UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 15, 2021

Clene Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-39834	85-2828339
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6550 South Millrock Drive, Suite G50 Salt Lake City, Utah	84121
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (801) 676-9695

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value US$0.0001 per share	CLNN	The Nasdaq Capital Market
Warrants, to acquire one-half of one share of Common Stock for $11.50 per share	CLNNW	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On November 15, 2021, Clene Inc. (the "Company") issued a press release announcing completion of patient enrollment in the HEALEY ALS Platform Trial. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report") and is incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in any such filings, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated November 15, 2021 announcing completion of patient enrollment in the HEALEY ALS Platform Trial.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Clene Inc.

Date: November 15, 2021

By: /s/ Robert Etherington
Robert Etherington
President and Chief Executive Officer

Exhibit 99.1

Clene Announces Completion of Patient Enrollment in the HEALEY ALS Platform Trial

- *Registration trial for CNM-Au8®, a gold nanocrystal suspension*
- *Topline data anticipated 2H 2022*
- *World's first ALS platform trial accelerating the path to new ALS therapies*

SALT LAKE CITY, November 15, 2021 -- Clene Inc. (NASDAQ: CLNN) along with its subsidiaries "Clene" and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease with potential first-in-class nanotherapeutics, today announced the completion of enrollment in the HEALEY ALS Platform Trial, led by the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital. Clene's lead drug candidate, *CNM-Au8®*, a gold nanocrystal suspension, which has received U.S. Food and Drug Administration (FDA) Orphan Drug designation for the treatment of amyotrophic lateral sclerosis (ALS), is one of several drugs being evaluated in this innovative platform trial.

"We are grateful to people living with ALS, whose support and participation have made possible the completion of this critical milestone for this first-of-its-kind platform trial. This achievement is pivotal for trial completion and result reporting, paving the way to continue groundbreaking research and find life-saving treatments for people with ALS," said Merit Cudkowicz, MD, MSc, Principal Investigator and Sponsor of the HEALEY ALS Platform Trial, Director of the Sean M. Healey & AMG Center for ALS and chief of the Department of Neurology at Mass General, and the Julieanne Dorn Professor of Neurology at Harvard Medical School.

"Having reached this significant milestone, we look forward to completing the 24-week, double-blind treatment phase and the release of top-line unblinded data in the second half of 2022. If CNM-Au8 meets its primary endpoint in this registration trial, we plan to file a New Drug Application with the FDA for disease-modification in ALS also in the second half of 2022. By catalyzing cellular energy metabolism, we believe CNM-Au8 may improve outcomes for ALS patients who currently have few treatment options," said Robert Glanzman, MD, Chief Medical Officer of Clene.

The HEALEY ALS Platform Trial is a multi-center clinical program evaluating the safety and efficacy of multiple investigational products in ALS patients. It is the first ever platform trial implemented in ALS and was designed with a shared placebo arm to reduce trial time, reduce costs, and increase patient participation in developing novel therapies for ALS. It includes substantial financial support from philanthropic donors and foundations and is currently being conducted at more than 50 expert ALS clinical trial sites across the U.S.

Clene's CNM-Au8, a catalytically active gold nanotherapeutic, was selected by the Healey Center Therapy Selection Committee to be one of the first entrants into the trial. In the CNM-Au8 treatment regimen, at least 160 participants were randomized 3:1 (active:placebo), with 120 planned for randomization across two active arms (CNM-Au8 30 mg and 60mg) and at least 40 planned in placebo. Clinical data from an additional 80 placebo-treated participants are shared within the platform trial from two other regimens for an overall 1:1 allocation of active:placebo.

About CNM-Au8®, a gold nanocrystal suspension

Clene's lead drug candidate, CNM-Au8, a catalytically active gold nanotherapeutic, is the result of a patented manufacturing breakthrough. The catalytically active nanocrystals of CNM-Au8 drive critical cellular energy producing reactions in the brain that enable neuroprotection and remyelination by increasing neuronal and glial resilience to disease-relevant stressors. CNM-Au8 crosses the blood-brain barrier and is not associated with the toxicities related to synthetic gold compounds or nanoparticles manufactured via alternative methods. CNM-Au8 is being evaluated in a Phase 3 registration trial for the treatment of amyotrophic lateral sclerosis (ALS). In the REPAIR Program Phase 2 open-label biomarker clinical trials, CNM-Au8 demonstrated target engagement in the treatment of Parkinson's disease (PD) and multiple sclerosis (MS). REPAIR-PD has concluded, and REPAIR-MS will continue with the initiation of a second MS dosing cohort. Preclinical data, both published in peer-reviewed journals and presented at scientific congresses, demonstrate that treatment of neuronal cultures with CNM-Au8 improves survival of neurons, protects neurite networks, decreases intracellular levels of reactive oxygen species and improves mitochondrial capacity in response to cellular stresses induced by numerous disease-relevant neurotoxins. Oral treatment with CNM-Au8 improved functional behaviors in rodent models of ALS, MS and PD versus vehicle (placebo). CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc.

About the HEALEY ALS Platform Trial

The HEALEY ALS Platform Trial is a perpetual multi-center, randomized, double-blind, placebo-controlled Phase 3 registration program designed to evaluate the efficacy and safety of multiple investigational products in people living with amyotrophic lateral sclerosis (ALS). Funded by philanthropic donors and led by Harvard's Massachusetts General Hospital, the HEALEY ALS Platform Trial is the first-ever platform trial in ALS and was designed to reduce trial time, costs, and increase patient participation in developing novel therapies. This landmark platform trial tests multiple treatments utilizing a shared placebo group. CNM-Au8 was selected as one of the first three drugs to be evaluated. Participants are randomized 3:1 to receive one of three active treatments or placebo daily for a 24-week treatment period which is followed by an Open Label Extension where all participants receive active drug. The primary endpoint is rate of change in disease severity over time as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R). Secondary endpoints include change in respiratory function over time as measured by slow vital capacity and change in muscle strength over time as measured isometrically using hand-held dynamometry. Topline data are expected in 2H 2022. For more information, please see ClinicalTrials.gov Identifier: NCT04297683.

About Clene

Clene is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease with potential first-in-class nanotherapeutics to treat energetic failure, an underlying cause of many neurological diseases. Our lead drug candidate, CNM-Au8, is an oral suspension of gold nanocrystals that drive critical cellular energetic metabolism in the central nervous system (CNS). CNM-Au8 increases energy production and utilization to accelerate neurorepair and improve neuroprotection. CNM-Au8 is currently being evaluated in a Phase 3 registration trial in amyotrophic lateral sclerosis (ALS) and a Phase 2 trial for the treatment of chronic optic neuropathy in patients with stable relapsing multiple sclerosis (MS). Clene has also advanced into the clinic an aqueous solution of ionic zinc and silver for anti-viral and anti-microbial uses. 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 Twitter, LinkedIn and Facebook.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Clene's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "might" and "continues," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant known and unknown risks and uncertainties, many of which are beyond Clene's control and could cause actual results to differ materially and adversely from expected results. Factors that may cause such differences include Clene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its 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; Clene's ability to achieve commercial success for its marketed products and drug candidates, if approved; Clene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Clene's reliance on third parties to conduct drug development, manufacturing and other services; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the licensing or development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on Clene's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in Clene's Annual Report filed on Form 10K, as well as discussions of potential risks, uncertainties, and other important factors in Clene's subsequent filings with the U.S. Securities and Exchange Commission. Clene undertakes no obligation to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, subject to applicable law. 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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Source: Clene Inc.