Clene Reports Third Quarter 2022 Financial Results and Recent Operating Highlights

November 7, 2022

- *Secondary survival endpoint for the CNM-Au8® 30 mg dose investigated in the Healey ALS Platform Trial demonstrated a >90% reduction in the risk of death or death equivalent (permanently assisted ventilation) and risk of death alone at 24 weeks. This survival benefit was consistent with prior results reported from the Phase 2 RESCUE-ALS trial long term open-label extension.*
- *Topline results from the Phase 2 VISIONARY-MS clinical trial of CNM-Au8® met the primary and secondary endpoints of Low Contrast Letter Acuity (LCLA) and global neurological improvement measured by the modified Multiple Sclerosis Functional Composite (mMSFC) compared to placebo over 48 weeks in the modified intent to treat (mITT) population .*
- *Cash, cash equivalents, and marketable securities of $16.2 million as of September 30, 2022.*
- *Closed a registered direct offering of $10.8 million with certain existing stockholders, including existing stockholders affiliated with Clene's board of directors, for the purchase and sale of 10,723,926 shares of the Company's common stock at a purchase price per share of $1.01, priced at-the-market based on the October 28, 2022, closing stock price, in a registered direct offering.*
- *Executed a Commitment Letter with the Maryland Department of Housing and Community Development to borrow $5.0 million.*

SALT LAKE CITY, Nov. 07, 2022 (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 disease, today reported its third quarter 2022 financial results and recent operating highlights.

"Clene was pleased to report the significant survival benefit in people living with ALS in the Healey ALS Platform Trial at six months with the CNM-Au8® 30 mg dose. To our knowledge, this is the only study to show a survival benefit at 6-months in ALS," said Rob Etherington, President and CEO of Clene. "Subsequent to the Healey data read-out, we have been able to secure sufficient capital to further strengthen our balance sheet, extend our financial runway, and support the regulatory path to potential marketing authorization. We remain in active discussions with potential strategic partners regarding CNM-Au8. We are also looking forward to the further results from the full Healey data set, including biomarker data and exploratory endpoints, during the coming months."

Third Quarter 2022 and Recent Operating Highlights

CNM-Au8®, a gold nanocrystal suspension, for the treatment of amyotrophic lateral sclerosis (ALS)

- The Company reported positive results from a pre-specified secondary endpoint in the Healey ALS Platform Trial, demonstrating a statistically significant reduction in mortality at 6 months. In this trial, prespecified exploratory analyses by dose of the secondary survival endpoint demonstrated a >90% reduction in risk of death or permanently assisted ventilation and death alone at 24 weeks for CNM-Au8 30 mg (p=0.028 to p=0.075, unadjusted for multiple comparisons).
- Demonstrated a statistically significant reduction in mortality during long term follow-up of the RESCUE ALS trial participants. CNM-Au8 was well-tolerated, and the safety profile in the open-label extension was consistent with previously reported data.
- Received European Orphan Drug Designation for CNM-Au8® in amyotrophic lateral sclerosis from the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) on August 10, 2022.
- Clene continues to support expanded access programs (EAPs), providing CNM-Au8 treatment at key ALS clinical sites. Clene will also continue the open-label extension of CNM-Au8 in the Healey ALS Platform Trial and is in discussions with the Healey & AMG ALS Center to design and offer an EAP of CNM-Au8 30mg for eligible participants of closed regimens and others.

CNM-Au8 for the treatment of multiple sclerosis (MS)

- Reported that topline results from the Phase 2 VISIONARY-MS clinical trial of CNM-Au8® met the primary and secondary endpoints of LCLA and mMSFC compared to placebo over 48 weeks in the mITT population.
  - Primary endpoint: LCLA letter change in the clinically affected eye (least squares [LS] mean difference, 3.13; 95% CI: -0.08 to 6.33, p = 0.056)
  - Secondary outcomes:
    - mMSFC mean standardized change (LS mean difference, 0.28; 95% CI: 0.04 to 0.52, p = 0.0207)

    - mMSFC average rank score (LS mean difference, 13.38; 95% CI: 2.83 to 23.94, p = 0.0138)
    - Time to first repeated clinical improvement to Week 48 (45% vs. 29%, log-rank p=0.3991)
- Clene has initiated a second cohort of the more severe non-active, progressive MS population in the REPAIR-MS Phase 2 clinical trial to confirm target engagement following the target engagement demonstrated in the first cohort of relapsing MS patients.
- The Company is planning to advance the MS program once a strategic development partner has been identified.

CNM-ZnAg for the treatment of COVID-19

- Topline results for the ZnAg COVID Phase 2 clinical trial in acutely symptomatic, non-hospitalized COVID-19 patients in Brazil are expected in the fourth quarter of 2022.

Third Quarter 2022 Financial Results

Clene's cash, cash equivalents and marketable investments securities totaled $16.2 million as of September 30, 2022, compared to $50.3 million as of December 31, 2021. Subsequent to the end of the third quarter, the Company raised an additional $10.8 million via a registered direct offering of common shares, and the Company also executed a Commitment Letter with the Maryland Department of Housing and Community Development ("DHCD") to borrow $5.0 million.

Research and development expenses were $6.4 million for the quarter ended September 30, 2022, compared to $6.1 million for the same period in 2021. The year-over-year increase is primarily attributable to the development of CNM-ZnAg, including full enrollment in the clinical trial for treatment of COVID-19, and an increase in personnel expenses.

General and administrative expenses were $3.6 million for the quarter ended September 30, 2022, compared to $4.4 million for the same period in 2021. The year-over-year decrease is primarily attributable to a decrease in stock-based compensation expense, a decrease in directors' and officers' insurance fees, and a decrease in other general and administrative expenses, including decreases in investor relations, accounting, legal and consulting fees.

Clene reported a net loss of $11.0 million, or $0.17 per share, for the quarter ended September 30, 2022, compared to net income of $28.9 million, or $0.47 per basic share and $0.42 per diluted share, for the same period in 2021. A significant part of the quarter-over-quarter decline is attributed to the change in fair value of the Clene Nanomedicine contingent earn-out liability and the Initial Stockholders contingent earn-out liability.

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.

About CNM-ZnAg
CNM-ZnAg, a proprietary zinc-silver ionic solution, has demonstrated broad antiviral and antimicrobial activity.

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 INCOME (LOSS)
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Product revenue	$ 130	$ 63	$ 139	$ 400
Royalty revenue	44	47	100	124
Total revenue	174	110	239	524
Operating expenses:				
Cost of revenue	19	14	19	812
Research and development	6,403	6,146	24,149	18,893
General and administrative	3,557	4,400	12,807	16,739
Total operating expenses	9,979	10,560	36,975	36,444
Loss from operations	(9,805)	(10,450)	(36,736)	(35,920)
Other income (expense), net:				
Interest expense	(857)	80	(2,390)	(497)
Gain on extinguishment of notes payable	—	—	—	647
Gain on termination of lease	—	—	420	—
Change in fair value of common stock warrant liability	149	414	151	547
Change in fair value of Clene Nanomedicine contingent earn-out liability	(1,591)	35,042	6,662	18,072
Change in fair value of Initial Stockholders contingent earn-out liability	(205)	3,439	849	1,710
Australia research and development credit	1,346	364	2,001	1,078
Other income (expense), net	(13)	(14)	179	(13)
Total other income (expense), net	(1,171)	39,325	7,872	21,544
Net income (loss) before income taxes	(10,976)	28,875	(28,864)	(14,376)
Income tax benefit	—	69	—	213
Net income (loss)	(10,976)	28,944	(28,864)	(14,163)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	33	—	(54)	—
Foreign currency translation adjustments	(39)	(87)	(99)	(124)
Total other comprehensive loss	(6)	(87)	(153)	(124)
Comprehensive income (loss)	$ (10,982)	$ 28,857	$ (29,017)	$ (14,287)
Net income (loss) per share				
Basic	$ (0.17)	$ 0.47	$ (0.46)	$ (0.23)
Diluted	$ (0.17)	$ 0.42	$ (0.46)	$ (0.23)
Weighted average common shares outstanding				
Basic	63,508,928	62,071,754	63,234,757	61,307,699
Diluted	63,508,928	70,038,634	63,234,757	61,307,699

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,267	$ 50,288
Marketable securities	8,966	—
Accounts receivable	126	49
Inventory	38	41
Prepaid expenses and other current assets	5,089	4,205
Total current assets	21,486	54,583
Restricted cash	58	58
Right-of-use assets	4,707	3,250
Property and equipment, net	9,753	5,172
TOTAL ASSETS	$ 36,004	$ 63,063
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,454	$ 1,923
Accrued liabilities	2,136	3,610
Operating lease obligations, current portion	467	347
Finance lease obligations, current portion	97	146
Total current liabilities	6,154	6,026
Operating lease obligations, net of current portion	5,711	4,370
Finance lease obligations, net of current portion	45	97
Notes payable	15,726	14,484
Convertible notes payable	4,763	4,598
Common stock warrant liability	18	474
Clene Nanomedicine contingent earn-out liability	11,438	18,100
Initial Stockholders contingent earn-out liability	1,468	2,317
TOTAL LIABILITIES	45,323	50,466
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 150,000,000 shares authorized; 63,541,984 and 62,312,097 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	182,760	175,659
Accumulated deficit	(192,165)	(163,301)
Accumulated other comprehensive income	80	233
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(9,319)	12,597
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 36,004	$ 63,063

Source: Clene Inc.