarily due to increasing rates on cash, cash equivalents and marketable investment securities.

Clene reported a net loss of $11.8 million, or $0.15 per share, for the quarter ended March 31, 2023, compared to a net loss of $13.4 million, or $0.21 per share, for the same period in 2022.

About Clene
Clene is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease by targeting energetic failure, an underlying cause of many neurological diseases. 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 Twitter, LinkedIn and Facebook.

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 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 March 31,	
	2023	2022
Revenue:		
Product revenue	$ 64	$ 7
Royalty revenue	43	23
Total revenue	107	30
Operating expenses:		
Cost of revenue	5	—
Research and development	7,395	8,580
General and administrative	3,439	4,786
Total operating expenses	10,839	13,366
Loss from operations	(10,732)	(13,336)
Other income (expense), net:		
Interest income	172	24
Interest expense	(1,066)	(782)
Gain on termination of lease	—	420
Commitment share expense	(399)	—
Change in fair value of common stock warrant liability	—	(18)
Change in fair value of Clene Nanomedicine contingent earn-out liability	(55)	(57)
Change in fair value of Initial Stockholders contingent earn-out liability	(7)	(12)
Research and development tax credits and unrestricted grants	314	299
Other income (expense), net	3	108
Total other income (expense), net	(1,038)	(18)
Net loss before income taxes	(11,770)	(13,354)
Income tax expense	—	—
Net loss	(11,770)	(13,354)
Other comprehensive income:		
Unrealized gain (loss) on available-for-sale securities	14	(50)
Foreign currency translation adjustments	4	50
Total other comprehensive income	18	—
Comprehensive loss	$ (11,752)	$ (13,354)
Net loss per share – basic and diluted	$ (0.15)	$ (0.21)
Weighted average common shares used to compute basic and diluted net loss per share	76,049,665	62,852,863

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,442	$ 18,332
Marketable securities	—	4,983
Accounts receivable	63	189
Inventory	88	43
Prepaid expenses and other current assets	6,229	5,648
Total current assets	24,822	29,195
Restricted cash	58	58
Operating lease right-of-use assets	4,494	4,602
Property and equipment, net	10,514	10,638
TOTAL ASSETS	$ 39,888	$ 44,493
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		

Accounts payable	$ 608	$ 3,014
Accrued liabilities	5,933	3,863
Operating lease obligations, current portion	508	488
Finance lease obligations, current portion	76	74
Notes payable, current portion	9,751	6,418
Total current liabilities	16,876	13,857
Operating lease obligations, net of current portion	5,399	5,557
Finance lease obligations, net of current portion	3	34
Notes payable, net of current portion	6,713	9,483
Convertible notes payable	9,907	9,770
Clene Nanomedicine contingent earn-out liability	2,319	2,264
Initial Stockholders contingent earn-out liability	298	291
TOTAL LIABILITIES	41,515	41,256
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 150,000,000 shares authorized; 77,987,349 and 74,759,591 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	8	7
Additional paid-in capital	203,133	196,246
Accumulated deficit	(204,989)	(193,219)
Accumulated other comprehensive income	221	203
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(1,627)	3,237
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 39,888	$ 44,493