Clene Reports Second Quarter 2022 Financial Results and Recent Operating Highlights

August 15, 2022

- ***Topline results from the Phase 2 VISIONARY-MS clinical trial with CNM- Au8® met the primary and secondary endpoints of Low Contrast Letter Acuity (LCLA) and modified Multiple Sclerosis Functional Composite (mMSFC) compared to placebo over 48 weeks in the mITT population***
- ***Updated data from RESCUE-ALS demonstrate a statistically significant decrease in mortality in participants who entered open-label extension study (5 CNM-Au8 deaths vs. 14 placebo deaths, HR=0.301, p=0.0143)***
- ***Topline results from HEALEY ALS Platform Trial expected this quarter***
- ***Cash, cash equivalents and marketable securities of $26.3 million as of June 30, 2022***
- ***Entered into a $3.0 million loan facility from State of Maryland to support development of commercial manufacturing facility***

SALT LAKE CITY, Aug. 15, 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 second quarter 2022 and recent operating highlights.

“We are on the cusp of a transformative period for the Company as we await a key data readout in ALS for our lead asset, CNM-Au8®,” said Rob Etherington, President and CEO of Clene. “The ALS patient population is desperate for new treatments to help mitigate the disease course and following the statistically significant survival benefits demonstrated in our open label trial, we are hopeful that we can deliver an effective therapy for people living with ALS.”

Second Quarter 2022 and Recent Operating Highlights

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

- Topline data from the HEALEY ALS Platform Trial, led by the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital, are expected this quarter.
- Demonstrated statistically significant reduction in mortality in the open-label extension of the RESCUE-ALS trial. As of the July 5, 2022, data cutoff, early CNM-Au8 treatment resulted in a significant survival benefit (5 CNM-Au8 deaths vs. 14 placebo deaths, HR=0.301, p=0.0143). CNM-Au8 was well-tolerated, and the safety profile was consistent with previously reported data.
- Received European Orphan Drug Designation for CNM-Au8 in amyotrophic lateral sclerosis (ALS) from the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP).
- Presented five posters from the RESCUE-ALS trial at the European Network to Cure ALS (ENCALS) conference on June 1-3, 2022. The data included information on the neuroprotective efficacy and survival benefits of CNM-Au8 in ALS as well as on patient quality of life and biomarker data. The posters are available in the Scientific Posters & Presentations section of the Clene website.
- Clene continues to support expanded access programs, providing CNM-Au8 treatment at five clinical sites for up to 55 total participants with ALS.

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

- Reported topline results from the Phase 2 VISIONARY-MS clinical trial with CNM-Au8 that met the primary and secondary endpoints of LCLA and mMSFC compared to placebo over 48 weeks in a modified intent to treat (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)
    - CNM-Au8 treatment was well-tolerated and there were no significant safety findings reported.

- Results provide support to advance CNM-Au8 into Phase 3 clinical development.

- As announced in February 2022, the trial was stopped prematurely due to COVID-19 pandemic operational challenges, limiting enrollment to 73 out of the 150 planned participants. Due to the limited enrollment, the threshold for significance was pre-specified at p=0.10 prior to database lock. The primary analysis was conducted in a modified intent to treat (mITT) population, which censored invalid data. The mITT population excluded data from a single site (n=9) with LCLA testing execution errors and the timed 25-foot walk data from one subject with a change in mobility assist device. The ITT results were directionally consistent with the mITT results, although the ITT results were not significant.

- 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.

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 this quarter.

Second Quarter 2022 Financial Results

Clene's cash, cash equivalents and marketable investments securities totaled $26.3 million as of June 30, 2022, compared to $50.3 million as of December 31, 2021.

Research and development expenses were $9.2 million for the quarter ended June 30, 2022, compared to $6.5 million for the same period in 2021. The year-over-year increase is primarily attributable to the development of CNM-Au8 and CNM-ZnAg (including the rapid completion of the COVID study due to a viral wave leading to increased patient recruitment), rent expense for the newly-leased facility in Elkton, Maryland, and personnel expenses due to increased headcount as a result primarily of increased manufacturing hours, partially offset by decreased stock-based compensation expense.

General and administrative expenses were $4.5 million for the quarter ended June 30, 2022, compared to $6.9 million for the same period in 2021. The year-over-year decrease is primarily attributable to a decrease in directors' and officers' insurance costs, stock-based compensation expense and other general and administrative costs, including decreases in investor relations, accounting and consulting fees. These decreases were offset by increases in personnel compensation due to increased headcount as well as increases on other miscellaneous general and administrative expenses.

Clene reported a net loss of $4.5 million, or $0.07 per share, for the quarter ended June 30, 2022, compared to a net loss of $3.4 million, or $0.05 per share, for the same period in 2021. Included in net loss for the quarter ended June 30, 2022, is an unrealized gain from the change in fair value of contingent earn-out liabilities of $9.4 million, compared to an unrealized gain of $9.9 million in the prior year period.

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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Source: Clene Inc.

CLENE INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue	$ 2	$ 138	$ 9	$ 337
Royalty revenue	33	63	56	77
Total revenue	35	201	65	414
Operating expenses:				
Cost of revenue	—	555	—	798
Research and development	9,166	6,472	17,746	12,747
General and administrative	4,464	6,949	9,250	12,339
Total operating expenses	13,630	13,976	26,996	25,884
Loss from operations	(13,595)	(13,775)	(26,931)	(25,470)
Other income (expense), net:				
Interest expense	(751)	(26)	(1,533)	(577)
Gain on extinguishment of notes payable	—	—	—	647
Gain on termination of lease	—	—	420	—
Change in fair value of common stock warrant liability	20	133	2	133
Change in fair value of Clene Nanomedicine contingent earn-out	8,310	8,640	8,253	(16,970)
Change in fair value of Initial Stockholders contingent earn-out	1,066	1,232	1,054	(1,729)
Australia research and development credit	356	375	655	714
Other income (expense), net	60	(2)	192	1
Total other income (expense), net	9,061	10,352	9,043	(17,781)
Net loss before income taxes	(4,534)	(3,423)	(17,888)	(43,251)
Income tax benefit	—	72	—	144
Net loss	(4,534)	(3,351)	(17,888)	(43,107)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(37)	—	(87)	—
Foreign currency translation adjustments	(110)	(61)	(60)	(37)
Total other comprehensive loss	(147)	(61)	(147)	(37)
Comprehensive loss	$ (4,681)	$ (3,412)	$ (18,035)	$ (43,144)
Net loss per share-- basic and diluted	$ (0.07)	$ (0.05)	$ (0.28)	$ (0.71)
Weighted average common shares used to compute basic and diluted net loss per share	63,335,271	61,165,018	63,095,400	60,919,340

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

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,253	$ 50,288
Marketable securities	19,033	—
Accounts receivable	—	49
Inventory	107	41
Prepaid expenses and other current assets	5,194	4,205
Total current assets	31,587	54,583
Restricted cash	58	58
Right-of-use assets	4,808	3,250
Property and equipment, net	8,089	5,172
TOTAL ASSETS	$ 44,542	$ 63,063
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,526	$ 1,923
Accrued liabilities	2,566	3,610
Operating lease obligations, current portion	440	347
Finance lease obligations, current portion	123	146
Total current liabilities	7,655	6,026
Operating lease obligations, net of current portion	5,858	4,370
Finance lease obligations, net of current portion	55	97
Notes payable	15,551	14,484
Convertible notes payable	4,709	4,598
Common stock warrant liability	167	474
Clene Nanomedicine contingent earn-out	9,847	18,100
Initial Stockholders contingent earn-out	1,263	2,317
TOTAL LIABILITIES	45,105	50,466
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 150,000,000 shares authorized; 63,421,908 and 62,312,097 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	180,534	175,659
Accumulated deficit	(181,189)	(163,301)
Accumulated other comprehensive income	86	233
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(563)	12,597
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 44,542	$ 63,063

Source: Clene Inc.