



Clene Announces New Drug Application Submission to FDA for CNM-Au8 for the Treatment of ALS

October 19, 2026

- NDA submission seeks accelerated approval of CNM-Au8 based on neurofilament light chain biomarker data and clinical outcomes

SALT LAKE CITY, Oct. 19, 2026 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN), a clinical-stage biotechnology company focused on revolutionizing the treatment of neurodegenerative diseases, announced that it has submitted a New Drug Application (NDA) earlier in October to the U.S. Food and Drug Administration (FDA) seeking accelerated approval of CNM-Au8[®] for the treatment of amyotrophic lateral sclerosis (ALS).

"The submission of our NDA for CNM-Au8 represents an important achievement for Clene, CNM-Au8, and especially for people living with ALS," said Rob Etherington, President and Chief Executive Officer of Clene. "We appreciate the FDA's constructive engagement throughout this process and look forward to working closely with the Agency during its review."

"Reaching this stage reflects years of dedicated work by the Clene team, our clinical investigators, patients and families, and our partners," continued Mr. Etherington. "We remain focused on advancing CNM-Au8 through the regulatory process as efficiently as possible while continuing our preparations for the confirmatory Phase 3 RESTORE-ALS study. People living with ALS urgently need additional treatment options, and we believe CNM-Au8 has the potential to restore and protect neuronal health and function and improve survival."

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](#).

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 for the confirmatory Phase 3 RESTORE-ALS study and the potential benefits of CNM-Au8. 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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