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): January 18, 2022

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 8.01 Other Events.

On January 18, 2022, Clene Inc. (the "Company") issued a press release announcing the Company's second asset, CNM-ZnAg, completed more than 50% patient enrollment in its COVID-19 Phase 2 clinical trial. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished in this Item 8.01, 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 January 18, 2022, announcing the Company's second asset, CNM-ZnAg, completes 50% patient enrollment in COVID-19 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: January 18, 2022

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

Exhibit 99.1

Clene Nanomedicine's Second Asset, CNM-ZnAg, Completes 50% Patient Enrollment in COVID-19 Trial

- *Topline data is expected in 1H 2022*
- *Trial is evaluating acutely symptomatic, non-hospitalized COVID-19 patients in Brazil*
- *CNM-ZnAg is a proprietary zinc-silver ionic solution that has demonstrated both antiviral and antibacterial activity.*

SALT LAKE CITY, January 18, 2022 -- -- Clene Inc. (NASDAQ: CLNN) along with its subsidiaries "Clene" and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, today announced it has enrolled more than 50% of the approximately 276 planned participants for its Phase 2 multicenter, randomized, double-blind, placebo-controlled study assessing the efficacy and safety of CNM-ZnAg in acutely symptomatic, non-hospitalized COVID-19 patients in Brazil. CNM-ZnAg is a proprietary zinc-silver ionic solution that has demonstrated both antiviral and antibacterial activity.

Study participants are randomized 1:1:2 to receive either a low dose of CNM-ZnAg, a high dose of CNM-ZnAg or placebo in addition to standard supportive care. The primary endpoint of the study is the prevention of hospitalization (measured as frequency of hospital admissions) up to day 28, with a key secondary endpoint assessing time to complete symptom resolution. Topline results are expected in 1H 2022.

"Given the COVID-19 virus' continued mutations and its impact on healthcare systems and society's ability to fully reopen, we need additional therapeutic options in the public health arsenal. CNM-ZnAg's antiviral activity is broadly based, and if it proves effective in this Phase 2 study, we believe it will be well positioned to advance toward a potential registration trial for COVID-19 as well as becoming a potential candidate for other viral and bacterial indications," stated Rob Etherington, Clene's President and CEO.

About CNM-ZnAg, a zinc and silver nanocrystal suspension
Clene's drug candidate, CNM-ZnAg, an ionic solution of zinc and silver, is the result of a patented manufacturing process. CNM-ZnAg is being evaluated in a Phase 2 study for the treatment of COVID-19.

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” which are intended to be covered by 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 on Form 10-K, 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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