Clene Issues Stockholder Letter Highlighting Upcoming CNM-Au8® 2026 Catalysts

February 24, 2026

- *Operating capital runway sufficient into the fourth quarter of 2026*
- *In-person Type C FDA meeting scheduled by end of the first quarter of 2026 to discuss the latest CNM-Au8 data submitted in late 2025*
- *Anticipated submission of a New Drug Application (NDA) to FDA for CNM-Au8 via an accelerated regulatory pathway in the second quarter of 2026*
- *Potential for FDA acceptance of this NDA and issuance of a Prescription Drug User Fee Act (PDUFA) date in the second half of 2026*

SALT LAKE CITY, Feb. 24, 2026 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, “Clene” or the “Company”) 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 issued a letter to stockholders outlining key anticipated regulatory and clinical milestones for CNM-Au8® in 2026.

CEO Letter to Stockholders

As we look to the year ahead, I want to extend my sincere gratitude for your ongoing support of Clene. As the founding CEO with over 12 years at the helm, I am driven by Clene’s mission to develop impactful and safe treatments for neurodegenerative diseases, particularly through our focus on ALS.

Following the completion of multiple Phase 2 clinical trials and continued support of open label expanded access programs, we have now treated over 800 patients with CNM-Au8, our orally administered nanocrystal suspension, encompassing one of the largest sets of clinical experience in ALS. The learnings and data that we have discovered place us at an exciting and critical juncture.

Sufficient cash to fund operations into the fourth quarter of 2026

In January we completed an oversubscribed registered direct offering of over $28 million. The initial tranche of over $6 million is expected to provide operating runway into the fourth quarter of 2026, sufficient funding through a potential NDA acceptance decision by the FDA. Two potential additional financing tranches totaling over $22 million are structured to align with NDA acceptance and FDA approval milestones and are expected to provide the Company with sufficient capital into 2027. We are immensely grateful for the support of our investors who have an unwavering conviction in the value of our programs.

Next Regulatory Steps and 2026 Catalysts

Since late 2024, we have been closely engaged on multiple occasions with the neurology division of the FDA regarding CNM-Au8. Our discussions have culminated in an in-person Type C FDA meeting scheduled by the end of this quarter to discuss the data in our extensive briefing package submitted in late 2025. We expect to receive the FDA minutes from this meeting early in the second quarter, with the Company ready to submit a New Drug Application (NDA) to the FDA for CNM-Au8 via an accelerated regulatory pathway in the second quarter of 2026. FDA acceptance of this NDA and issuance of a Prescription Drug User Fee Act (PDUFA) date for regulatory decision under the accelerated approval pathway could occur in the second half of 2026, with potential approval for commercial launch in 2027.

Based on the significance of our clinical data and our engagement with the FDA, we believe that CNM-Au8 is well suited for the accelerated approval pathway as described below:

1. **Prolonged Survival and Associated Declines in Biomarkers of Neurodegeneration:**

We have generated extensive clinical data demonstrating prolonged survival in ALS associated with CNM-Au8 30mg treatment. Survival critically matters in ALS, a fatal condition with median life expectancy of approximately 2-4 years following diagnosis. CNM-Au8 drove a statistically significant and clinically meaningful reduction of mortality risk and slowed clinical worsening, both as pre-specified secondary and/or exploratory endpoints in clinical trials and sustained benefits in open label extensions. This evidence demonstrating prolonged survival benefit with CNM-Au8 treatment was accompanied by statistically significant declines in ALS-relevant biomarkers, including neurofilament light chain (NfL) and glial fibrillary acidic protein (GFAP), key markers of neuronal and glial cell injury and degeneration, providing a biological basis for the decreased mortality risk. We believe these combined findings across validated biomarkers of neurodegeneration support NfL as a viable surrogate endpoint for accelerated FDA approval of CNM-Au8. Notably, NfL biomarker change has recently been used for accelerated approval by FDA of another ALS medicine, and we believe this data will address the agency’s requests to link NfL reductions to clinical benefit. Finally, Clene has also provided supporting evidence to address the FDA’s proposed framework for potential accelerated approval consideration as described in our prior FDA meeting minutes which we have previously discussed publicly.

2. **Favorable Safety and Benefit/Risk Profile:**

CNM-Au8’s groundbreaking clean-surfaced nanotherapeutic suspension, an oral liquid that patients drink daily and tastes like water, has demonstrated a consistent safety and tolerability profile. Across all our clinical trial and expanded access programs, now totaling over 1,000 patient years of treatment, the adverse event profile has been assessed as predominantly mild-to-moderate. Additionally, there have been no CNM-Au8-related Serious Adverse Events (SAEs), and no safety signals have been associated with long-term use. This benign tolerability profile should be important to the FDA as it considers the benefit/risk profile associated with CNM-Au8 treatment. Furthermore, there is regulatory precedent in ALS

whereby other investigational drugs with a derisked tolerability profile have been granted accelerated approval based solely on Phase 2 efficacy data.

3. **Confirmatory Phase 3 RESTORE-ALS Trial Planned to Begin Later in 2026:**

To confirm the survival benefit observed with CNM-Au8 30 mg treatment across several Phase 2 trials and to meet FDA requirements for the accelerated approval pathway, we are planning to dose the first patient in our confirmatory Phase 3 RESTORE-ALS trial later this year. The study will be a double-blind, placebo-controlled Phase 3 trial evaluating the effects of CNM-Au8 on survival and clinical worsening events in ALS. The trial design protocol has already been discussed with and reviewed by the FDA.

Our Commitment to the ALS Community Remains Unwavering:

The development of CNM-Au8 has been exceptionally collaborative with many stakeholders involved. Over nearly a decade, we have engaged with the ALS community, including leading scientists, treating physicians, disease advocates, non-profit ALS organizations, and hundreds of patients and their respective caregivers. CNM-Au8 is well known to many of these ALS stakeholders. CNM-Au8 is also well known to the regulators within the FDA, and we look forward to presenting our robust body of evidence supporting CNM-Au8 to them in later in this first quarter of 2026. We expect the totality of our biomarker, survival, and bioanalytic evidence supporting CNM-Au8, coupled with the favorable tolerability profile of the drug and the significant unmet need in ALS, will be extremely compelling in our upcoming discussions with the FDA for consideration of the accelerated approval pathway.

Other Promising 'Pipeline-in-a-Product' Indications Advancing in 2026:

CNM-Au8 has also shown promising clinical benefits in MS and Parkinson's disease. In our MS program, we plan to build on our 2025 momentum as we incorporate FDA feedback to finalize our Phase 3 clinical trial design focused on cognition in MS as an adjunct to standard of care therapies. We view CNM-Au8 as a potential "pipeline in a product," with the initial ALS indication serving as the foundation for a much larger clinical development pipeline within the neurodegenerative field.

Thank you for your partnership in this journey.

Sincerely,
Rob Etherington, President and CEO, Clene, Inc.

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 the timing of the Company's meeting with the FDA, the timing of the Company's NDA submission, and that the biomarker findings support an NDA submission. 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 general market conditions, whether clinical trials demonstrate the efficacy and safety of our drug candidates to the satisfaction of regulatory authorities, or do 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; 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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