Clene Reports Full Year 2023 Financial Results and Recent Operating Highlights

March 13, 2024

- *Initiated discussions with FDA regarding accelerated approval pathway for CNM-Au8® for the treatment of ALS with the objective of submitting an NDA in 2024*
- *Released long-term data from the open-label extension of the HEALEY ALS Platform Trial in which CNM-Au8 demonstrated statistically significant reductions of plasma neurofilament light chain (NfL) levels at 76 weeks relative to placebo (18 months from randomization, p=0.023) as well as a 60% decreased risk of long-term all-cause mortality using rank-preserving structural failure time model analysis (>18 months, p=0.0167)*
- *Demonstrated a statistically significant survival benefit (p=0.0001) in Expanded Access Program (EAP) participants (n=220) treated with CNM-Au8 compared to historical ALS disease progression controls with decreased risk of all-cause mortality ranging from 57%-68%*
- *Reported additional long-term data from the Phase 2 VISIONARY-MS trial in which CNM-Au8 treatment was associated with vision improvement as measured by low contrast letter acuity (LCLA) across both eyes vs. baseline through 35 months from randomization, p<0.0001*
- *Announced peer-reviewed publication characterizing CNM-Au8 brain target engagement in the Journal of Nanobiotechnology*
- *Announced the peer-reviewed publication describing the catalytic neuroprotective mechanism of action of CNM-Au8 in the journal SMALL*

- *Cash, cash equivalents and marketable securities of $35.0 million as of December 31, 2023, which includes gross proceeds of $40.0 million from a public offering completed in June 2023 that may provide additional capital up to $130.0 million through future warrant exercises*

SALT LAKE CITY, March 13, 2024 (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 improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today announced its full year 2023 financial results and provided recent operating highlights for the clinical programs in ALS and MS.

“In 2024 we will continue to advance our regulatory discussions with the U.S. Food and Drug Administration (FDA) that we anticipate will include new data on biomarkers, as well as additional clinical function and survival data in people living with ALS,” said Rob Etherington, President and CEO of Clene. “Having held our initial discussion with the FDA in the fourth quarter of last year, we have a clear understanding of the additional data required to support an accelerated approval pathway filing for CNM-Au8®. We believe that we can provide additional supportive evidence to advance discussions with the FDA with the potential to file an NDA later this year.”

Fourth Quarter 2023 and Recent Operating Highlights

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

- In October 2023, 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 a new EAP for the Company’s investigational drug, CNM-Au8, in ALS.

- In December 2023, Clene reported new data from the ongoing open-label extension of the HEALEY ALS Platform Trial. CNM-Au8 30 mg treatment demonstrated statistically significant reductions of plasma NfL levels at 76 weeks relative to placebo (18 months from randomization, p=0.023) as well as a 60% decreased risk of long-term all-cause mortality (>18 months, p=0.0167) in participants originally randomized to CNM-Au8 30 mg compared to those originally randomized to placebo using the rank-preserving structural failure time model (RPSFTM). Additionally, CNM-Au8 30 mg treatment had greater overall treatment effect in delaying the time to morbidity events in the highest risk participants based on baseline NfL levels. These biomarker and survival data from the long-term open label extension together reinforce evidence of a treatment effect consistent with delayed time to event results observed in the original double-blind Phase 2 period analyses.

- In December 2023, Clene announced that it met with the FDA to discuss the regulatory pathway for CNM-Au8 for the treatment of ALS and to explore the potential for an accelerated NDA filing under an accelerated approval pathway. The FDA determined that the initial findings on biomarker NfL reduction from the Phase 2 programs submitted earlier in 2023 were insufficient to support accelerated approval at that time. Clene is currently preparing supplemental data on NfL

biomarkers and improved clinical outcomes in people living with ALS to address the FDA's questions, including increased survival time. Clene plans to submit additional data to the FDA to advance the CNM-Au8 accelerated approval discussions in 2024.

- In February 2024, Clene reported data from a pooled survival analysis of EAP participants treated with CNM-Au8 30 mg compared to two independent datasets derived from PRO-ACT and the ALS/MND Natural History Consortium. The EAP dataset was comprised of 256 participants with ALS of which 220 EAP participants had all baseline values available for matching. A statistically significant survival benefit (p=0.0001) was observed in EAP participants treated with CNM-Au8 compared to historical ALS survival controls (participants not treated with CNM-Au8) in two independent analyses: a 68% decreased risk of all-cause mortality compared to PRO-ACT matched controls, and a 57% decreased risk of all-cause mortality compared to ALS Natural History Consortium matched controls.

CNM-Au8 for the treatment of MS

- In January 2024, Clene reported statistically significant clinical improvements from the long-term open-label extension of the VISIONARY-MS trial in patients followed through 35 months. CNM-Au8 treatment demonstrated continued vision improvement as measured by LCLA, an assessment of visual function in people living with MS, through 35 months from randomization compared to baseline ($p<0.0001$). Additionally, long-term CNM-Au8 treatment demonstrated continued improvement of cognition, measured by the Symbol Digit Modality Test (SDMT), through 35 months from randomization compared to original baseline ($p<0.0001$). Treatment was well-tolerated, without a single serious adverse event attributed to CNM-Au8, and no significant safety findings were reported.
- In February 2024, Clene reported statistically significant improvements of global neurological function measured by the modified MS Functional Composite (mMSFC) scale (p=0.018) through 35 months in the long-term open-label extension of the VISIONARY-MS trial compared to the original baseline.

Publications

- In December 2023, Clene announced the publication of a peer-reviewed article describing brain target engagement by CNM-Au8. The paper, entitled, "Evidence of Brain Target Engagement in Parkinson's Disease and Multiple Sclerosis by the Investigational Nanomedicine, CNM-Au8, in the REPAIR Phase 2 Clinical Trials," was published in the *Journal of Nanobiotechnology*, a *Springer Nature* journal that communicates significant advances in the fields of medicine and biology with an emphasis in their interface with nanoscale sciences. This publication describes results from the successful Phase 2 REPAIR clinical studies that measured changes in brain energy metabolites in MS and Parkinson's disease with CNM-Au8 treatment. These studies demonstrated a significant increase in the primary endpoint of brain NAD+/NADH ratio from baseline following 12 weeks of daily oral dosing of CNM-Au8. ($p<0.05$). Additionally, CNM-Au8 treatment resulted in favorable modulation of additional brain energy metabolites that have been shown to be dysregulated in neurodegenerative diseases. The article is available via Open Access at: https://jnanobiotechnology.biomedcentral.com/articles/10.1186/s12951-023-02236-z.
- Clene announced the publication of a scientific paper describing the catalytic mechanism of action of its investigational drug CNM-Au8® in *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," is co-authored by lead investigators at the University of South Carolina and Clene. The publication is available via Open Access at https://onlinelibrary.wiley.com/doi/10.1002/smll.202304082.

Full-Year 2023 Financial Results

Clene's cash, cash equivalents and marketable securities totaled $35.0 million as of December 31, 2023, compared to $23.3 million as of December 31, 2022. Clene expects that its resources as of December 31, 2023, will be sufficient to fund its operations into the fourth quarter of 2024.

Research and development expenses were $26.7 million for the year ended December 31, 2023, compared to $31.9 million for the same period in 2022. The year-over-year decrease was primarily related to lower expenses related the HEALEY ALS Platform Trial and the Phase 2 RESCUE-ALS, REPAIR-MS, REPAIR-PD, and VISIONARY-MS trials due to completion of the blinded period of each trial, as well as completion of the trial for the treatment of COVID-19 with our CNM-ZnAg asset in 2022, partially offset by an increase in expenses related to the two ongoing EAPs and the long-term extension for the VISIONARY-MS trial as well as increased stock-based compensation expense.

General and administrative expenses were $14.4 million for the year ended December 31, 2023, compared to $16.9 million for the same period in 2022. The year-over-year decrease was primarily attributable to lower insurance fees, personnel expenses, legal fees, public and investor relations fees and stock-based compensation, partially offset by higher finance and accounting fees.

Total other expense, net, was $9.0 million for the year ended December 31, 2023, compared to total other income, net, of $18.5 million for the same period in 2022. The year-over-year increase in expense was primarily attributable to a loss on initial issuance of equity and changes in the fair value of contingent earn-out liabilities as well as higher interest expense and less research and development tax credits; partially offset by a decrease in fair value of common stock warrant liabilities in 2023 and increased interest income.

Clene reported a net loss of $49.5 million, or $0.47 per share, for the year ended December 31, 2023, compared to a net loss of $29.9 million, or $0.46 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.

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," "could," "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 clinical trials of our drug candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or may not otherwise produce positive results, which may cause us to incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates; changes in government regulation or in practices relating to the pharmaceutical and biotechnology industries, including potential healthcare reform, could decrease the need for our drug candidates, or make it more difficult to obtain regulatory approvals for our drug candidates and commercialize them; we depend substantially on the successful commercialization of our drug candidates in the future, which may fail to materialize or may experience significant delays; we have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance; and our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations, which may not be available on acceptable terms, or at all, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce, or terminate our drug development or commercialization efforts; 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.

Media Contact
Ignacio Guerrero-Ros, Ph.D., or David Schull
Russo Partners, LLC
Ignacio.guerrero-ros@russopartnersllc.com
David.schull@russopartnersllc.com
(858) 717-2310

Investor Contact
Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com
617-283-2856

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

	Year Ended December 31,	
	2023	**2022**
Revenue:		
Product revenue	$ 498	$ 329
Royalty revenue	156	144
Total revenue	654	473
Operating expenses:		
Cost of revenue	121	26
Research and development	26,655	31,920
General and administrative	14,418	16,936

Total operating expenses	41,194	48,882
Loss from operations	(40,540)	(48,409)
Other income (expense), net:		
Interest income	1,389	225
Interest expense	(4,558)	(3,296)
Gain on termination of lease	—	420
Commitment share expense	(402)	—
Issuance costs for common stock warrant liabilities	(333)	—
Loss on initial issuance of equity	(14,840)	—
Change in fair value of common stock warrant liabilities	6,337	169
Change in fair value of Clene Nanomedicine contingent earn-out liability	2,189	15,836
Change in fair value of Initial Stockholders contingent earn-out liability	281	2,026
Research and development tax credits and unrestricted grants	963	3,079
Other income, net	10	32
Total other income (expense), net	(8,964)	18,491
Net loss before income taxes	(49,504)	(29,918)
Income tax benefit	—	—
Net loss	(49,504)	(29,918)
Other comprehensive loss:		
Unrealized gain (loss) on available-for-sale securities	16	(14)
Foreign currency translation adjustments	(20)	(16)
Total other comprehensive loss	(4)	(30)
Comprehensive loss	$ (49,508)	$ (29,948)
Net loss per share – basic and diluted	$ (0.47)	$ (0.46)
Weighted average common shares used to compute basic and diluted net loss per share	104,938,819	65,204,663

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,821	$ 18,332
Marketable securities	6,179	4,983
Accounts receivable	143	189
Inventory	37	43
Prepaid expenses and other current assets	3,672	5,648
Total current assets	38,852	29,195
Restricted cash	58	58
Operating lease right-of-use assets	4,168	4,602
Property and equipment, net	9,263	10,638
TOTAL ASSETS	$ 52,341	$ 44,493
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,504	$ 3,014
Accrued liabilities	3,720	3,863
Operating lease obligations, current portion	576	488
Finance lease obligations, current portion	27	74
Notes payable, current portion	14,627	6,418
Convertible notes payable, current portion	4,876	—
Total current liabilities	25,330	13,857
Operating lease obligations, net of current portion	4,903	5,557
Finance lease obligations, net of current portion	—	34

Notes payable, net of current portion	1,894	9,483
Convertible notes payable, net of current portion	5,258	9,770
Common stock warrant liabilities	1,481	—
Clene Nanomedicine contingent earn-out liability	75	2,264
Initial Stockholders contingent earn-out liability	10	291
TOTAL LIABILITIES	38,951	41,256
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value: 300,000,000 and 150,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; 128,422,851 and 74,759,591 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	13	7
Additional paid-in capital	255,901	196,246
Accumulated deficit	(242,723)	(193,219)
Accumulated other comprehensive income	199	203
TOTAL STOCKHOLDERS' EQUITY	13,390	3,237
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 52,341	$ 44,493