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 23, 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 23, 2021, Clene Inc. (the "Company") issued a press release announcing initiation of a second U.S. Food and Drug Administration (FDA) Expanded Access Program with CNM-Au8 for people living with amyotrophic lateral sclerosis (ALS). 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 23, 2021 announcing initiation of a second FDA Expanded Access Program with CNM-Au8 for people living with amyotrophic lateral sclerosis.
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 23, 2021

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

Exhibit 99.1

Clene Announces Initiation of a Second FDA Expanded Access Program with CNM-Au8 for People Living with Amyotrophic Lateral Sclerosis

SALT LAKE CITY, September 23, 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 launch of a second U.S. Food and Drug Administration (FDA) expanded access program (CNMAu8.EAP02) with CNM-Au8 for people living with amyotrophic lateral sclerosis (ALS).

This expanded access program will be implemented in conjunction with the Healey ALS Platform Trial, a registration trial in which CNM-Au8®, a catalytically-active gold nanocrystal suspension, is currently being evaluated for the treatment of ALS, with topline results expected mid-2022. The Healey ALS Platform trial is led by Dr. Merit Cudkowicz, Director of the Sean M. Healey & AMG Center for ALS, Chief of the Department of Neurology at Massachusetts General Hospital (MGH) and the Julieanne Dorn Professor of Neurology at Harvard Medical School, and her team. The expanded access program is designed to provide people with ALS who are not eligible to enroll in the Healey ALS Platform Trial access to CNM-Au8, an investigational cellular energetic catalyst that supports energy production.

The Healey Center will support the expanded access program at three participating clinical trial sites in the Healey ALS Platform Trial. CNMAu8.EAP02 will enroll participants across three sites. The first two sites to be included are the Holy Cross Hospital in Fort Lauderdale, Florida and the Hospital for Special Care in New Britain, Connecticut.

Robert Glanzman, MD, FAAN, Clene's Chief Medical Officer, commented, "We are honored to be collaborating with the Healey Center for ALS in this critically important effort of providing access to CNM-Au8 to people with ALS who may benefit. The Healey Center is an outstanding partner, and we proudly share its goal of developing lifesaving therapies for the treatment of ALS."

CNMAu8.EAP02 is the second expanded access program with CNM-Au8 that Clene is currently supporting for people with ALS. The initial expanded access program (CNMAu8.EAP01) was also launched in partnership with the Sean M. Healey & AMG Center for ALS at MGH and presently supports access to CNM-Au8 for 40 people living with ALS. CNMAu8.EAP01 started enrolling participants in September 2019 with long-term participants now treated for over 100 weeks.

"While CNM-Au8 advances through the registration platform trial with an aim to become available to all patients with ALS, expanded access programs enable more people with ALS to benefit today from the potential of our first-in-class neuroreparative energetic nanotherapeutic. Clene is committed to supporting communities living with devastating neurodegenerative diseases, and we are doing our utmost each day to reach and treat more patients," stated Rob Etherington, Clene's President and CEO.

About Amyotrophic Lateral Sclerosis (ALS)

ALS is a universally fatal neurodegenerative disorder that results in loss of motor neurons in the cerebral cortex, brain stem, and spinal cord. ALS (also known as Lou Gehrig's disease) leads to the death of the neurons controlling voluntary muscles resulting in weakness, muscle atrophy, and progressive paralysis. ALS affects more than 15,000 patients in the United States and is the most prevalent adult-onset progressive motor neuron disease.

About the HEALEY-ALS Platform Trial

The HEALEY ALS Platform Trial is led by a panel of expert amyotrophic lateral sclerosis (ALS) scientists. This breakthrough trial, the first ever platform trial for the treatment of ALS, is designed to reduce trial time, reduce costs and increase patient participation in developing novel therapies for ALS. The trial includes substantial financial support from philanthropic donors and foundations, and presently involves more than 50 expert ALS clinical trial sites across the United States.

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 registration enabling trial in amyotrophic lateral sclerosis (ALS), a Phase 2 trial examining disease progression via a novel electrophysiology 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.

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 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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