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): September 9, 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 Stock Market LLC
Warrants, to acquire one-half of one share of Common Stock for $11.50 per share	CLNNW	The Nasdaq Stock Market LLC

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 September 9, 2021, Clene Inc. (the "Company") issued a press release announcing the final patient visit has been completed in its Phase 2 RESCUE-ALS clinical study, with unblinded topline data expected in Q4 2021. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K 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, 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 September 9, 2021 announcing Clene completes final patient visit in Phase 2 RESCUE-ALS study: topline data expected Q4 2021.
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: September 9, 2021

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

Exhibit 99.1

Clene Completes Final Patient Visit in Phase 2 RESCUE-ALS Study:
Topline Data Readout Expected Q4 2021

- ***Final patient visit has been completed in its Phase 2 RESCUE-ALS study; study close-out activities have commenced***
- ***90% of eligible patients are continuing to be treated under a long-term open label extension***
- ***Interim blinded efficacy data after 9-months of treatment with CNN-Au8®, a catalytically-active gold nanocrystal suspension, showed absolute improvement from baseline in neurophysiology endpoints as compared to progressive worsening seen in published data sets***

SALT LAKE CITY, September 9, 2021 -- Clene Inc. (NASDAQ: CLNN) along with its subsidiaries "Clene" and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company dedicated to the treatment of neurodegenerative disease using nanotechnology to treat cellular energetic failure, announced the final patient visit has been completed in its Phase 2 RESCUE-ALS study and that trial close-out activities have begun. RESCUE-ALS investigated the efficacy, safety, pharmacokinetics and pharmacodynamics of Clene's lead drug candidate, CNM-Au8®, a catalytically-active gold nanocrystal suspension, in patients with early amyotrophic lateral sclerosis (ALS). The trial enrolled a total of 45 patients with ALS, with unblinded topline data expected in Q4 2021.

90% of eligible patients from the double-blind study elected to roll over into active treatment with 30mg CNM-Au8 under a long-term open label extension (OLE) of the study. The OLE is intended to offer treatment to those originally randomized to placebo in the double-blind, treatment period and to collect longer term efficacy and safety data.

"Thus far the blinded interim data we have seen on the primary and secondary endpoints of our RESCUE-ALS study are very encouraging. We look forward to the unblinded topline readout before the end of the year. We are grateful to the patients and their families for participating in this important study and are hopeful that those who continue to be treated under the open label extension may continue to benefit from CNM-Au8," stated Robert Glanzman, MD, FAAN, Chief Medical Officer of Clene.

"Our clinical trial teams in Sydney are very pleased to have reached this important landmark for RESCUE-ALS. It is a tribute to the ALS patients involved in the trial that we were able to recruit for the trial throughout the COVID-19 pandemic. ALS patients have shown great resilience and a willingness to contribute to research and discovery. Now, like them, we look forward to the trial analysis and outcomes," said Professor Matthew Kiernan, AM MBBS(Hons), PhD, DSc, FRACP, FAHMS, Bushell Chair of Neurology, University of Sydney.

Interim blinded efficacy results from the Phase 2 RESCUE-ALS study were presented at the ENCALS 2021 Annual Meeting on May 12, 2021. The study's primary endpoint, the Motor Unit Number Index (MUNIX), a sensitive predictor of clinical decline in ALS, showed absolute improvements from baseline for approximately 18% of the study population, as compared to the expected continuous decline seen in published data from prior observational studies[1]. Less loss in forced vital capacity (FVC) was also evident as compared to published data sets[2].

About RESCUE-ALS

RESCUE-ALS is a Phase 2 multi-center, randomized, double-blind, parallel-group, placebo-controlled study examining the efficacy, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in patients with early amyotrophic lateral sclerosis (ALS). The trial completed enrollment in 2H 2020. 45 subjects were randomized 1:1 to receive either active treatment with CNM-Au8 (30 mg) or placebo in addition to their current standard of care over a 36-week treatment period. The objective of the study is to assess the impact of improving cellular energy production, reducing oxidative stress, and enhancing energetic homeostasis with CNM-Au8 on disease progression in patients with early-stage ALS. CNM-Au8 was selected by FightMND of Australia and Clene was provided a substantial grant to investigate efficacy in ALS utilizing novel neurophysiological endpoints at two expert clinical sites in Australia. Topline data are expected in Q4 2021. For more information, please see ClinicalTrials.gov Identifier: NCT04098406.

About CNM-Au8®

Clene's lead drug candidate, CNM-Au8, is an aqueous suspension of catalytically-active, clean-surfaced, faceted gold nanocrystals. Resulting from a patented manufacturing breakthrough, the catalytically active nanocrystals of CNM-Au8 drive critical cellular energy producing reactions in the brain that enable neurorepair 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 has demonstrated safety in Phase 1 studies in healthy volunteers and has shown both remyelination and neuroprotective effects in multiple preclinical (animal) models. 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-Au8Ò is a federally registered trademark of Clene Nanomedicine, Inc.

About Clene

Clene, a clinical-stage biopharmaceutical company focused on neurodegenerative disease treatments, is leading the way by using nanotechnology to treat energetic failure, which underlies many neurological diseases. Clene has innovated a novel nanotherapeutic platform to create a new class of drugs. Clene's lead drug candidate, CNM-Au8, is an aqueous suspension of catalytically-active, clean-surfaced, faceted gold nanocrystals that drive critical cellular energetic metabolism in the central nervous system (CNS). CNM-Au8 increases cellular energy production to accelerate neurorepair and improve neuroprotection. CNM-Au8 is currently being evaluated in a Phase 3 registration trial in amyotrophic lateral sclerosis (ALS), a Phase 2 trial examining disease progression via a novel electromyography technique in patients with early ALS, a Phase 2 trial for the treatment of chronic optic neuropathy in patients with stable relapsing multiple sclerosis (MS), and Phase 2 brain target engagement studies in patients with Parkinson's disease (PD) and 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.

About FightMND

FightMND is a not-for-profit registered charity, founded in 2014. It was established to raise the awareness of Motor Neurone Disease (MND) in Australia, to increase funding for research to find an effective treatment and cure and to provide care equipment for MND patients. We have a clear objective – to a have a world free from MND.

FightMND is Australia's largest independent MND foundation focused on funding large- scale, collaborative research and clinical trials. The generous donations contributed by everyday Australians, right across the country, has enabled FightMND to raise and commit millions to cure and care initiatives.

References

[1] Neuwirth et al. J Neurol Neurosurg Psychiatry. 2015 Nov;86(11):1172-9.
[2] Andrews et al. JAMA Neurol. 2018 Jan 1;75(1):58-64.

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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