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): February 22, 2024

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)

(801) 676-9695

(Registrant's telephone number, including area code)

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:

☐ 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, $0.0001 par value	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.

In connection with the press release discussed under Item 8.01 in this Current Report on Form 8-K, on February 22, 2024, Clene Inc. (the "Company") released a presentation (the "Presentation") on its website, invest.clene.com. The Presentation discusses a significant survival benefit with CNM-Au8 treatment in the Company's amyotrophic lateral sclerosis ("ALS") compassionate use expanded access programs ("EAPs"). A copy of the Presentation 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 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 8.01 Other Events.

On February 22, 2024, the Company issued a press release announcing a significant survival benefit with CNM-Au8® treatment in its ALS EAP compassionate use programs. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	EAP Presentation.
99.2	Press Release, dated February 22, 2024, announcing significant survival benefit with CNM-Au8 treatment in ALS EAP compassionate use programs.
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: February 22, 2024

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

Exhibit 99.1

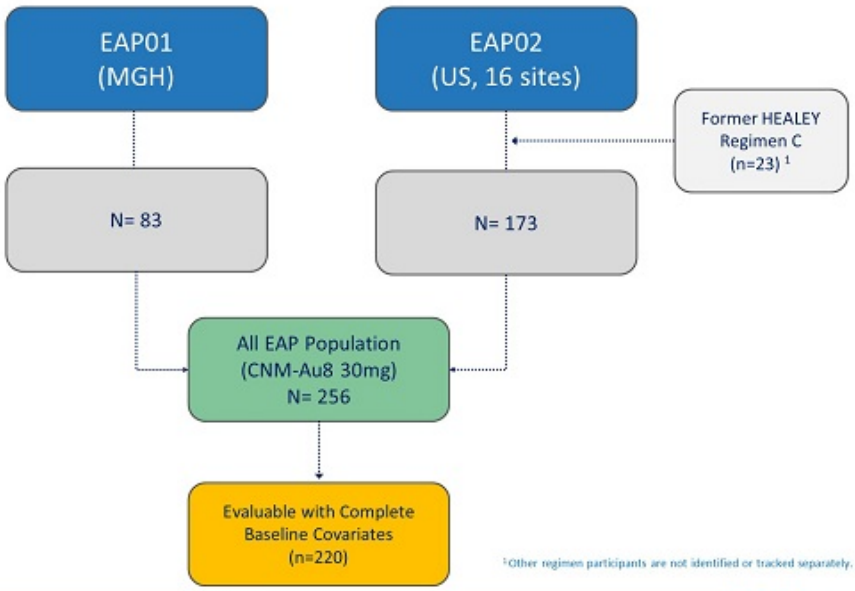
EAP Participant Enrollment

- All EAP participants (CNM-Au8 30mg) enrolled through 15-December-2023 with EDC data entry
- Survival updated through the 14-January-2024 data cut

EAP01 in collaboration with the:

Healey Center
Sean M. Healey & AMG Center for ALS at Mass General

The Healey center covered all site costs and EDC management through philanthropic donations; Clene provided CNM-Au8 and conducted analyses



[1] Other regimen participants are not identified or tracked separately.

Data on File, Clene Nanomedicine, Inc.

EAP Baseline Demographics | At Study Entry

Baseline Category Mean (SD) or n (%) Range [Min, Max]	EAP01 (n=83)	EAP02 (n=173)	All EAP (n=256)
Age at Baseline, (n= 256)	55.5 (12.2) [27, 78]	61.1 (10.9) [22, 84]	59.3 (11.6) [22, 84]
Months from Symptom Onset, (n= 256)	40.5 (39.4) [5.7, 244]	54.2 (32.1) [6.5, 234.4]	49.7 (35.2) [5.7, 244]
Diagnostic Delay (Months), (n= 256)	16.6 (24.8) [0, 203]	20.7 (23.2) [0.5, 192]	19.4 (23.7) [0, 203]
Vital Capacity (% predicted), (n= 225)	69.3 (25.4) [22, 118]	57.6 (24.9) [9, 146]	60.4 (25.4) [9, 146]
ALSFRS-R (Total), (n=256)	31.4 (10.7) [1, 48]	25.9 (9.8) [1, 47]	27.7 (10.4) [1, 48]
Delta-FS (Pre-treatment Slope), (n=256)	0.60 (0.48) [0, 2.56]	0.50 (3.9) [0, 2.24]	0.53 (0.42) [0, 2.56]
TRICALS Risk Score (6-factor), (n=225)	-5.1 (2.3) [-10.2, -1.5]	-4.8 (2.1) [-11.4, 2.03]	-4.86 (2.1) [-11.4, 2.03]
BMI (kg/m^2), (n= 228)	25.5 (5.2) [17.4, 51]	25.6 (5.3) [14, 46.2]	25.6 (5.2) [14, 51]
Sex, Male (%), (n= 256)	69%	61%	63%
Bulbar Onset (%), (n=256)	23%	25%	24%
El Escorial, Clinically Definite (%), (n= 256)	57%	58%	58%
Riluzole Background Treatment (%), (n= 254)	76%	70%	72%

Data on File, Clene Nanomedicine, Inc.

Propensity Matched ALS Controls | Sources

ALS EXPANDED ACCESS PROTOCOLS (EAP)

Healey Center
Sean M. Healey & AMG Center for ALS at Mass General

PRO-ACT

The PRO-ACT database

Design, initial analyses, and predictive features

ABSTRACT

ALS Natural History Study

Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration, 2023; 0: 1–9

RESEARCH ARTICLE

The natural history of ALS: Baseline characteristics from a multicenter clinical cohort

Atassi et al. Neurology. 2014 Nov 4;83(19):1719-25. Berget et al. Amyotroph Lateral Scler Frontotemporal Degener. 2023 Jul 17:1-9.

CLENE NANOMEDICINE

Survival Analyses | Methodology

- Utilize longitudinal data from historical ALS controls:

PRO-ACT

ALS Natural History Study

- Propensity matching based on baseline covariates (nominal caliper: 0.4)

Age at Onset

Bulbar Onset

TRICALS Risk Score

Pre-Treatment ALSFSR-R Slope

Sex

BMI

Diagnostic Delay

Matching covariates

- Observation time as an additional matching covariate for sensitivity analyses

Data on File, Clene Nanomedicine, Inc.

Survival Analyses | All-Cause Mortality

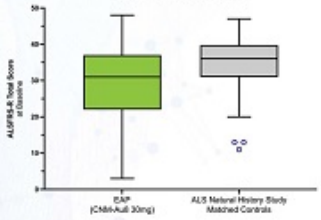
- Log-rank (unadjusted) of all EAP (n=256) vs. propensity matched controls (n=220)
- Covariate adjusted hazard ratio (EAP treatment vs. controls)
  - EAP participants with baseline covariates (n=220) vs. propensity matched (n=220)
  - Baseline Covariates:
    - Onset Age
    - Sex
    - BMI
    - Delta-FS (ALSFRS-R Pretreatment Slope)
    - ALSFRS-R Total Score
    - Diagnostic Delay (Months)
    - Vital Capacity (% predicted)
    - TRICALS Risk Score

Data on File, Clene Nanomedicine, Inc.

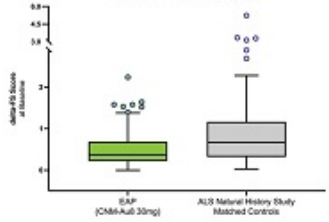
EAP Participants vs. Propensity Matched Controls

ALS Natural History Study

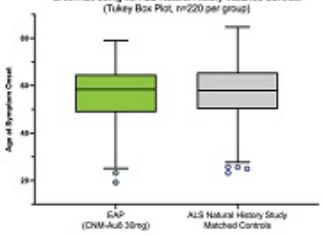
ALSFRS-R Score



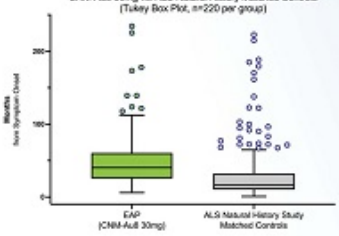
Delta-FS



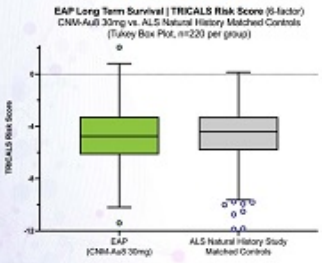
Onset Age



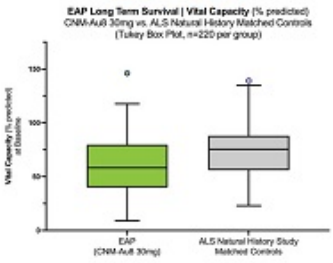
Months Post-Onset



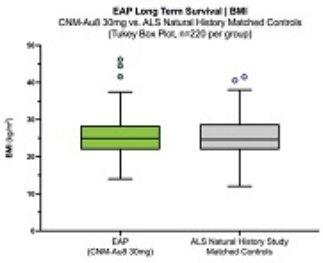
TRICALS Risk Score



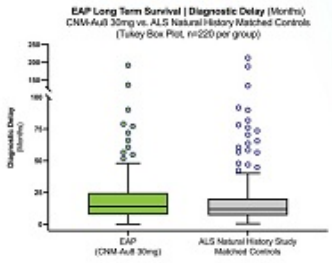
Vital Capacity (%)



BMI



Diagnostic Delay



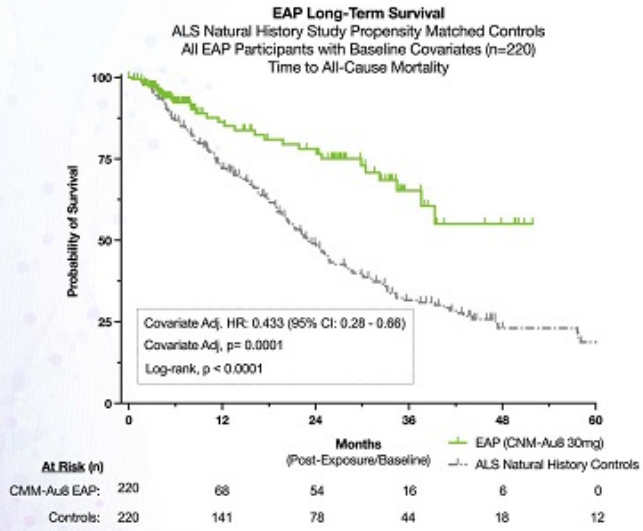
Matching covariates were balanced except for ALSFRS-R and vital capacity in favor of matched controls, while delta-FS favored EAP participants. Time from symptom onset was longer in EAP participants.

Data on File, Clene Nanomedicine, Inc.

EAP Survival vs. ALS Natural History Matched Controls

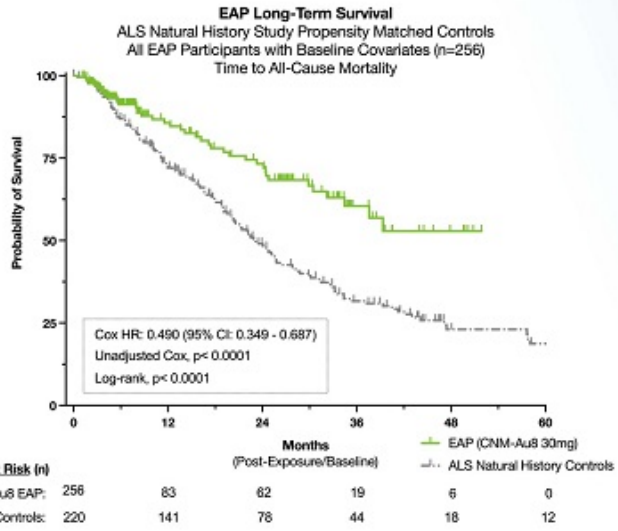
Control-Matched EAP and All EAP

ALS Natural History Study | EAP Matched (n=220)



At Risk (n)						
CNM-Au8 EAP:	220	68	54	16	6	0
Controls:	220	141	78	44	18	12

ALS Natural History Study | All EAP (n=256)



At Risk (n)						
CNM-Au8 EAP:	256	83	62	19	6	0
Controls:	220	141	78	44	18	12

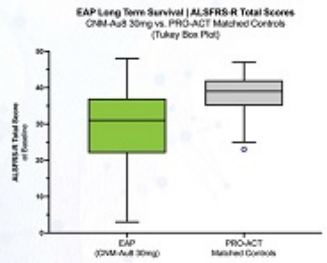
Baseline covariates include: (i) onset age, (ii) sex, (iii) BMI, (iv) pre-treatment ALSFRS-R slope, (v) ALSFRs-R, (vi) vital capacity (% predicted), (vii) vital capacity pre-treatment slope, and (viii) TRICALS risk score. Propensity matching caliper minimized at 0.41. All EAP participants alive are right censored as of the January 18, 2024 data cut.

Data on File, Clene Nanomedicine, Inc.

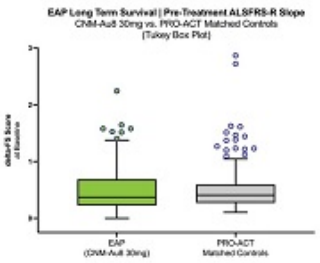
EAP Participants vs. Propensity Matched Controls

PRO-ACT

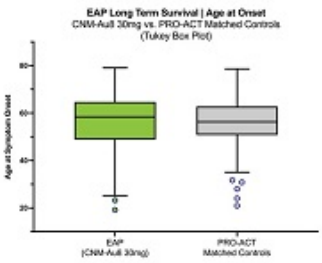
ALSFRS-R Score



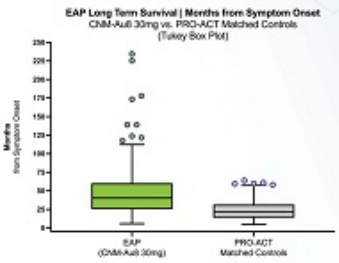
Delta-FS



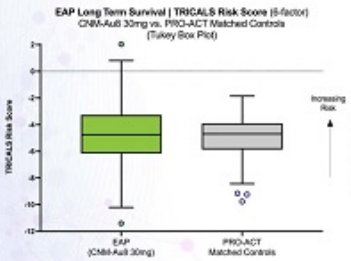
Onset Age



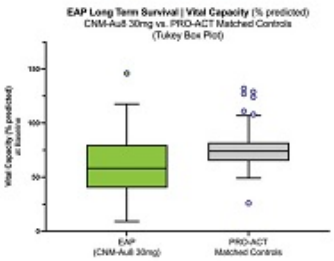
Months Post-Onset



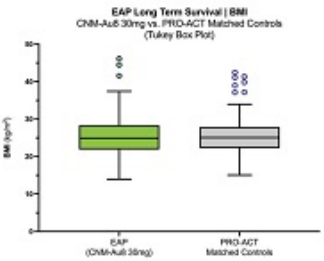
TRICALS Risk Score



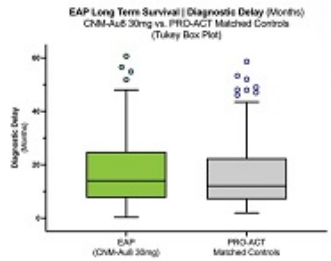
Vital Capacity (%)



BMI



Diagnostic Delay



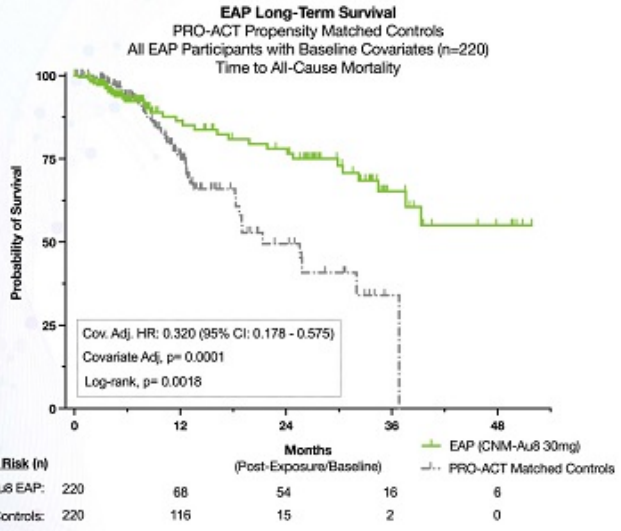
Matching covariates were balanced except for ALSFRS-R and vital capacity, which favored matched controls). Months post-symptom onset was longer in EAP participants.

Data on File, Clene Nanomedicine, Inc.

EAP Survival vs. PRO-ACT Matched Controls

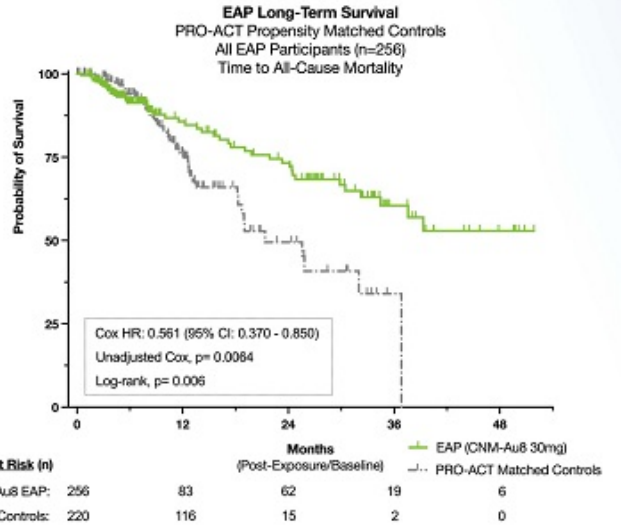
Control-Matched EAP and All EAP

PRO-ACT | EAP Matched (n=220)



At Risk (n)					
CNM-Au8 EAP:	220	68	54	16	6
Controls:	220	116	15	2	0

PRO-ACT | All EAP (n=256)



At Risk (n)					
CNM-Au8 EAP:	256	83	62	19	6
Controls:	220	116	15	2	0

Baseline covariates include: (i) onset age, (ii) sex, (iii) BMI, (iv) pre-treatment ALSFRS-R slope, (v) ALSFRs-R, (vi) vital capacity (% predicted), (vii) vital capacity pre-treatment slope, and (viii) TRICALS risk score. Propensity matching caliper minimized at 0.43. All EAP participants alive are right censored as of the January 18, 2024 data cut.

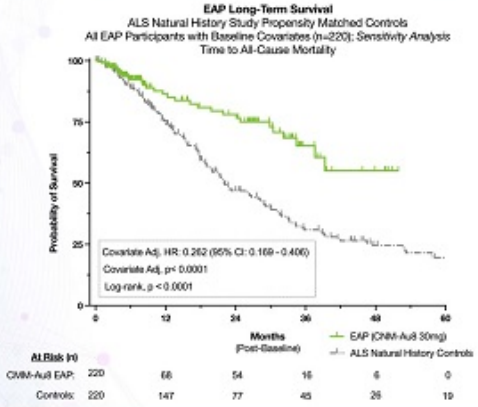
Data on File, Clene Nanomedicine, Inc.

Survival | Sensitivity Analyses

Including Observation Time as an Additional Covariate for Propensity Score Matching

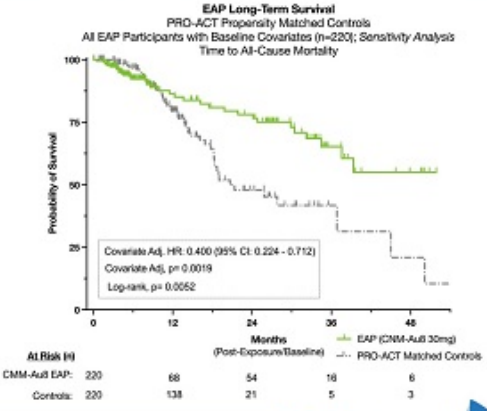
ALS Natural History Study | EAP Matched

ALS Nat. Hist. Scenario	Hazard Ratio	95% CI	p-value
Primary covariate model	0.433	0.282 – 0.663	p= 0.0001
+ Observation time for propensity matching	0.262	0.169 – 0.406	p< 0.0001



PRO-ACT | EAP Matched

PRO-ACT Scenario	Hazard Ratio	95% CI	p-value
Primary covariate model	0.320	0.178 – 0.575	p= 0.0001
+ Observation time for propensity matching	0.400	0.224 – 0.712	p= 0.0019



Data on File, Clene Nanomedicine, Inc.

Conclusions

- Clene's Expanded Access programs represent the longest continuous intermediate sized compassionate use program in ALS with over 256 participants treated
  - CNM-Au8 EAP longitudinal treatment duration exceeds 4 years of daily therapy
- A significant survival benefit was observed from long-term CNM-Au8 treatment in people living with later-stage ALS compared to two independently collected control groups
- Open-label long-term data from EAPs can provide evidence of efficacy and safety in broader ALS populations than traditionally enrolled in clinical studies
- Limitations: these are uncontrolled data (i.e., studies without randomization) that may not appropriately account for unknown covariates influencing ALS disease progression (e.g., standard of care may be different between EAP sites and those not participating in EAPs)

Data on File, Clene Nanomedicine, Inc.

Clene Inc.

HQ & Clinical Development
6550 South Millrock Drive, Suite G50
Salt Lake City, UT 84121

R&D and Manufacturing
500 Principio Parkway, Suite 400
North East, MD 21901

Exhibit 99.2

CLENE REPORTS SIGNIFICANT SURVIVAL BENEFIT WITH CNM-Au8® TREATMENT IN ALS EAP COMPASSIONATE USE PROGRAMS

- Two "Compassionate Use" Expanded Access Programs (EAPs) provided access to treatment with CNM-Au8 to more than 250 people living with amyotrophic lateral sclerosis (ALS).
- A significant survival benefit (p=0.0001) was observed in EAP participants treated with CNM-Au8 compared to historical ALS disease progression controls (participants untreated with CNM-Au8) in two independent analyses: a 68% decreased risk of all-cause mortality compared to PRO-ACT matched controls, and a 57% decreased risk of all-cause mortality compared to ALS Natural History Consortium matched controls.
- CNM-Au8 30 mg treatment was well-tolerated, without a single serious adverse event attributed to CNM-Au8, and no significant safety findings reported.

SALT LAKE CITY, Feb. 22, 2024 – Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including ALS and multiple sclerosis (MS), today reported new, significant survival results from two independent analyses of the pooled data from the intermediate-size EAPs supported by Clene. People living with ALS who were generally too advanced in their disease to qualify for clinical trials received daily oral CNM-Au8® 30 mg for up to four years to date.

A pooled survival analysis of EAP participants treated with CNM-Au8 30 mg was compared to two independent datasets derived from PRO-ACT and the ALS/MND Natural History Consortium. The EAP dataset was comprised of 256 participants with ALS of which 220 EAP participants had all baseline values available for matching. These participants were matched for similar baseline characteristics compared to each non-CNM-Au8 treated control.

The results in the EAP participants versus the matched controls demonstrated a significant survival benefit for each comparison:

- The PRO-ACT dataset is the largest publicly available repository of longitudinal ALS clinical trial data, containing more than 12,000 records of trial participants:
  - **CNM-Au8 EAP vs. PRO-ACT matched controls: The baseline risk-adjusted hazard ratio demonstrated a 68% decreased risk of all-cause mortality with CNM-Au8 treatment (HR: 0.320, 95% CI: 0.178 – 0.575, p = 0.0001).**
- The ALS/MND Natural History Consortium data set contained approximately 1,700 records of people living with ALS from researchers across nine academic sites collecting recent real-world data:
  - **CNM-Au8 EAP vs. ALS/MND Natural History Consortium matched controls: The baseline risk-adjusted hazard ratio demonstrated a 57% decreased risk of all-cause mortality with CNM-Au8 treatment (HR: 0.433, 95% CI: 0.282 – 0.663, p = 0.0001).**

Analyses including all 256 EAP participants compared to the 220 matched controls also showed statistically significant survival benefits with log-rank p-values of $p < 0.0001$ and $p=0.006$ for the PRO-ACT and ALS/MND Natural History Consortium matched controls, respectively.

"The long-term safety and survival data from the CNM-Au8 expanded access programs add to the available data supporting CNM-Au8 moving rapidly to Phase 3 testing in ALS," said Merit Cudkowicz, MD, MSc, an internationally renowned clinician in the treatment of ALS and Chair of Neurology, Director of the Sean M. Healey and AMG Center for ALS at Mass General Hospital and the Julieanne Dorn Professor of Neurology at Harvard Medical School. "This is one of a few therapies with positive Phase 2 data that must go forward to Phase 3 trials."

"These EAP results help us better understand how people living with more advanced disease respond to treatment," said Richard S. Bedlack Jr., MD, PhD, MS Stewart, Hughes and Wendt Distinguished Professor, Neurology, Neuromuscular Disease at Duke University School of Medicine, and a member of the EAP02 steering committee. "Collecting data of peoples' experience beyond clinical trials is extremely important in rare diseases like ALS. These data warrant consideration to be included in Clene's discussions about CNM-Au8 with regulatory agencies."

An EAP is an FDA-regulated pathway that allows patients with a serious or immediately life-threatening condition to gain access to an investigational drug outside of clinical trials when no comparable or satisfactory alternative therapy is available.

The Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital and Clene supported the first EAP (EAP01) launched in 2019. EAP01 was initiated by Dr. Cudkowicz as the principal investigator. EAP01 is a single-site, intermediate sized EAP that allows individuals with ALS who are otherwise unable to qualify for CNM-Au8 in clinical trials access to CNM-Au8. This is currently the longest running intermediate-sized EAP in ALS.

The second EAP (EAP02) was started in 2021 for people living with ALS who did not qualify for participation in the concurrent HEALEY ALS Platform Trial, which is a perpetual multi-center, randomized, double-blind, placebo-controlled clinical trial program designed to evaluate the efficacy and safety of multiple investigational products in people living with ALS. EAP02 is sponsored by Clene and is presently available at 16 clinical sites across the U.S. associated with the Northeast ALS Consortium (NEALS).

Clene was also part of a consortium that was recently awarded a four-year grant totaling $45.1 million from the National Institute of Neurological Disorders and Stroke (NINDS), a division of the National Institutes of Health (NIH), to conduct a third EAP in ALS. Consortium partners include Synapticure and Columbia University. This EAP is expected to commence enrollment in the first half of 2024.

As previously announced, treatment with CNM-Au8 produced consistent survival and delayed time to ALS clinical worsening data in two independent Phase 2, randomized, placebo-controlled, double-blind ALS trials and their open-label extensions. The Phase 2 HEALEY ALS Platform Trial in the U.S. and the RESCUE-ALS Trial in Australia studied 285 participants with ALS at specialty clinics. CNM-Au8 was well-tolerated in all its clinical studies. No serious adverse events have been associated with CNM-Au8 treatment in any Phase 1 or Phase 2 study conducted, including all those involving ALS participants.

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 our or our management team's expectations, hopes, beliefs, intentions or strategies regarding our future operations. 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 our ability to demonstrate the efficacy and safety 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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