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 21, 2023

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 releases discussed under Item 8.01 in this Current Report on Form 8-K, on December 21, 2023, 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 December 21, 2023, the Company issued a press release reporting a reduction in biomarker plasma neurofilament light ("NfL") levels and improved survival with CNM-Au8 treatment from the HEALEY ALS Platform Trial long-term open label extension, and a second press release providing an update on the Company's amyotrophic lateral sclerosis ("ALS") clinical development meeting with the U.S. Food and Drug Administration ("FDA"). Copies of the press releases are filed as Exhibit 99.2 and Exhibit 99.3, respectively, to this Current Report on Form 8-K and are 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 December 21, 2023, reporting a reduction in biomarker plasma neurofilament light levels and improved survival with CNM-Au8 treatment from HEALEY ALS Platform Trial long-term open label extension.
99.3	Press Release, dated December 21, 2023, providing an update on ALS clinical development meeting with FDA.
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 21, 2023

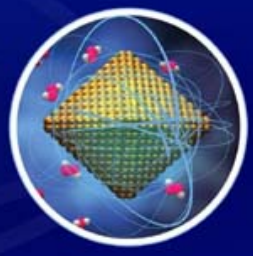
By: /s/ Robert Etherington
Robert Etherington
President and Chief Executive Officer


clene.com
clene
NASDAQ: CLNN

Forward Looking Statements

This presentation contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, which are intended to be covered by the "safe harbor" provisions created by those laws. Clene's forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements represent our views as of the date of this presentation and involve a number of judgments, risks and uncertainties. We anticipate that subsequent events and developments will cause our views to change. We undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include our substantial dependence on the successful commercialization of our drug candidates, if approved, in the future; our inability to maintain the listing of our common stock on Nasdaq; our significant net losses and net operating cash outflows; our ability to demonstrate the efficacy and safety of our drug candidates; the clinical results for our drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; our ability to achieve commercial success for our drug candidates, if approved; our ability to obtain and maintain protection of intellectual property for our technology and drugs; our reliance on third parties to conduct drug development, manufacturing and other services; our limited operating history and our ability to obtain additional funding for operations and to complete the licensing or development and commercialization of our drug candidates; the impact of the COVID-19 pandemic on our clinical development, commercial and other operations; changes in applicable laws or regulations; the effects of inflation; the effects of staffing and materials shortages; the possibility that we may be adversely affected by other economic, business, and/or competitive factors; and other risks and uncertainties set forth in "Risk Factors" in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements. All information in this presentation is as of the date of this presentation. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this presentation.

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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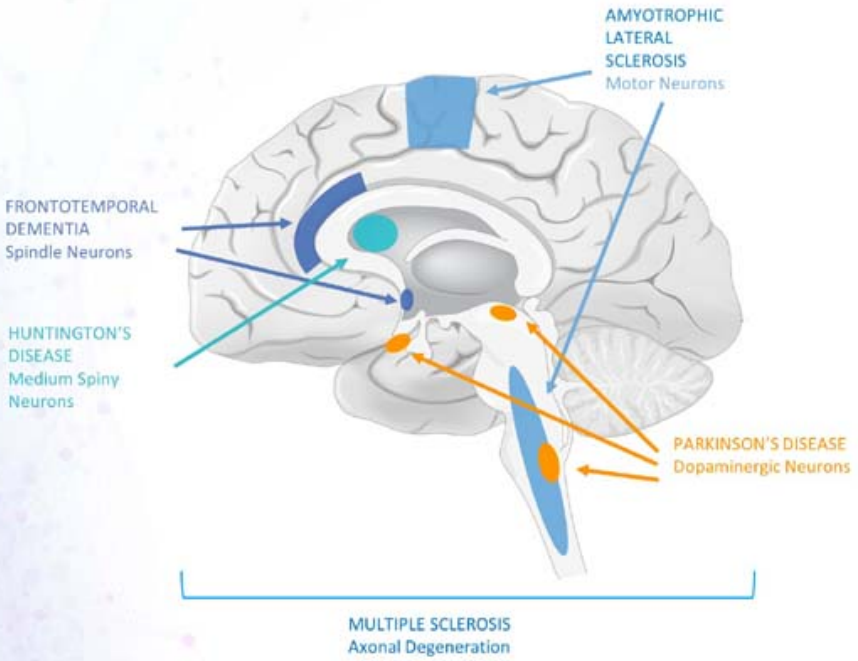
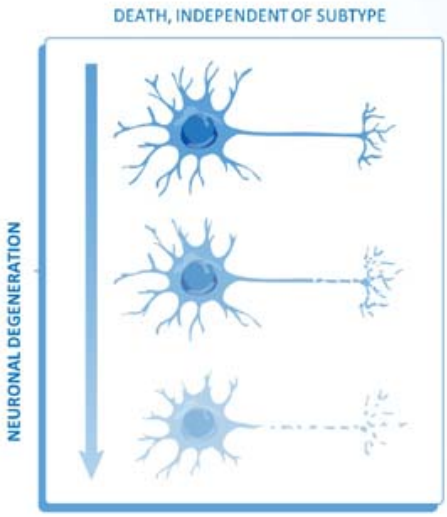
All Neurodegenerative Diseases Involve Neuronal Death





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

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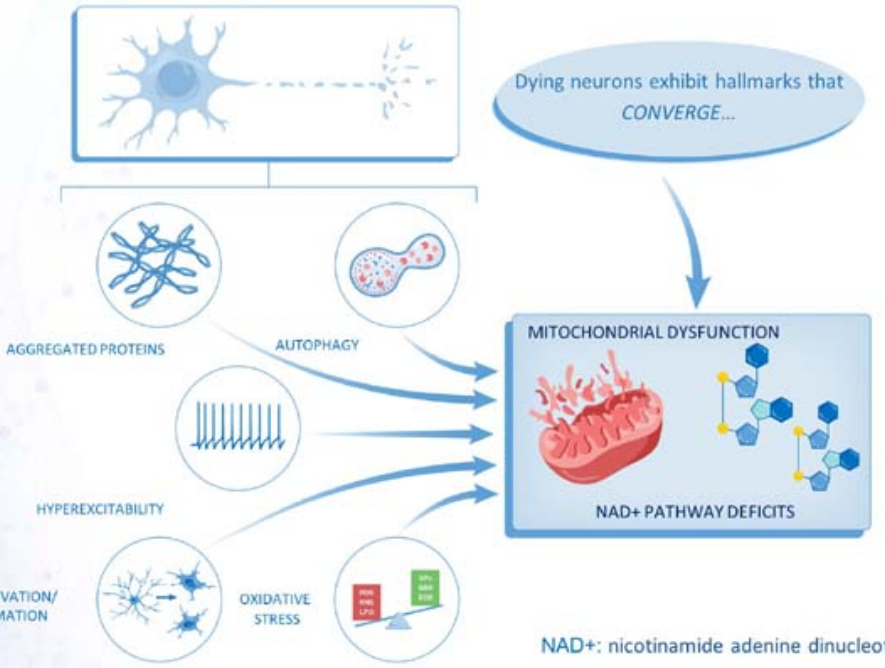
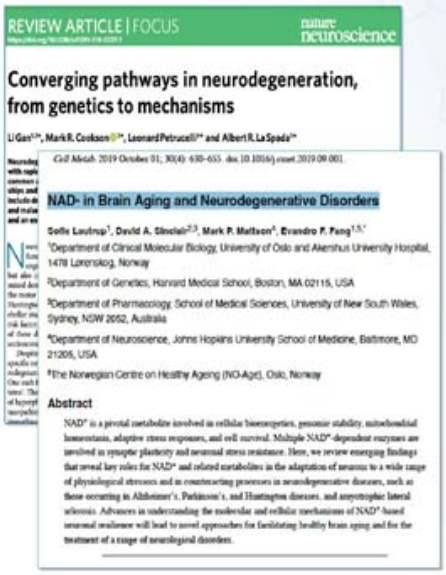
Hallmarks of Neuronal Death Converge on ***Mitochondrial Dysfunction*** and ***NAD+ Pathway Deficits***



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

Sofie 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

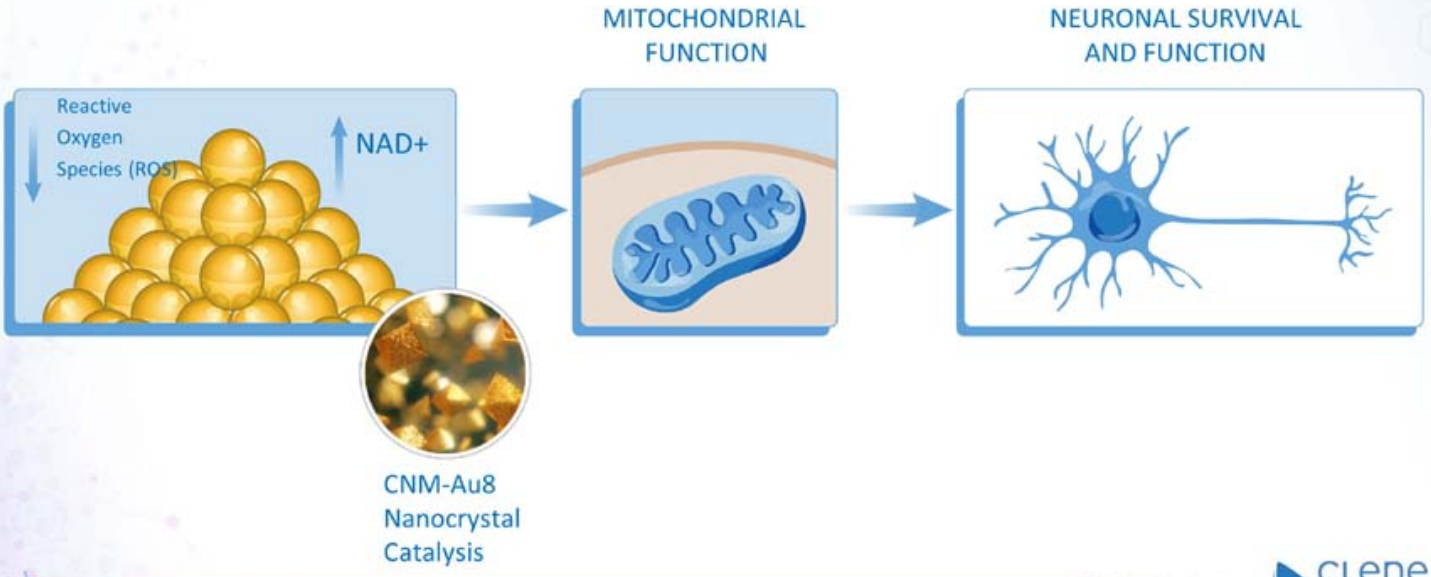
Abstract

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.

CLene NANOMEDICINE

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.

CLene NANOMEDICINE

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

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)

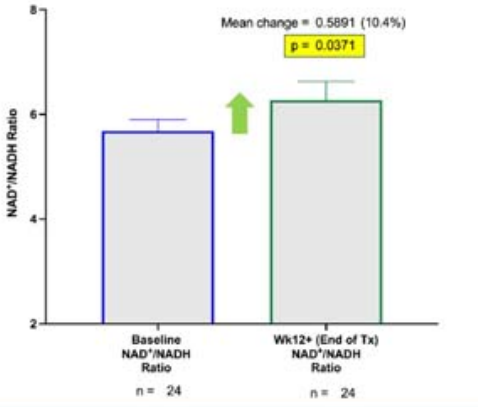
RepairPD
Early Parkinson's Disease

RepairMS
Stable Relapsing MS

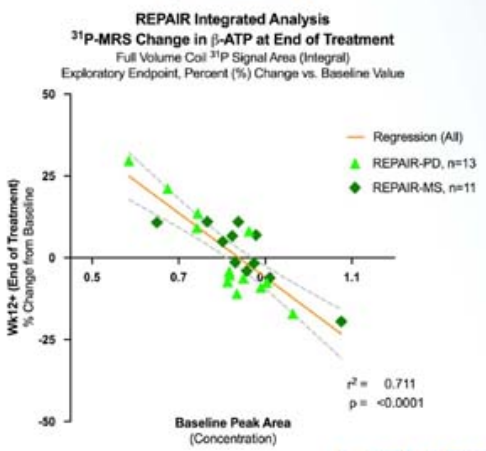
RepairMS
Non-Active Progressive MS
(Ongoing)

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.

CLene NANOMEDICINE

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 ↓	

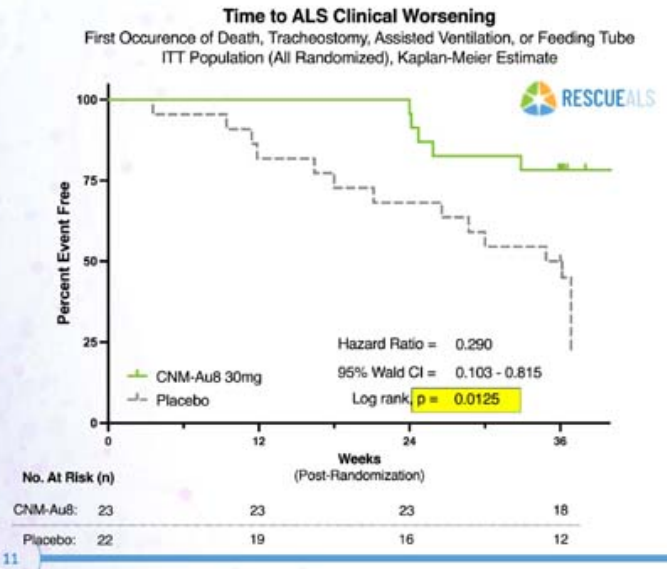
Consistent Evidence for CNM-Au8 30mg Dose Across Broad ALS Patient Population

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

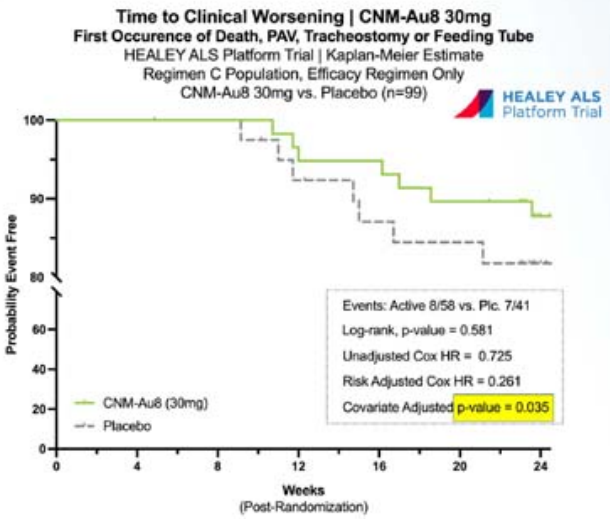
CNM-Au8 | Clinical Worsening Concordant in Two Phase 2 Trials

Evidence for Decreased Clinical Worsening Events Across Two Phase 2 Studies

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



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

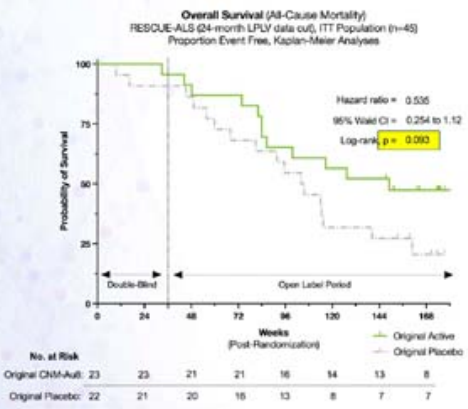
RESCUEALS

Up to 75% decreased risk of death through 168 weeks

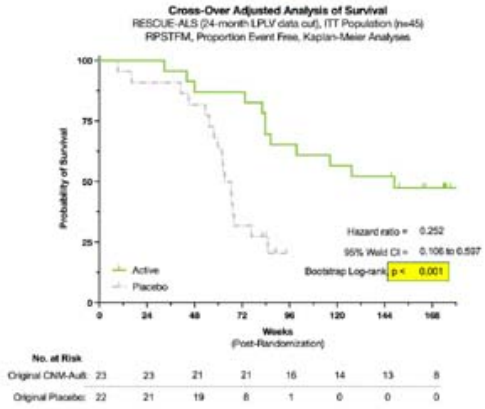
HEALEY ALS Platform Trial

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

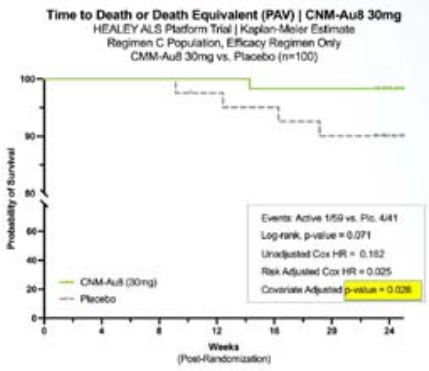
Unadjusted Survival



Cross-Over Adjusted Survival



Survival During Blinded Period



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

Data on File, Clene Nanomedicine, Inc.

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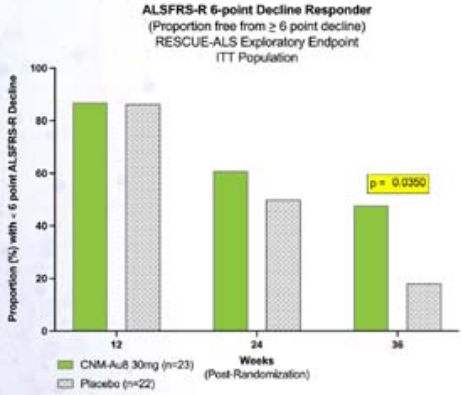
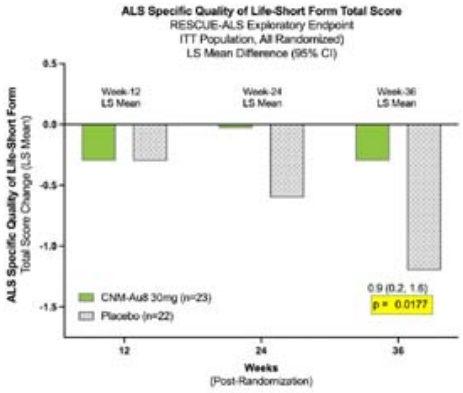
Improved Exploratory Endpoints: Patient Function, QOL, and Slowed Time to ALS Clinical Worsening

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

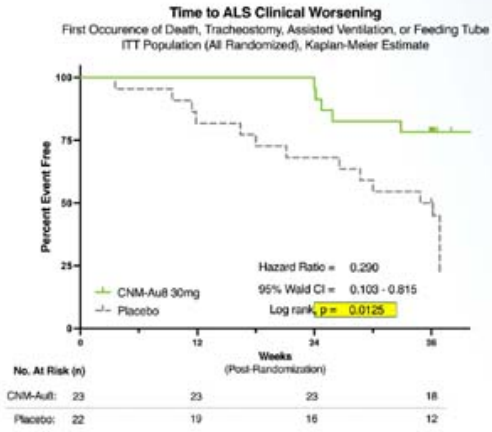
Proportion with <6 point decline



ALS Specific QOL



ALS Clinical Worsening *



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

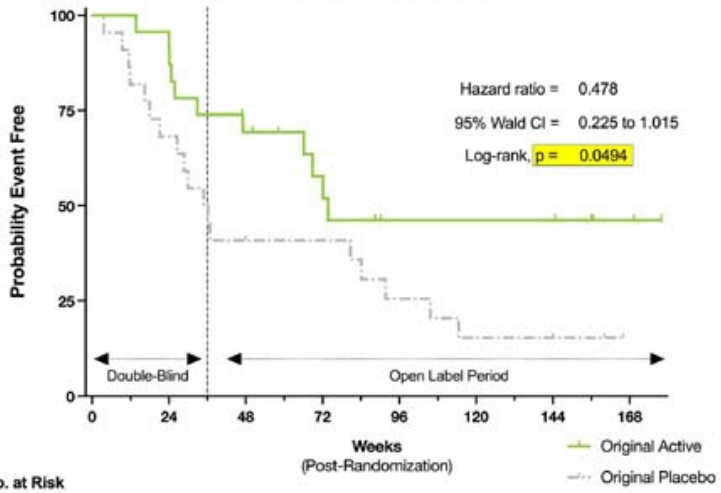
Vucic et al. EClinicalMedicine. 2023 Jun 8;60:102036.

* 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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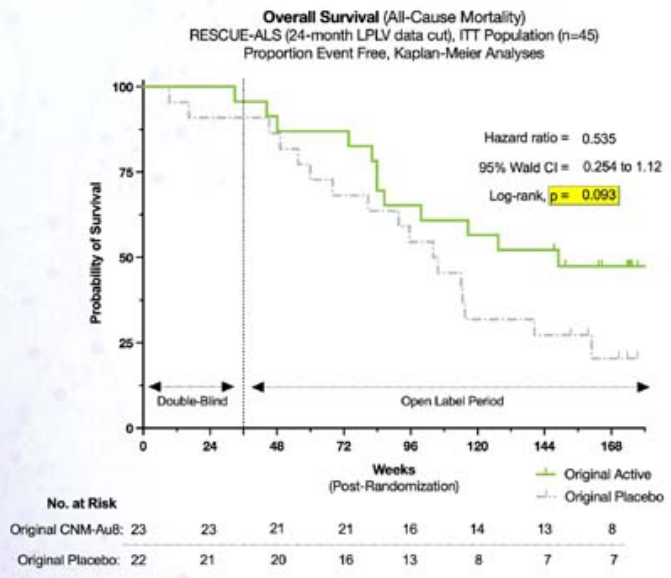
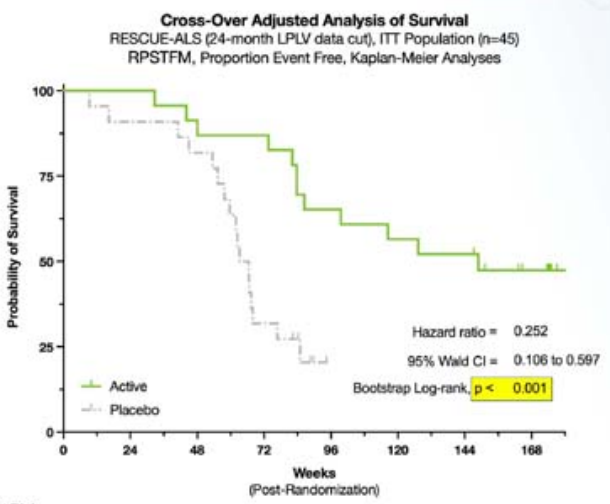
RESCUEALS Up to 19.3 Month Survival Benefit vs. Original Placebo

Unadjusted Survival Difference: 10.1 Months



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



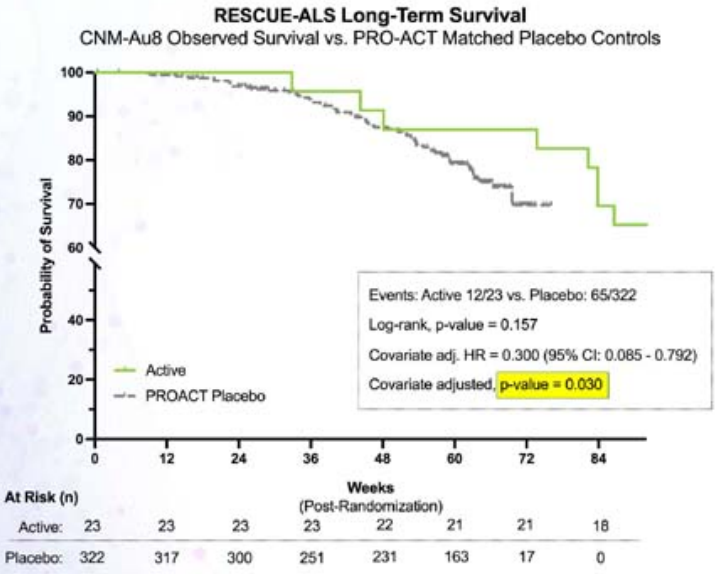
No. at Risk								
Original CNM-Au8:	23	23	21	21	16	14	13	8
Original Placebo:	22	21	19	8	1	0	0	0

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.

CLENE NANOMEDICINE

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.

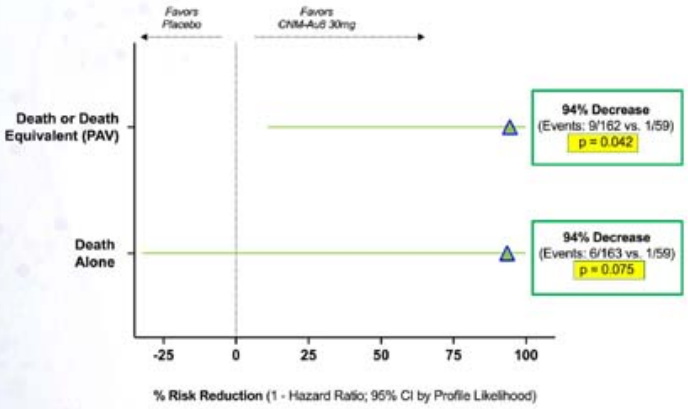
CLene NANOMEDICINE

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

HEALEY ALS Platform Trial

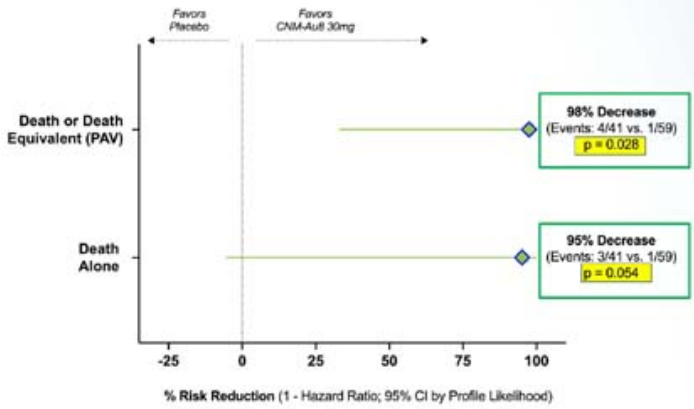
Shared Placebo Across Regimens

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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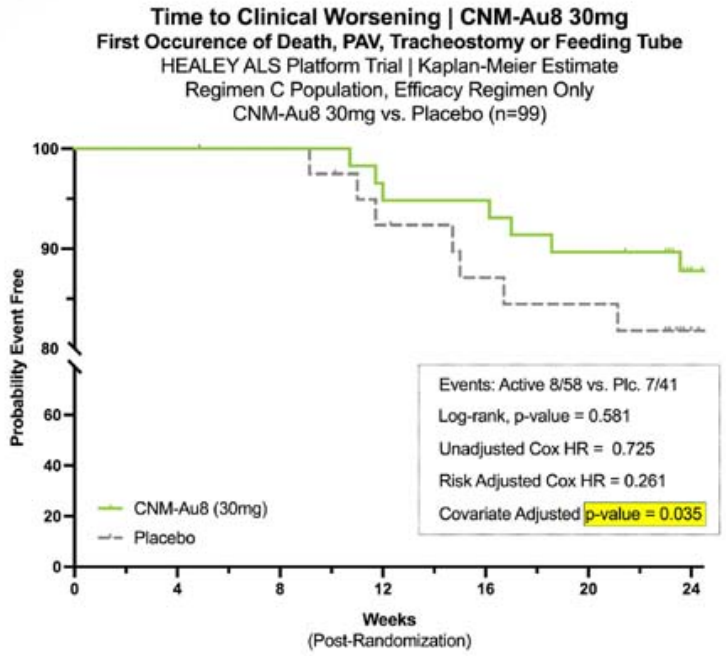
Delayed Time to ALS Clinical Worsening

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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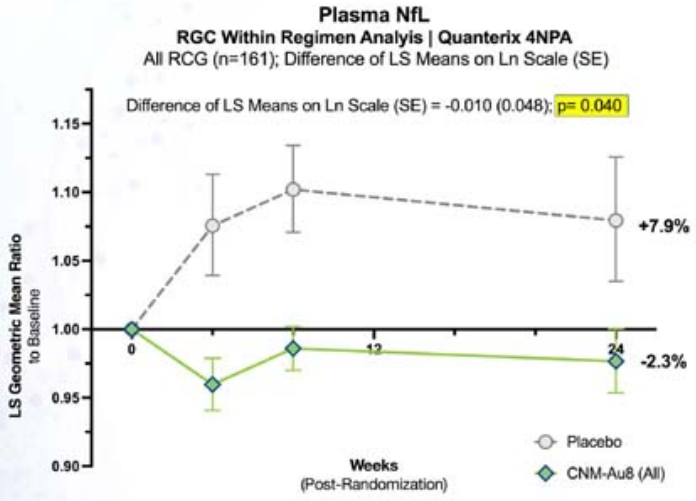
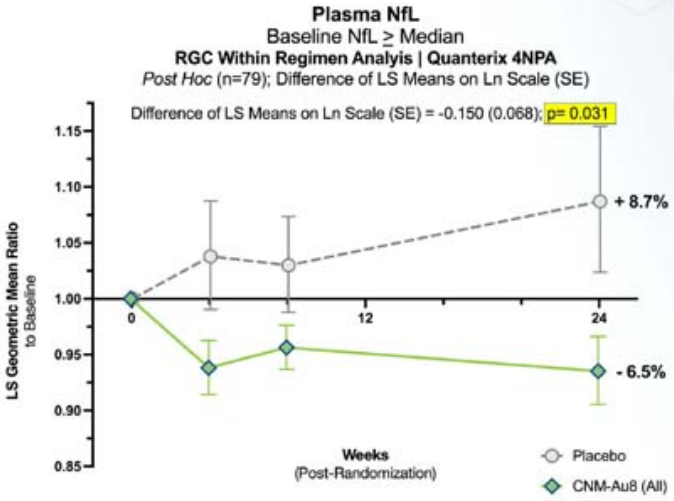
Significant Biomarker Plasma NfL Difference

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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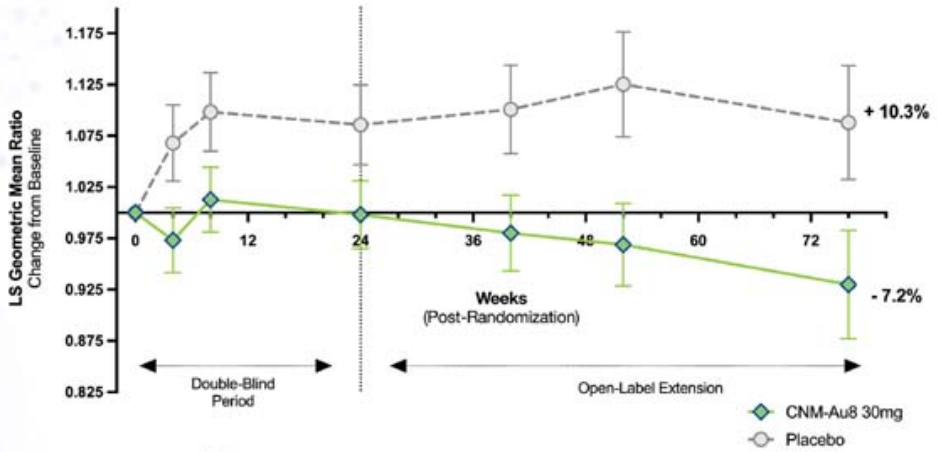
Continued Long Term Plasma NfL Decline in the OLE

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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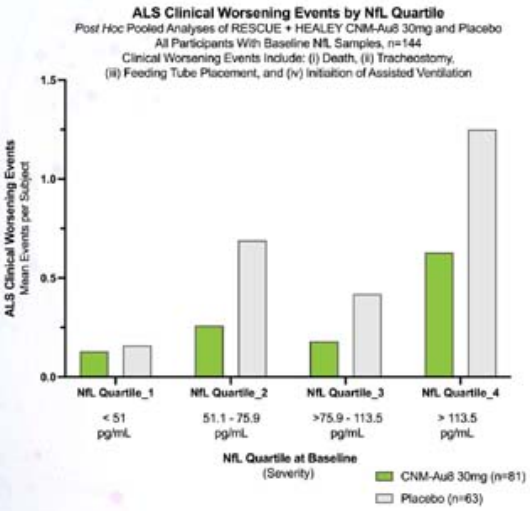
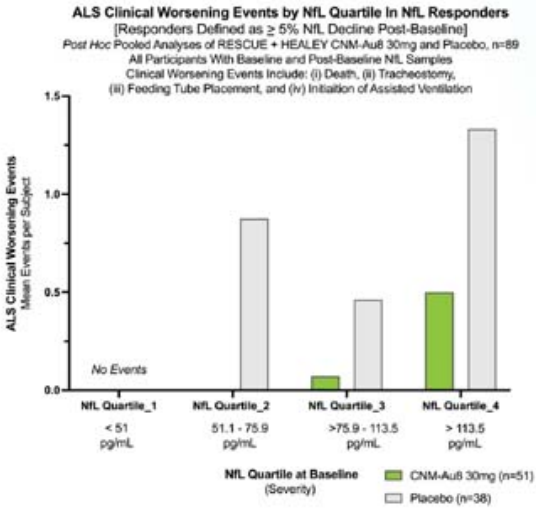
Validation of NfL Association with Clinical Outcomes

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, Clene Nanomedicine, Inc.

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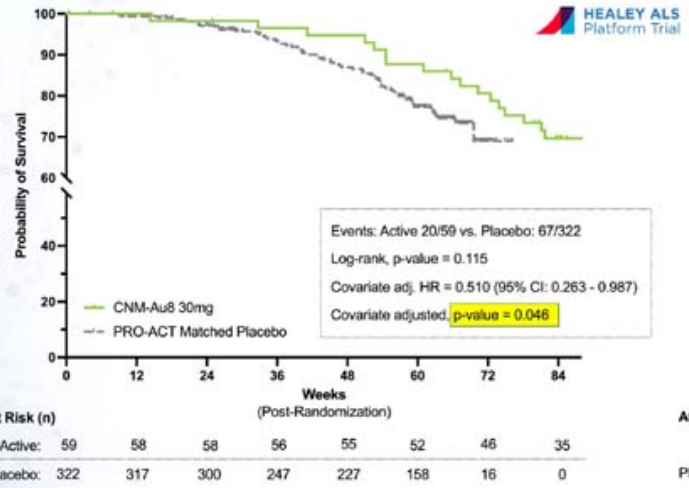
Long-Term Survival | Propensity Matched Placebo

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



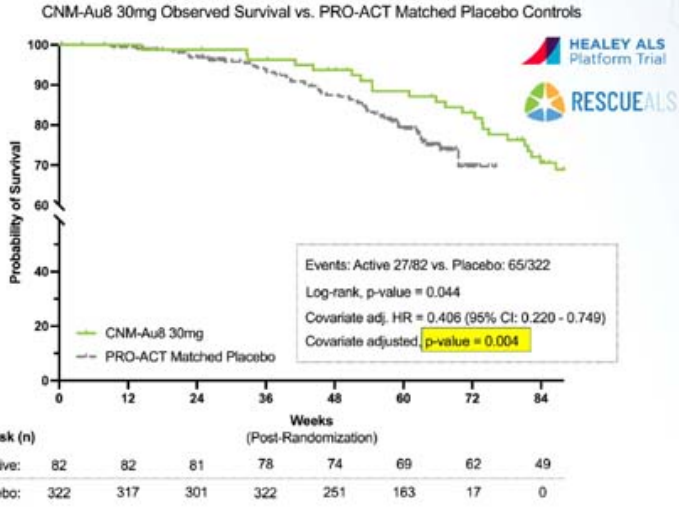
At Risk (n)								
Active:	59	58	58	56	55	52	46	35
Placebo:	322	317	300	247	227	158	16	0

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.

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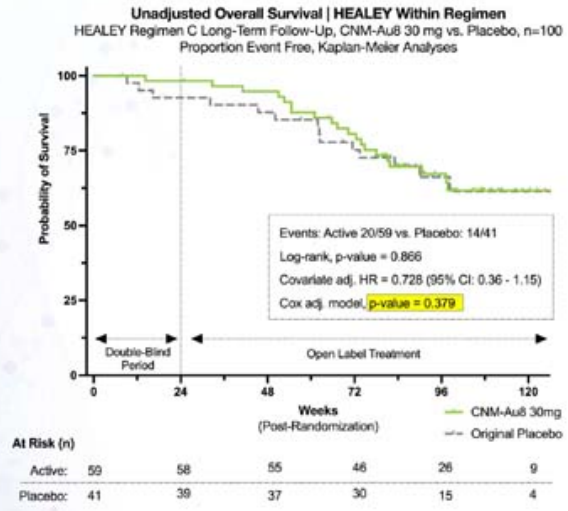
Phase 2 HEALEY Platform Long-Term Survival

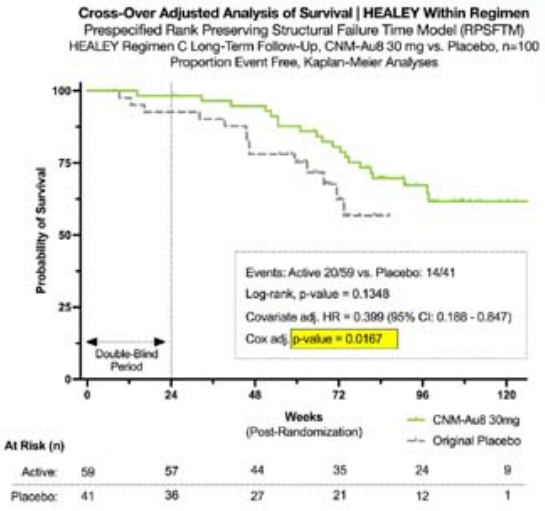
HEALEY ALS Platform Trial

Unadjusted Survival (Delayed Start)

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



RPSFTM Cross-Over Adjusted Survival



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) subtracts the estimated benefit from cross-over to active treatment in ex-placebo participants.

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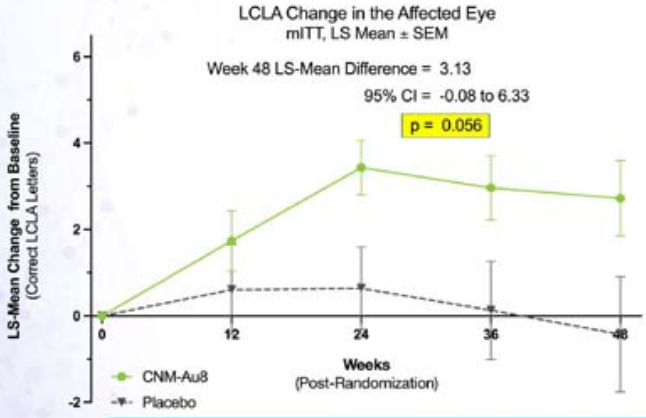
CNM-Au8 Demonstrated Vision and Global Neurological Improvement in Stable MS patients on DMTs

VISIONARY-MS STUDY

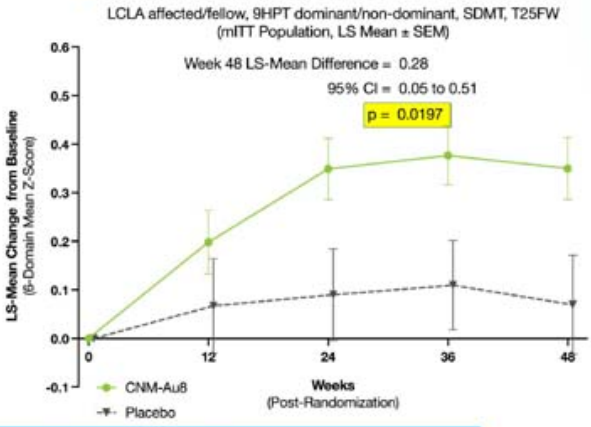
Significantly Improved Vision

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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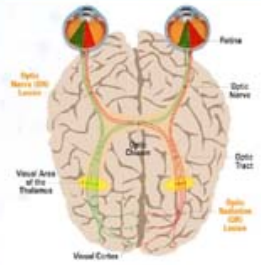
CNM-Au8 Improved Information Signal in the Visual Pathway

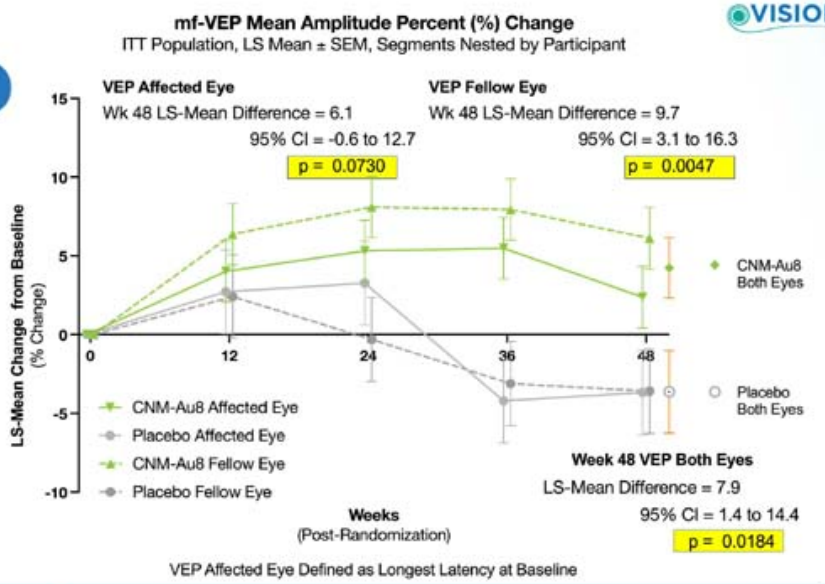
VISIONARY-MS STUDY

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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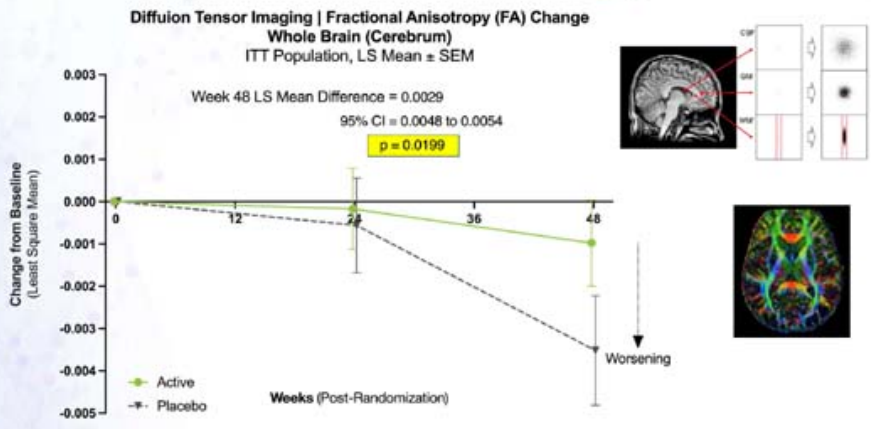
CNM-Au8 Preserved White Matter Integrity Throughout the Brain

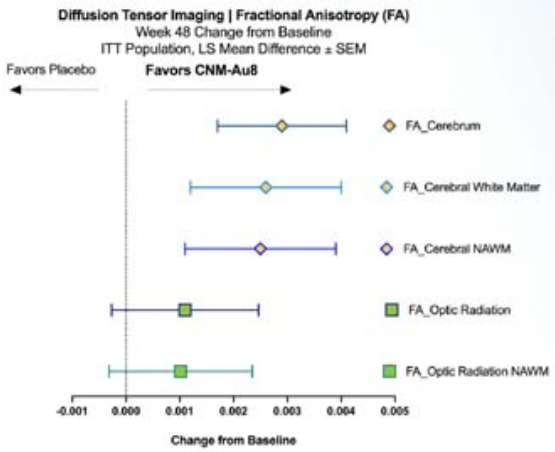
VISIONARY-MS STUDY

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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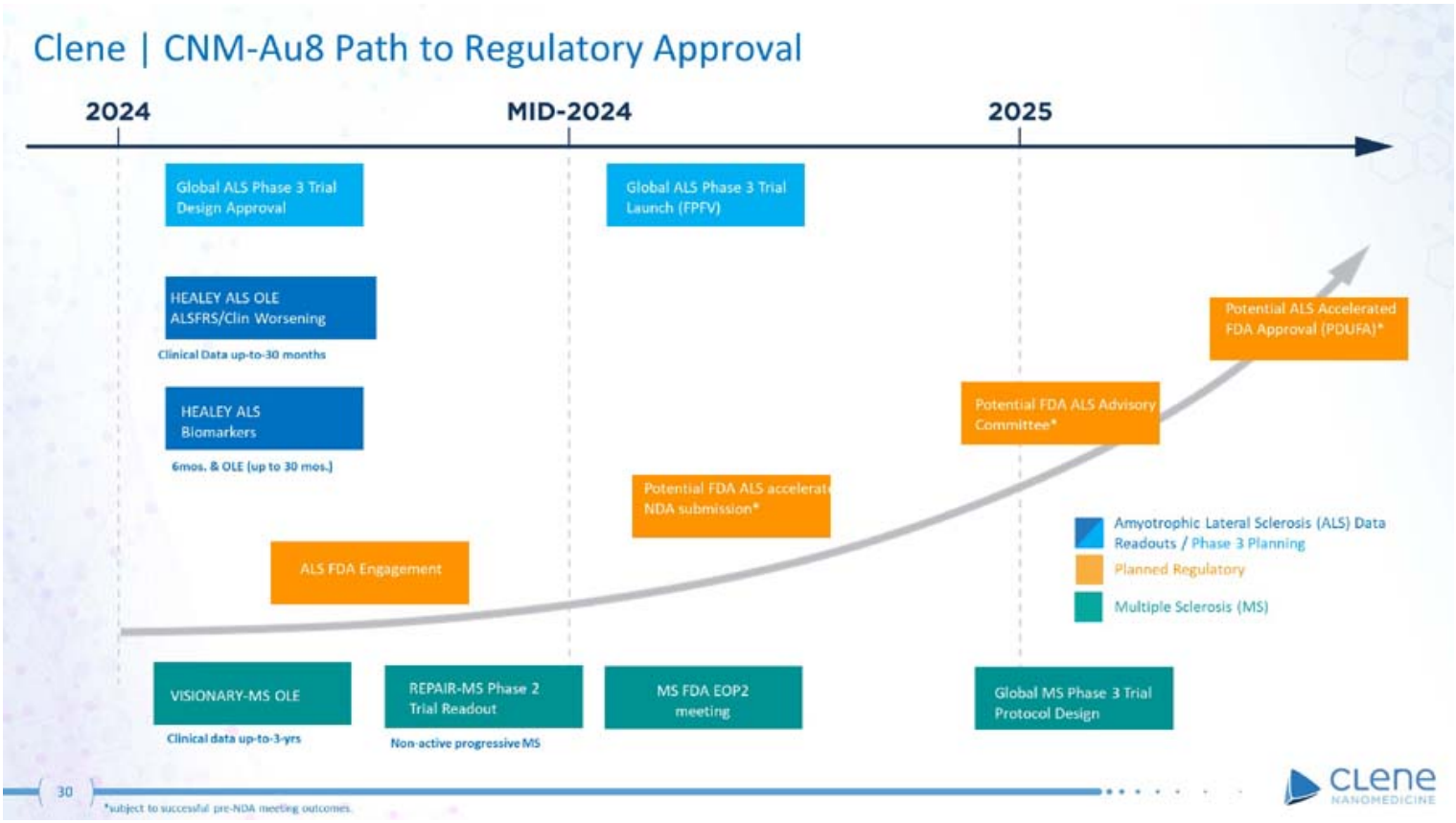

Clene | CNM-Au8 Path to Regulatory Approval
2024
MID-2024
2025
Global ALS Phase 3 Trial Design Approval
Global ALS Phase 3 Trial Launch (FPFV)
HEALEY ALS OLE ALSFRS/Clin Worsening
Clinical Data up-to-30 months
HEALEY ALS Biomarkers
6mos. & OLE (up to 30 mos.)
Potential ALS Accelerated FDA Approval (PDUFA)*
Potential FDA ALS Advisory Committee*
Potential FDA ALS accelerate NDA submission*
ALS FDA Engagement
Amyotrophic Lateral Sclerosis (ALS) Data Readouts / Phase 3 Planning
Planned Regulatory
Multiple Sclerosis (MS)
VISIONARY-MS OLE
Clinical data up-to-3-yrs
REPAIR-MS Phase 2 Trial Readout
Non-active progressive MS
MS FDA EOP2 meeting
Global MS Phase 3 Trial Protocol Design
30
*subject to successful pre-NDA meeting outcomes.
clene
NANOMEDICINE

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

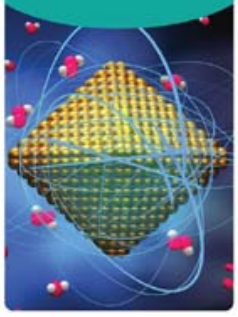
>90% decreased risk of death with 30 mg in ALS

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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Version: 21 December-2023

Exhibit 99.2

CLENE REPORTS REDUCTION IN BIOMARKER PLASMA NEUROFILAMENT LIGHT (NfL) LEVELS AND IMPROVED SURVIVAL WITH CNM-Au8® TREATMENT FROM HEALEY ALS PLATFORM TRIAL LONG-TERM OPEN LABEL EXTENSION

- *CNM-Au8 30mg treatment demonstrated significantly reduced plasma neurofilament light chain (NfL) levels at 76 weeks relative to placebo (18 months from randomization, p=0.023)*
- *60% decreased risk of long-term all-cause mortality (>18 months, p=0.0167) in participants originally randomized to CNM-Au8 30mg compared to those originally randomized to placebo using the rank-preserving structural failure time model (RPSFTM)*
- *CNM-Au8 30mg had greater overall treatment effect in delaying the time to morbidity events in the highest risk participants based on baseline NfL levels*
- *NfL biomarker and survival data from the long-term open label extension reinforces evidence of a treatment effect consistent with time to event results observed in the original double-blind Phase 2 period*

SALT LAKE CITY, Dec. 21, 2023 – 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 amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today reported new data from the 12-month long-term open label extension (OLE) of the CNM-Au8® treatment arm in the HEALEY ALS Platform Trial.

Long-Term Plasma NfL Biomarker Findings from Regimen C (CNM-Au8) in the HEALEY ALS Platform Trial Open Label Extension (OLE)

Plasma neurofilament light chain (NfL), a blood-based biomarker associated with neurodegeneration, declined by 16% (95% CI: 2% to 28%) from baseline to 76 weeks of treatment in the HEALEY ALS Platform Trial Open Label Extension (OLE) in participants randomized to CNM-Au8 30 mg relative to participants initially randomized to placebo (p=0.023). CNM-Au8 was associated with a 10% relative reduction in plasma NfL over the 24-week double-blind treatment period of the HEALEY ALS Platform Trial (p=0.040). This effect on NfL appears durable over the long-term follow-up period.

NfL, a key biomarker of neurodegeneration, is released from neurons following axonal injury, especially in people living with ALS, where higher levels of NfL have been found to predict more rapid decline in clinical function and increased mortality risk. Biomarkers such as NfL that are considered reasonably likely to serve as surrogates of effects on clinical endpoints have recently been used to support an FDA approval of a drug for the treatment of ALS.

The *post hoc* NfL results are based on analyses of plasma NfL collected from participants in the HEALEY OLE who were treated with CNM-Au8 for up to 76 weeks compared to participants treated with placebo for 24 weeks prior to crossing over to active treatment.

CNM-Au8 30mg treatment reduced plasma NfL levels compared to baseline: Mixed Model with Repeat Measures (MMRM), Least Squared Means on a Natural Log (Ln) Scale for the 76-week change from baseline of plasma NfL: CNM-Au8 = -0.075 (SE: 0.053); placebo = +0.098 (SE: 0.056); CNM-Au8 30mg vs. original placebo difference of LS Means on a Ln Scale = -0.173 (SE: 0.076), p=0.023. Combined analyses of both CNM-Au8 doses (30mg and 60mg) also demonstrated nominally significant reductions in plasma NfL, CNM-Au8 vs. placebo difference of LS Means on a Ln Scale = -0.144 (SE: 0.066), p=0.029.

Participants were treated with CNM-Au8 in the OLE for as long as 2.6 years from original randomization, providing long-term data on treatment effects in people living with ALS.

James D. Berry MD, Associate Professor of Neurology, Chief of the Motor Neuron Disorder Division and Director of the Neurological Clinical Research Institute at Massachusetts General Hospital commented, "As consensus is building that neurofilament is an important biomarker reasonably likely to predict clinical benefit, it is important to see NfL continue to decrease during long-term follow-up, and correlate with time to event clinical outcomes in the Clene regimen of the double-blind and OLE portions of the HEALEY ALS Platform Trial."

Long-Term Survival Improvement from Regimen C (CNM-Au8) in the HEALEY ALS Platform Trial Open Label Extension (OLE)

Long-term survival analyses included the prespecified rank-preserving structural failure time model (RPSFTM) to account for the effects of CNM-Au8 in participants randomized to placebo who crossed-over to treatment with CNM-Au8. Under an assumption of a constant common treatment effect from CNM-Au8, treatment with CNM-Au8 demonstrated a 60% decreased risk of long-term all-cause mortality in participants originally randomized to treatment with CNM-Au8 compared to those originally randomized to placebo, after adjusting for the estimated benefit received after switching to CNM-Au8 (Cox HR= 0.40, 95% CI: 0.19 to 0.85; p-value= 0.017).

The RPSFTM analysis estimates the survival gained by receiving active treatment using the data from all study participants and then subtracting the estimated benefit from ex-placebo participants switched to CNM-Au8 during the OLE to provide a comparison of CNM-Au8 versus placebo across the entire study period.

Merit Cudkowicz, M.D., Chair Neurology Department, Director, Sean M Healey & AMG Center for ALS at Mass General Hospital, Julianne Dorn Professor of Neurology Harvard Medical School, and the Principal Investigator of the HEALEY ALS Platform Trial, said, "These long-term results provide additional promising evidence that CNM-Au8 may offer more time to people living with ALS. The survival analyses using RPSFTM is a well-recognized method that has been used to estimate cross-over effects in another recent ALS trial, as well as oncology and other rare diseases. Additional analyses of the open label data are underway."

Post-hoc Analysis Validates Association of NfL levels with Clinical Morbidity Outcomes and the Effects of CNM-Au8 in High Risk ALS Patients

To investigate the role of NfL in the incidence of ALS clinical worsening events, the pooled population of the HEALEY ALS Platform and the RESCUE-ALS trial were stratified by baseline plasma NfL levels by quartile (<51 pg/mL, 51 – 76 pg/mL, >76 – 114 pg/mL, and >114 pg/mL). The average number of ALS clinical worsening events including death, tracheostomy, feeding tube placement, and initiation of assisted ventilation were calculated for each treatment group (CNM-Au8 30 mg vs. placebo) during the double-blind periods. Results of these analyses suggested a beneficial effects of CNM-Au8 in delaying occurrence of clinical worsening events in the highest risk NfL quartiles.

In participants with the highest baseline plasma NfL levels (> median), the apparent benefit of CNM-Au8 30 mg was enhanced (Cox HR: 0.25, 95% CI: 0.11 to 0.61; p-value= 0.003). In the same post hoc analyses, nominally significant reduced rates of time to death or permanently assisted ventilation (PAV), and all-cause mortality, were also observed.

Benjamin Greenberg, M.D., Head of Medical at Clene, said, "The clinical correlation seen with plasma neurofilament change, as well as long-term survival using RPSFTM, provides further independent evidence to strongly support CNM-Au8 as a potential treatment for ALS. The concordance of these long-term biomarker and survival results with previously reported clinical outcomes from two Phase 2 ALS trials is encouraging. Additional biomarker and clinical data from the HEALEY ALS Platform Trial open-label extension periods have been collected and are undergoing analysis for expected results to be reported in the first quarter of 2024."

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.

About Healey ALS Platform Trial
The HEALEY ALS Platform Trial is a perpetual multi-center, randomized, double-blind, placebo-controlled Phase 2 program designed to evaluate the efficacy and safety of multiple investigational products in people living with ALS. This landmark platform trial tests multiple treatments utilizing a shared placebo group. 161 participants were randomized to 30 mg CNM-Au8, 60 mg CNM-Au8, or placebo as adjunct to standard of care for a 24-week treatment period. Active drug was offered to all participants who were eligible and elected to continue into the Open Label Extension (OLE). The primary outcome of the trial was the change in disease severity over time as measured by ALSFRS-R through 24 weeks accounting for mortality (analyzed using a Bayesian shared parameter model). Prespecified secondary efficacy endpoints included the Combined Assessment of Function and Survival joint rank test (CAFS), change in respiratory function as measured by slow vital capacity (SVC), and overall survival. For more information, please see ClinicalTrials.gov Identifier: NCT04297683.

Forward-Looking Statements

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

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Exhibit 99.3

CLENE PROVIDES UPDATE ON ALS
CLINICAL DEVELOPMENT MEETING WITH FDA

SALT LAKE CITY, Dec. 21, 2023 – 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 amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today provided an ALS regulatory update from its recent meeting with the U.S. Food and Drug Administration (FDA).

Clene met with the FDA to discuss CNM-Au8® for the treatment of ALS, presenting initial clinical and Neurofilament Light Chain (NfL) biomarker results from the completed Phase 2 ALS studies. Clene also presented the evidence of long-term survival data from these studies as well as the supportive safety data of more than 500 years of participant exposure to date without any identified safety signals across ALS, MS, and Parkinson's disease.

The FDA determined that the initial findings on biomarker NfL reduction from the Phase 2 programs were insufficient to support accelerated approval at this time. Clene is looking forward to providing supplemental data for further engagement with the FDA in the first half of 2024, including additional long-term clinical evidence and biomarker results of CNM-Au8's treatment benefit in people living with ALS. Clene plans to demonstrate how CNM-Au8's mechanism of action is linked to the reduction in NfL, and the association between observed NfL reductions and improved clinical outcomes in ALS patients, including increased survival time.

"As we continue to analyze the data from our Phase 2 clinical program, we believe the evidence supports that CNM-Au8 treatment improved survival in people living with ALS," said Benjamin Greenberg, M.D., Clene's Head of Medical. "We are also encouraged that the recently disclosed long-term NfL biomarker decreases are consistent with delayed clinical time-to-event outcomes."

Rob Etherington, CEO of Clene, said, "Clene is committed to people living with ALS. We presently support two ongoing CNM-Au8 compassionate use (expanded access) programs and are shortly commencing a third compassionate use program that is supported by a $45.1M grant from the National Institutes of Health. In addition, we anticipate launching the Phase 3 ALS confirmatory study in 2024. Importantly, we also plan to submit new information to the FDA for further discussions on the totality of evidence in order to advance the accelerated development of CNM-Au8 for the treatment of ALS."

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.

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