After Successful FDA Meeting, Clene Filing Accelerated Approval NDA for ALS

May 4, 2026

- *FDA stated that the "proposed data may be capable of supporting the submission and review of an [NDA] under the accelerated approval pathway" for CNM-Au8 based on neurofilament light (NfL) biomarker data*
- *FDA acknowledged NfL could potentially serve as a reasonably likely surrogate endpoint*
- *Clene expects to submit an NDA for CNM-Au8 to the FDA in the third quarter of 2026*
- *CNM-Au8 represents a potential first-in-class therapeutic approach for ALS, a disease area with significant unmet medical need*

SALT LAKE CITY, May 04, 2026 (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 receipt of final meeting minutes following its recent Type C meeting with the U.S. Food and Drug Administration (FDA).

During the meeting and confirmed in the final meeting minutes, the FDA stated that Clene's " *proposed data may be capable of supporting the submission and review of an [New Drug Application (NDA)] under the accelerated approval pathway for the treatment of ALS."* The FDA reminded the Company that the submission should demonstrate the effectiveness of an effect of CNM-Au8 on NfL and show that the magnitude of change in NfL is reasonably likely to predict clinical benefits in patients with ALS. Clene intends to submit its NDA in the third quarter of 2026, which will remain a matter of FDA review.

The Agency also noted that "*NfL could potentially serve as a reasonably likely surrogate endpoint to support (an) accelerated approval.*" This submission would occur under the Subpart H accelerated approval pathway (21 CFR 314.510) in ALS. The Agency has also requested that the Company provide additional information in its NDA, including to support a connection between the reported magnitude of reduction in NfL and clinical benefit, which Clene has prepared and will include in the submission.

Clene's journey with the FDA has been constructive. Today, we express our great appreciation for the FDA's clear display of regulatory flexibility and its recent communications of a willingness to consider receipt of an NDA submission. That the Agency has now agreed to review our extensive data dossier is a critical moment in our company's history.

"We are encouraged by the FDA's careful evaluation of the benefits and risks associated with Clene's ALS drug candidate, CNM-Au8, including the biomarker data the Company provided. The filing of an NDA submission represents an important milestone for CNM-Au8 and for the ALS community," said Rob Etherington, President and CEO of Clene. "We are committed to working with the Agency on this filing and are conducting the Phase 3 confirmatory study for CNM-Au8, which we intend to commence in the first quarter of 2027."

"People living with ALS cannot afford to wait," said Sandra Abrevaya, I AM ALS Co-Founder and Board Member. "Flexible, science-driven regulatory approaches such as this can play a critical role in accelerating access to new therapies for a fast-progressing, fatal disease. We're grateful for the Agency's recognition of the urgency and unmet need in ALS."

The planned NDA submission will be supported by NfL biomarker and clinical data from the Phase 2 HEALEY ALS Platform Trial and its open-label extension, as well as the Phase 2 RESCUE-ALS Trial, and the NIH-sponsored Expanded Access Protocol for CNM-Au8. Supporting data include reductions in plasma NfL associated with longer survival in the open-label extension and additional clinical outcomes. CNM-Au8 has previously received Orphan Drug Designation from the FDA for the treatment of ALS.

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 NDA submission, that the biomarker findings support an NDA submission, and the timing of the initiation of the Phase 3 trial. 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.

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

Media Contact: Caroline Wagner, Forbes Tate Partners; CWagner@forbes-tate.com; (267) 294-6563