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 14, 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 14, 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 14, 2022

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

Exhibit 99.1

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 | Commitment and Experienced Leadership

COMMITTED TO **REVOLUTIONIZING** TREATMENT FOR PEOPLE WITH **NEURODEGENERATIVE DISEASES** TO RESTORE AND **PROTECT NEURONAL HEALTH**

BOARD CHAIR	CEO	CMO	CSO, FOUNDER	CDO	CFO	HR
						
David J. Matlin	Rob Etherington	Robert Glanzman	Mark Mortenson	Michael Hotchkin	Morgan Brown	Mary Anne McNeil

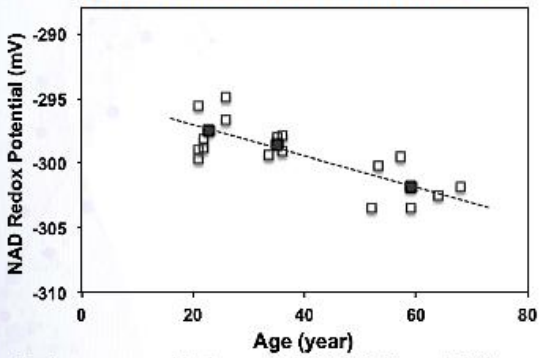
MatlinPatterson · Roche · ACTELION · Credit Suisse · NOVARTIS · Pfizer · PARKE-DAVIS · NPS Pharma

CLene NANOMEDICINE

Clene is Focused on Core Brain Energy Deficits in Neurodegenerative Diseases

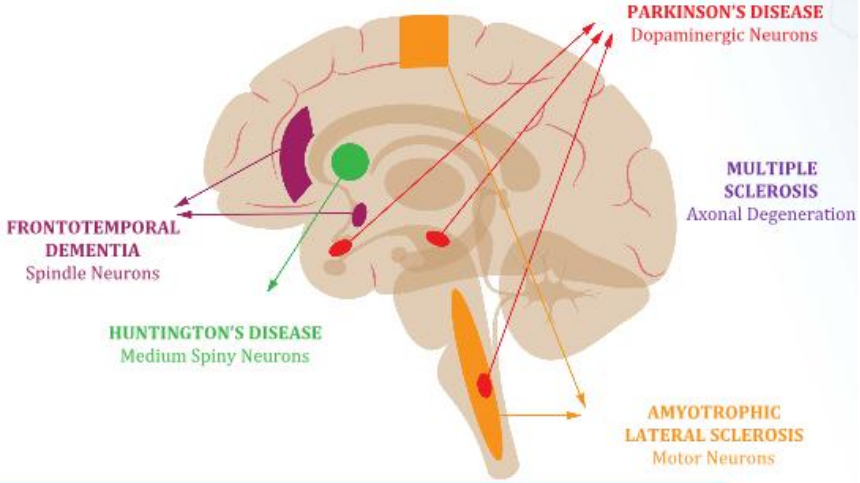
Brain Energy Potential Declines With Normal Aging

~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



Neurons with high energetic demand are at increased risk for neurodegenerative disease

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.

Significant Global Opportunity

Motor Neuron Disease (ALS, Other Orphan Disorders)

ALS PATIENTS IN US & EU ~40K

$1B GLOBAL SALES BY 2029[1]

Current drugs are largely ineffective, mostly generic.

3-5 YEARS LIFE EXPECTANCY

100% FATAL

Multiple Sclerosis

MS PATIENTS GLOBALLY 2.2M

$23B MARKET[2]

Existing treatments only target immunomodulation

EMERGING EVIDENCE THAT EARLY MS IS NEURODEGENERATIVE

Parkinsons Disease

2ND MOST COMMON DISORDER

$6B PROJECTED BY 2026[3]

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

30% OF DOPAMINERGIC NEURONS ARE LOST AT DIAGNOSIS[4]

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

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

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CNM-Au8® | Catalytically-Active Nanocrystals Improves Energy Production to Promote Neuroprotection and Remyelination

CNM-Au8 Nanocrystals

Clean Surfaced, Highly Faceted Shapes

CNM-Au8 Nanocrystal Suspension

Mechanistic Effects

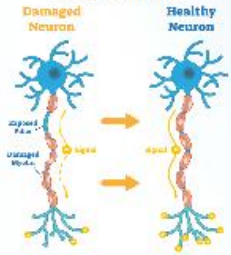
- ↑ Increased NAD
- ↑ Increased ATP
- ↓ Decreased reactive oxygen species
- ↑ Increased proteostasis

Improved Energy Production and Utilization

- ↑ Increased energetic potential
- ↑ Improved resistance to oxidative, mitochondrial, and excitotoxic stressors
- ↓ Reduction in levels of misfolded proteins

Promotes Neuroprotection and Remyelination

Remyelination



Neuroprotection

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

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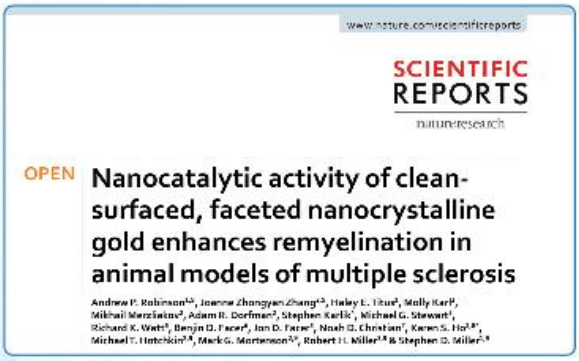
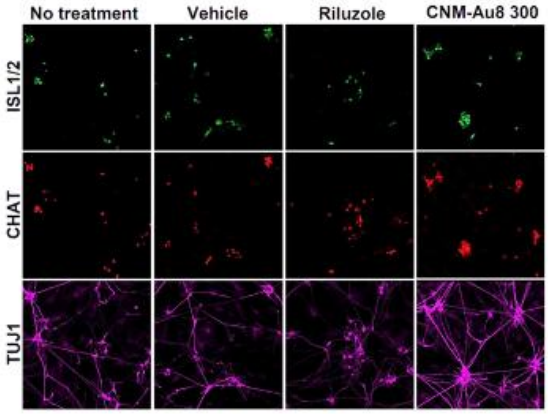
CNM-Au8® | Preclinical Evidence for Energetic Improvement

Supports Myelin Integrity & Remyelination



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

CNM-Au8 Improves ALS Motor Neuron Survival & Neuron Connections



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 enables neuroprotection and remyelination by helping nervous system cells increase their resilience to the energetic deficits driving disease progression in ALS

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CNM-Au8® | Neuroprotection & Remyelination

Growing Evidence Supports CNM-Au8 Clinical Potential

RepairPD
RepairMS

- Established brain target engagement in early Parkinson's Disease (PD) and stable relapsing Multiple Sclerosis (MS)
- Phase 2 REPAIR non-active progressive MS underway

RESCUEALS
HEALEY ALS Platform Trial

- CNM-Au8 treatment effect on ALS disease progression and potential impact on survival
- Phase 2/3 HEALEY-ALS Platform Trial Ongoing
- Expected readout 3Q 2022

VISIONARY-MS STUDY

- Interim blinded observations: Stable relapsing multiple sclerosis (MS) participants suggests improved function (modified MSFC) including low contrast vision
- Expected readout 3Q 2022

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CNM-Au8® | Safety Summary

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 PD, MS, & ALS

Over 350 Years of Subject Exposure Without Identified Safety Signals

- Long-term dosing experience up to 125 weeks

Data on File, Clene Nanomedicine, Inc.

CNM-Au8® | REPAIR Program Demonstrated Target Engagement and Improved Brain Energy Metabolism

RepairPD
Early Parkinson's Disease

RepairMS
Stable Relapsing MS

RepairMS
Non-Active Progressive MS
(Ongoing)

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)

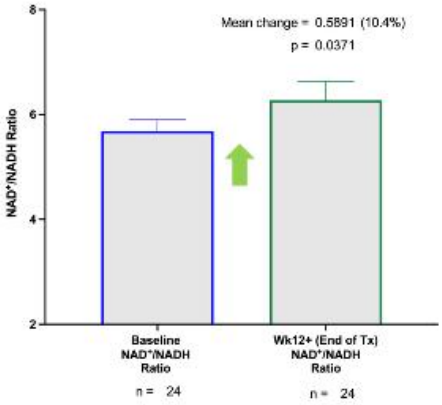
Brain Energy Potential Declines With Normal Aging

~0.5% NAD+/NADH unit decline per decade in healthy people
(by ^{31}P-MRS Imaging)[1]

Results demonstrated 10% improvement in NAD+/NADH ratio, which may translate to decades of improvement in cellular energy production and utilization

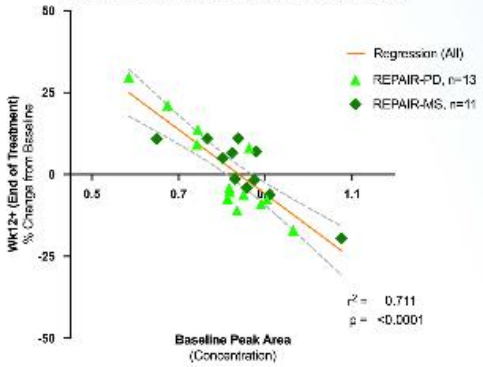
1° Endpoint (integrated PD & MS)[2]

^{31}P-MRS Change in Brain NAD$^+$/NADH Ratio at End of Treatment
Partial Volume Coil; Ratio of NAD$^+$/NADH (% Fraction of NAD$^+$/ % Fraction NADH)
Primary Endpoint, Mean ± SEM (Paired t-test)



Exploratory
(ATP Normalization)

REPAIR Integrated Analysis
^{31}P-MRS Change in β-ATP at End of Treatment
Full Volume Coil ^{31}P Signal Area (Integral)
Exploratory Endpoint, Percent (%) Change vs. Baseline Value



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

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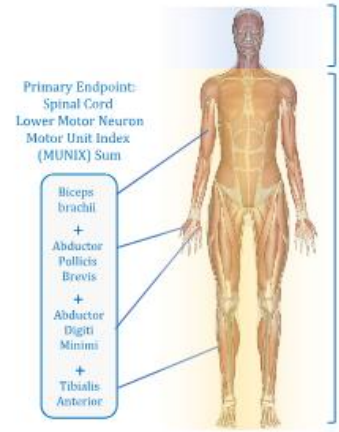
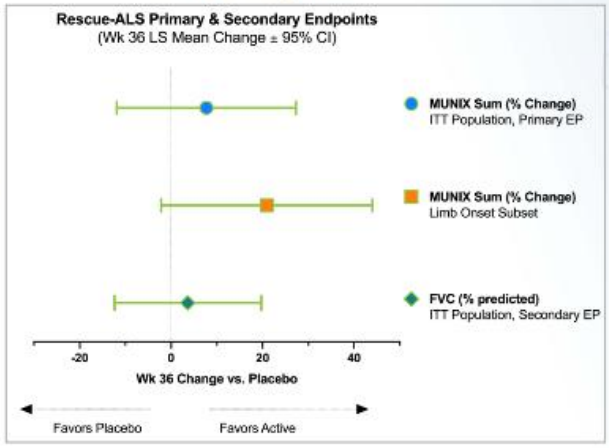
RESCUEALS CNM-Au8® | Evidence for Motor Neuron Protection

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



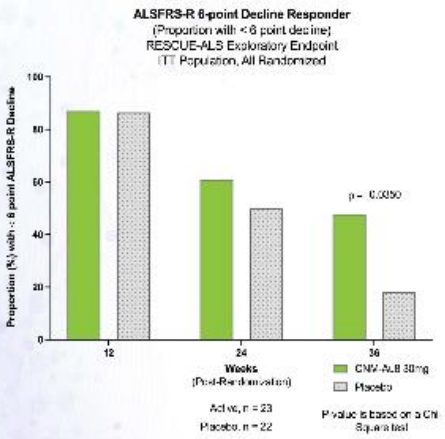
By targeting energy metabolism, CNM-Au8 may be able to protect motor neurons and restore ALS function

Results in favor of CNM-Au8 treatment but study underpowered

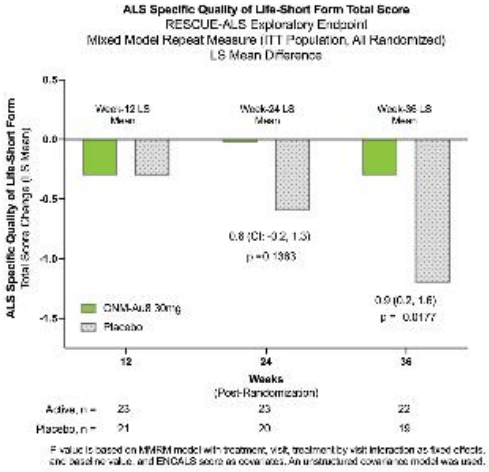
Vucic et al. BMJ Open. 2021 Jan 11;11(1):e041479. Data on File, Clene Nanomedicine, Inc.

RESCUEALS CNM-Au8® | Significant Impact on Key Functional ALS Measures (Exploratory Endpoint Pre-specified)

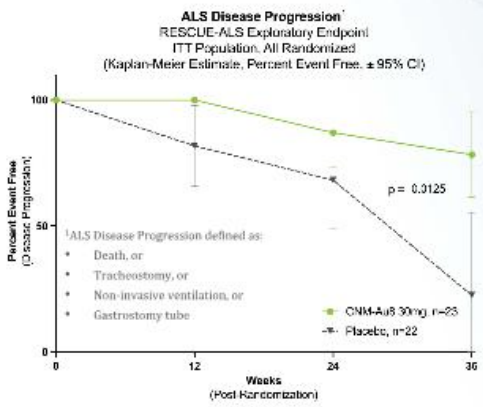
Proportion with <6 point decline



ALS Specific QOL



ALS Disease Progression



RESCUE-ALS: A Phase 2, randomized, double-blind, placebo-controlled study of CNM-Au8 to slow disease progression in ALS. MNDA Virtual Symposium, 2021.

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RESCUEALS CNM-Au8® | CAFS: Survival & ALSFRS-R

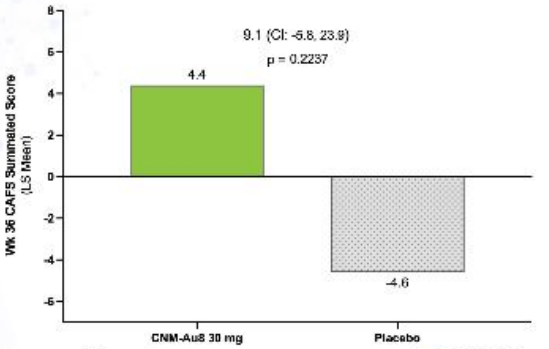
Exploratory Endpoint Pre-specified

CAFS

Survival

ALSFRS-R Decline

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

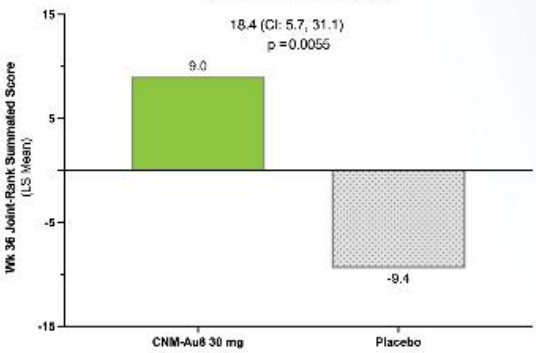
P-value is based on ANCOVA model with baseline ENCALS score as a covariate. Change in ALSFRS-R total score and date of death were combined to determine the CAFS score.

Exploratory Endpoint Post Hoc

Modified CAFS

King's Clinical Stage 4

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.

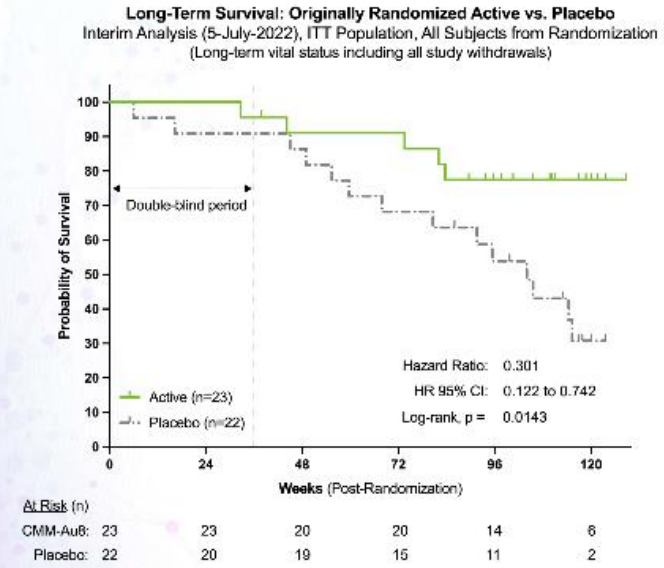
Berry et al. Amyotroph Lateral Scler Frontotemporal Degener. 2013 Apr;14(3):162-8. Data on File, Clene Nanomedicine, Inc.

CLene NANOMEDICINE

CNM-Au8® | 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)



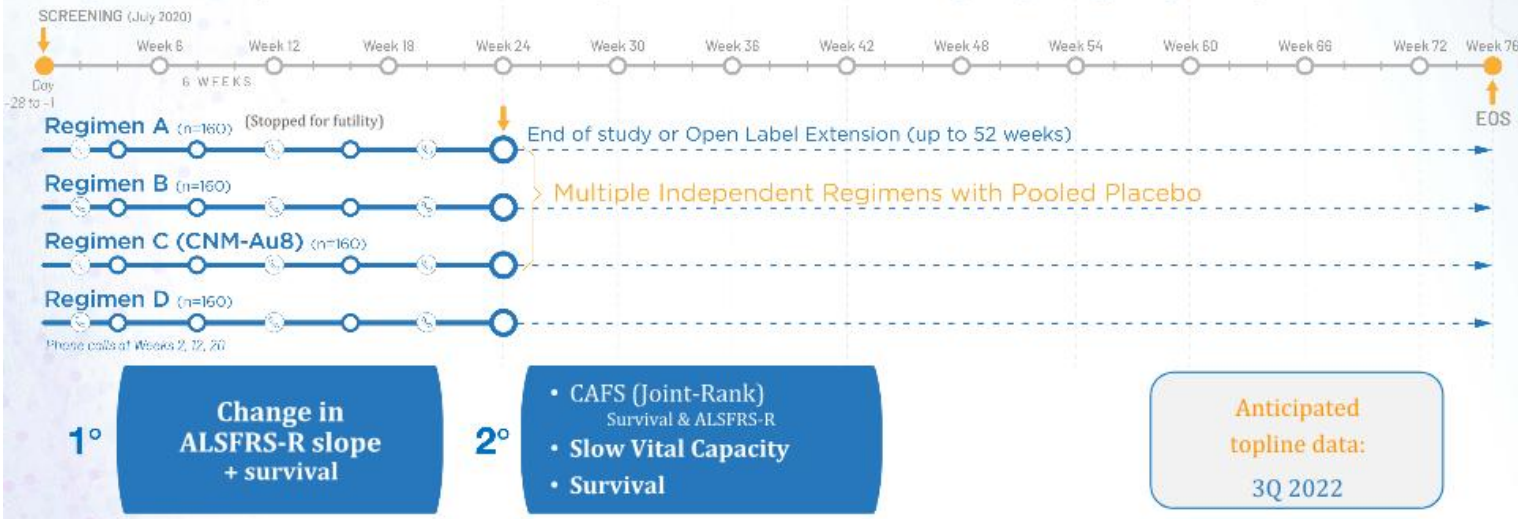
Early CNM-Au8 treatment demonstrated a significant survival benefit during long-term follow-up compared to initial placebo randomization (9-month delayed treatment start or no treatment), resulting in a 70% decreased risk of death.

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**

2°
- CAFS (Joint-Rank) Survival & ALSFRS-R
- **Slow Vital Capacity**
- **Survival**

Anticipated topline data: 3Q 2022

Paganoni et al. Ann Neurol. 2022 Feb;91(2):165-175. https://clinicaltrials.gov/ct2/show/NCT04414345.

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Phase 2/3
HEALEY ALS Platform Trial

Integrated Function & Survival
1° and Key 2° Endpoints

Primary Endpoint

Change in Slope of ALSFRS-R

+

Survival Improvement (Hazard Ratio)

Weighted Average of (1-slope change) and Hazard Ratio

(Weighting based on # of Mortality Events)

Key Secondary Endpoint
(Combined Assessment of Function & Survival)

Rank participants based on time to death or ALSFRS-R change

Individual Scoring

If...	Score
Better function or died later than comparison	+1
Same function or died at the same time as comparison	0
Worse function or died before comparison subject	-1

CAFS

Survival

ALSFRS-R Decline

Paganoni et al. Ann Neurol. 2022 Feb;91(2):165-175. Berry et al. Amyotroph Lateral Scler Frontotemporal Degener. 2013 Apr;14(3):162-8.

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Phase 2

VISIONARY-MS STUDY

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

24-Week Blinded Fixed Treatment Period

Up to 24-Week Blinded Extension Period (Until LPLV 24Wk Visit)

Up to 48-Week Placebo-Control

2:1 Randomization (Active: Placebo)

15mg, 30mg, Placebo **(n=73 of 150)**

1° **Change in Low Contrast Letter Acuity (LCLA)**
At Week 24

2° **Change Composite Clinical Response**
9HPT / SDMT / T25FW / LCLA

Exploratory Endpoints

- Optical Coherence Tomography (OCT)
- Multi-focal VEP Amplitude & Latency
- Full field-VEP Amplitude & Latency
- MRI Endpoints
- Visual Function (High Contrast)
- QOL / EDSS

Anticipated topline data:
3Q 2022
Insights to inform new Phase 2/3 MS trial

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

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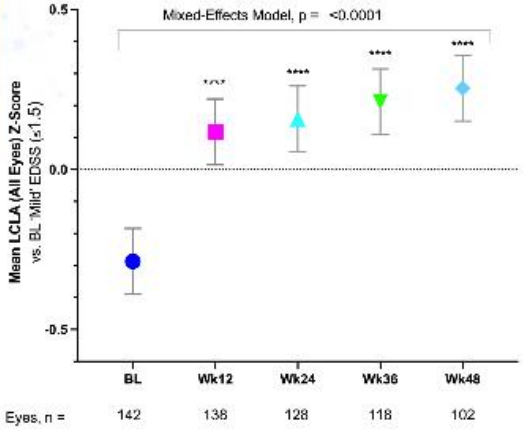
Phase 2 VISIONARY-MS STUDY

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)



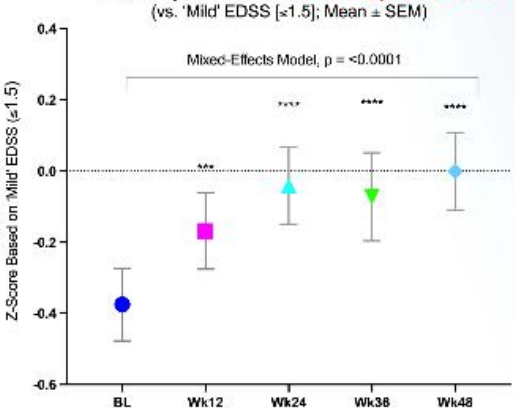
Eyes, n =	142	138	128	118	102

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.

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ZnAgSTUDY BRAZIL

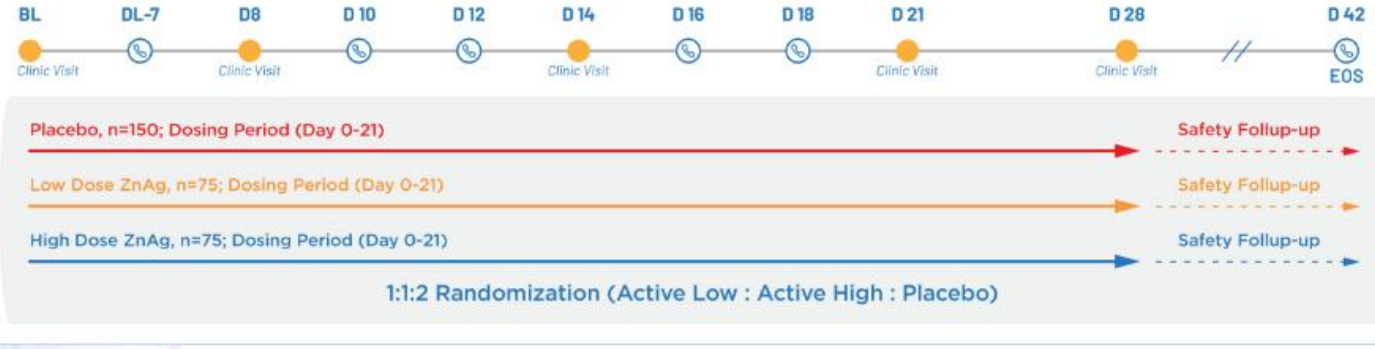
Patient Population: Predominantly in vaccinated, symptomatic patients

Primary Endpoint: Time to substantial alleviation[1] of COVID-19 symptoms through Day 28

Secondary Endpoint: Time to complete alleviation[2] of COVID-19 symptoms through Day 28

Exploratory Endpoints:
- Number of hospital free days through Day 28
- Mean change in SARS-CoV-2 viral load
- Change in oxygen saturation slope
- Change in Global Impression (severity and change)

Anticipated topline data: 3Q 2022



1. **Substantial alleviation** is a patient global impression of severity scored as mild or normal.
2. **Complete alleviation** is a patient global impression of severity scored as normal.

https://clinicaltrials.gov/ct2/show/NCT04610138

CLene NANOMEDICINE

Strong IP & MFG Capability

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

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.

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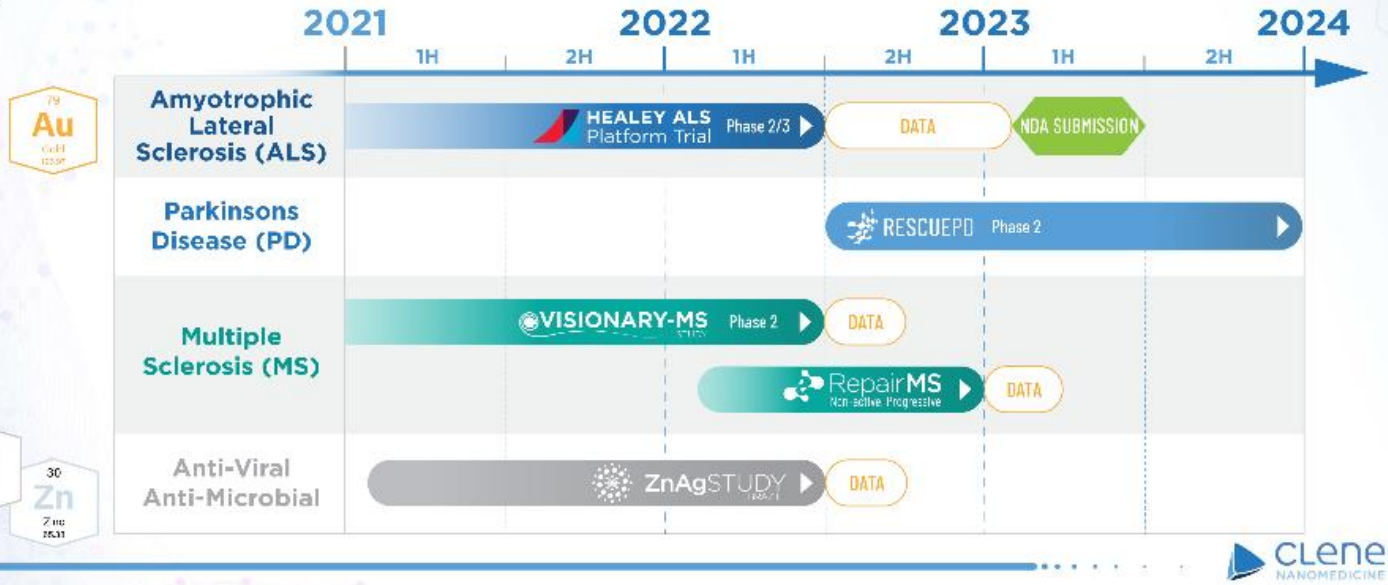
Anticipated Timeline & Upcoming Milestones

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



clene NANOMEDICINE

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

RepairMS
RepairPD

Established brain target engagement

RESCUEALS

Potential reduction in risk of disease progression and survival

HEALEY ALS Platform Trial
VISIONARY-MS

Topline data expected 3Q 2022

CNM-Au8
A gold nanocrystal suspension, in development as the first cellular energetic catalyst to remyelinate & protect neurological function

CLene

Strong IP: 150+

patents and robust manufacturing trade secret portfolio

Manufacturing expansion in progress, preparing for possible commercialization in 2023

>350

patient years of CNM-Au8® clinical exposure

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

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