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): January 8, 2024

CLENE INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39834**	**85-2828339**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6550 South Millrock Drive, Suite G50 **Salt Lake City, Utah**	**84121**
(Address of Principal Executive Offices)	(Zip Code)

(801) 676-9695

(Registrant's telephone number, including area code)

N/A

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	CLNN	The Nasdaq Capital Market
Warrants, to acquire one-half of one share of Common Stock for $11.50 per share	CLNNW	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

In connection with the press release discussed under Item 8.01 in this Current Report on Form 8-K, on January 8, 2024, 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 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 Securities Exchange Act of 1934 (the "Exchange Act"), as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in any such filings, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On January 8, 2024, the Company issued a press release announcing significant improvement in vision and cognition with CNM-Au8® treatment in the VISIONARY-MS trial long-term open label extension. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Corporate Presentation.
99.2	Press Release, dated January 8, 2024, announcing significant improvement in vision and cognition with CNM-Au8 treatment in VISIONARY-MS trial long-term open label extension.
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: January 8, 2024

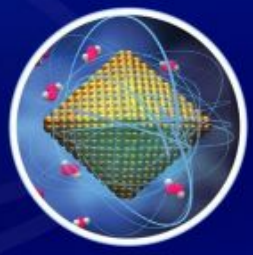
By: /s/ Robert Etherington
Robert Etherington
President and Chief Executive Officer

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.

Focused on Improving Mitochondrial Health and Protecting Neuronal Function to Treat Neurodegenerative Diseases



THE PROBLEM

- The World Health Organization predicts **neurodegenerative diseases will become the second-most prevalent cause of death** within the next 20 years.
- A therapeutic breakthrough is urgently needed.
- In neurodegenerative diseases, **impaired mitochondrial activity and compromised cellular metabolism can lead to neuronal death**.

A NEW APPROACH

- **Clene is pioneering catalytic nanotherapeutics** to treat neurodegenerative diseases, such as amyotrophic lateral sclerosis, Parkinson's disease and multiple sclerosis.
- By **targeting the improvement of mitochondrial function** via the nicotinamide adenine dinucleotide pathway, Clene's first-in-class drug, CNM-Au8, is **pioneering a new way to restore and protect neuronal function**.

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Building the Clinical Case for Neuroprotection & Remyelination

HEALEY ALS Platform Trial

RESCUEALS

VISIONARY-MS STUDY

RepairPD

RepairMS

Growing Body of Clinical Evidence Across ALS and MS Supports CNM-Au8 Therapeutic Potential to Treat Neurodegenerative Diseases

Proprietary Nanotherapeutic Manufacturing
Strong IP: 150+ granted patents PLUS Trade Secrets

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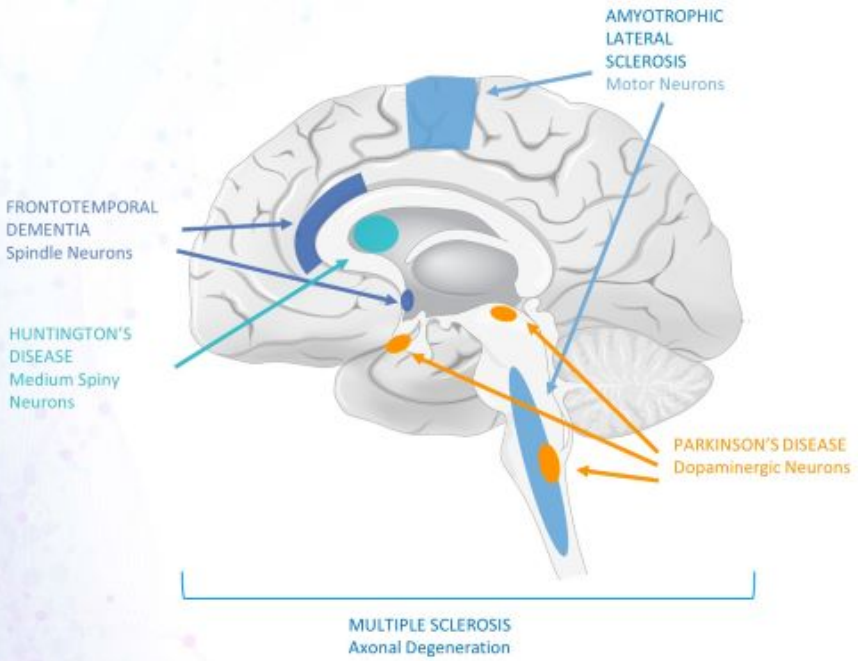
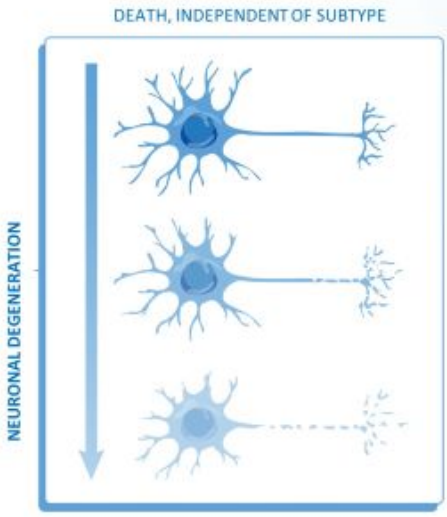
All Neurodegenerative Diseases Involve Neuronal Death

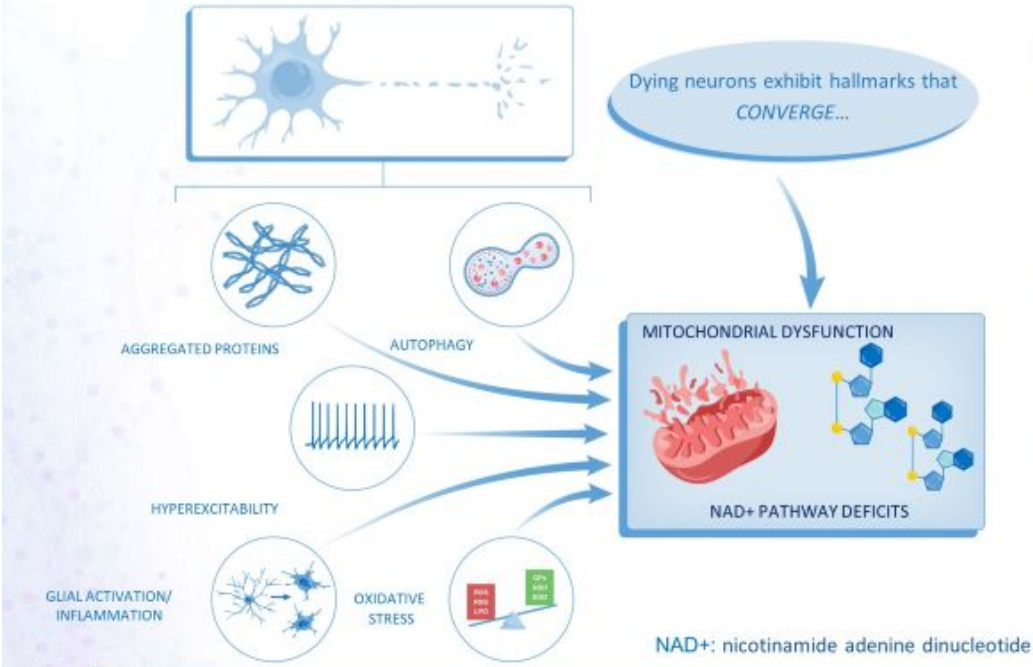




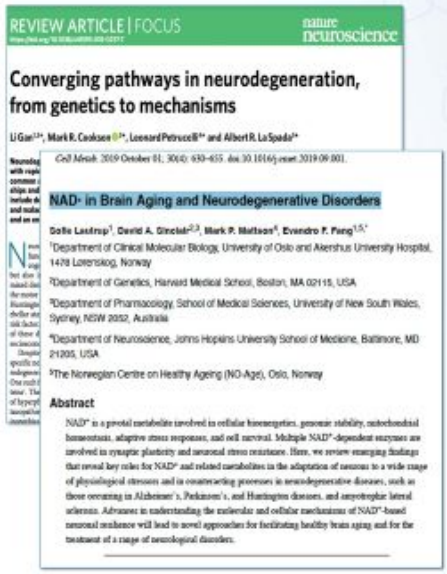
Fu, H., et al; Nature Neuroscience (2018) 21: 1350-1358. Rone et al. J Neurosci. 2016 Apr 27;36(17):4698-707.

CLENE NANOMEDICINE

Hallmarks of Neuronal Death Converge on ***Mitochondrial Dysfunction*** and ***NAD+ Pathway Deficits***



NAD+: nicotinamide adenine dinucleotide



REVIEW ARTICLE | FOCUS

nature neuroscience

Converging pathways in neurodegeneration, from genetics to mechanisms

Li Gan[1,2*], Mark R. Cookson[3*], Leonard Petrucelli[4*] and Albert R. La Spada[5*]

Cell Metab. 2019 October 01; 30(4): 630–655. doi:10.1016/j.cmet.2019.09.001.

NAD+ in Brain Aging and Neurodegenerative Disorders

Dalle Lautrup[1], David A. Sinclair[2,3], Mark P. Mattson[4], Evandro F. Fang[1,5,*]

[1]Department of Clinical Molecular Biology, University of Oslo and Akershus University Hospital, 1478 Lørenskog, Norway

[2]Department of Genetics, Harvard Medical School, Boston, MA 02115, USA

[3]Department of Pharmacology, School of Medical Sciences, University of New South Wales, Sydney, NSW 2052, Australia

[4]Department of Neuroscience, Johns Hopkins University School of Medicine, Baltimore, MD 21205, USA

[5]The Norwegian Centre on Healthy Ageing (NO-Age), Oslo, Norway

Abstract

NAD+ is a pivotal metabolite involved in cellular bioenergetics, genomic stability, mitochondrial homeostasis, adaptive stress responses, and cell survival. Multiple NAD+-dependent enzymes are involved in synaptic plasticity and neuronal stress resistance. Here, we review emerging findings that reveal key roles for NAD+ and related metabolites in the adaptation of neurons to a wide range of physiological stressors and in counteracting processes in neurodegenerative diseases, such as those occurring in Alzheimer's, Parkinson's, and Huntington diseases, and amyotrophic lateral sclerosis. Advances in understanding the molecular and cellular mechanisms of NAD+-based neuronal resilience will lead to novel approaches for facilitating healthy brain aging and for the treatment of a range of neurological disorders.

Lautrup et al. Cell Metab. 2019 Oct 1;30(4):630-655. Gan et al. Nat Neurosci. 2018 Oct;21(10):1300-1309.

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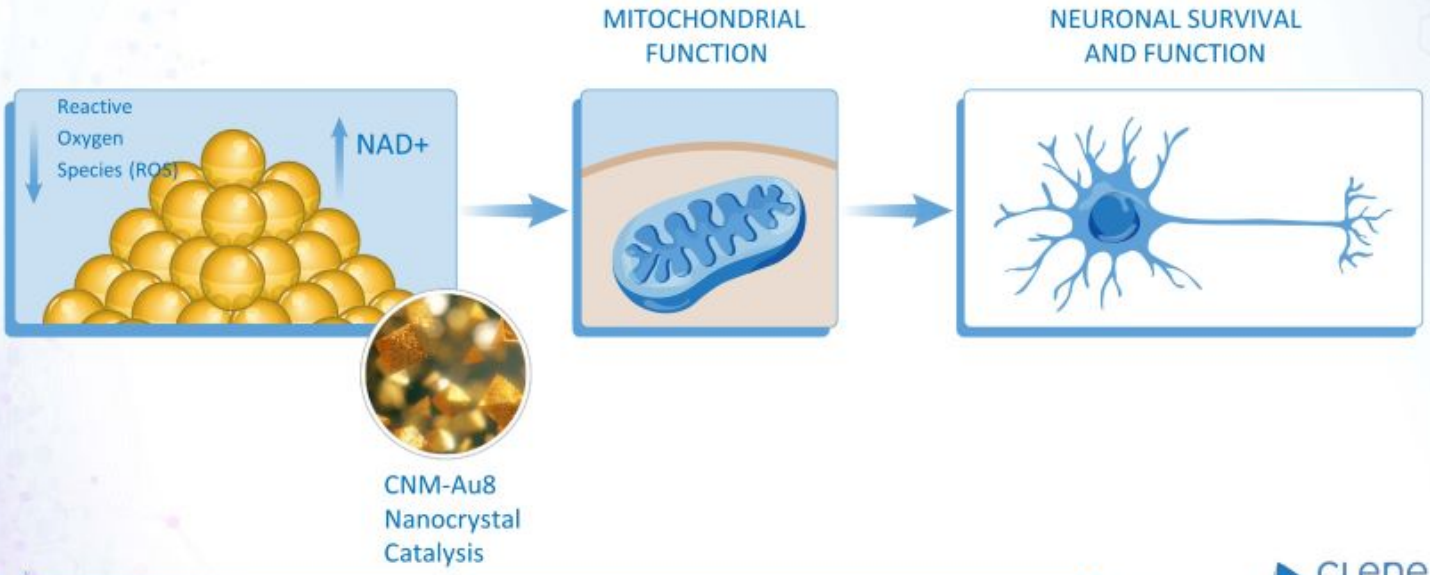
CNM-Au8® | Surface Catalysis Improves Mitochondrial Function



CNM-Au8 Nanocrystal Catalysis

Robinson et al. Sci Rep. 2020 Feb 11;10(1):1936. Wang et al 2023, Small. 2023 Sep 28:e2304082.

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Over 500 Years of Subject Exposure Without Identified Safety Signals Across ALS, MS, and 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 transient/mild-to-moderate** severity (GI/Headache)

Patient Exposure Across ALS, MS & PD

Over 500 Years of Subject Exposure Without Identified Safety Signals

- Long-term dosing experience **over 4 years**

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

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

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

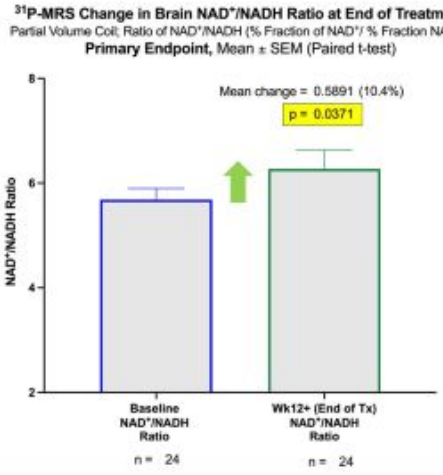
RepairPD
Early Parkinson's Disease

RepairMS
Stable Relapsing MS

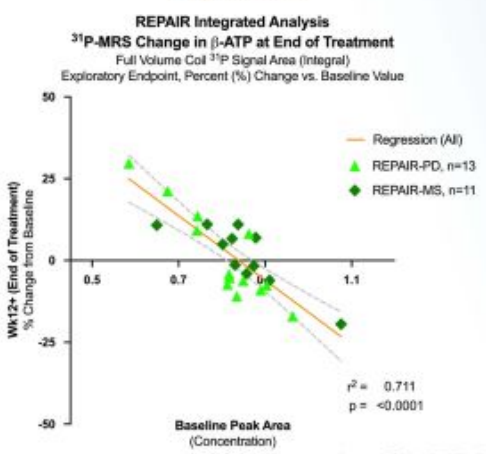
RepairMS
Non-Active Progressive MS
(Ongoing)

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)



Ren et al. J Nanobiotechnology. 2023 Dec 13;21(1):478.

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Promising Evidence from Two Phase 2 Trials and Long-Term Data

CNM-Au8 Demonstrated Survival, Delayed Clinical Worsening, and Preserved Function

	RESCUE-ALS	RESCUE-OLE	HEALEY ALS Platform	HEALEY OLE	EAP
ALS Patient Demographics	Early-to-Mid-Stage (45)	Early-to-Mid-Stage	Mid-to-Late-Stage (161 Regimen C)	Mid-to-Late-Stage	Real-World Experience (256)
Duration	36-weeks	Up to 173 weeks	24-weeks	Up to 133 weeks	Over 4.0 years
Survival	--	✓	✓	✓ PRO-ACT	✓
Delayed Time to Clinical Worsening	✓	✓	✓	Pending data 1Q 2024	Not routinely collected
Preserved Function (ALSFRS-R)	--	✓	--		
Progression Biomarkers	p75 trend	↓ UCHL1 *	✓ NfL ↓	✓ NfL ↓	

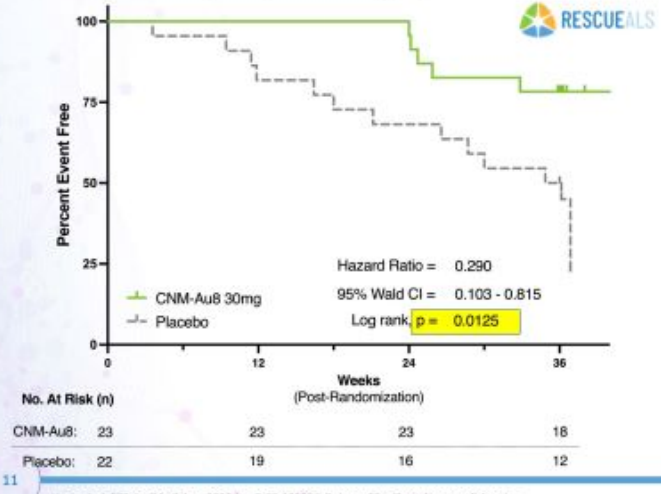
Consistent Evidence for CNM-Au8 30mg Dose Across Broad ALS Patient Population

Data on File, Clene Nanomedicine, Inc. *Small simple available for analyses in RESCUE OLE

CNM-Au8 | Clinical Worsening Concordant in Two Phase 2 Trials

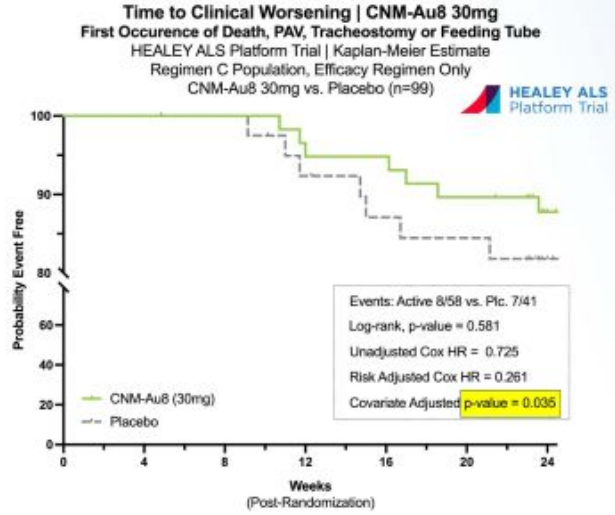
Evidence for Decreased Clinical Worsening Events Across Two Phase 2 Studies

Phase 2 RESCUE-ALS CNM-Au8 30mg
Decreased Time to Clinical Worsening



No. At Risk (n)				
CNM-Au8:	23	23	23	16
Placebo:	22	19	16	12

Phase 2 HEALEY ALS Platform CNM-Au8 30mg
Decreased Time to Clinical Worsening



Vucic et al. EClinicalMedicine. 2023 Jun 8;60:102036. Data on File, Clene Nanomedicine, Inc.

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CNM-Au8 | ALS Survival at 30mg Concordant in Two Phase 2 Trials

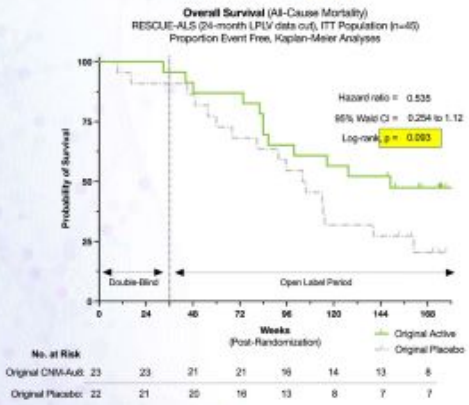
RESCUEALS

Up to 75% decreased risk of death through 168 weeks

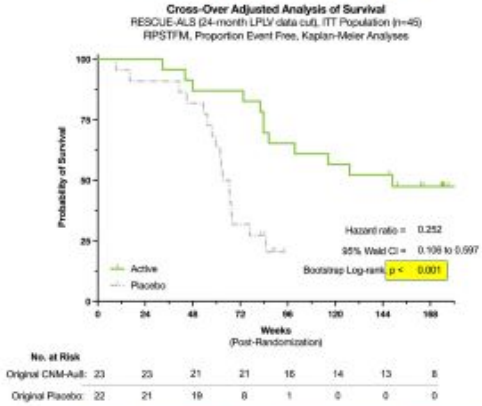
HEALEY ALS Platform Trial

>90% risk reduction of death at 30mg at 24 weeks

Unadjusted Survival

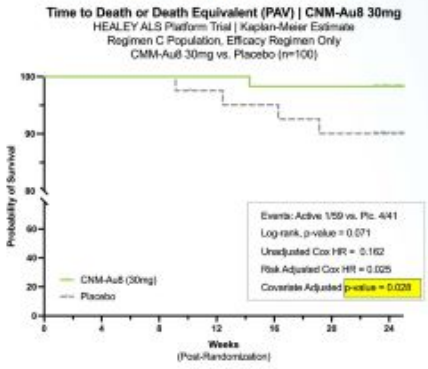


Cross-Over Adjusted Survival



RPSFTM (Rank Preserving Structural Failure Time Model) removes estimated benefit from cross-over to active treatment in ex-placebo participants

Survival During Blinded Period



Data on File, Clene Nanomedicine, Inc.

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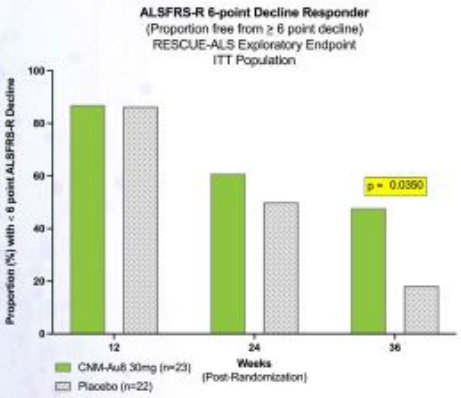
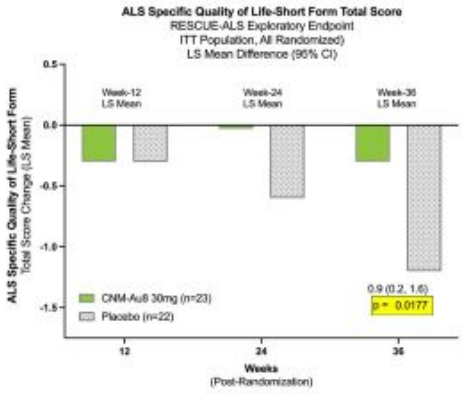
Improved Exploratory Endpoints: Patient Function, QOL, and Slowed Time to ALS Clinical Worsening

Phase 2 Study: 36-Week Placebo-Control Treatment Period 1:1 Randomization (Active 30 mg: Placebo); N=45 enrolled with early ALS

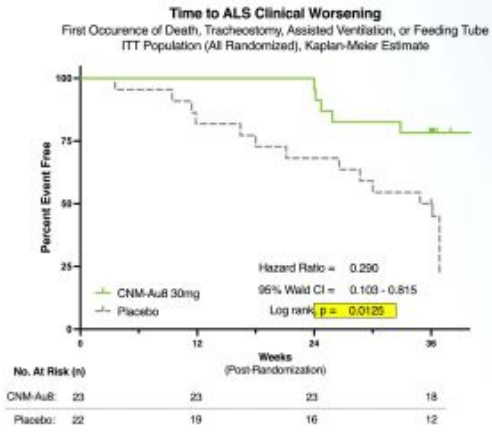
Proportion with <6 point decline



ALS Specific QOL



ALS Clinical Worsening *



Primary endpoint was not significant (Motor Unit Index Change at Week 36)

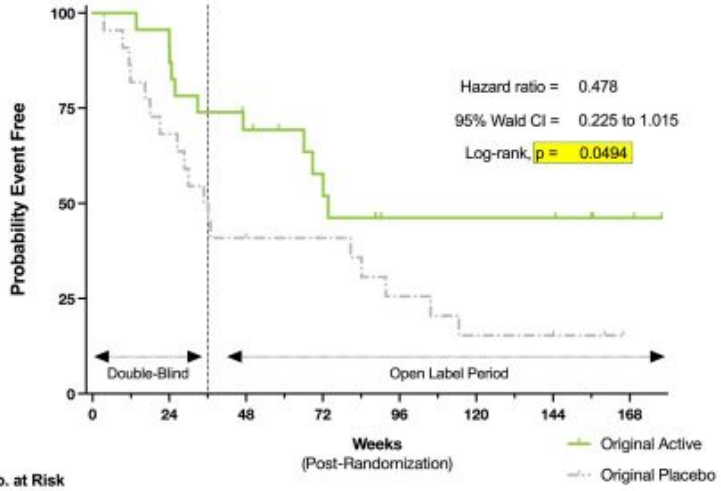
Vucic et al. EClinicalMedicine. 2023 Jun 8;60:102036.

* ALS clinical worsening defined as (i) Death, (ii) Tracheostomy, (iii) Non-invasive ventilation, or (iv) Feeding tube

RESCUEALS OLE | 52% Reduced Risk of ALS Clinical Worsening

- Death
- Tracheostomy
- Non-Invasive Ventilation
- Feeding Tube Placement

ALS Clinical Worsening Events
Time to Death, Tracheostomy, Assisted Ventilation, or Feeding Tube
RESCUE-ALS Double-Blind & OLE Periods (24-month LPLV data cut)
Proportion Event Free, Kaplan-Meier Analyses



No. at Risk								
Original CNM-Au8:	23	23	16	11	6	6	6	3
Original Placebo:	22	16	10	9	6	4	4	1

52% decrease in risk of ALS clinical worsening for CNM-Au8 compared to placebo in OLE up to 168 weeks

Participants were right-censored at loss of follow-up with OLE withdrawal, as applicable

Data on File, Clene Nanomedicine, Inc.

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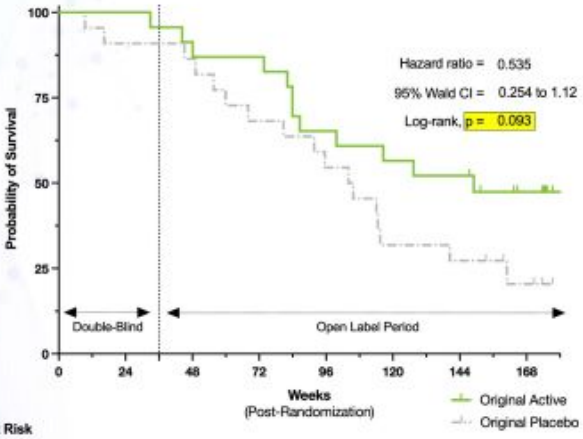
RESCUEALS Up to 19.3 Month Survival Benefit vs. Original Placebo

Unadjusted Survival Difference: 10.1 Months

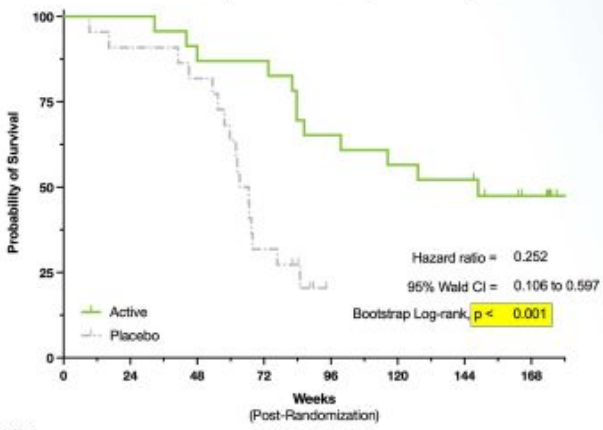
Overall Survival (All-Cause Mortality)
RESCUE-ALS (24-month LPLV data cut), ITT Population (n=45)
Proportion Event Free, Kaplan-Meier Analyses



No. at Risk								
Original CNM-Au8:	23	23	21	21	16	14	13	8
Original Placebo:	22	21	20	16	13	8	7	7

Cross-Over Adjusted Survival Difference: 19.3 Months

Cross-Over Adjusted Analysis of Survival
RESCUE-ALS (24-month LPLV data cut), ITT Population (n=45)
RPSTFM, Proportion Event Free, Kaplan-Meier Analyses



No. at Risk								
Original CNM-Au8:	23	23	21	21	16	14	13	8
Original Placebo:	22	21	19	8	1	0	0	0

RPSFTM (Rank Preserving Structural Failure Time Model) subtracts the estimated benefit from cross-over to active treatment in ex-placebo participants

Data on File, Clene Nanomedicine, Inc.

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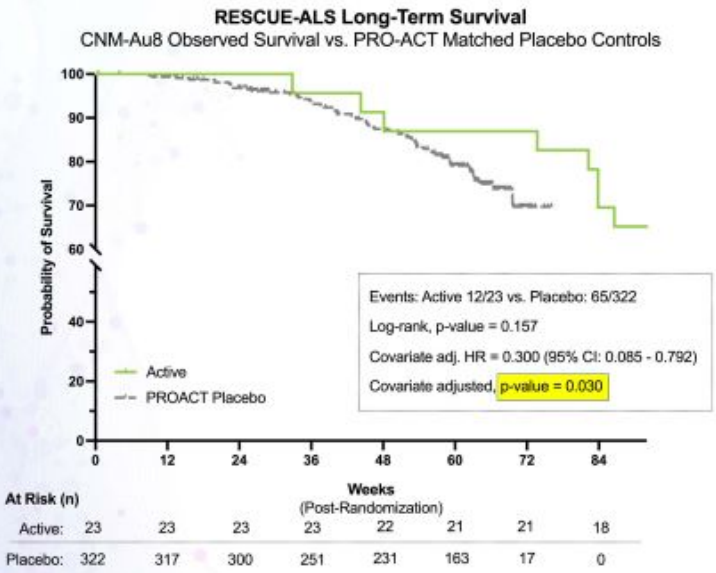
Long-Term Survival Benefit Compared to Historical Matched PRO-ACT Placebo Controls



At Risk (n)								
Active:	23	23	23	23	22	21	21	18
Placebo:	322	317	300	251	231	163	17	0

CNM-Au8 treatment demonstrated a significant survival benefit:

- 70% decreased risk of death
- Follow-up of active compared to matched placebo from PRO-ACT

PRO-ACT contains approximately 12,000 patient records from multiple completed clinical trials.

Time to all-cause mortality amongst participants originally randomized to CNM-Au8 compared to propensity matched placebo controls derived from the PRO-ACT database (n=322). Covariates included: Onset Age, Sex, BMI, Pre-Treatment ALSFRS-R Slope (Delta-FS), ALSFRS-R Total Score, Vital Capacity (% predicted), and Diagnostic Delay (Covariates selected by minimizing AICc).

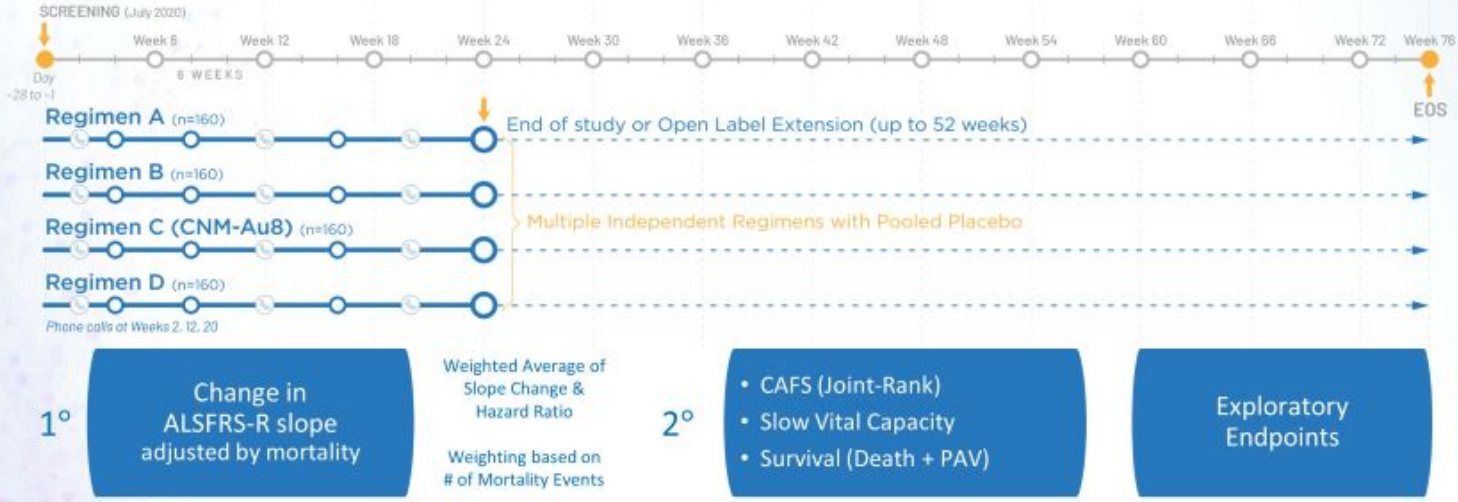
Propensity matching is a statistical technique used to find the closest like-to-like placebo patients for comparison beyond the 36-week blinded period

Data on File, Clene Nanomedicine, Inc.

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

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



1° Change in ALSFRS-R slope adjusted by mortality

Weighted Average of Slope Change & Hazard Ratio

Weighting based on # of Mortality Events

2°
- CAFS (Joint-Rank)
- Slow Vital Capacity
- Survival (Death + PAV)

Exploratory Endpoints

No evidence for treatment effect at 24 weeks for either adjusted ALSFRS-R change, CAFS, or SVC (combined 30 & 60 mg doses)

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

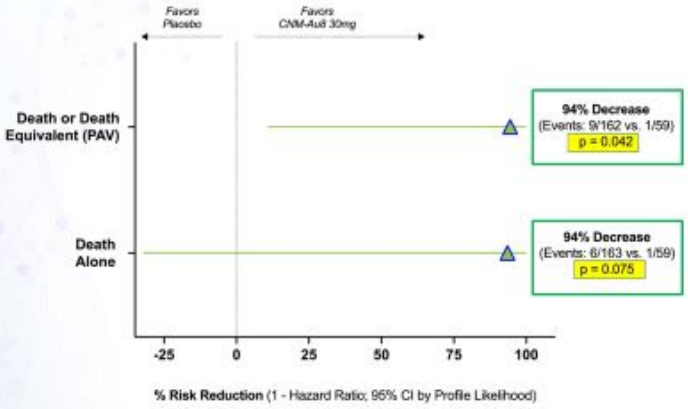
CLene NANOMEDICINE

Survival Signal | >90% Reduced Risk of Death with CNM-Au8 30mg

HEALEY ALS Platform Trial

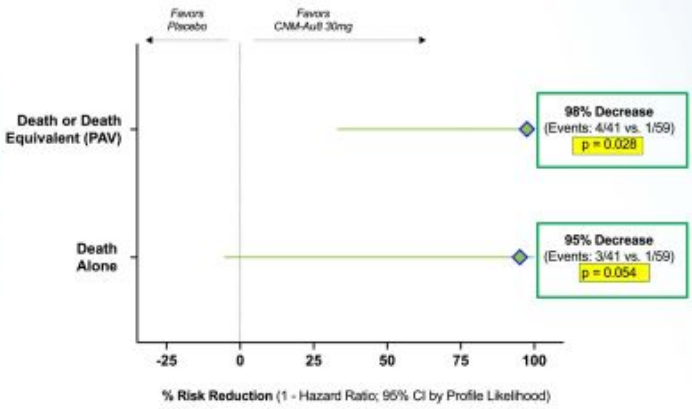
Shared Placebo Across Regimens

CNM-Au8 30mg Survival | Adjusted Cox Proportional Hazard
Full Analysis Set (All Shared Placebo, Regimens A, B, C, D)
% Hazard Reduction at Week 24
(1 - Hazard Ratio, 95% Confidence Interval)



CNM-Au8 Regimen Only (Regimen C)

CNM-Au8 30mg Survival | Adjusted Cox Proportional Hazard
Efficay Regimen Only Set (Within Regimen Analysis)
% Hazard Reduction at Week 24
(1 - Hazard Ratio, 95% Confidence Interval)



PAV = Permanently Assisted Ventilation; Prespecified covariate adjustments include: (i) time from symptom onset, (ii) pre-baseline ALSFRS-R slope, (iii) riluzole use, (iv) edaravone use, (v) age. Events (placebo vs. active). p-values are not adjusted for multiple comparisons; exploratory analyses by dose.

Data on File, Clene Nanomedicine, Inc.

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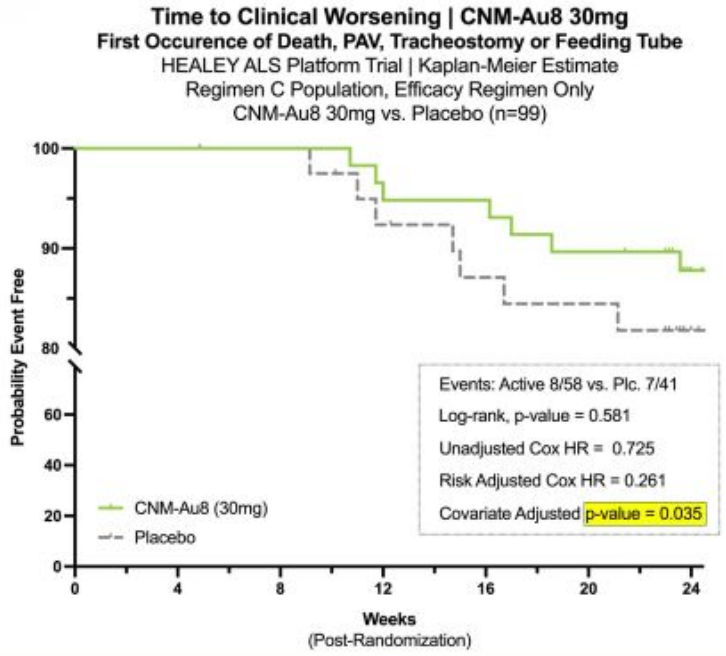
Delayed Time to ALS Clinical Worsening

CNM-Au8 30mg | Within Regimen Analysis (Primary Model)

HEALEY ALS Platform Trial



Prespecified covariate risk adjustments included: (i) time from symptom onset, (ii) pre-baseline ALSFRS-R slope, (iii) riluzole use, (iv) edaravone use, and (v) age.

Data on File, Clene Nanomedicine, Inc.

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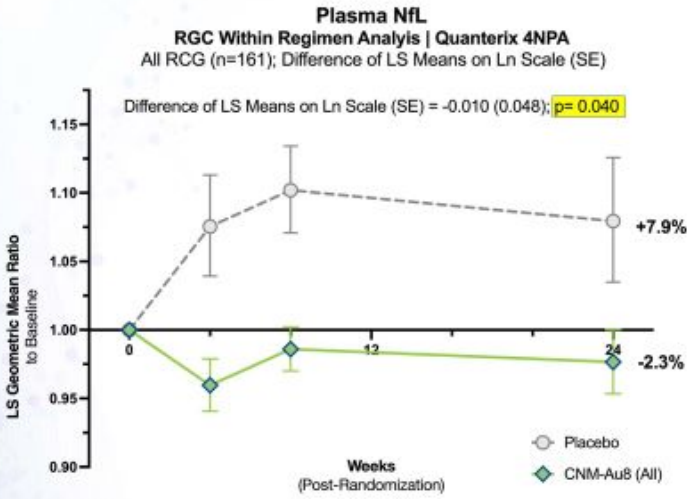
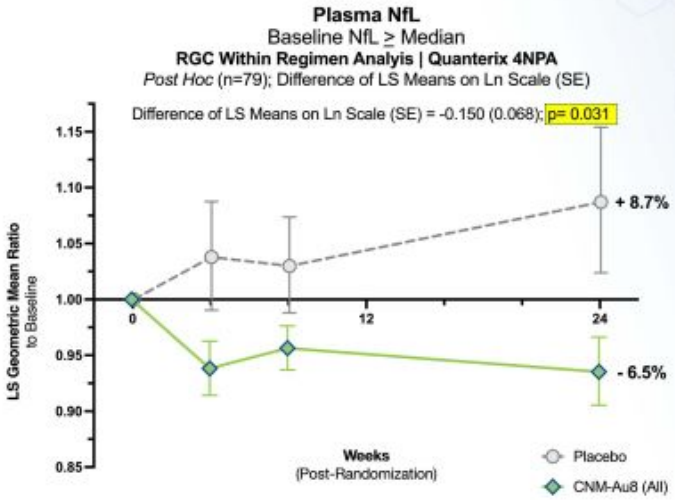
Significant Biomarker Plasma NfL Difference

CNM-Au8 vs. Placebo | All RGC Participants During Double-Blind Period

HEALEY ALS Platform Trial





MMRM log NfL by group, contrast model; prespecified covariates included: (i) pre-treatment ALSFRS-R slope (delta-FS), (ii) months from symptom onset, (iii) use of riluzole, (iv) use of edaravone; (v) covariate by visit interaction, (vi) treatment by visit interaction

Data on File, Clene Nanomedicine, Inc.

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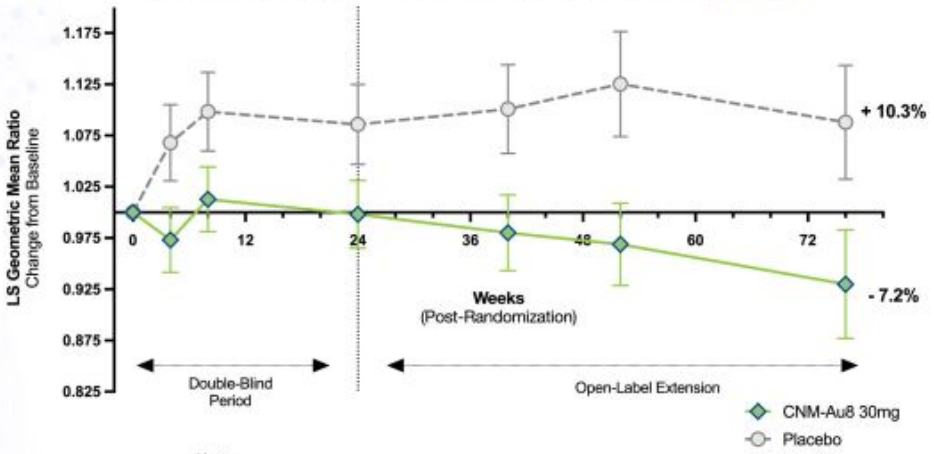
Continued Long Term Plasma NfL Decline in the OLE

76-Weeks post baseline MMRM (CNM-Au8 30mg)

HEALEY ALS Platform Trial

CNM-Au8 30mg Plasma NfL Geometric Mean Change
RGC Within Regimen Analyis | Long Term Extension | Quanterix 4NPA
All Evaluable with Baseline, n=99; LS Geometric Mean Difference ± SEM

Week 76 LS Difference of LS Mean on Ln Scale (SE) = -0.1730 (0.076); p= 0.023



Notes:
[1] All visits graphed with n ≥ 10 participant data.
[2] MMRM analysis uses LS means to account for missing data.

Covariates included: (i) months from symptom onset, (ii) pretreatment ALSFRS-R slope, (ii) background riluzole, (iv) background edaravone. Mixed model repeat measures (MMRM).

Data on File, Clene Nanomedicine, Inc.

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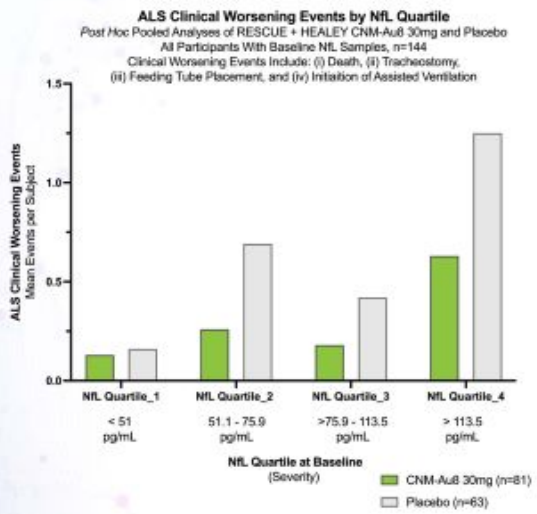
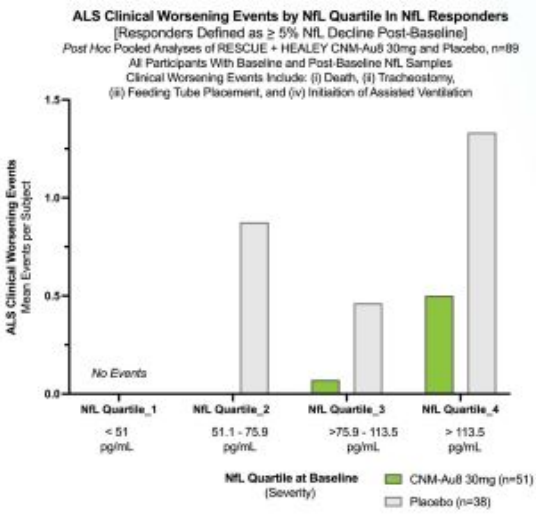
Validation of NfL Association with Clinical Outcomes

Post Hoc | Clinical Worsening Event (Average Events per Patient per Group)

Clinical Worsening Events Frequency is Associated with Higher Baseline NfL Levels (by Quartile)



NfL Responder Analyses in Participants with a NfL Decline of ≥5% (Post-Baseline) Demonstrated Greater Treatment Effect



Data on File, Clene Nanomedicine, Inc.

Long-Term Survival | Propensity Matched Placebo

PRO-ACT Placebo Matching vs. Regimen C CNM-Au8 30mg

HEALEY ALS Platform Trial

Baseline Values Mean (SD) or Percent (%)	HEALEY Regimen C		Integrated Meta-Analysis	
	CNM-Au8 30mg (n=59)	PRO-ACT Placebo Matches (i) (n=322)	CNM-Au8 30mg (n=82)	PRO-ACT Placebo Matches (ii) (n=322)
Onset Age	55.4 (10.4)	55.5 (11.0)	55.4 (11.1)	55.0 (11.4)
Sex (Male, %)	56%	62%	56%	65%
BMI (kg/m²)	27.4 (5.3)	26.5 (4.9)	27.2 (5.2)	26.6 (5.0)
ALSFRS-R (Total Score)	34.5 (5.8)	37.7 (5.5)	35.7 (6.3)	37.9 (5.5)
Delta-FS (Pre-treatment slope)	0.77 (0.58)	0.75 (0.50)	0.76 (0.57)	0.74 (0.51)
Vital Capacity (% predicted)	74.4 (16.0)	89.2 (17.0)	77.3 (17.1)	89.3 (16.9)
Diagnostic Delay (months)	9.8 (5.2)	8.8 (5.2)	10.6 (6.1)	8.9 (5.4)
Site of Onset (Bulbar, %)	17%	20%	21%	20%
Riluzole Treatment (%)	76%	98%	82%	98%

Source(s): Data on File, Cene Nanomedicine, Inc. (Table 14.1.4.1.1 Pooled vs. PROACT; Table 14.1.4.1.2 Healey vs. PROACT)
Notes: Vital capacity reported as SVC or FVC based on individual study characteristics.

Propensity matching is a statistical technique used to find the closest like-to-like placebo patients for comparison beyond the 24-week blinded period

Data on File, Cene Nanomedicine, Inc.

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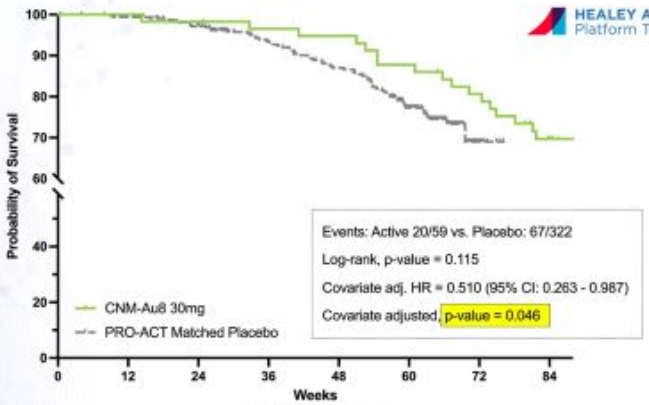
Long-Term Survival | Propensity Matched Placebo

PRO-ACT Placebo vs. CNM-Au8 30mg

CNM-Au8 30mg HEALEY

HEALEY-ALS Platform Long-Term Survival

CNM-Au8 30mg Observed Survival vs. PRO-ACT Matched Placebo Controls

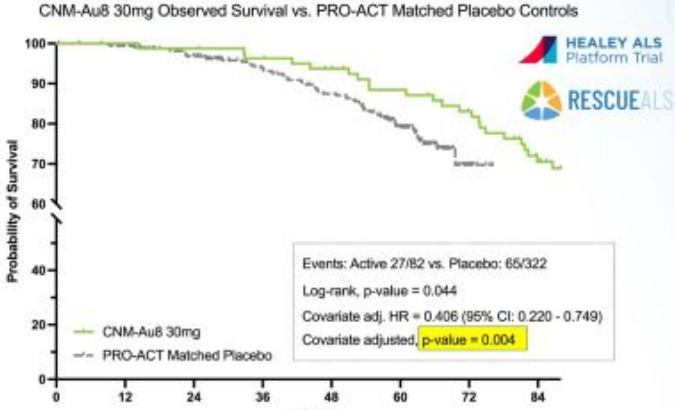


At Risk (n)								
Active:	59	58	58	56	55	52	46	35
Placebo:	322	317	300	247	227	158	16	0

CNM-Au8 30mg Integrated Meta-Analysis

Integrated Meta-Analysis of CNM-Au8 30mg Long-Term Survival
RESCUE-ALS + HEALEY ALS Platform Trial

CNM-Au8 30mg Observed Survival vs. PRO-ACT Matched Placebo Controls



At Risk (n)								
Active:	82	82	81	78	74	69	62	49
Placebo:	322	317	301	322	251	163	17	0

Covariates: Onset Age, Sex, BMI, Pretreatment ALSFRS-R Slope, ALSFRS-R Total at Baseline, Vital Capacity % at Baseline, Diagnostic Delay

Data on File, Clene Nanomedicine, Inc.

Phase 2 HEALEY Platform Long-Term Survival

HEALEY ALS Platform Trial

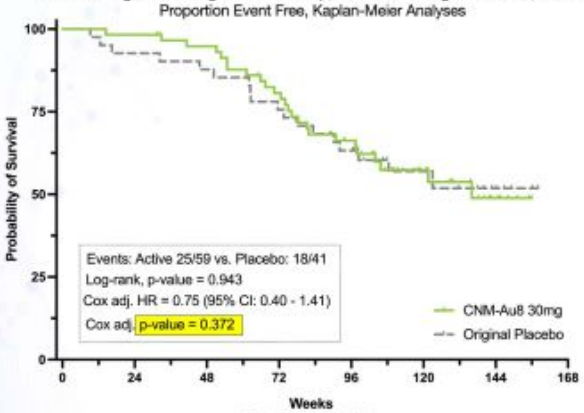
Unadjusted Survival (Delayed Start)

(~90% cross-over to active at Week 24)

Unadjusted Overall Survival | HEALEY Within Regimen

HEALEY Regimen C Long-Term Follow-Up, CNM-Au8 30 mg vs. Placebo, n=100

Proportion Event Free, Kaplan-Meier Analyses



At Risk (n)							
Active:	59	57	54	45	34	18	6
Placebo:	41	38	36	31	25	11	5

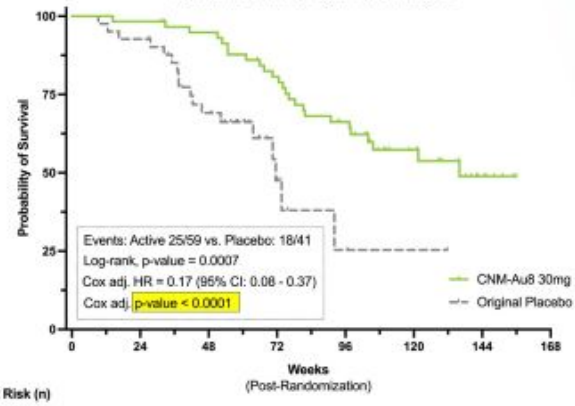
RPSFTM Cross-Over Adjusted Survival

Cross-Over Adjusted Analysis of Survival | HEALEY Within Regimen

Prespecified Rank Preserving Structural Failure Time Model (RPSFTM)

HEALEY Regimen C Long-Term Follow-Up, CNM-Au8 30 mg vs. Placebo, n=100

Proportion Event Free, Kaplan-Meier Analyses



At Risk (n)							
Active:	59	57	54	45	34	18	6
Placebo:	41	38	25	7	2	1	0

Time to all-cause mortality amongst participants originally randomized to CNM-Au8 vs. placebo. HEALEY covariates included: (i) months from symptom onset, (ii) pre-treatment ALSFRS-R slope, (iii) age, (iv) background riluzole treatment, and (iv) background edaravone treatment. RPSFTM (Rank Preserving Structural Failure Time Model) removes the estimated benefit from cross-over to active treatment in ex-placebo participants by accelerating events in cross-over participants. Source(s): Second OmniTrace update and Long-Term EAP survival status.

Data on File, Clene Nanomedicine, Inc.

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VISIONARY-MS STUDY Core Design Elements

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

- Enrolled stable relapsing remitting MS participants with chronic optic neuropathy on background DMTs
- 92% treated with background DMTs (inc 53% monoclonal antibodies, 32% oral)
- n=73 of 150 planned (~50%) study ended prematurely due to COVID-19 pandemic enrollment challenges
- Modified ITT (mITT) Analysis Population; Pre-specified statistical threshold set at p=0.10
- CNM-Au8 Open Label Extension (OLE) for original active and placebo continued for up-to-96 weeks

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

2° **Change in modified MS Functional Composite (mMSFC)**

9HPT SDMT T25FWT LCLA

Data on File, Clene Nanomedicine, Inc.

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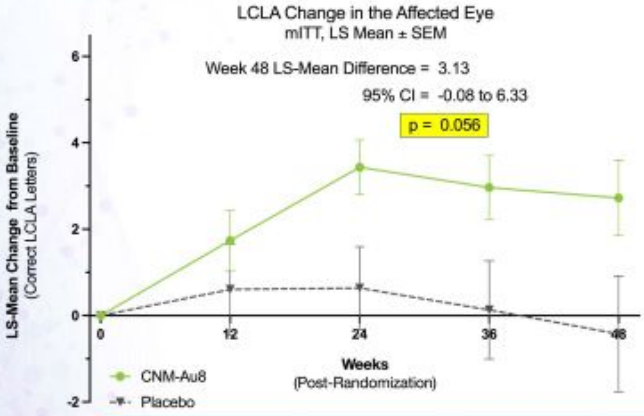
CNM-Au8 Demonstrated Vision and Global Neurological Improvement in Stable MS patients on DMTs

VISIONARY-MS STUDY

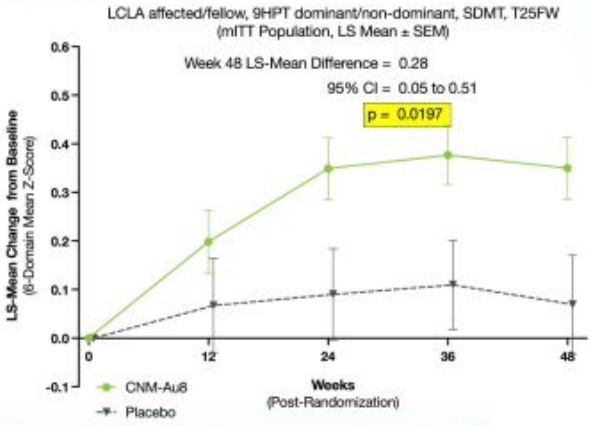
Significantly Improved Vision

Change in Low Contrast Letter Acuity (LCLA)



Global Neurological Improvement

Change in modified MS Functional Composite (mMSFC)



Global neurological clinical improvement was driven by cognition, manual dexterity, and low contrast letter acuity

Data on File, Clene Nanomedicine, Inc.

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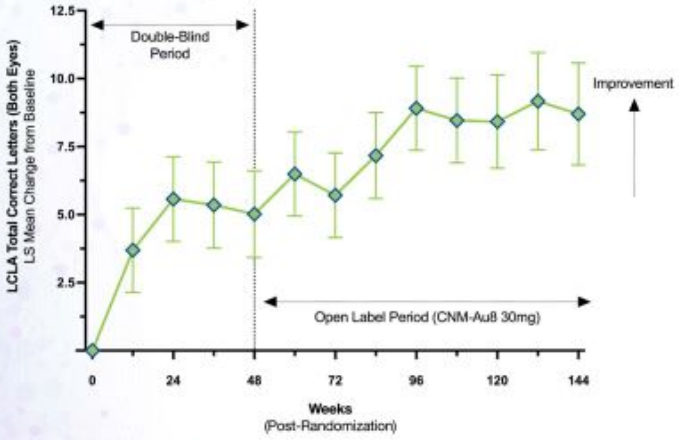
Long-Term LCLA Improvement in LTE Participants

Low Contrast Letter Acuity

VISIONARY-MS STUDY

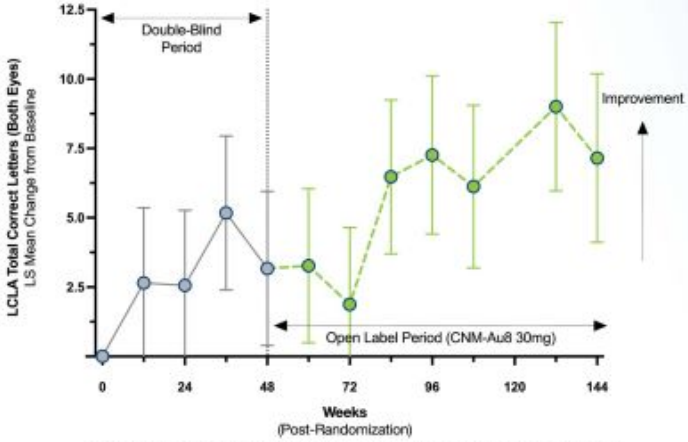
Original Active

Longitudinal LCLA | Change from Baseline (Total Correct, Both Eyes) | All Active
In LTE Participants Originally Randomized to CNM-Au8 (n=35), mITT Population
LS Mean ± SEM, Change from Baseline (Preliminary)



Original Placebo

Longitudinal LCLA | Change from Baseline (Total Correct, Both Eyes)
In LTE Participants Originally Randomized to Placebo (n=11), mITT Population
LS Mean ± SEM, Change from Baseline (Preliminary)



MMRM accounts for missing data; all visits with ≥ 60% participant values are graphed.

Data on File, Clene Nanomedicine, Inc.

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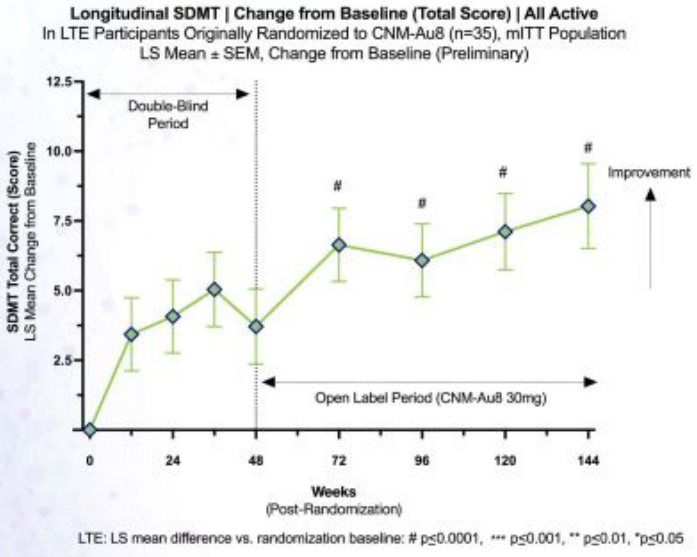
Long-Term SDMT Improvement in LTE Participants

Symbol Digit Modality Test | Working Memory & Cognition

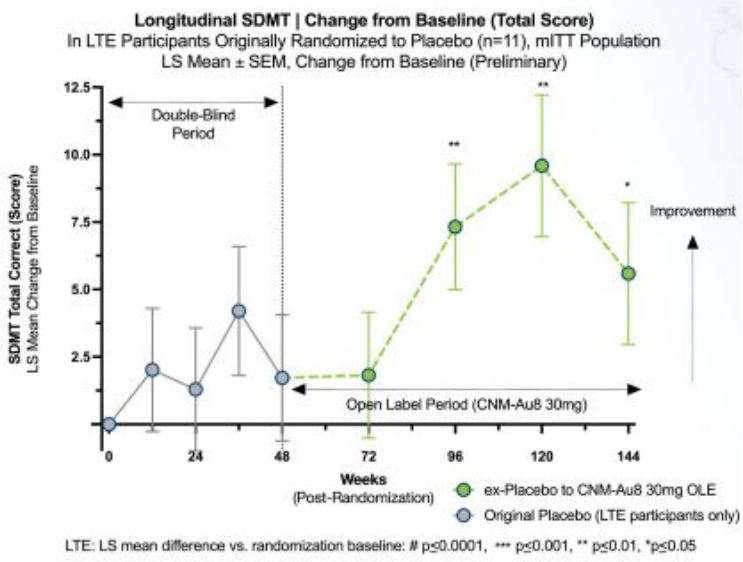
VISIONARY-MS STUDY

Original Active (CNM-Au8)



LTE: LS mean difference vs. randomization baseline: # p≤0.0001, *** p≤0.001, ** p≤0.01, *p≤0.05

Original Placebo



LTE: LS mean difference vs. randomization baseline: # p≤0.0001, *** p≤0.001, ** p≤0.01, *p≤0.05

Data on File, Clene Nanomedicine, Inc.

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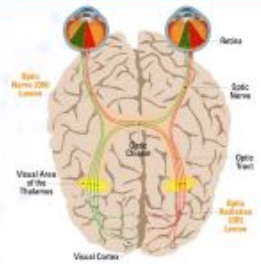
CNM-Au8 Improved Information Signal in the Visual Pathway

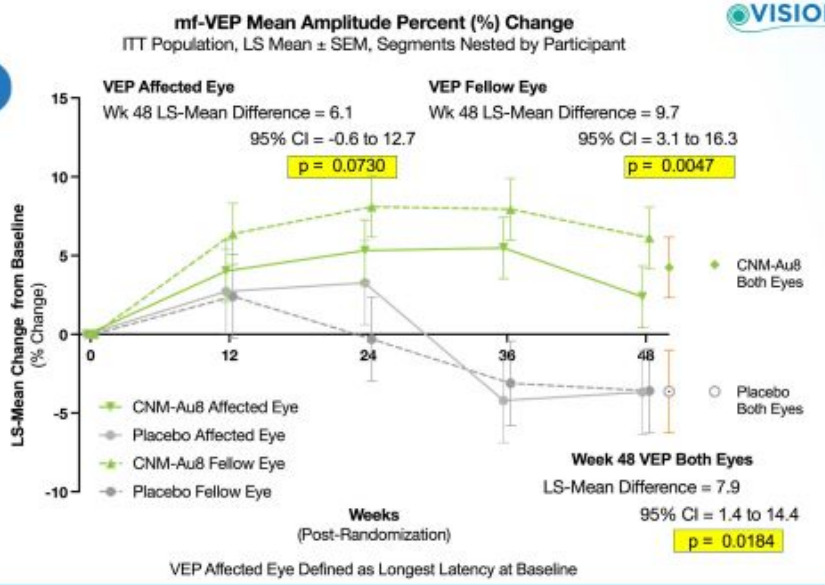
VISIONARY-MS STUDY

Visual Evoked Potentials (VEP)



Increased Amplitude (Signal Strength)

From the Eye to the Brain's Visual Cortex



Increased VEP amplitude is associated with improved axonal integrity; provides evidence that previously impaired neurons can contribute to information signaling after treatment

Data on File, Clene Nanomedicine, Inc.

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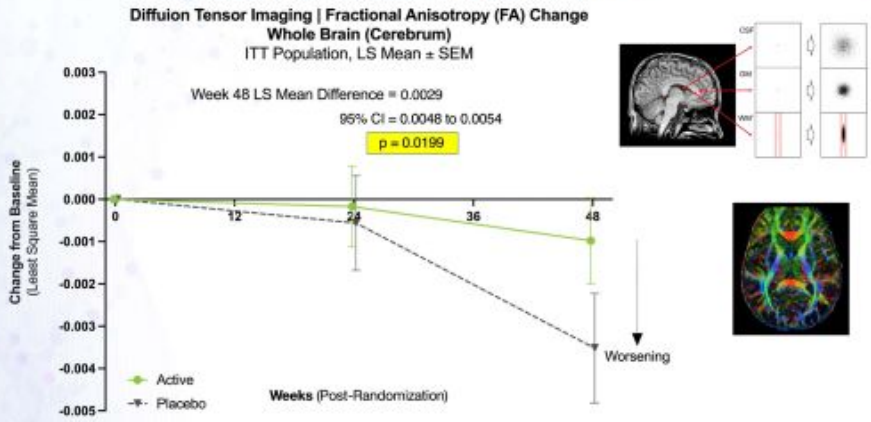
CNM-Au8 Preserved White Matter Integrity Throughout the Brain

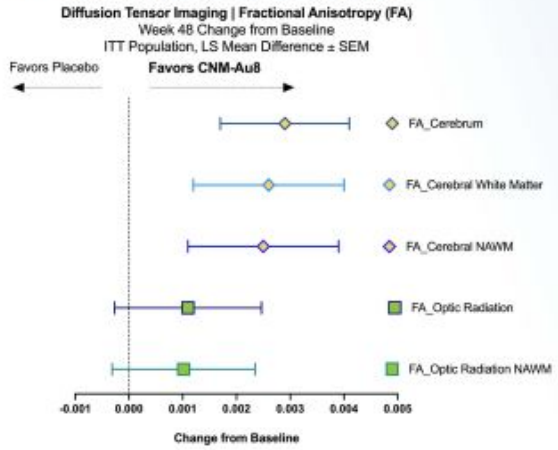
VISIONARY-MS STUDY

Advanced MRI Techniques

Preserved Whole Brain White Matter Integrity



Consistent Effect Across All Brain Regions



Preservation of white matter integrity associated with decreased cognitive and functional decline in MS patients

Data on File, Clene Nanomedicine, Inc.

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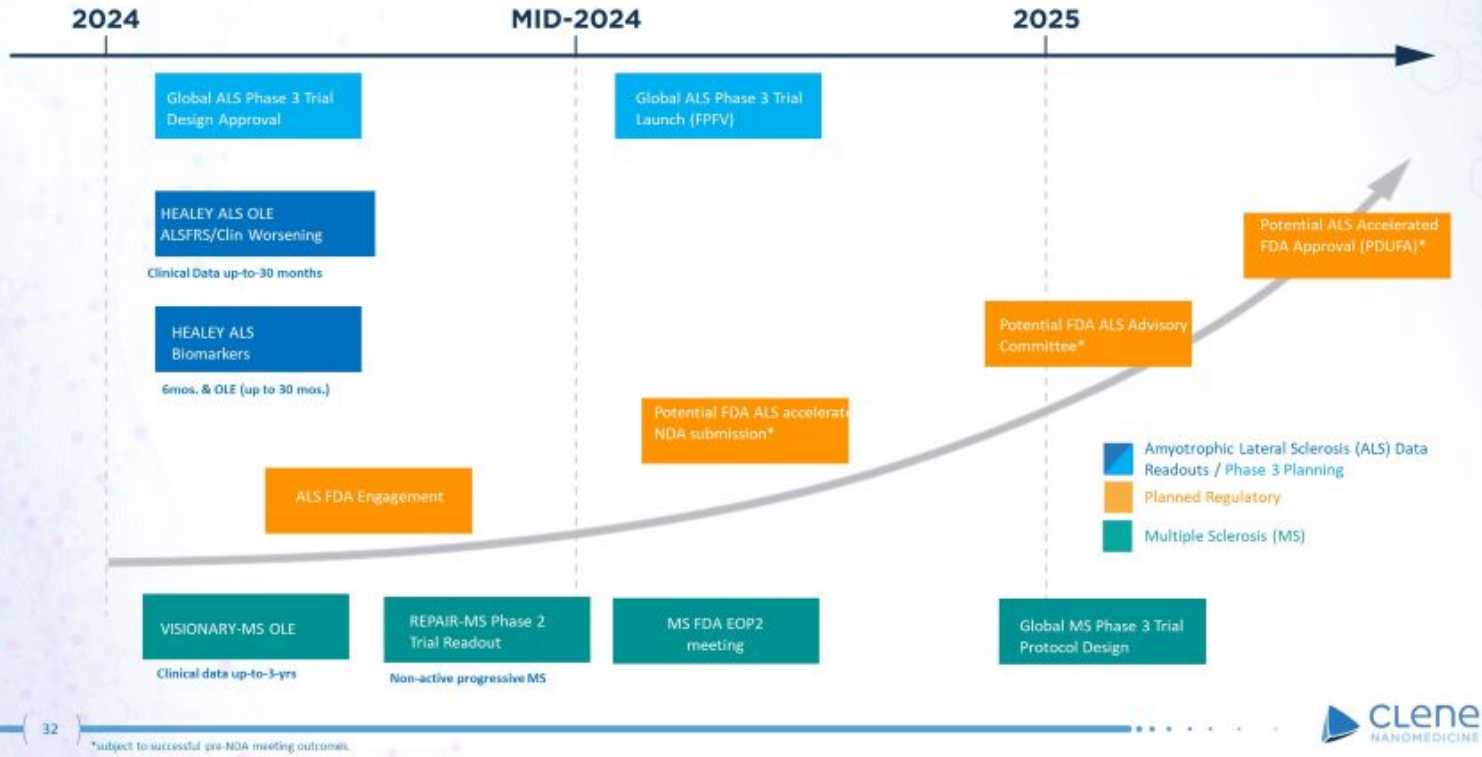
Clene | CNM-Au8 Path to Regulatory Approval



*subject to successful pre-NDA meeting outcomes

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Evidence Supports CNM-Au8 Therapeutic Potential to Treat Neurodegenerative Diseases

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

RESCUEALS

75% decreased risk of death in ALS through 168 weeks

HEALEY ALS Platform Trial

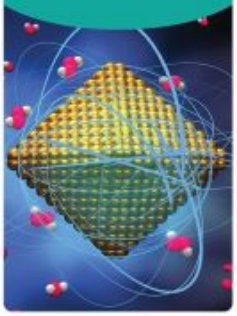
>90% decreased risk of death with 30 mg in ALS

VISIONARY-MS

Demonstrated global neurological improvement in MS patients on adjunctive DMT standard of care

>500
patient years of CNM-Au8 clinical exposure

Strong IP:
150+
patents on nanotherapeutic platform, plus trade secret protection



As of Sept 30, 2023, cash and equivalents on hand (unaudited):

$42.1M

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.

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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: 8 January 2024

Exhibit 99.2

CLENE REPORTS SIGNIFICANT IMPROVEMENT IN VISION AND COGNITION WITH CNM-Au8® TREATMENT IN VISIONARY-MS TRIAL LONG-TERM OPEN LABEL EXTENSION

- Long-term CNM-Au8 treatment demonstrated improvement of vision as measured by low contrast visual acuity (LCLA), an assessment of visual function in people living with multiple sclerosis (MS), through 35 months from randomization, $p<0.0001$
- Long-term CNM-Au8 treatment demonstrated improvement of cognition, measured by the Symbol Digit Modality Test (SDMT), through 35 months from randomization, $p<0.0001$
- Treatment was well-tolerated, without a single serious adverse event attributed to CNM-Au8 and no significant safety findings reported

SALT LAKE CITY, Jan. 8, 2024 – Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., a clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including (ALS) and multiple sclerosis (MS), today reported new CNM-Au8® results from the long-term open label extension (LTE) of the VISIONARY-MS trial in participants with stable relapsing multiple sclerosis (RMS) totaling nearly three years of follow-up.

After completion of the double-blind period, study participants were offered to continue on CNM-Au8 30mg for up to an additional 96-weeks in the LTE. Analyses are reported for the modified intent to treat (mITT) population that included all study participants with valid clinical data.

- **Progressive Vision Improvement:** The least-square mean difference (SE) at Week 144 for low contrast visual acuity (LCLA) change across both eyes versus the original randomization baseline of participants assigned to CNM-Au8 was: +8.70 letters (1.88), 95% CI: 5.0 to 12.4, $p<0.0001$.
    - The LCLA least-squared mean difference (SE) vs. the end of the double-blind period was: +4.0 letters (1.67), 95% CI: 0.72 to7.30, $p=0.017$.

Low contrast vision demonstrated sustained improvement by up to 38 letters across both eyes in individual participants, which represents multiple row gains on a greyed-out MS eye chart.

- **Progressive Cognitive Improvement:** The least-square mean difference (SE) at Week 144 for symbol digit modality test (SDMT) change versus the original randomization baseline of participants assigned to CNM-Au8 was: +8.03 (1.52), 95% CI: 5.01 to 11.0, $p<0.0001$.
    - The SDMT least-square mean difference (SE) vs. the end of the double-blind period was: +3.11 (1.3), 95% CI: 0.55 to 5.68, $p=0.018$.

Cognitive improvement, particularly working memory and information processing speed, was improved by up to 35 points in individual participants, where a three-point change in cognitive processing speed has been deemed notable in other MS studies.

Improvements demonstrated during the 48-week double-blind period were maintained in the LTE for timed 25-foot walk test (T25FWT) and nine-hole peg test (9HPT).

Placebo participants who transitioned to CNM-Au8 during the LTE showed significant improvements versus original baseline in LCLA and SDMT that were generally consistent with the increases observed in participants originally randomized to CNM-Au8. Full clinical results for the LTE will be presented at the ninth annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum taking place February 29 – March 2, 2024 in West Palm Beach, Florida.

VISIONARY-MS, designed to investigate the protection or improvement of neurological function in stable relapsing remitting MS participants with chronic optic neuropathy, was a Phase 2 multicenter, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of CNM-Au8 (15 mg or 30 mg daily) versus placebo over 48 weeks of double-blind treatment. The primary outcome was LCLA improvement. Global neurological improvement, measured by the modified Multiple Sclerosis Functional Composite (mMSFC) including vision, cognition, upper extremity function, and walking speed assessment was the secondary outcome. Nearly all participants (92%) were treated with highly effective immunomodulatory disease modifying therapies (DMTs) as background standard of care. In the double-blind portion of the trial, 73 participants were randomized, with 55 of 69 eligible (80%) participants continued in the LTE.

“These observed long-term clinical improvements for participants with stable disease, over and above background immunomodulatory disease modifying therapy, are unprecedented,” commented Professor Michael Barnett, one of the trial’s key clinical advisors. “The data show clear overall improvements in vision and cognition for participants treated for nearly three years from randomization. Importantly, these results were robust and consistent. Positive impacts on disease progression and the potential to at least partially reverse established disability, if confirmed in a larger study, represent a major therapeutic leap for patients with MS.”

“Despite tremendous advances in immunotherapies for MS, there is a significant unmet need for treatments to prevent neurodegeneration and create opportunities for clinical improvement,” added Dr. Benjamin Greenberg, M.D., Head of Medicine at Clene. “Years have been spent investigating neuroprotective therapies for multiple sclerosis and other neurodegenerative diseases. These data continue to build a strong case in favor of pursuing CNM-Au8 in upcoming Phase 3 studies. Clinically significant improvement is rarely seen in MS patients and this trial provides evidence of CNM-Au8’s potential to improve function in this population. Clene is currently reviewing these data with prospective pharmaceutical partners interested in MS.”

About Clene

Clene Inc., (Nasdaq: CLNN) (along with its subsidiaries, “Clene”) and its wholly owned subsidiary Clene Nanomedicine Inc., is a late clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis, Parkinson’s disease and multiple sclerosis. CNM-Au8® is an investigational first-in-class therapy that improves central nervous system cells’ survival and function via a mechanism that targets mitochondrial function and the NAD pathway while reducing oxidative stress. CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc. The company is based in Salt Lake City, Utah, with R&D and manufacturing operations in Maryland. For more information, please visit www.clene.com or follow us on X (formerly Twitter) and LinkedIn.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, which are intended to be covered by the “safe harbor” provisions created by those laws. Clene’s forward-looking statements include, but are not limited to, statements regarding our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would,” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements represent our views as of the date of this press release and involve a number of judgments, risks and uncertainties. We anticipate that subsequent events and developments will cause our views to change. We undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include our ability to demonstrate the efficacy and safety of our drug candidates; the clinical results for our drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; our ability to achieve commercial success for our drug candidates, if approved; our limited operating history and our ability to obtain additional funding for operations and to complete the development and commercialization of our drug candidates; and other risks and uncertainties set forth in “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements. All information in this press release is as of the date of this press release. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this press release.

Media Contact
Ignacio Guerrero-Ros, Ph.D., or David Schull
Russo Partners, LLC
Ignacio.guerrero-ros@russopartnersllc.com
David.schull@russopartnersllc.com
(858) 717-2310

Investor Contact
Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com
617-283-2856