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): July 21, 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** **(Address of Principal Executive Offices)**	**84121** **(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:

☐ 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.

On July 21, 2022, Clene Inc. (the "Company") released an updated corporate presentation (the "Corporate Presentation") on its website, invest.clene.com. A copy of the Corporate Presentation is furnished as Exhibit 99.1 to this Current Report and is incorporated herein by reference. The Company plans to use its website to disseminate future updates to the Corporate Presentation and may not file or furnish a Current Report on Form 8-K alerting investors if the Corporate Presentation is updated.

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	Corporate Presentation
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: July 21, 2022

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

Exhibit 99.1


Corporate Presentation
July 2022
clene.com
clene
NASDAQ: CLNN

Forward Looking Statements

This presentation 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 presentation 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 substantial dependence on the successful commercialization of our drug candidates, if approved, in the future; our inability to maintain the listing of our common stock on Nasdaq; our significant net losses and net operating cash outflows; 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 ability to obtain and maintain protection of intellectual property for our technology and drugs; our reliance on third parties to conduct drug development, manufacturing and other services; our limited operating history and our ability to obtain additional funding for operations and to complete the licensing or development and commercialization of our drug candidates; the impact of the COVID-19 pandemic on our clinical development, commercial and other operations; changes in applicable laws or regulations; the effects of inflation; the effects of staffing and materials shortages; the possibility that we may be adversely affected by other economic, business, and/or competitive factors; 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 presentation, 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 presentation is as of the date of this presentation. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this presentation.

CLENE | Entering a Transformative Period

Significant Opportunity

- Targeting neurodegenerative diseases such as ALS and Multiple Sclerosis
- >$1B commercial opportunity in each indication

CNM-Au8® Emerging Clinical Results

- Long-term follow-up of RESCUE-ALS Phase 2 participants demonstrated statistically significant survival benefit; 70% decreased risk of death
- VISIONARY-MS Phase 2 blinded data suggests encouraging efficacy and consistent safety; Unblinded top-line results expected in 3Q 2022
- HEALEY ALS Platform Trial Phase 2/3 top-line results expected in 3Q 2022

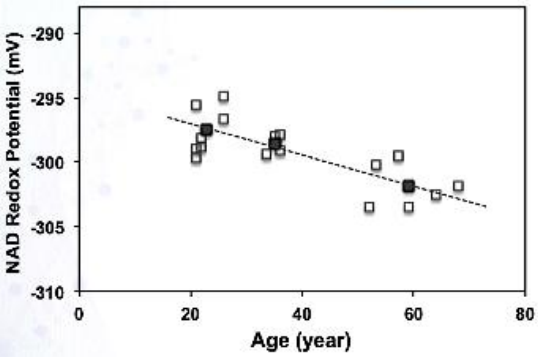
Proprietary Platform

Strong IP

- Proprietary nanotherapeutic manufacturing, scalable to commercialization
- Strong IP, including 150+ granted patents and manufacturing trade secrets

Neurodegenerative Diseases Share A Common Mechanism: A Decline In The Brain's Ability To Produce Energy

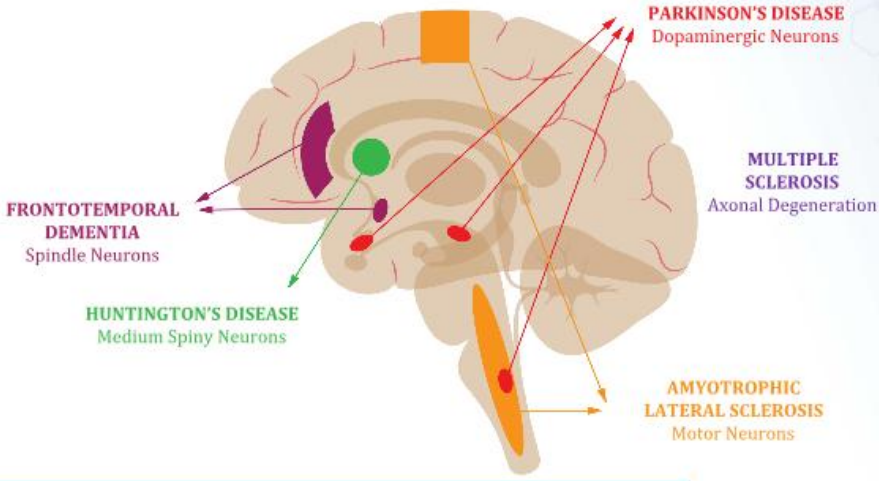
Brain Energy Potential Declines With Normal Aging



~0.5% NAD^+/NADH unit decline per decade
(~0.13 mV units per year by ^{31}P-MRS Imaging)

Closed squares = averaged data by age group: 21–26 yrs, 33–36 yrs, and 59–68 yrs old; Open squares = individual subject values

Specific Neuronal Populations Are Vulnerable to Energetic Failure



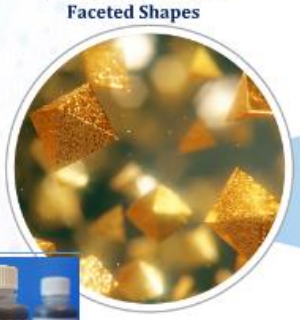
Although energy decline occurs as a part of normal aging, it is amplified and exacerbated by neurodegenerative diseases such as ALS and MS

Fu, H., et al; Nature Neuroscience (2018) 21: 1350-1358, Zhu et al. Proc Natl Acad Sci USA 2015 Mar 3;112(9):2876-81. Rone et al. J Neurosci. 2016 Apr 27;36(17):4698-707.

CNM-Au8® | Pioneering A New Drug Class To Improve Cellular Energy Production And Utilization

CNM-Au8 Nanocrystals

Clean Surfaced, Highly Faceted Shapes



CNM-Au8 Nanocrystal Suspension

+

Mechanistic Effects

- ↑ Increased NAD
- ↑ Increased ATP
- ↓ Decreased reactive oxygen species
- ↑ Increased proteostasis

=

Improved Energy Production and Utilization

By targeting energy metabolism, CNM-Au8 may protect and restore neuronal function.

For more information, watch CNM-Au8 MOA Video

MOA = Mechanism of Action

Robinson et al. Sci Rep. 2020 Feb 11;10(1):1936. Data on File, Clene Nanomedicine, Inc.

Preclinical Evidence of Remyelination and Neuroprotection

Remyelination

CNM-Au8 Supports Remyelination

www.nature.com/scientificreports

SCIENTIFIC REPORTS
nature research

OPEN

Nanocatalytic activity of clean-surfaced, faceted nanocrystalline gold enhances remyelination in animal models of multiple sclerosis

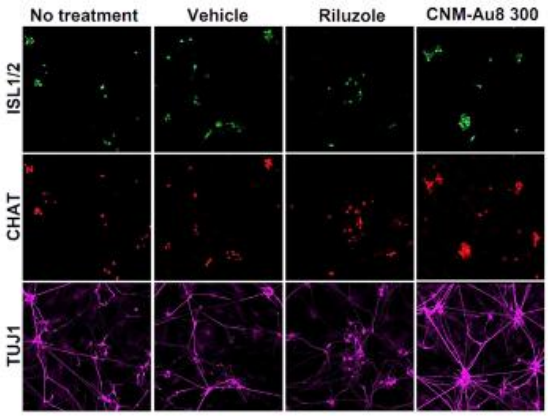
Andrew P. Robinson[1,2], Joanne Zhongyan Zhang[1,2], Haley E. Titus[1], Molly Karl[1], Mikhail Merzliakov[1], Adam R. Dorfman[1], Stephen Karlik[3], Michael G. Stewart[1], Richard K. Watt[1], Benjn D. Facer[1], Jan D. Facer[1], Noah D. Christon[1], Karen S. Ho[1,2], Michael T. Hotchkin[1,2], Mark G. Mortenson[1,2], Robert H. Miller[1,4] & Stephen D. Miller[1,4]

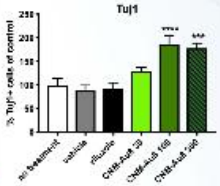
Robinson et al. Sci Rep. 2020 Feb 11;10(1):1936.

Neuroprotection

CNM-Au8 Improves ALS Motor Neuron Function & Survival

Induced Pluripotent Stem Cell *In Vitro* Results – Motor Neuron Markers





Karen S. Ho et al. "Redox-enhancing nanocatalysis improves motor neuron survival in vitro and SOD1 mouse motor function and survival in vivo." Presented at 30th International Symposium on ALS/MND 2019. December 4-6, 2019.

CNM-Au8 novel MOA may be complementary to existing therapies to enable better disease control

CLene NANOMEDICINE

Significant Global Opportunity for Treatment in Combination with Standard of Care

Motor Neuron Disease (ALS, Other Orphan Disorders)

ALS PATIENTS IN US & EU ~40K[1]

$1B GLOBAL SALES BY 2028[1]

Current drugs are largely ineffective, mostly generic.

2-5 YEARS[2] LIFE EXPECTANCY

100% FATAL

Multiple Sclerosis (MS)

MS PATIENTS GLOBALLY 2.2M

$23B MARKET[3]

Existing treatments only target immunomodulation

EMERGING EVIDENCE THAT EARLY MS IS NEURODEGENERATIVE

Parkinsons Disease (PD)

2ND MOST COMMON DISORDER

$6B PROJECTED BY 2026[4]

No disease-modifying treatments available, only symptom-targeted options

30% OF DOPAMINERGIC NEURONS ARE LOST AT DIAGNOSIS[5]

Urgent unmet need to develop neuroprotective treatment to support cells' energetic efficiency and resilience

1 Clarivate, DRG, ALS 2020 2. https://pubmed.ncbi.nlm.nih.gov/17974351/ 3. Westad et al. 2017, doi:10.1038/nrd.2017.107;-4. Parkinson's Market Data Forecast, April 2021.- 5. Cheng HC, Ulane CM, Burke RE. Clinical progression in Parkinson disease and the neurobiology of axons. Ann Neurol 2010;67:715-725.

Building the Case for Neuroprotection & Remyelination

RepairPD
RepairMS

RESCUEALS
HEALEY ALS Platform Trial

VISIONARY-MS

Established brain target engagement in early PD and stable relapsing MS patients

RESCUE-ALS trial supports CNM-Au8 slowed disease progression in ALS

Demonstrated statistically significant survival benefit; 70% decreased risk of death

Interim blinded observations: Stable relapsing MS participants suggests improved function (modified MSFC) including low contrast vision

REPAIR-MS Phase 2 in non-active progressive MS underway

HEALEY ALS Platform Trial topline results expected 3Q 2022

VISIONARY-MS topline results expected 3Q 2022

Growing Body of Evidence from Multiple Trials Supports CNM-Au8 Clinical Potential

CLene NANOMEDICINE

Over 350 Years of Subject Exposure Without Identified Safety Signals Across MS, ALS & PD

Clean Toxicology Findings

All Animal Toxicology Studies Resulted in No-Adverse Effect Level (NOAEL) Findings

- Multiple species up to 9-months treatment
- Up to maximum feasible dosing without any toxicology findings related to CNM-Au8

Well Tolerated Adverse Event (AE) Profile

Assessed as Predominantly Mild-to-Moderate Severity and Transient

- No SAEs related to CNM-Au8 considered severe, life-threatening, or resulting in death
- AEs predominantly mild-to-moderate

Patient Exposure Across MS, ALS & PD

Over 350 Years of Subject Exposure Without Identified Safety Signals

- Long-term dosing experience up to 125 weeks

Data on File, Clene Nanomedicine, Inc. MS: Multiple Sclerosis, ALS: Amyotrophic lateral sclerosis, and PD: Parkinson's Disease.

Two REPAIR Trials Demonstrated Target Brain Engagement and Improved Energy Metabolism in Early Parkinson's and Stable Relapsing MS

Study Objective: to demonstrate target engagement for CNM-Au8 on CNS biomarkers related to energetic effects in the brain using Magnetic Resonance Spectroscopy (^{31}P-MRS)

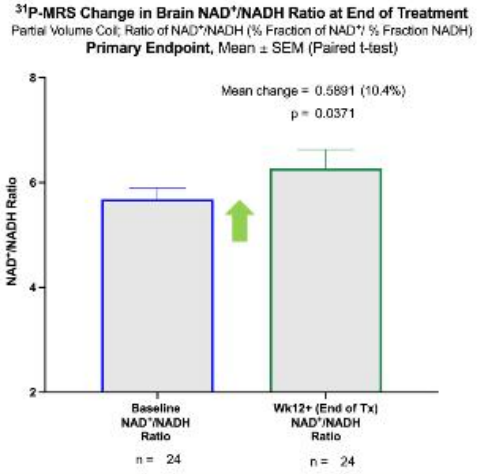
RepairPD
Early Parkinson's Disease

RepairMS
Stable Relapsing MS

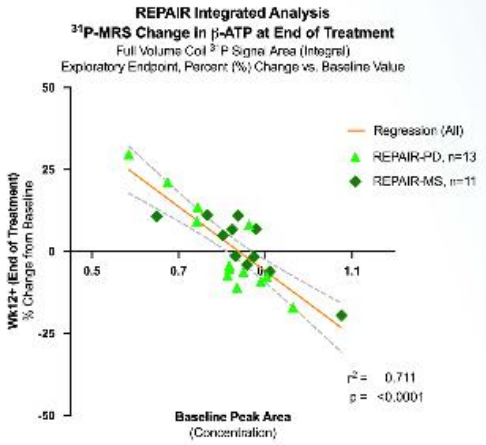
RepairMS
Non-Active Progressive MS
(Ongoing)

Results demonstrated a potentially meaningful 10% improvement in NAD+/NADH ratio, an essential molecule for energy production[1]

1° Endpoint (integrated PD & MS)[2]



Exploratory
(ATP Normalization)



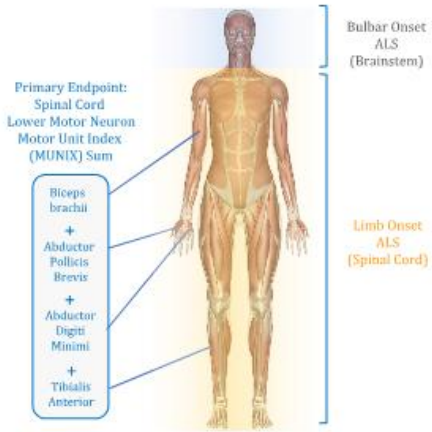
1. Zhu et al. Proc Natl Acad Sci USA 2015 Mar 3;112(9):2876-81. 2. Glanzman et al Improvement of Brain Energy Metabolism in Relapsing Multiple Sclerosis Patients – Results from Phase 2 REPAIR-MS Clinical Trial With CNM-Au8, ACTRIMS February 2022

CLene NANOMEDICINE

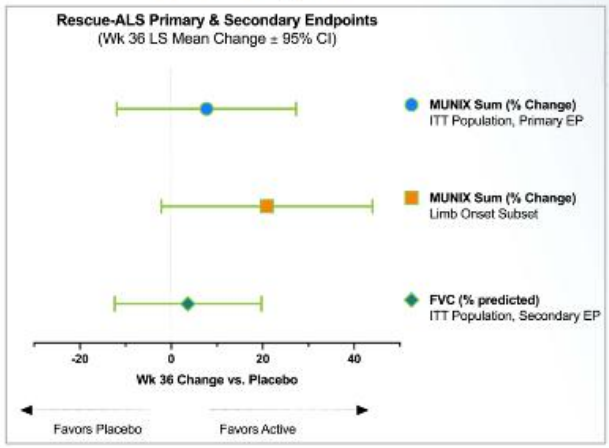
RESCUEALS Encouraging Efficacy Signals in Phase 2 Trial

Study Objective: Detect preservation of motor neuron function in people with early ALS as measured by MUNIX

Study Design:
36-week blinded treatment with ongoing long-term open-label follow-up



1° & 2° Endpoints



Results in favor of CNM-Au8 treatment but study underpowered

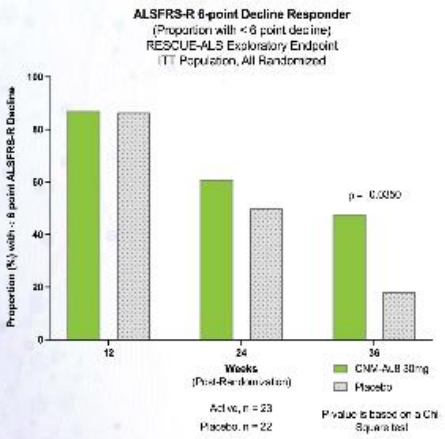
Vucic et al. RESCUE-ALS Trial Results: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of CNM-Au8 to Slow Disease Progression in Amyotrophic Lateral Sclerosis; Presented at International Symposium on ALS/MND; 7-10 December 2021

CLene NANOMEDICINE

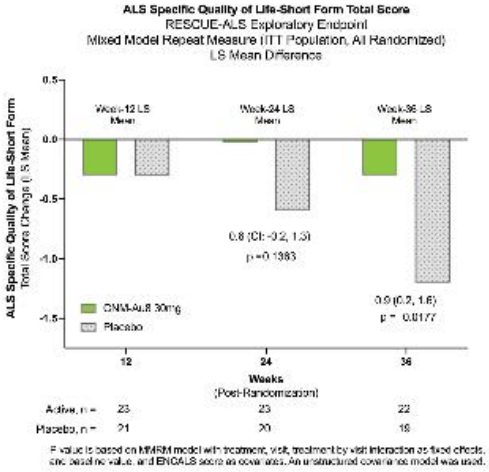
CNM-Au8 Improved Patient Function and QOL, and Slowed ALS Disease Progression

Across Multiple Pre-specified Exploratory Endpoints

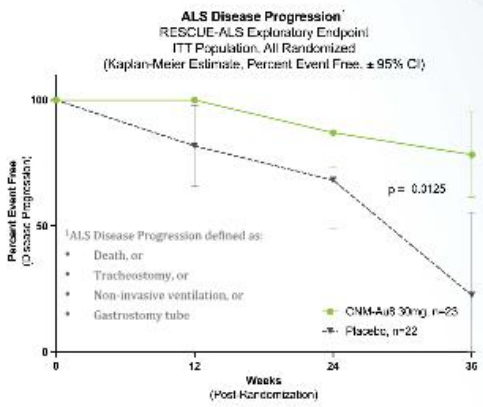
Proportion with <6 point decline



ALS Specific QOL



ALS Disease Progression



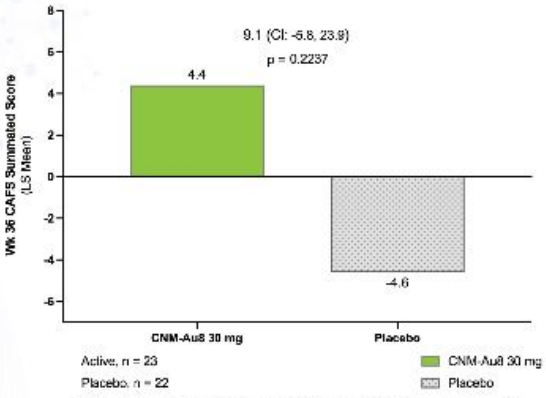
Vucic et al. RESCUE-ALS Trial Results: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of CNM-Au8 to Slow Disease Progression in Amyotrophic Lateral Sclerosis; Presented at International Symposium on ALS/MND; 7-10 December 2021

RESCUEALS CAFS Results: Slowed Disease Progression

Exploratory Endpoint Pre-specified

CAFS

CAFS Joint Rank: (i) Survival and (ii) ALSFRS-R Change
RESCUE-ALS Exploratory Endpoint
ANCOVA Model (ITT Population, All Randomized)
Week 36 LS Mean Difference



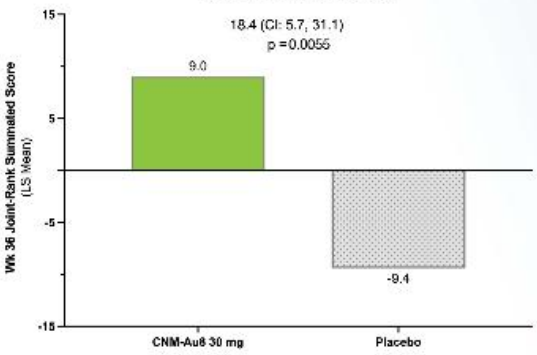
Active, n = 23
Placebo, n = 22
CNM-Au8 30 mg
Placebo

P-value is based on ANCOVA model with baseline ENCALS score as a covariate. Change in ALSFRS-R total score and date of death were combined to determine the CAFS score.

Exploratory Endpoint Post Hoc

Modified CAFS

Joint-Rank of (i) Survival, (ii) King's Clinical Stage 4, and (iii) ALSFRS-R Change
RESCUE-ALS *Post Hoc* Endpoint
ANCOVA Model (ITT Population, All Randomized)
Week 36 LS Mean Difference



Active, n = 23
Placebo, n = 22
CNM-Au8 30 mg
Placebo

P-value is based on ANCOVA model with baseline ENCALS score as a covariate. Change in ALSFRS-R total score, date of non-invasive ventilation or gastrostomy, and date of death were combined to determine the joint-rank score.

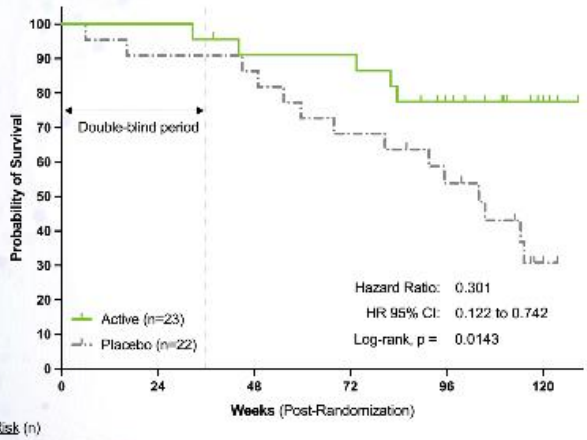
Data on File, Clene Nanomedicine, Inc.

RESCUE-ALS Demonstrated Significant Impact on Long-Term Survival with 70% Decreased Risk of Death

RESCUE-ALS Active vs. Placebo Randomization

Long-Term Observed Survival (Interim Analysis)

Long-Term Survival: Originally Randomized Active vs. Placebo
Interim Analysis (5-July-2022), ITT Population, All Subjects from Randomization
(Long-term vital status including all study withdrawals)



At Risk (n)

CNM-Au8:	23	23	20	20	14	6
Placebo:	22	20	19	15	11	2

Early CNM-Au8 treatment demonstrated a significant survival benefit:

- Long-term follow-up compared to initial placebo randomization*
- 70% decreased risk of death

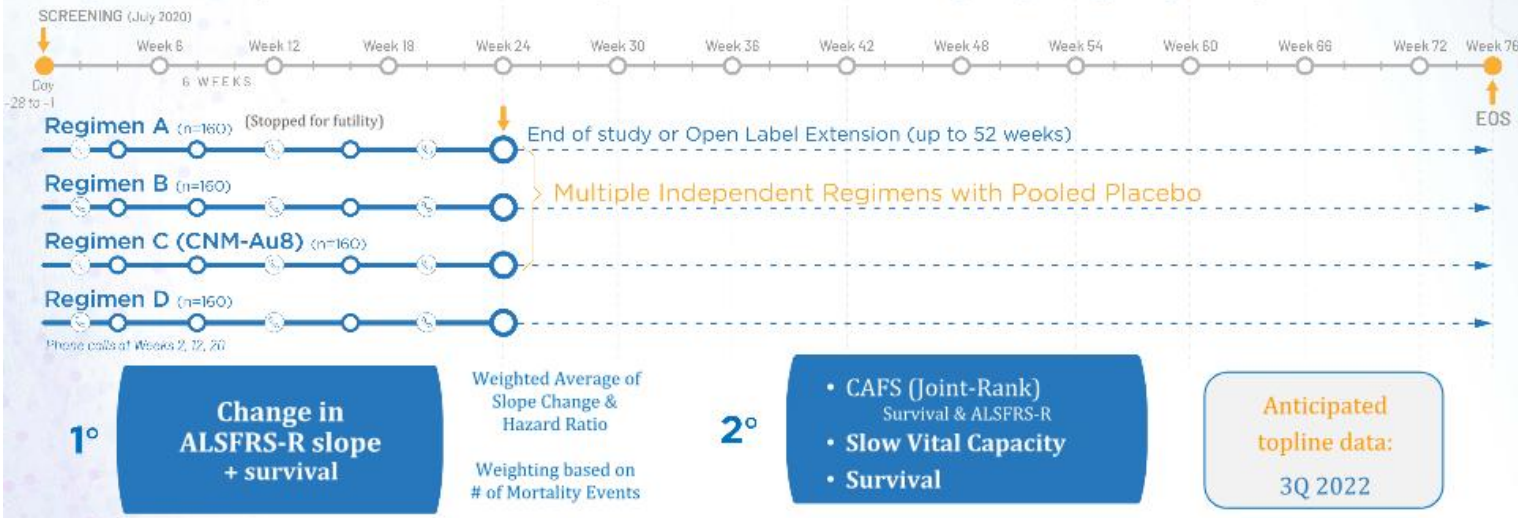
*9-month delayed treatment start or no treatment

Data on File, Clene Nanomedicine, Inc.

Phase 2/3
HEALEY ALS Platform Trial

A Multi-center, Randomized Double-Blind, Placebo-Controlled Clinical Trial Assessing the Efficacy, Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of CNM-Au8 in Participants with Amyotrophic Lateral Sclerosis

Registration Study: 24-Week Treatment Period(3:1 randomization, 120 active [30mg, 60mg]: 40 placebo)



1° **Change in ALSFRS-R slope + survival**

Weighted Average of Slope Change & Hazard Ratio

Weighting based on # of Mortality Events

2°

- CAFS (Joint-Rank) Survival & ALSFRS-R
- **Slow Vital Capacity**
- **Survival**

Anticipated topline data: 3Q 2022

Paganoni et al. Adaptive Platform Trials to Transform Amyotrophic Lateral Sclerosis Therapy Development. Ann Neurol. 2022; 91:165-175.

CLene NANOMEDICINE

VISIONARY-MS STUDY

Treatment of Visual Pathway Deficits In Chronic Optic Neuropathy for Assessment of Remyelination in Non-Active Relapsing MS

Phase 2 Study: 48-Week Placebo-Control Treatment Period2:1 Randomization (Active [15mg, 30 mg]: Placebo)

(**n=73 of 150 planned,** Study ended prematurely due to pandemic-related enrollment challenges)

1° **Change in Low Contrast Letter Acuity (LCLA)**

2° **Change in modified MS Functional Composite [(m)MSFC]**

Anticipated topline data: 3Q 2022

https://clinicaltrials.gov/ct2/show/NCT03536559, Data on File, Clene Nanomedicne, Inc.

clene NANOMEDICINE

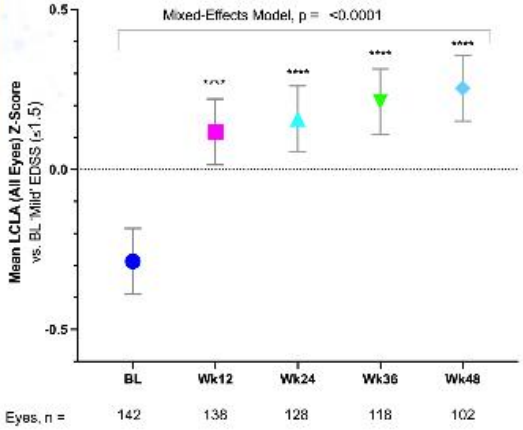
Phase 2 VISIONARY-MS STUDY

Significant Clinical Improvement Across Blinded Study Population

Primary Endpoint: LCLA (Best-Corrected) & Secondary Endpoint: (m)MSFC

1° | LCLA

LCLA (All Eyes) Average Z-Score
14-February-2022 Data Cut, Preliminary Blinded Data
(vs. 'Mild' EDSS [≤1.5]; Mean ± SEM)



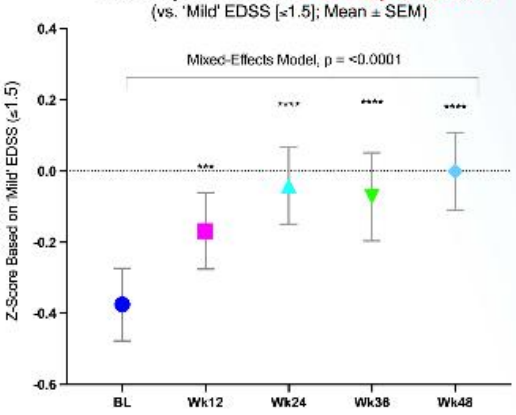
Eyes, n =	142	138	128	118	102

Z-Score Change Based on EDSS 'Mild' Severity (e.g., BL Low EDSS [≤1.5])
All Available Values (by Completed Subject Visit)

Mixed Effects Model, Dunnett's test for multiplicity:
* p<0.05, ** p<0.01, *** p<0.001, **** p<0.0001

2° | (m)MSFC

(m)MSFC 6-Component Average Z-Score
14-February-2022 Data Cut, Preliminary Blinded Data
(vs. 'Mild' EDSS [≤1.5]; Mean ± SEM)



n =	73	70	65	60	53

Z-Score Change Based on EDSS 'Mild' Severity (e.g., BL Low EDSS [≤1.5])
All Subjects with at least 4 of 6 (m)MSFC Domains by Completed Subject Visit.
(m)MSFC domains include LCLA (OD/OD), 9HPT (D/ND), T25FW, SDMT.

Mixed Effects Model, Dunnett's test for multiplicity:
^ p<0.05, ^^ p<0.01, ^^^ p<0.001, ^^^^ p<0.0001

Glanzman et al. VISIONARY-MS: Update to a Phase 2 Clinical Trial of CNM-Au8, Catalytically Active Gold Nanocrystals Suspension, for the Treatment of Chronic Optic Neuropathy ACTRIMS, February 2022.

CLENE NANOMEDICINE

Strong IP & Manufacturing Capability

Extensive Patent Portfolio With Protection Through 2035[a] & Proprietary Trade Secrets; Plus 7-year Orphan Drug Designation, and Scalable to Commercialization

Global Patent Status [b]

- Issued & Allowed Patents 150+
- Pending Applications ~20
- Total Patents/ Applications >170

Patent Description

- Process And Method/Device (Clean Surface; Gold CSN)
- State of Matter (CNM-Au8)
- Method of Use (Prevent Demyelination & MoA)
- Method of Use (Bi-Metallic Au/Pt; Antimicrobial)

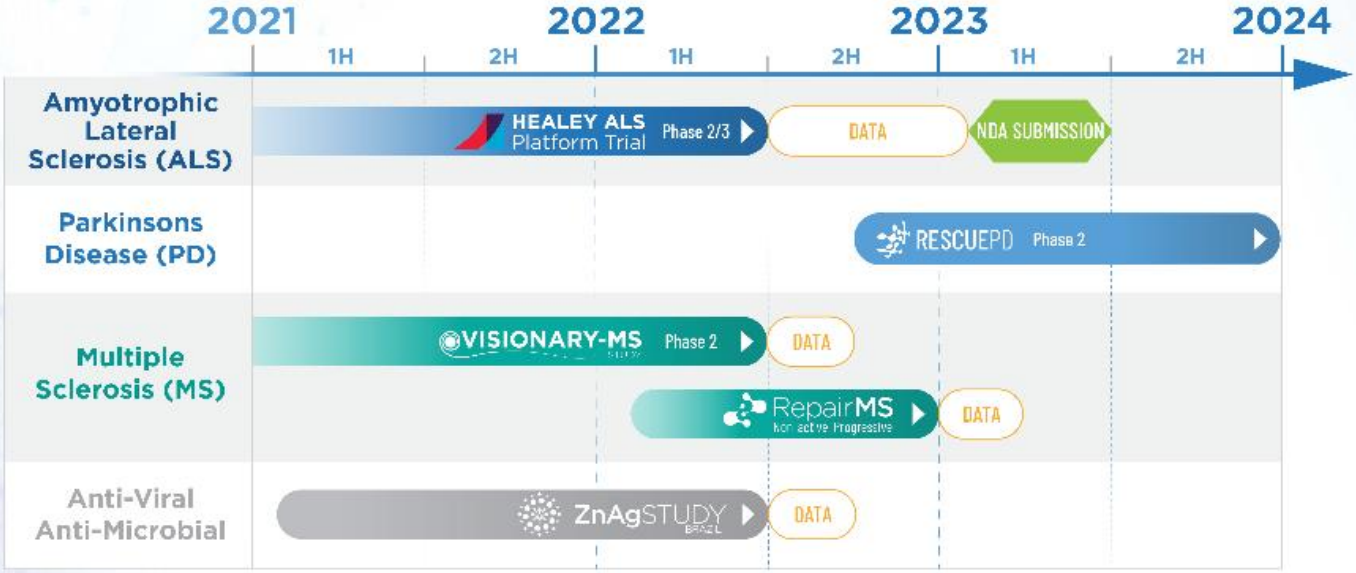
Trade Secrets

- Plasma Conditioning
- Electrode Design & Cycling
- Trough Flow, Temp, Pressure
- Concentration & Filtration

In-House ISO8 Clean Room Clinical Production in Maryland

[a] With Patent Restoration Term (assuming 5-year extension). [b] As of 31-December-2021.

Anticipated Timeline & Upcoming Milestones



Sufficient Cash to Hit Key Milestones in 2022

March 31, 2022
Cash and investments on hand (unaudited):
$36.6M

clene NANOMEDICINE

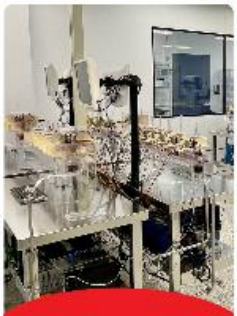
CLENE | Growing Phase 2 Evidence Supports CNM-Au8 Commercial Potential

CNM-Au8®
a gold nanocrystal suspension, in development as the first cellular energetic catalyst to remyelinate[1] & protect neurological function

ALS Registration Trial

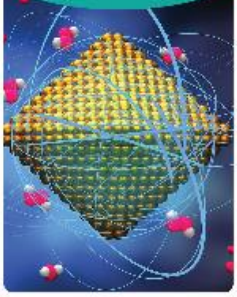
Topline data in 3Q 2022[2]

>350
patient years of CNM-Au8 clinical exposure



Manufacturing expansion in progress, preparing for possible commercialization in
2023

Strong IP:
150+
patents on Clean-Surface-Nanocrystal technology (CSN®) platform



March 31, 2022 Cash and restricted cash on hand (unaudited):
$36.6M

Data on File, Clene Nanomedicine, Inc. [1]Robinson et al. Sci Rep. 2020 Feb 11;10(1):1936 [2]https://clinicaltrials.gov/ct2/show/NCT04414345.

Clene NANOMEDICINE

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

Version: 21-July-2022