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): December 15, 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 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 December 15, 2021, Clene Inc. (the "Company") released an updated corporate presentation (the "Corporate Presentation") on its website, www.clene.com. A copy of the Corporate Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K 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 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.

Forward-Looking Statements

This Current Report on Form 8-K and the Corporate Presentation may contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. The forward-looking statements include, but are not limited to, our expectations, hopes, beliefs, intentions, strategies, estimates and assumptions concerning events and financial trends that may affect our future results of operations or financial condition. 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," "could," "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. The forward-looking statements are based on information available as of the date of this report and our management's current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. As a result of a number of known and unknown risks and uncertainties, our actual results and the timing of events may differ materially from those expressed or implied by these forward-looking statements due to a number of factors. Applicable risks and uncertainties include those related to the possibility that any results of operations and financial condition of the Company are preliminary and subject to final audit, and the risks listed under the heading "Risk Factors" and elsewhere in our Quarterly Report on Form 10-Q filed on November 8, 2021 and our Annual Report on Form 10-K filed on March 29, 2021, and our subsequent filings with the U.S. Securities and Exchange Commission. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. We disclaim any 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 specifically required under applicable securities laws.

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: December 16, 2021

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 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 the section entitled "Risk Factors" in Clene's recently filed Quarterly Report on Form 10-Q (filed November 8, 2021), 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 presentation is as of the date of presented or the date made publicly available. 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™ | Management Team

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

MatlinPatterson · Credit Suisse · Actelion · Roche · Novartis · Pfizer · Parke-Davis · KSV Kensington Global · NeuroBo Pharmaceuticals

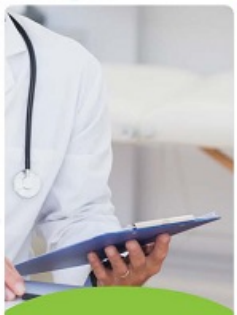
Creating Elemental Solutions for Human Health™

CLENE NANOMEDICINE

CLENE | Overview

CNM-Au8®

a gold nanocrystal suspension, in development as the first cellular energetic catalyst to remyelinate[1] & neuroprotect

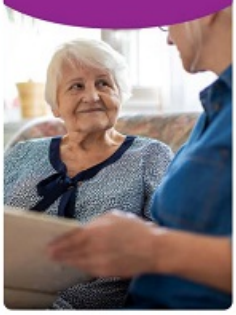


ALS Registration Trial

Topline data in 2H 2022[2]

>270

patient years of CNM-Au8 clinical exposure



Manufacturing expansion in progress, preparing for possible commercialization in 2023

Strong IP:

150+

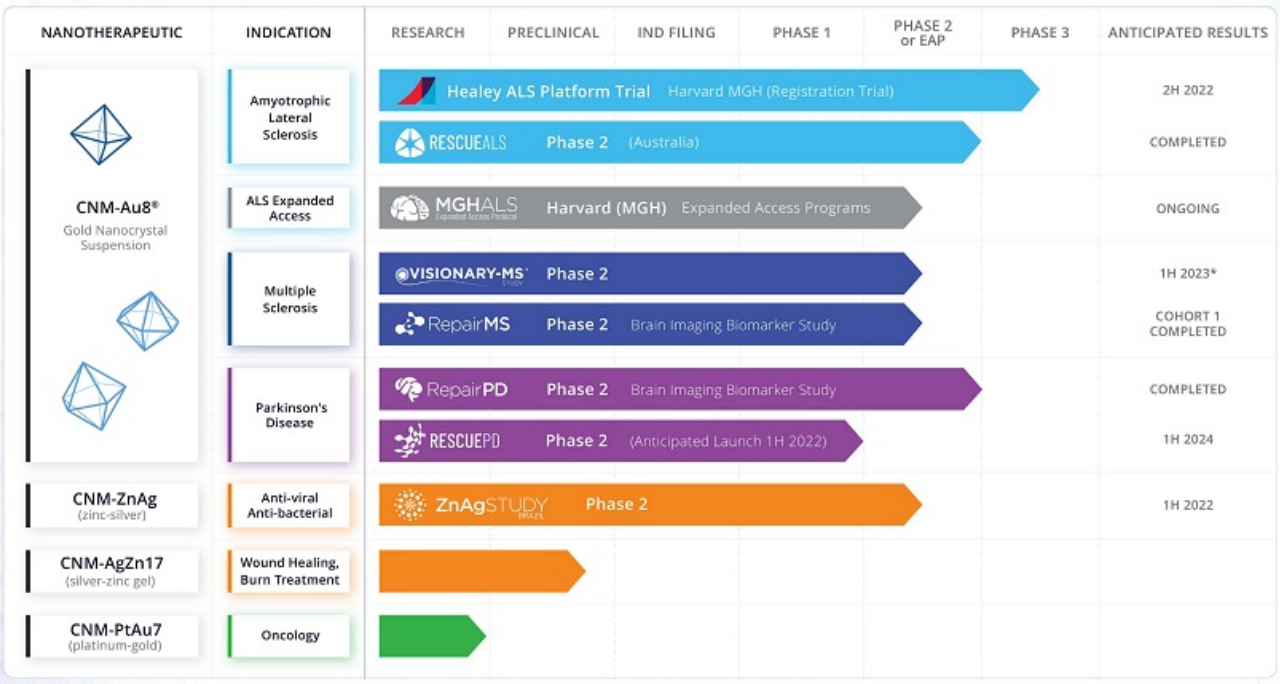
patents on Clean-Surface-Nanocrystal technology (CSN®) platform

September 30, 2021 Cash and restricted cash on hand (unaudited):

$60.6M

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 | Pipeline



*Subject to ongoing COVID-19 related site research restrictions generally implemented to protect MS patients taking standard-of-care immunosuppressive therapies

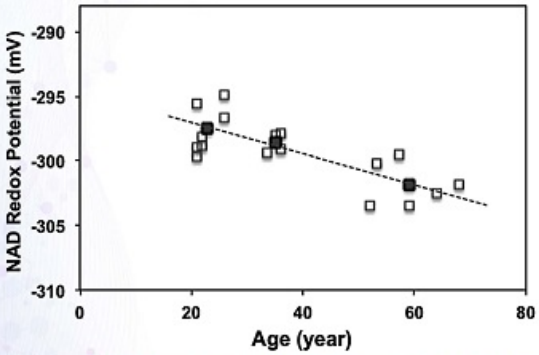
CLENE NANOMEDICINE

Neurons With High Energetic Demand Are At Increased Risk For Neurodegenerative Disease

Brain Energy Potential Declines With Normal Aging

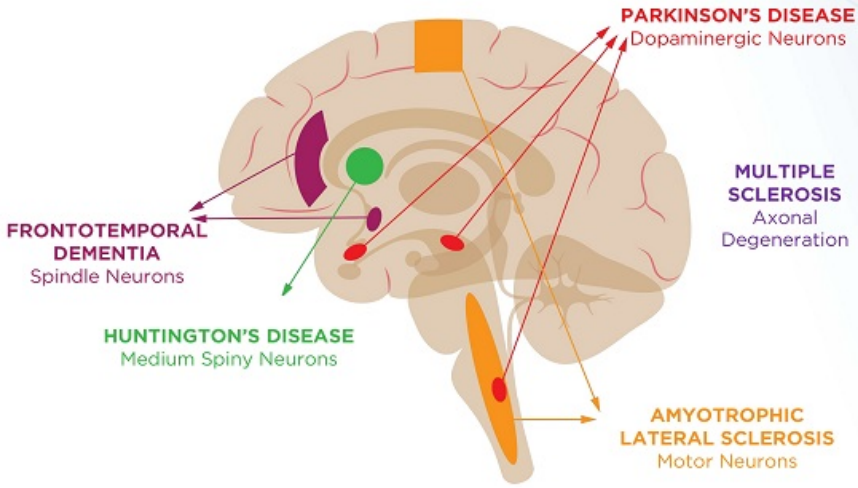
~0.5% NAD^+/NADH unit decline per decade

(~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

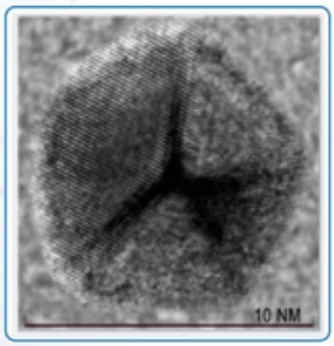


Fu, H., et al; Nature Neuroscience (2018) 21: 1350-1358. Zhu et al. Proc Natl Acad Sci USA . 2015 Mar 3;112(9):2876-81. Rone et al. J Neurosci. 2016 Apr 27;36(17):4698-707.

CNM-Au8® | Catalytically-Active Nanocrystals

Intersection of Physics and Biology

CNM-Au8 Nanocrystal



> 100 Trillion Nanocrystals per 60 mL Dose (At 30mg)

Clean Surfaced, Highly Faceted Shape Enhances Catalytic Activity

Electron Sharing Drives Catalytic Activity

Vertices, Edges, & Facets Key to Catalytic Activity

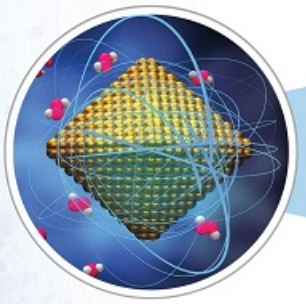
CNM-Au8 Catalytically Active Nanocrystal Suspension

60 mL per bottle (once daily)

CLene NANOMEDICINE

CNM-Au8 | Improves Energy Production to Promote Neuroprotection and Remyelination

CNM-Au8 Nanocrystal



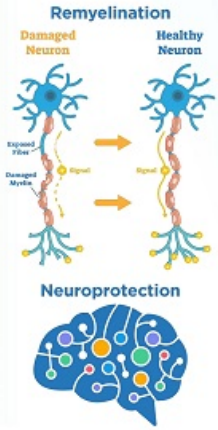
Mechanistic Effects

- ↑ 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

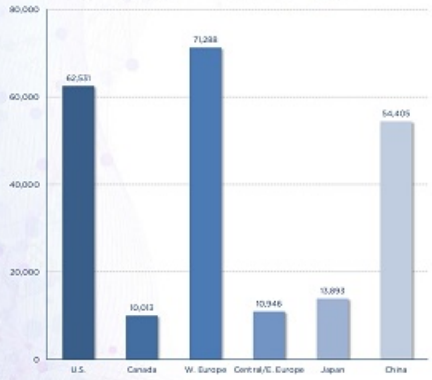


CLene NANOMEDICINE

CNM-Au8 | Significant Global Opportunity

MOTOR NEURON DISEASE
(ALS, Other Orphan Disorders)

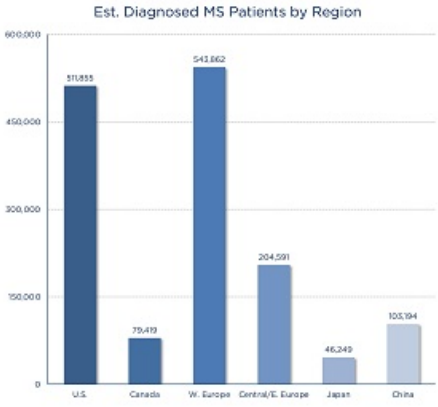
ALS sales >$1B globally by 2029[1]. Current drugs are largely ineffective, mostly generic



Source: Lancet Neurol. 2018 Dec;17(12):1083-1097.
MND includes amyotrophic lateral sclerosis, spinal muscular atrophy, hereditary spastic paraplegia, primary lateral sclerosis, progressive muscular atrophy, and pseudobulbar palsy

MULTIPLE SCLEROSIS
~2.2M pts globally; $23B market[2]

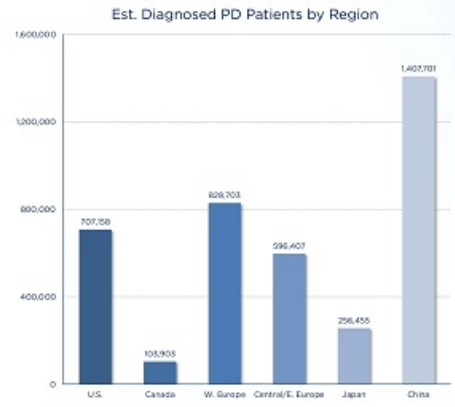
Only approved treatments are immunomodulators



Source: Lancet Neurol. 2019 Mar;18(3):269-285; ~2.2M patients globally, data as of 2016

PARKINSON'S DISEASE
~6.1M pts globally; $6B projected by 2026[3]

2ND most common neurodegenerative disorder; only symptomatic treatments



Source: Lancet Neurol. 2018 Nov;17(11):939-953; ~6.1M patients globally, data as of 2016.

[1] Clarivate, DRG, ALS 2020. [2] Westad et al. 2017, doi:10.1038/nrd.2017.107; [3] Parkinson's Market Data Forecast, April 2021.

CLene NANOMEDICINE

CNM-Au8 | Preclinical Evidence for Energetic Improvement

Therapeutic Activity Across Remyelination + Neuroprotection Models

REMYELINATION[1]

Chronic Global CNS Demyelination

- Chronic Cuprizone (CPZ) Pilot
- Chronic CPZ Repeat Validation
- Prevent CPZ Damage
- Post-Chronic CPZ Myelin Recovery
- Chronic CPZ Functional Outcome

Focal Spinal Cord Remyelination

- Lysolecithin Focal Remyelination (I)
- Lysolecithin Focal Remyelination (II)

Perinatal Myelin Injury

- Cerebral Palsy Remyelination *Ex Vivo*

PUBLICATION

Robinson et al.
Sci Rep. 2020
Feb 11

SCIENTIFIC REPORTS
nature research

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

NEUROPROTECTION[2]

Neuroprotection: Motor Neuron

- MN Neuroprotection iPSC MN *In Vitro, Astrocyte*
- MN Glutamate Excitotoxicity *In Vitro*
- MN Amyloid beta *In Vitro*
- MN Neuroprotection *ALS SOD1, In Vivo*
- MN Neuroprotection *ALS SOD1, In Vitro*

Neuroprotection: Dopaminergic

- PD Neurotoxin MPP *In Vitro*
- PD Neurotoxin *6-OHDA In Vitro*
- PD Neurotoxin *6-OHDA In Vivo*

Neuroprotection: Other

- Hippocampal Neuron Glutamate Excitotoxicity *In Vitro*
- Cortical Neuron Glutamate Excitotoxicity *In Vitro*
- Forebrain Neuroprotection *C9ORF72 In Vitro*
- Alzheimer's Disease Induced Neurons *In Vitro*

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

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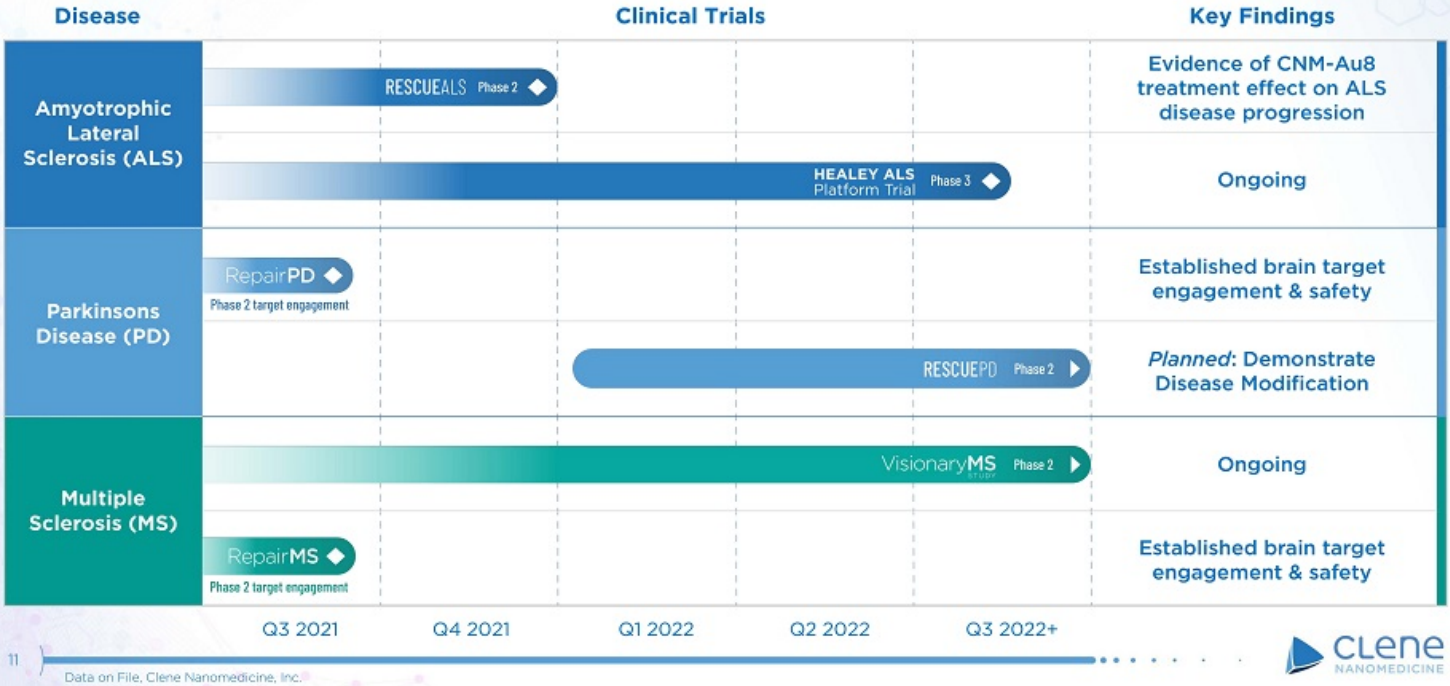
CNM-Au8 | Neuroprotection & Remyelination

Phase 2 and Phase 3 Clinical Trials



Data on File, Clene Nanomedicine, Inc.

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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 related CNM-Au8 AEs leading to discontinuation of treatment
- No SAEs related to CNM-Au8 considered severe, life-threatening, or resulting in death

Patient Exposure Across PD, MS, & ALS

Over 270 Years of Subject Exposure Without Any Safety Signals

- Long-term dosing experience up to 115 weeks

Data on File, Clene Nanomedicine, Inc.

Phase 2

RepairPD

RepairMS

CNM-Au8 Effects on Brain Energetic Metabolites

A Phase 2, Open Label, Sequential Group, Investigator Blinded Study of Magnetic Resonance Spectroscopy (^{31}P-MRS) to Assess the Effects of CNM-Au8 for the Bioenergetic Improvement of Impaired Neuronal Redox State (REPAIR)

RepairPD
Early Parkinson's Disease

RepairMS
Stable Relapsing MS

1° **Change in Brain Bioenergetic Potential (NAD^+/NADH) vs. Baseline**

N = Up to 15 per dosing cohort

(7.5, 15, 30, or 60 mg)

2°

- Difference in brain NAD^+ and NADH fraction at Week 12 (End of Treatment)

Exploratory

- Difference in bioenergetic metabolites (e.g., ATP, NAD) concentration at Week 12 – 16
- Difference in brain membrane markers (PE, PC, etc.) at Week 12 – 16

Data on File, Clene Nanomedicine, Inc.

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Phase 2 Results

RepairPD

RepairMS

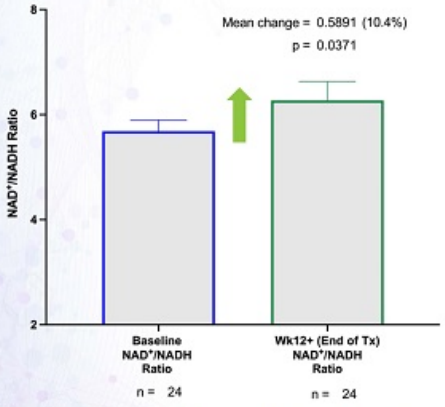
CNM-Au8 Improves Brain Energy Metabolism Increases NAD+/NADH Ratio in MS & PD

1° Endpoint

^{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)



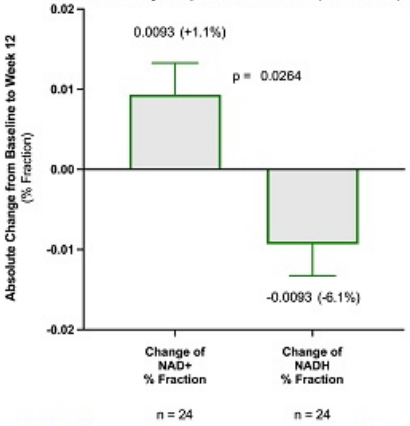
2° Endpoint

REPAIR Integrated Analysis

^{31}P-MRS Average Change in Brain NAD (% Fraction)

Partial Volume Coil; % Fraction of NAD$^+$ and NADH

Secondary Endpoint, Mean ± SEM (Paired t-test)



Exploratory

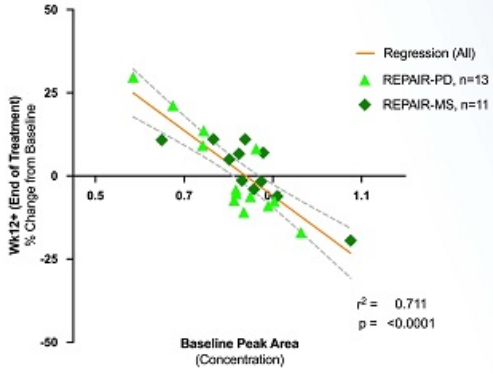
(ATP Normalization)

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



NAD is an essential molecule responsible for cellular energy production

Glanzman et al. 2021. International Parkinson and Movement Disorder Society (MDS) Virtual Congress 2021. September 17 – 22, 2021. Data on File, Clene Nanomedicine, Inc.

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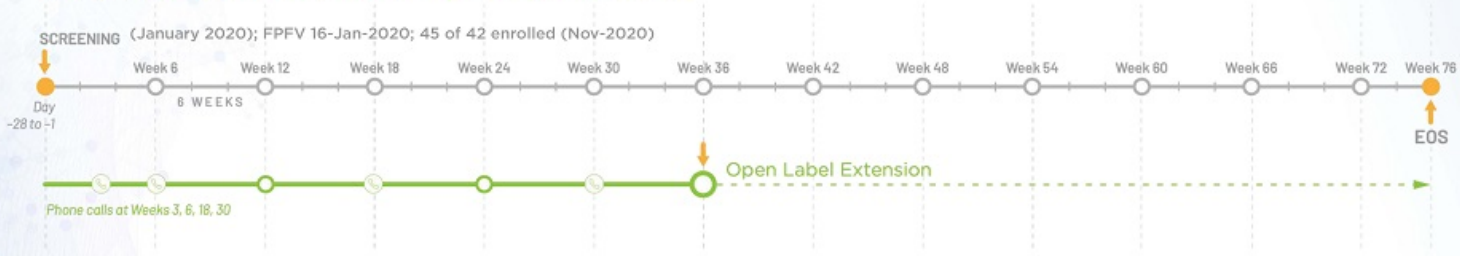
Phase 2
RESCUEALS

Randomized, Double-Blind, Placebo-Controlled Study in Early Symptomatic Amyotrophic Lateral Sclerosis Patients on Stable Background Therapy to Assess Bioenergetic Catalysis with CNM-Au8 to Slow Disease Progression in ALS

36-Week Treatment Period (n=42) 30mg, Placebo



Neurophysiology	Pulmonary Function	Function & QoL	Disease Progression & Survival
MUNIX[1]	Forced Vital Capacity	ALSFRS-R, ALSSQOL-SF	

[1] Study was powered for MUNIX primary endpoint

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

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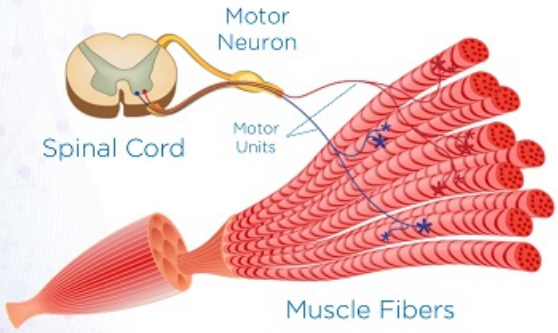
RESCUEALS | Pioneered Use of MUNIX Biomarker

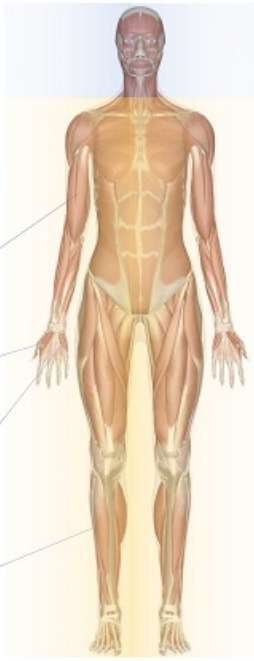
Primary Endpoint: Spinal Cord Lower Motor Neuron Protection

MUNIX biomarker estimates the number of functioning lower motor neurons serving specific muscles



Primary Endpoint: Spinal Cord Lower Motor Neuron Motor Unit Index (MUNIX) Sum

- Biceps brachii
- \+
- Abductor Pollicis Brevis
- \+
- Abductor Digiti Minimi
- \+
- Tibialis Anterior



Bulbar Onset ALS (Brainstem)

Limb Onset ALS (Spinal Cord)

Vucic et al. BMJ Open. 2021 Jan 11;11(1):e041479.

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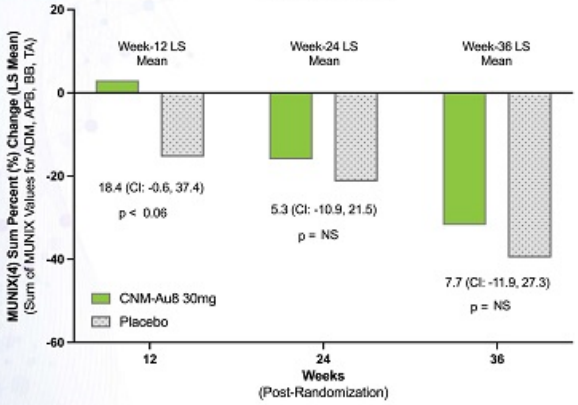
RESCUEALS | Evidence for Motor Neuron Protection

Primary Endpoint (MUNIX %, LS Mean Change)

All Randomized

MUNIX(4) Sum Percent Change from Baseline
RESCUE-ALS Primary Endpoint
Mixed Model Repeat Measure (ITT Population, All Randomized)
LS Mean Difference



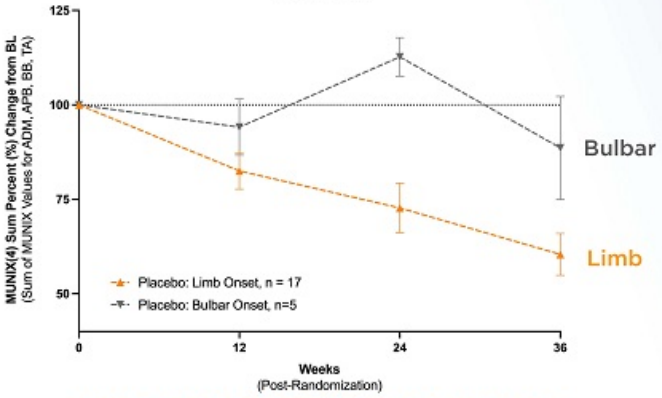
Active, n =	21	21	20
Placebo, n =	21	19	16

P-value is based on mixed model repeat measures with treatment, visit, treatment by visit interaction as fixed effects, and baseline value and ENCALS score as covariates. An unstructured covariance model was used.

All Placebo

Limited Rate of MUNIX Decline in Bulbar Onset

MUNIX(4) Sum Percent Change from Baseline
RESCUE-ALS: Placebo Rate of Progression
Observed Values (Limb Onset vs. Bulbar Onset)
(Mean ± SEM)



Insufficient Spinal Cord Lower Motor Neuron Progression in Early Bulbar Trial Participants

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

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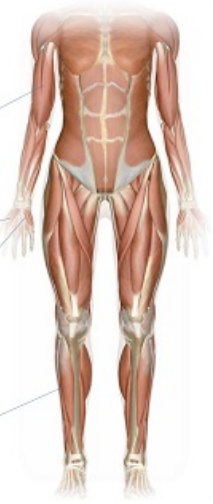
RESCUEALS | MUNIX Biomarker Efficacy in Limb Onset

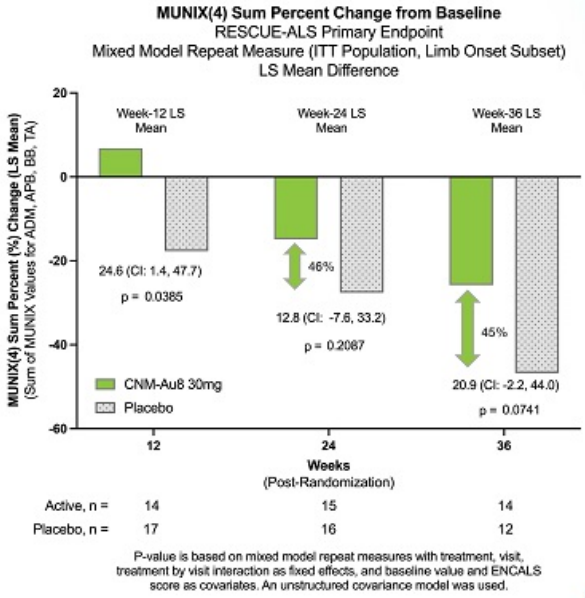
Primary Endpoint (MUNIX %, LS Mean Change, Limb Onset Subset)

Spinal Cord Lower Motor Neuron Motor Unit Index (MUNIX) Sum

- Biceps brachii
- \+ Abductor Pollicis Brevis
- \+ Abductor Digiti Minimi
- \+ Tibialis Anterior



Pre-specified: Limb Onset



P-value is based on mixed model repeat measures with treatment, visit, treatment by visit interaction as fixed effects, and baseline value and ENCALS score as covariates. An unstructured covariance model was used.

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

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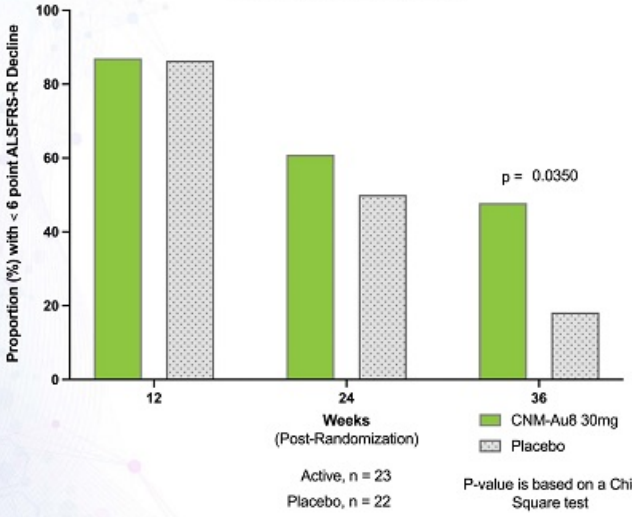
RESCUEALS | Significant Impact on ALSFRS-R Decline

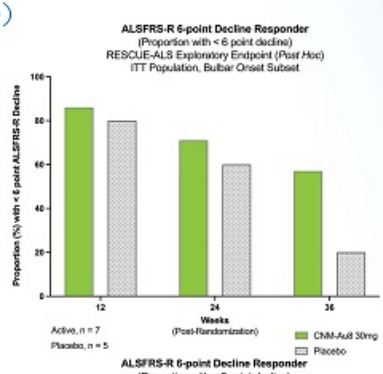
Exploratory (ALSFRS-R Responder Analysis, < 6-point decline)

All Randomized

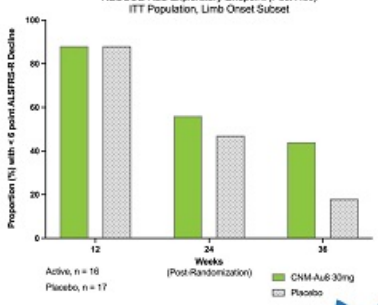


Sensitivity

All Bulbar



All Limb



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

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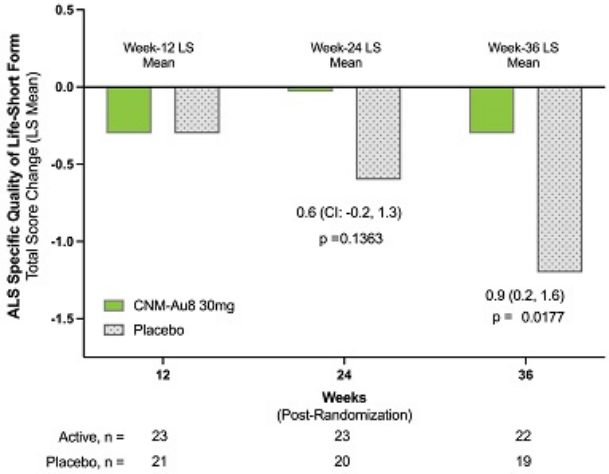
RESCUEALS | Significant Quality of Life Improvement

Exploratory (ALS Specific QOL-SF)

All Randomized

ALS Specific Quality of Life-Short Form Total Score
RESCUE-ALS Exploratory Endpoint
Mixed Model Repeat Measure (ITT Population, All Randomized)
LS Mean Difference



Active, n =	23	23	22
Placebo, n =	21	20	19

P-value is based on MMRM model with treatment, visit, treatment by visit interaction as fixed effects, and baseline value, and ENCALS score as covariates. An unstructured covariance model was used.

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

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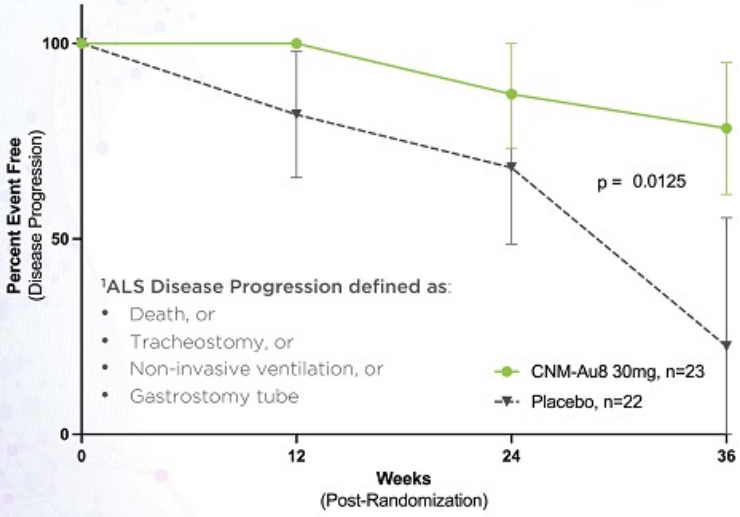
RESCUEALS | Significant Impact on ALS Disease Progression

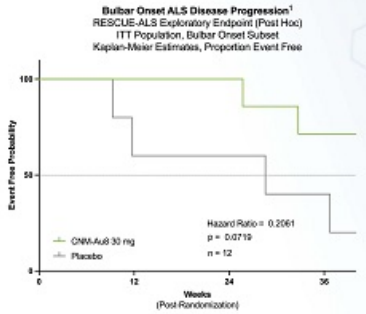
Exploratory Endpoint (Disease Progression)

ALS Disease Progression[1]
RESCUE-ALS Exploratory Endpoint
ITT Population, All Randomized
(Kaplan-Meier Estimate, Percent Event Free, ± 95% CI)



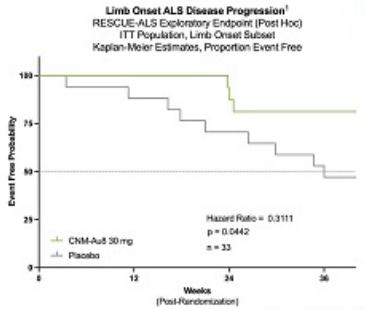
Sensitivity

All Bulbar



[1] Disease progression defined as death, tracheostomy, use of non-invasive ventilatory support, or insertion of gastrostomy tube.

All Limb



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

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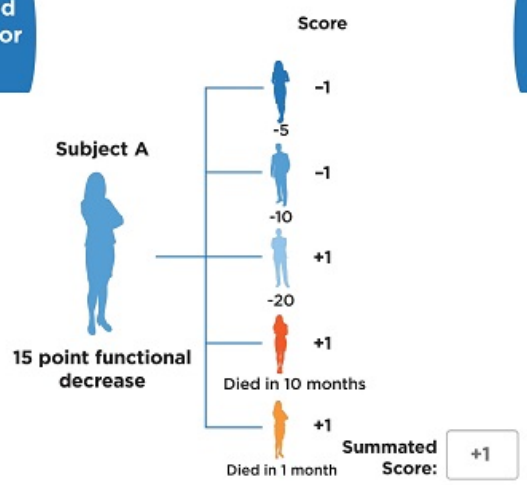
Joint Rank | Survival & Disease Progression

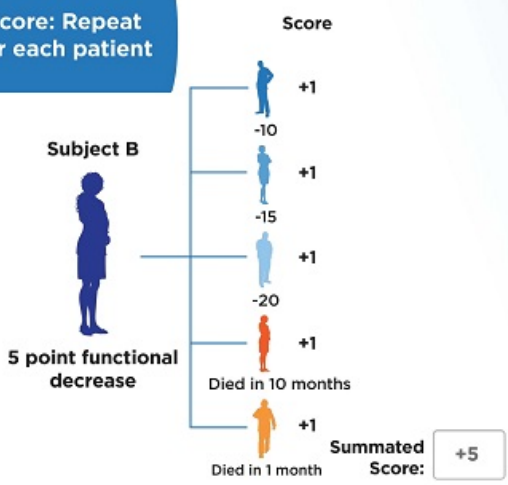
Summated Scoring Example

Score patients based on relative function or time of death

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



Score: Repeat for each patient



Berry et al. Amyotroph Lateral Scler Frontotemporal Degener. 2013 Apr;14(3):162-8.

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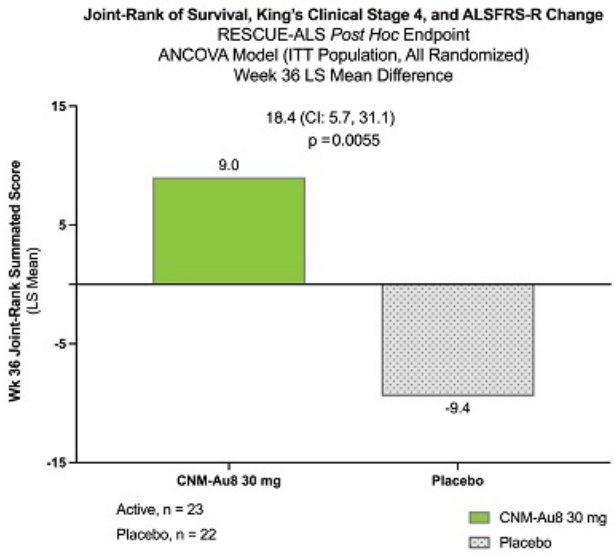
RESCUEALS | Impact on Joint Rank Score to Wk36

Post Hoc (Combined Assessment of (i) Survival, (ii) King's Clinical Stage 4, (iii) ALSFRS-R)

King's Clinical Stage 4

- Survival
- Non-Invasive Ventilation
- Gastrostomy Tube
- ALSFRS-R Decline

By Average of Summated Scores



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.

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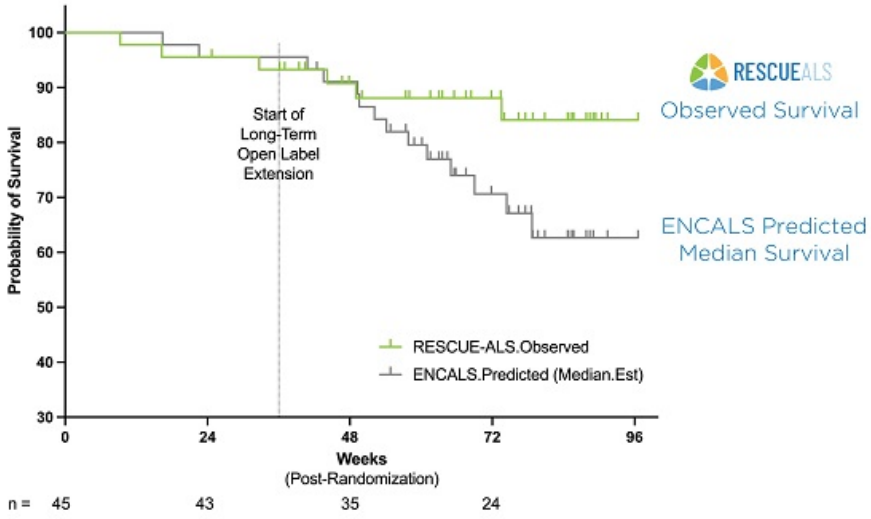
RESCUEALS | Potential Impact on Survival

Exploratory Endpoint (Observed Survival vs. Median Predicted)

Observed Survival vs. ENCALS Predicted Median Survival
RESCUE-ALS Exploratory Endpoint
ITT Population, All Randomized



RESCUEALS Observed Survival

ENCALS Predicted Median Survival

All observations censored as of 22-November-2021. Participants who did not transition into the long-term open label extension (n=5) are censored at the safety follow-up visit.

Data on File, Clene Nanomedicine, Inc.

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RESCUEALS | Well Tolerated & No Safety Signals

Safety Summary

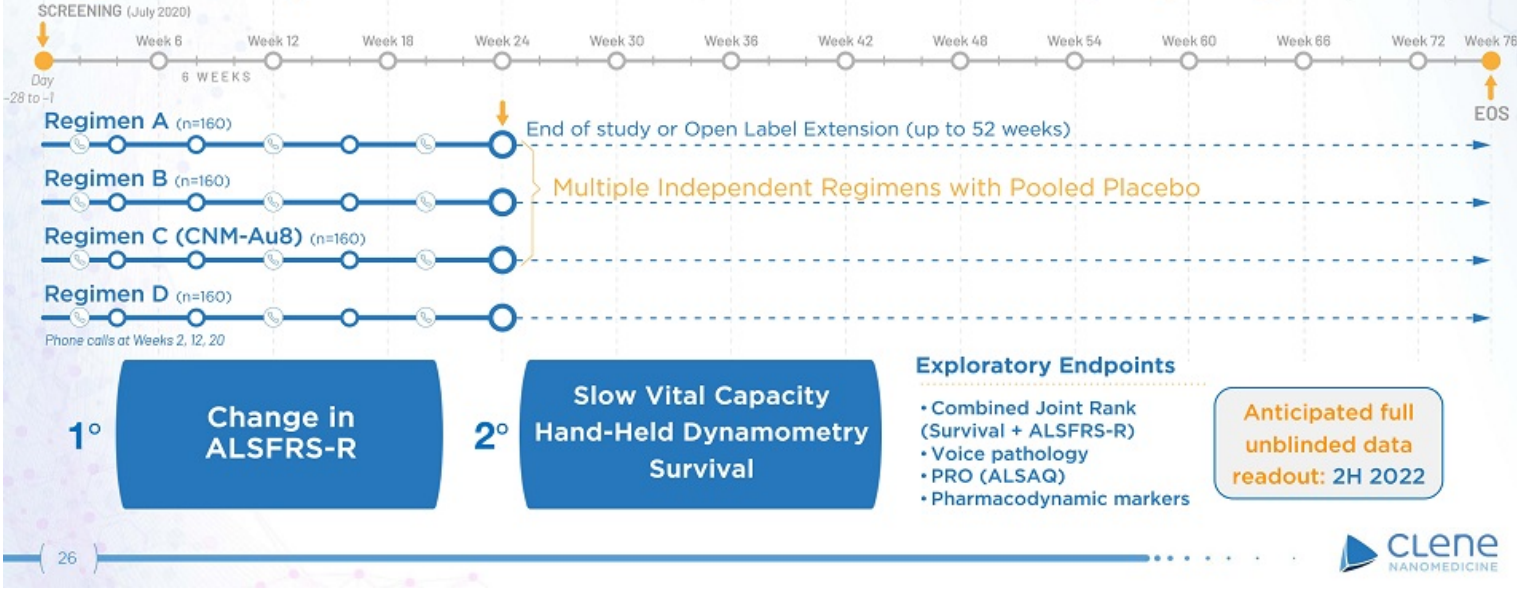
- No CNM-Au8 related serious adverse events (SAEs)
- No CNM-Au8 related drug discontinuations
- No imbalances in treatment emergent adverse event (TEAEs) by system organ class
- TEAEs were predominantly mild-to-moderate and transient
- Most common TEAEs associated with CNM-Au8
  (aspiration pneumonia, n=3; nausea, n=2; abdominal discomfort, n=2)

Data on File, Clene Nanomedicine, Inc.

Phase 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**

2° **Slow Vital Capacity**
Hand-Held Dynamometry
Survival

Exploratory Endpoints

- Combined Joint Rank (Survival + ALSFRS-R)
- Voice pathology
- PRO (ALSAQ)
- Pharmacodynamic markers

Anticipated full unblinded data readout: 2H 2022

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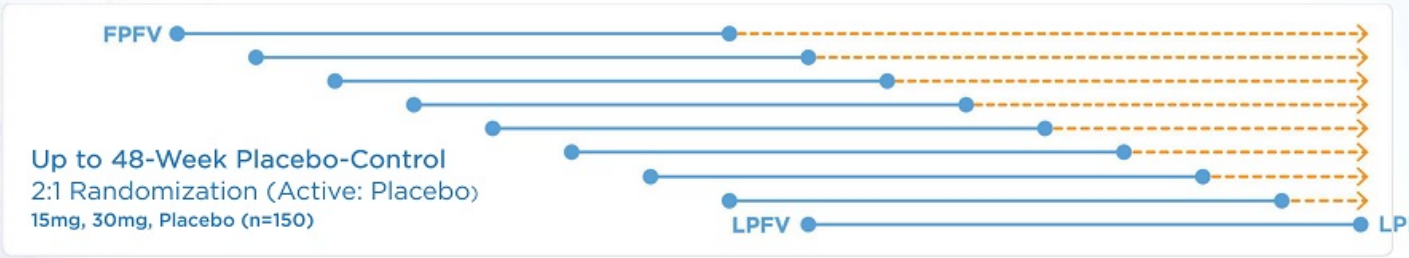
Phase 2

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=150)

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

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

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 top-line unblinded data:
1H 2023*

*Subject to ongoing COVID-19 related site research restrictions generally implemented to protect MS patients taking standard-of-care immunosuppressive therapies

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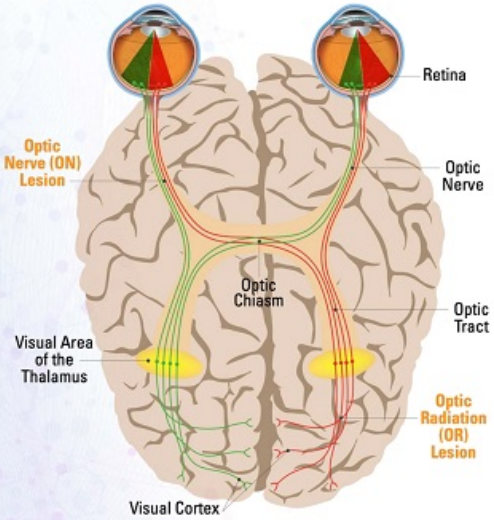
Measuring MS Functional Improvement

The Visual System is a Window into the Brain



LCLA

Phase 2 Primary:
Functional Visual Improvement

LCLA Correlates with clinically meaningful deficits in QOL, EDSS and MSFC, MRI, and OCT[1]

MS Functional Endpoints

Phase 2 Exploratory:
Neuroprotection/Remyelination Endpoints

9-Hole Peg Test

Symbol Digit Modalities

Timed 25-Ft Walk

[1]Balcer et la. Mult Scler. 2017 Apr;23(5):734-747. doi: 10.1177/1352458517690822.

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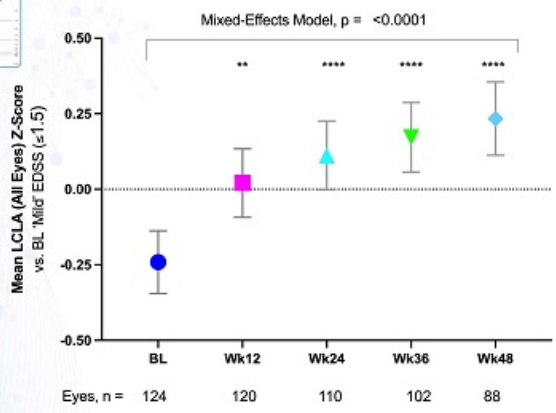
Phase 2 VISIONARY-MS STUDY

Significant Clinical Improvement Across Study Population Over 48-Weeks

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

1° - LCLA

LCLA (All Eyes) Average Z-Score (vs. Mild EDSS ≤1.5)
23-August-2021 Data Cut, Preliminary Blinded Data
(vs. 'Mild' EDSS [≤1.5]; Mean ± SEM)

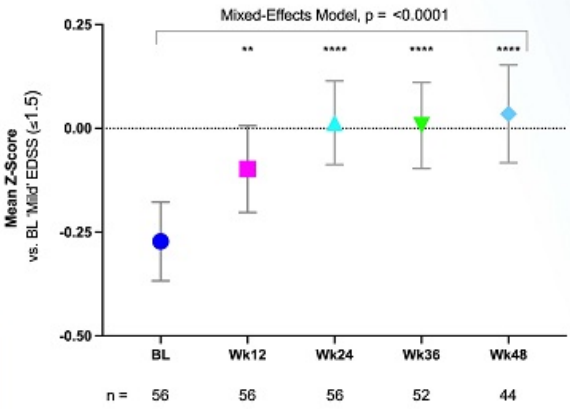


Z-Score Change Based on EDSS 'Mild' Severity (e.g., BL Low EDSS [≤1.5])
All Available Values (by Completed Subject Visit)

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
23-August-2021 Data Cut, Preliminary Blinded Data
(vs. 'Mild' EDSS [≤1.5]; Mean ± SEM)



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/SD), 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 catalytic gold nanocrystals, CNM-Au8; ECTRIMS 2021 – Late Breaking News ePoster, October 12, 2021

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Strong Intellectual Property

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

CSN®
Clean surface nanocrystal (CSN) therapeutics

Patent Status [b]	Patent Description	Trade Secrets
Issued & Allowed Patents 150+	Process And Method/Device (Clean Surface; Gold CSN)	Plasma Conditioning
Pending Applications ~20	State of Matter (CNM-Au8)	Electrode Design & Cycling
Total Patents/ Applications >170	Method of Use (Prevent Demyelination & MoA)	Trough Flow, Temp, Pressure
	Method of Use (Bi-Metallic Au/Pt; Antimicrobial)	Concentration & Filtration

[a] With Patent Restoration Term (assuming 5-year extension). [b] As of 30-Sepbember-2021.

Clene | Proprietary Nanocrystal Manufacturing

In-House ISO8 Clean Room Clinical Production in Maryland

Designed to be Scalable to Commercialization

- Patented Hydro-electro-Crystallization
- Proprietary Trade Secrets
- Validated CMC Processes

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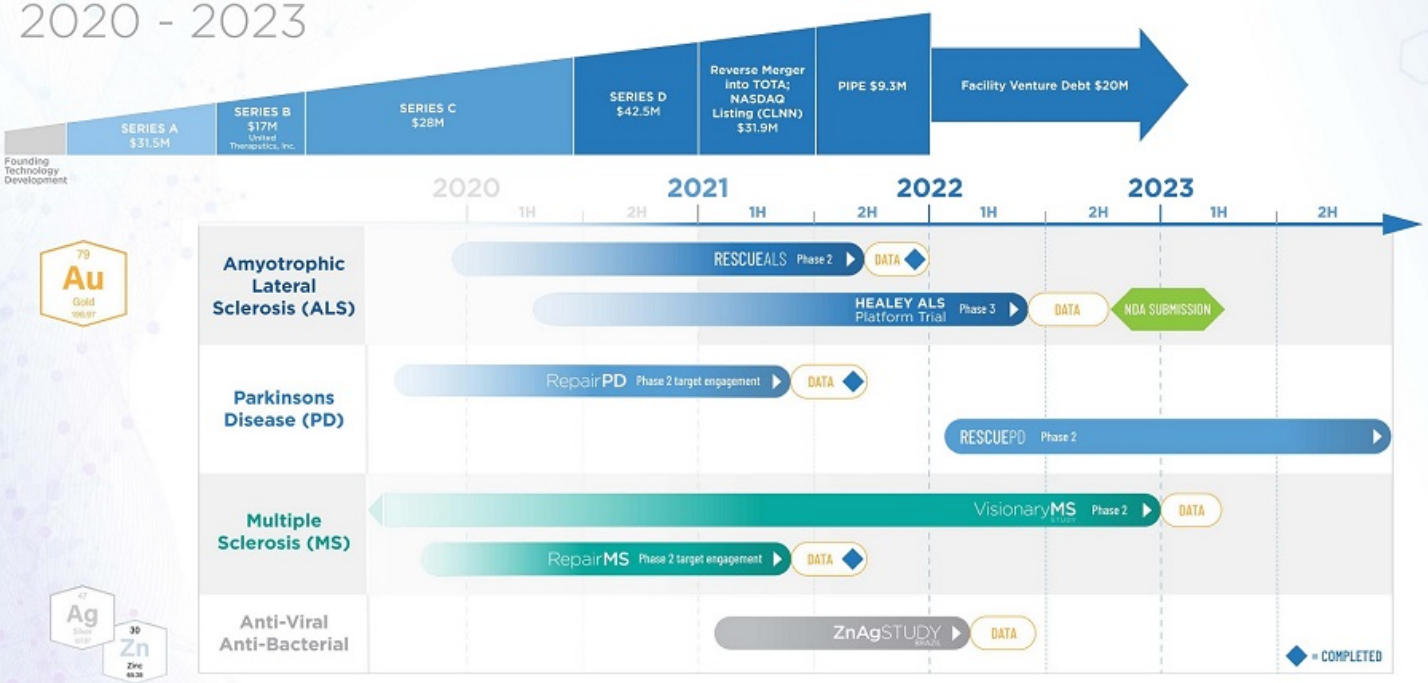
Anticipated Timeline & Upcoming Milestones

2020 - 2023



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CLENE | Company Highlights

Nanotherapeutics Platform

- Potential first-in-class nanotherapeutic with high catalytic activity to drive energy production and utilization in stressed CNS cells
- Applications across neurology, infectious disease, and oncology

Lead Asset: CNM-Au8 for Neurorepair

- CNM-Au8 improves cellular energy production and utilization to promote neuroprotection and remyelination
- Phase 2 ALS proof-of-concept evidence of efficacy across clinical endpoints
- Phase 3 Healey ALS platform trial results expected in 2H 2022
- Phase 2 VISIONARY-MS in multiple sclerosis underway

Strong Execution Capabilities

- Proprietary electrochemical manufacturing process produces nanotherapeutics, scalable to commercialization
- Strong IP, including 150+ granted patents, and trade secrets

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Version: 14-December-2021