



## Clene Reports Second Quarter 2023 Financial Results and Operating Highlights

August 14, 2023

- Reported statistically significant reductions in plasma neurofilament light chain (NfL) levels compared to placebo at 24 weeks ( $p=0.04$ ) in patients treated with CNM-Au8® in the HEALEY ALS Platform trial
- Announced publication of the results of the Phase 2 RESCUE ALS study and its open-label extension in the *Lancet* journal, *eClinicalMedicine*
- Received one-year grant from the National Multiple Sclerosis Society (NMSS) that will fund Cohort 2 of REPAIR-MS, a Phase 2 clinical study investigating target engagement of CNM-Au8 in patients with non-active progressive MS
- Company expects multiple near-term data announcements that will further support benefit and safety of CNM-Au8 in people living with ALS
- Company is preparing for upcoming ALS regulatory discussions with FDA
- Cash, cash equivalents and marketable securities of \$49.2 million as of June 30, 2023, which includes gross proceeds of \$40 million from a recent public offering and that may provide additional capital up to \$130 million through future warrant exercises

SALT LAKE CITY, Aug. 14, 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 revolutionizing the treatment of neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today announced its second quarter 2023 financial results and provided recent operating highlights for the clinical programs in ALS and MS.

"Our recent financing has strengthened our capital position and provided the runway needed to advance our ALS clinical program with upcoming engagement with regulatory agencies, the initiation of our global Phase 3 in ALS (RESTORE-ALS), and additional clinical trial data read-outs," said Rob Etherington, President and CEO of Clene. "We look forward to additional long-term clinical data, including survival, time-to-clinical-worsening and additional biomarker data, from the HEALEY ALS Platform trial. We are actively preparing for ALS regulatory discussions with the FDA and EMA, with meetings anticipated later this year. Additionally, we plan to continue advancing our clinical program in MS, while pursuing prospective partnering opportunities in parallel."

### Second Quarter 2023 and Recent Operating Highlights

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

- Results of the Phase 2 RESCUE ALS study and its open-label extension trial were published in the *Lancet* journal, *eClinicalMedicine*. The article can be accessed via the following link: <https://authors.elsevier.com/sd/article/S2589537023002134>.
- Clene reported that CNM-Au8 treatment demonstrated significantly reduced plasma NfL levels compared to placebo at 24 weeks ( $p=0.04$ ). The results are based on an analysis of the plasma NfL biomarker across all Regimen C participants (CNM-Au8 or placebo,  $n=161$ ) from the HEALEY ALS Platform trial.

#### **CNM-Au8 for the treatment of MS**

Clene received a one-year grant from NMSS that will fund Cohort 2 of REPAIR-MS, a Phase 2 clinical study investigating target engagement of CNM-Au8 in patients with non-active progressive MS. Using non-invasive brain imaging, the study will enroll up to 15 individuals with primary progressive or non-active secondary progressive MS and determine the effects of 12 weeks of daily oral dosing with CNM-Au8 on critical brain energy metabolites that have been shown to be compromised in individuals with MS.

#### **Corporate Updates**

On June 21, 2023, Clene announced the closing of its underwritten public offering. This financing raised gross proceeds of \$40 million with potentially up to an additional \$130 million in proceeds through future warrant exercises with expiration dates accelerated following the satisfaction of regulatory milestones. The investment was led by Vivo Capital with participation from SymBiosis, Acuta Capital Partners, AIGH Capital, Serrado Capital LLC and other new biotech investors, with support from existing investors.

#### **Second Quarter 2023 Financial Results**

Clene's cash, cash equivalents and marketable securities totaled \$49.2 million as of June 30, 2023, compared to \$23.3 million as of December 31, 2022. Clene expects that its resources as of June 30, 2023, will be sufficient to fund its operations through mid-2024.

Research and development expenses were \$6.6 million for the quarter ended June 30, 2023, compared to \$9.2 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, RESCUE-ALS, REPAIR-MS, REPAIR-PD, and VISIONARY-MS clinical trials.

General and administrative expenses were \$3.9 million for the quarter ended June 30, 2023, compared to \$4.5 million for the same period in 2022. The year-over-year decrease was primarily attributable to decreases in directors' and officers' insurance fees and personnel expenses. These decreases were offset by an increase in finance and accounting fees, primarily due to increased fees from auditors, consultants, advisors and other financial vendors.

Total other expense was \$14.8 million for the quarter ended June 30, 2023, compared to total other income of \$9.1 million for the same period in 2022. The year-over-year increase in other expense was primarily attributable to an increase in interest expense, primarily due to increasing interest rates and increased amortization of debt discount and debt issuance costs on notes payable, changes in the fair value of contingent earn-out liabilities and changes in the fair value of common stock warrant liabilities offset by increased interest income. Additionally, in 2023 there was a loss on initial issuance of equity and charges for issuance costs related to the closing of the \$40 million underwritten public offering in June 2023 that did not occur in 2022.

Clene reported a net loss of \$25.1 million, or \$0.29 per share, for the quarter ended June 30, 2023, compared to a net loss of \$4.5 million, or \$0.07 per share, for the same period in 2022.

#### About Clene

Clene is a late clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative diseases, including ALS and MS, 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](http://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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue	\$ 226	\$ 2	\$ 290	\$ 9
Royalty revenue	43	33	86	56

Total revenue	269	35	376	65
Operating expenses:				
Cost of revenue	66	—	71	—
Research and development	6,615	9,166	14,010	17,746
General and administrative	3,924	4,464	7,363	9,250
Total operating expenses	10,605	13,630	21,444	26,996
Loss from operations	(10,336)	(13,595)	(21,068)	(26,931)
Other income (expense), net:				
Interest income	213	61	385	85
Interest expense	(1,104)	(751)	(2,170)	(1,533)
Gain on termination of lease	—	—	—	420
Commitment share expense	(3)	—	(402)	—
Issuance costs for common stock warrant liability	(333)	—	(333)	—
Loss on initial issuance of equity	(14,840)	—	(14,840)	—
Change in fair value of common stock warrant liabilities	(383)	20	(383)	2
Change in fair value of Clene Nanomedicine contingent earn-out liability	1,165	8,310	1,110	8,253
Change in fair value of Initial Stockholders contingent earn-out liability	150	1,066	143	1,054
Research and development tax credits and unrestricted grants	341	356	655	655
Other income (expense), net	(13)	(1)	(10)	107
Total other income (expense), net	(14,807)	9,061	(15,845)	9,043
Net loss before income taxes	(25,143)	(4,534)	(36,913)	(17,888)
Income tax benefit	—	—	—	—
Net loss	(25,143)	(4,534)	(36,913)	(17,888)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	6	(37)	20	(87)
Foreign currency translation adjustments	(53)	(110)	(49)	(60)
Total other comprehensive loss	(47)	(147)	(29)	(147)
Comprehensive loss	<u>\$ (25,190)</u>	<u>\$ (4,681)</u>	<u>\$ (36,942)</u>	<u>\$ (18,035)</u>
Net loss per share – basic and diluted	\$ (0.29)	\$ (0.07)	\$ (0.46)	\$ (0.28)
Weighted average common shares used to compute basic and diluted net loss per share	86,050,405	63,335,271	81,077,661	63,095,400

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

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 49,243	\$ 18,332
Marketable securities	—	4,983
Accounts receivable	161	189
Inventory	52	43
Prepaid expenses and other current assets	3,915	5,648
Total current assets	53,371	29,195
Restricted cash	58	58
Operating lease right-of-use assets	4,383	4,602
Property and equipment, net	10,033	10,638
<b>TOTAL ASSETS</b>	<u>\$ 67,845</u>	<u>\$ 44,493</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 846	\$ 3,014

Accrued liabilities	4,298	3,863
Operating lease obligations, current portion	529	488
Finance lease obligations, current portion	62	74
Notes payable, current portion	—	6,418
Total current liabilities	<u>5,735</u>	<u>13,857</u>
Operating lease obligations, net of current portion	5,235	5,557
Finance lease obligations, net of current portion	—	34
Notes payable, net of current portion	16,017	9,483
Convertible notes payable	9,822	9,770
Common stock warrant liabilities	8,201	—
Clene Nanomedicine contingent earn-out liability	1,154	2,264
Initial Stockholders contingent earn-out liability	148	291
TOTAL LIABILITIES	<u>46,312</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 June 30, 2023 and December 31, 2022, respectively; 128,401,112 and 74,759,591 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	13	7
Additional paid-in capital	251,478	196,246
Accumulated deficit	(230,132)	(193,219)
Accumulated other comprehensive income	174	203
TOTAL STOCKHOLDERS' EQUITY	<u>21,533</u>	<u>3,237</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 67,845</u>	<u>\$ 44,493</u>