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 10, 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-fortieth of one share of Common Stock for $230.00 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 (the "Current Report"), on December 10, 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 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.

Additionally, in poster sessions at the 35th International Symposium on ALS/MND on December 6, 2024 and December 7, 2024, the Company presented additional data from its clinical trials and expanded access programs in amyotrophic lateral sclerosis ("ALS"), including (i) data on long-term survival with CNM-Au8 30 mg treatment and (ii) biomarkers of neurodegeneration, astrogliosis, and inflammation. Copies of the posters are furnished as Exhibit 99.2 and 99.3 to this Current Report and are incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibit 99.1, Exhibit 99.2, and Exhibit 99.3, 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 10, 2024, the Company issued a press release announcing the U.S. Food and Drug Administration ("FDA") provided a potential path for an accelerated approval through submission of additional CNM-Au8 biomarker data in ALS. A copy of the press release is filed as Exhibit 99.4 to this Current Report 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	Long-term survival poster.
99.3	ALS biomarker poster.
99.4	Press release, dated December 10, 2024, announcing FDA provides roadmap for accelerated approval pathway through submission of additional CNM-Au8 biomarker data in ALS.
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 10, 2024

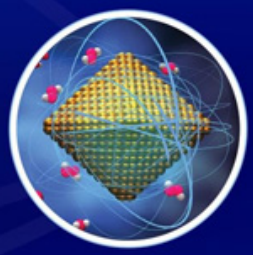
By: /s/ Robert Etherington
Robert Etherington
President and Chief Executive Officer


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," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this presentation may include, for example, statements about our drug candidate's trial results and potential impact on disease states, and other factors detailed under "Risk Factors" in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. 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 drug candidates; 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 epidemics, pandemics, and the ongoing conflicts between Ukraine and Russia and Israel and Hamas 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

Data on File, Clene Nanomedicine, Inc.

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What is CNM-Au8® ?

CNM-Au8 Nanocrystal Suspension
60 mL per bottle (once daily)

>100 Trillion Nanocrystals per 60 mL dose (at 30 mg)

CNM-Au8 Attributes:

- ✓ **Nanocrystal suspension**
- ✓ **Orally administered (or by feeding tube)**
- ✓ **Targets energy metabolism and oxidative stress**
- ✓ **Blood-brain-barrier penetrant**

Data on File, Clene Nanomedicine, Inc.

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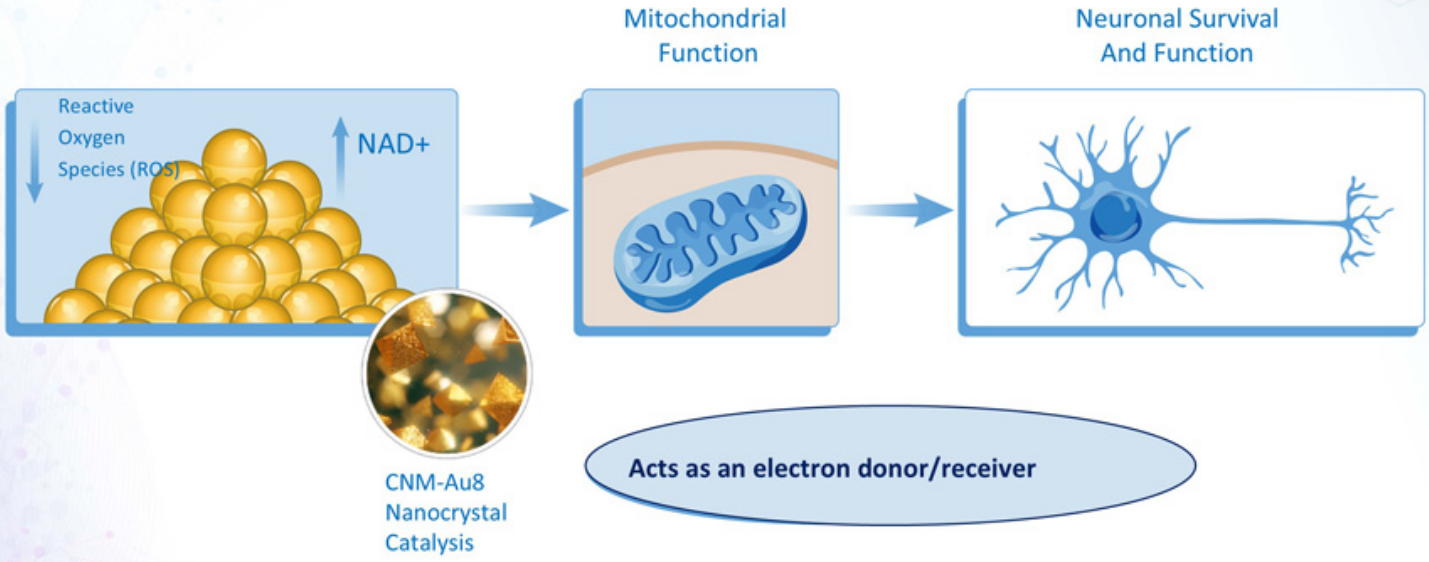
CNM-Au8® | Surface Catalysis Supports Mitochondrial Function



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

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Safety Review

- Over **700 participant-years** of exposure to CNM-Au8
- CNM-Au8 long-term **treatment duration up to 5.1 years**
- TEAEs (treatment-emergent adverse events) predominantly assessed as **mild-to-moderate severity, and transient**
- **No related SAEs** (serious adverse events) related to CNM-Au8 across all clinical programs
- No temporal association of increasing TEAE or SAE incidence based on exposure duration
- 'No Adverse Effect Level' **(NOAEL) findings across all toxicology studies** up to maximum feasible dose

RESCUEALS

HEALEY ALS Platform Trial

ALS EXPANDED ACCESS PROTOCOLS (EAP)

VISIONARY-MS STUDY

RepairPD Early Parkinson's Disease

RepairMS Stable Relapsing MS

RepairMS Non-Active Progressive MS

Data on File, Clene Nanomedicine, Inc.

Despite Missed Primary Endpoints, Concordant Survival Outcomes with CNM-Au8 Treatment in ALS are Promising

	RESCUE-ALS	RESCUE-OLE	HEALEY ALS Platform	HEALEY OLE	Expanded Access Protocols
ALS Participant Demographics	Early-to-Mid-Stage (n=45)	Early-to-Mid-Stage (n=36)	Mid-to-Late-Stage (n=161; Regimen C)	Mid-to-Late-Stage (n=134)	Real-World Experience (~300)
Duration	36-weeks	Up to 234 weeks	24-weeks	Up to 133 weeks	Over 5.0 years
Primary/ Secondary Endpoints	1. MUNIX % change 2. MUNIX total change 2. FVC (% predicted)	NA	1. ALSFRS-R adj. by death 2. CAFS 2. SVC (% predicted) 2. Time to Death or PAV	NA	NA
Survival	--	✓	✓	✓ vs. ALS natural history controls	✓ vs. ALS natural history controls
Delayed Time to Clinical Worsening	✓	✓	✓	✓	Not routinely collected
Preserved Function (ALSFRS-R)	--	✓	--	✓ in NfL Responders	
Progression Biomarkers	↓ p75 (trend)	Not routinely collected	✓ NfL ↓	✓ NfL ↓ ✓ GSH, GSH/GSSG ↑ ✓ NAD, NAD+/NADH ↑	
Safety	>700 Years of Participant Exposure without Identified Safety Signals across ALS, MS, and PD				

Data on File, Clene Nanomedicine, Inc.

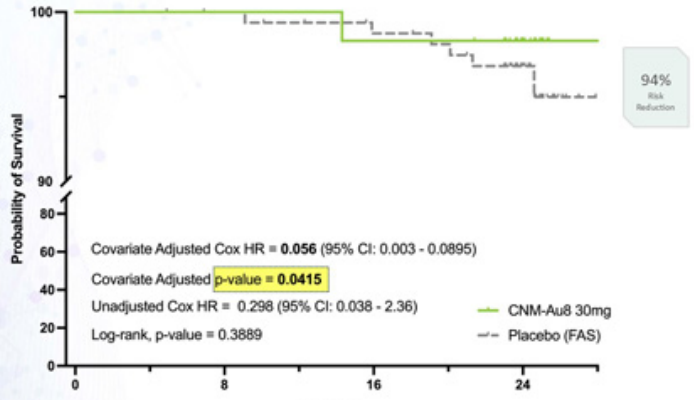
Time to Event | Survival During the Double-Blind Period

HEALEY ALS Platform Trial CNM-Au8 30 mg (Full Analysis Set | All Shared Placebo)

HEALEY ALS Platform Trial

Time to Death or PAV*

HEALEY ALS Platform Trial | Double-Blind Period | Kaplan-Meier Estimator
CNM-Au8 30 mg (n=59) vs. Placebo Full Analysis Set (n=162)

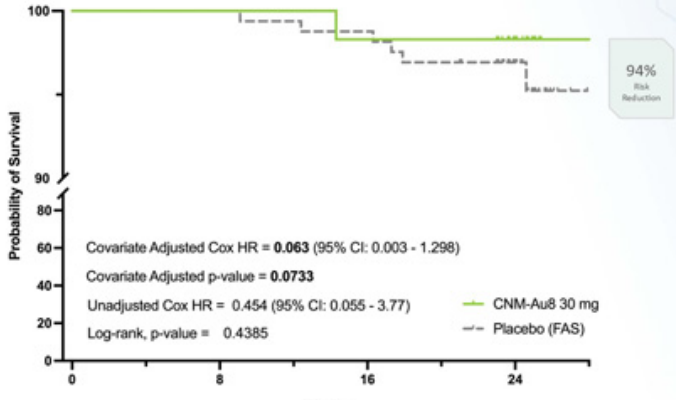


*PAV=Permanently Assisted Ventilation

At Risk				
CNM-Au8 30mg:	59	59	58	45
Placebo:	162	162	159	116

Time to Death

HEALEY ALS Platform Trial | Double-Blind Period | Kaplan-Meier Estimator
CNM-Au8 30 mg (n=59) vs. Placebo Full Analysis Set (n=163)



At Risk				
CNM-Au8 30mg:	59	59	58	45
Placebo:	163	163	161	119

Prespecified covariates included: age, months from symptom onset, pre-treatment ALSFRS-R slope (delta FRS), riluzole treatment, edaravone treatment. One placebo FAS participant had PAV at BL, so is excluded from the left figure (Time to Death or PAV).

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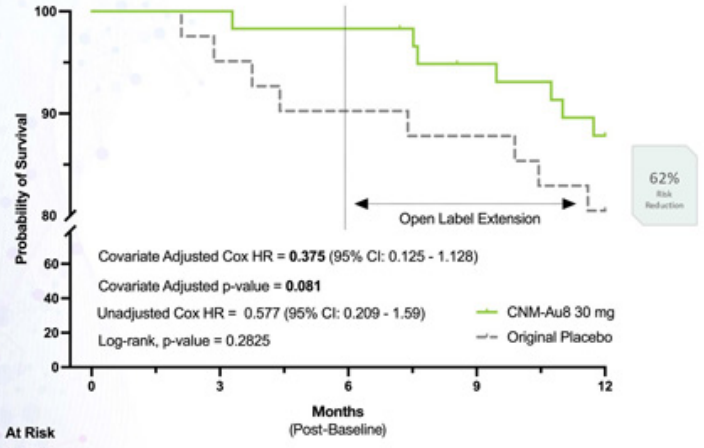
Time to Event | Improved Survival During the OLE to Month 12

HEALEY ALS Platform Trial CNM-Au8 30 mg

HEALEY ALS Platform Trial

Time to Death or PAV

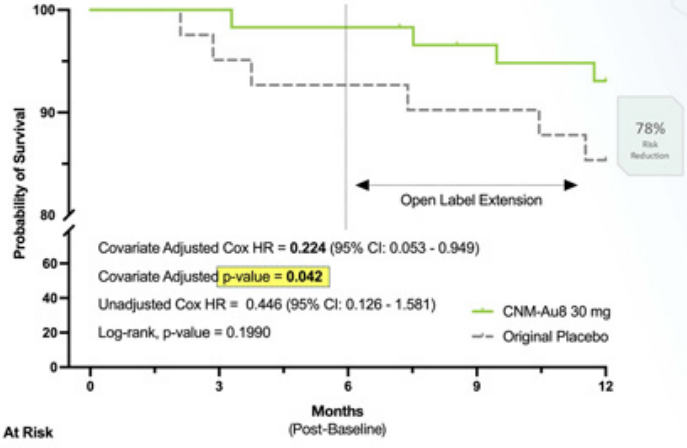
HEALEY ALS Platform Trial | Kaplan-Meier Estimator | Open Label Extension
Prespecified Covariate Adjusted Hazard Model at Week 52
CNM-Au8 30 mg (n=59) vs. Placebo Within Regimen (n=41)



At Risk					
CNM-Au8:	59	59	58	54	50
Placebo:	41	39	37	36	33

Time to Death

HEALEY ALS Platform Trial | Kaplan-Meier Estimator | Open Label Extension
Prespecified Covariate Adjusted Hazard Model at Week 52
CNM-Au8 30 mg (n=59) vs. Placebo Within Regimen (n=41)



At Risk					
CNM-Au8:	59	59	58	55	53
Placebo:	41	39	38	37	35

Prespecified covariates included: age, months from symptom onset, pre-treatment ALSFRS-R slope (delta-FRS), riluzole treatment, and edaravone treatment.

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CNM-Au8 | Delayed Time to Clinical Worsening Events Concordant in Double-Blind Periods of Two Independent Phase 2 Trials

Delayed Time to Clinical Worsening

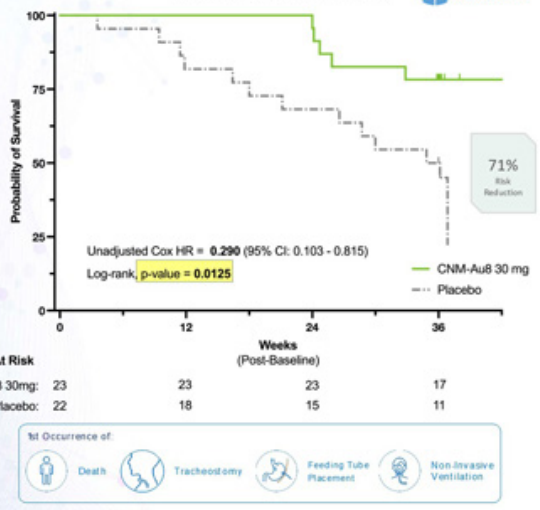
Prespecified Exploratory Clinical Composite Endpoint

Time to ALS Clinical Worsening | CNM-Au8 30mg

First Occurence of Death, Tracheostomy, Feeding Tube, or NIV Initiation

RESCUE-ALS | Kaplan-Meier Estimate

CNM-Au8 30mg vs. Placebo (n=45)



At Risk				
CNM-Au8 30mg:	23	23	23	17
Placebo:	22	18	15	11

Delayed Time to Clinical Worsening

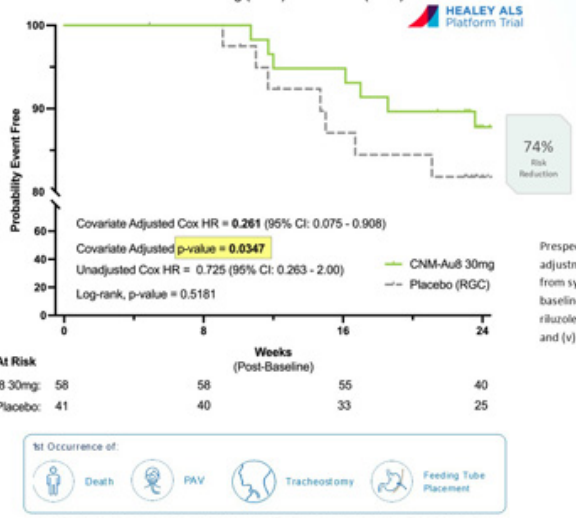
Prespecified Exploratory Clinical Composite Endpoint

Time to ALS Clinical Worsening | CNM-Au8 30mg

First Occurence of Death, PAV, Tracheostomy or Feeding Tube

HEALEY ALS Platform Trial Within Regimen | Kaplan-Meier Estimator

CNM-Au8 30mg (n=58) vs. Placebo (n=41)



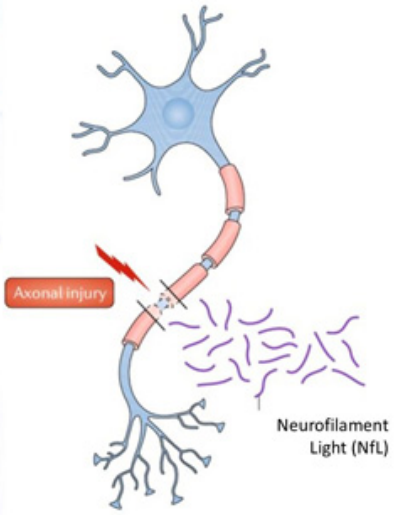
At Risk				
CNM-Au8 30mg:	58	58	55	40
Placebo:	41	40	33	25

PAV defined as continuous ventilatory support (>23 hr/day) by tracheostomy or NIV for at least 7-days

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.

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

NfL is a Key Biomarker of Disease Progression in ALS Patients



Neurofilament Light Chain (NfL) Protein

Cytoskeletal proteins that provide structure and support for the cell and are highly specific for neurons

Axonal damage: high NfL levels are associated with axonal damage

High NfL in ALS: predicts greater risk of disease progression

NfL: Neurofilament light chain. Benatar et al. Brain. 2023 Jul 3;146(7):2711-2716.

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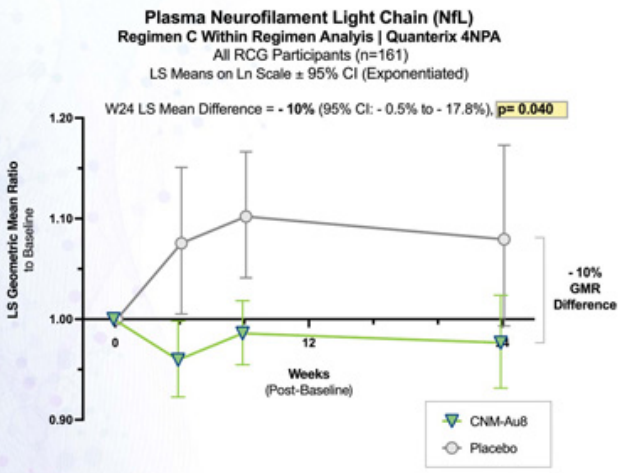
Plasma NfL Decline During Double-Blind & Long-Term Treatment

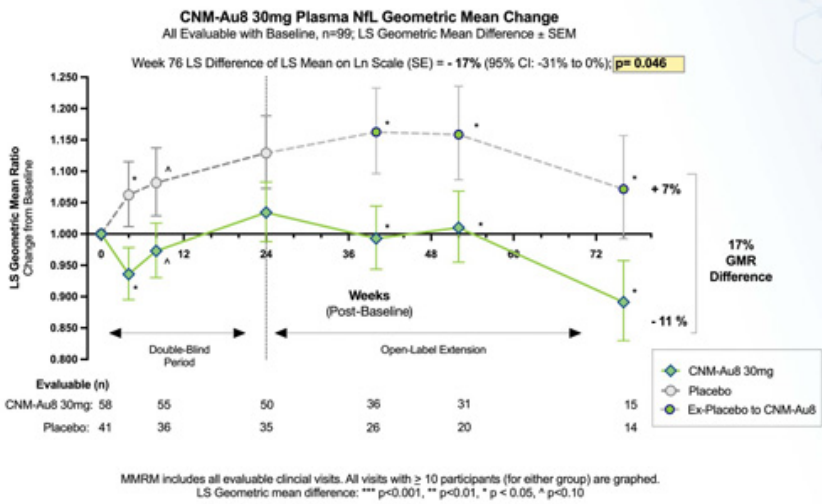
HEALEY ALS Platform Trial Double-Blind & Open Label Extension

HEALEY ALS Platform Trial

Double-Blind Period



Open Label Extension



MMRM includes all evaluable clincial visits. All visits with ≥ 10 participants (for either group) are graphed.
LS Geometric mean difference: *** p<0.001, ** p<0.01, * p < 0.05, ^ p<0.10

Mixed Model Repeat Measure analyses: HEALEY covariates included time from symptom onset, pre-treatment ALSFRS-R slope, background edaravone and riluzole, and interaction by week.

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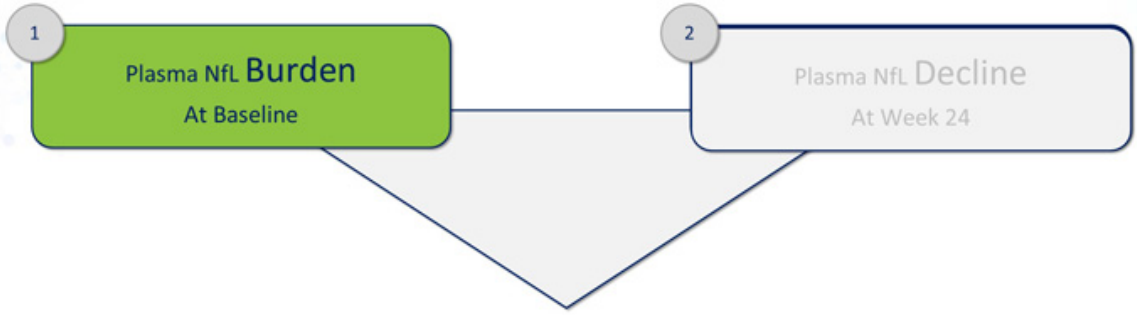
Evidence Linking Plasma NfL with CNM-Au8 Clinical Benefit



Time to Death or PAV to Month 12

Week 52 post-baseline was a prespecified time point for OLE analyses

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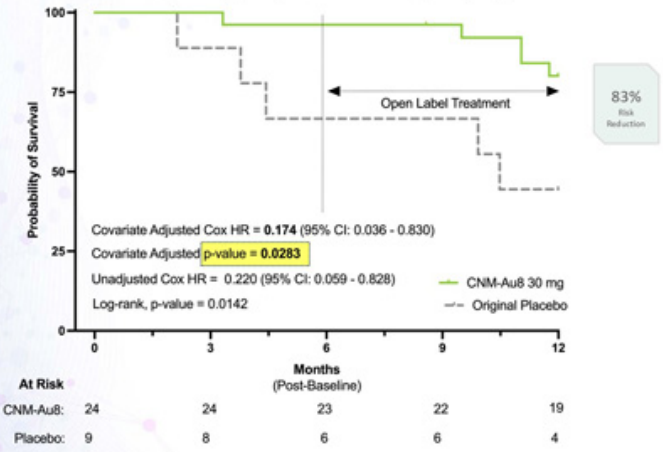
Greatest Benefit in Participants with Highest Baseline NfL Burden | Death or PAV

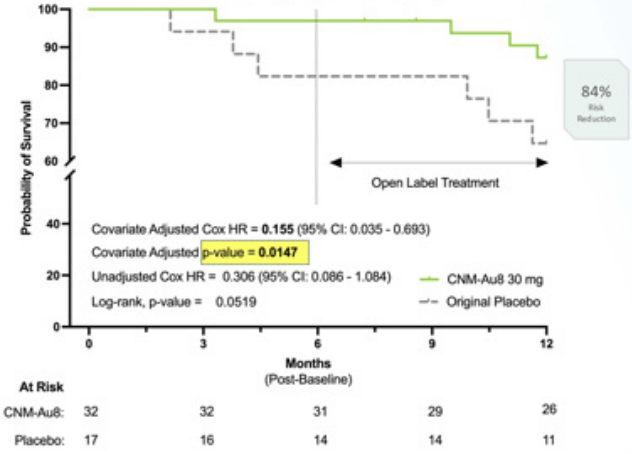
HEALEY ALS Platform (Through Month 12) | Upper Tertile & ≥ Median

HEALEY ALS Platform Trial

HEALEY | Upper NfL Tertile
By Baseline Plasma NfL



HEALEY | NfL > Median
By Baseline Plasma NfL



Prespecified HEALEY covariates included: age, months from symptom onset, pre-treatment ALSFRS-R slope (delta-FRS), riluzole treatment, edaravone treatment. Analyses are *post hoc*.

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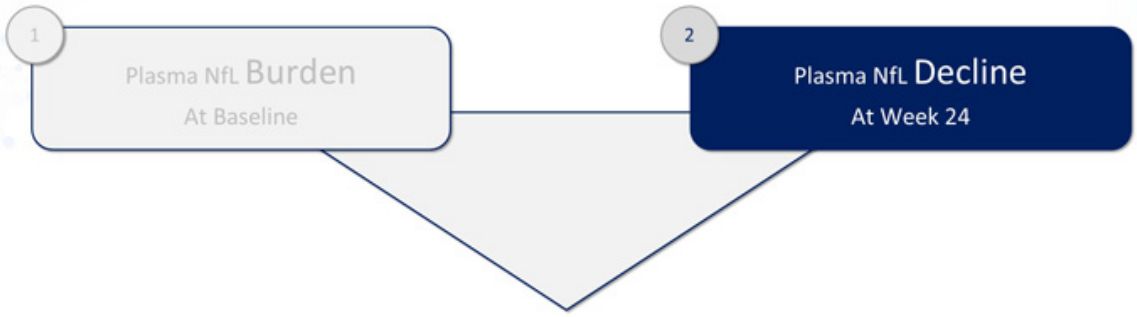
Evidence Linking Plasma NfL with CNM-Au8 Clinical Benefit



Time to Death or PAV to Month 12

Week 52 post-baseline was a prespecified time point for OLE analyses

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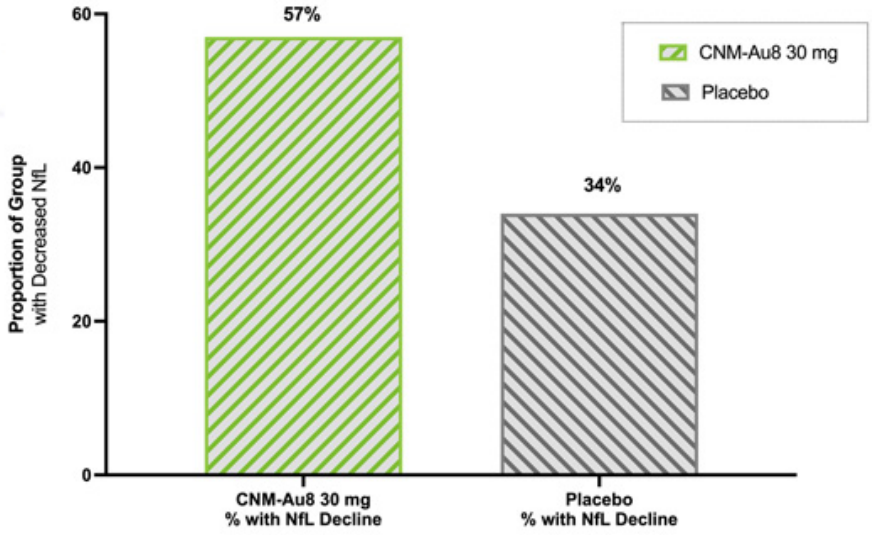
Proportion of Participants Demonstrating NfL Decline at Week 24

End of Double-Blind

HEALEY ALS Platform Trial

CNM-Au8 30 mg Plasma NfL Change at Week 24 (End of Double-Blind)
Proportion of Evaluable with NfL Decline



Data on File, Clene Nanomedicine, Inc.

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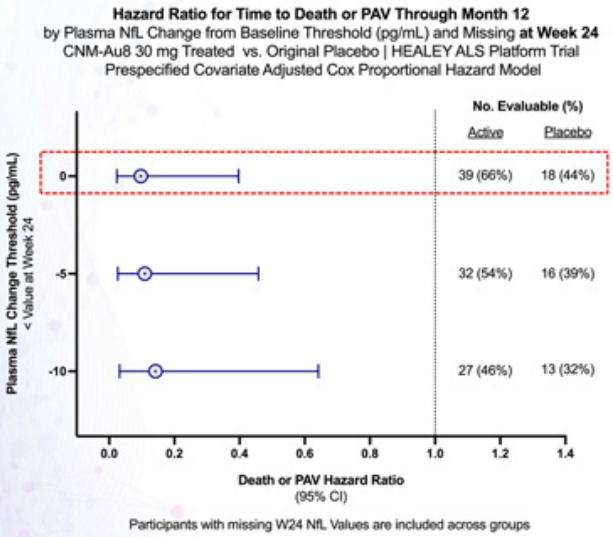
Long-Term Survival Benefit in Participants with Any NfL Decline at 24-Weeks

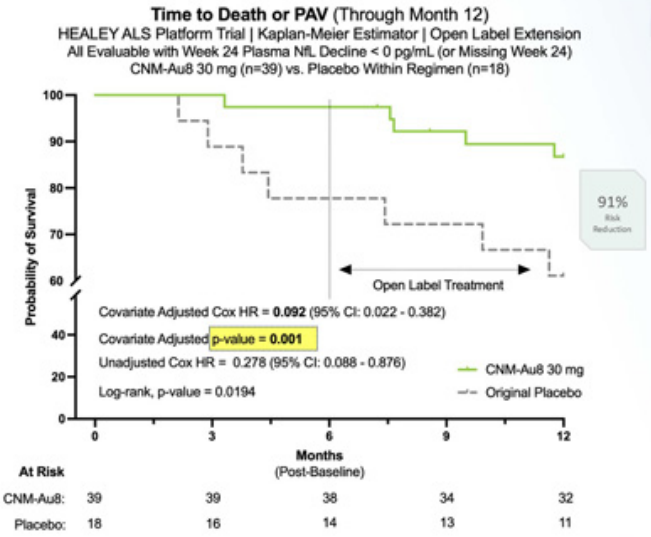
HEALEY ALS Platform (Through Month 12) | Time to Death or PAV

HEALEY ALS Platform Trial

Hazard Ratio for Death or PAV At 12 Months Post-Baseline



Time to Death or PAV In Participants with NfL Decline at Week 24



Prespecified covariates included: age, months from symptom onset, pre-treatment ALSFRS-R slope (delta-FRS), riluzole treatment, edaravone treatment. *Post hoc* analyses.

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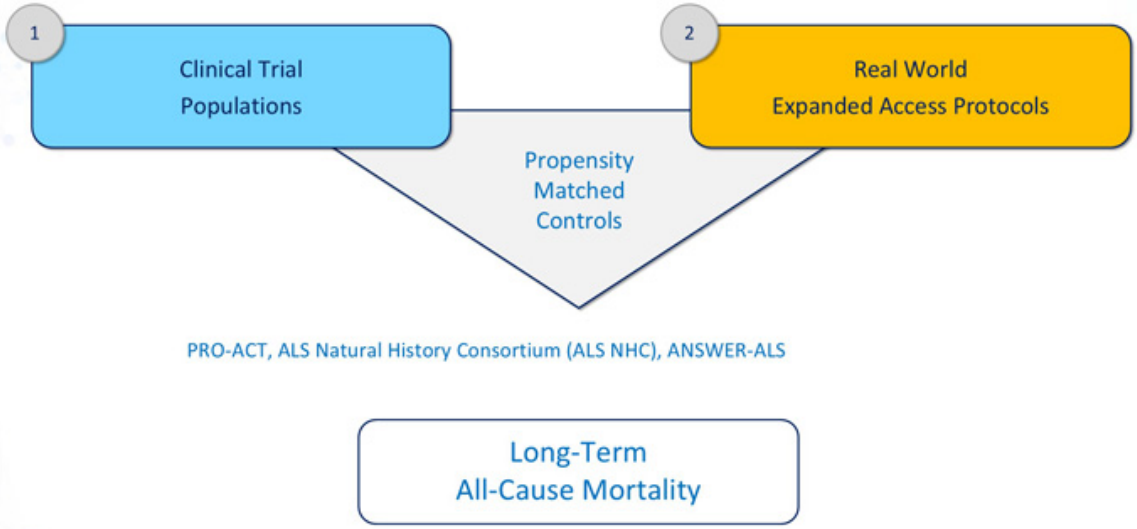
Evidence Supporting Long-Term Survival Benefit



PRO-ACT, ALS Natural History Consortium (ALS NHC), ANSWER-ALS

Long-Term
All-Cause Mortality

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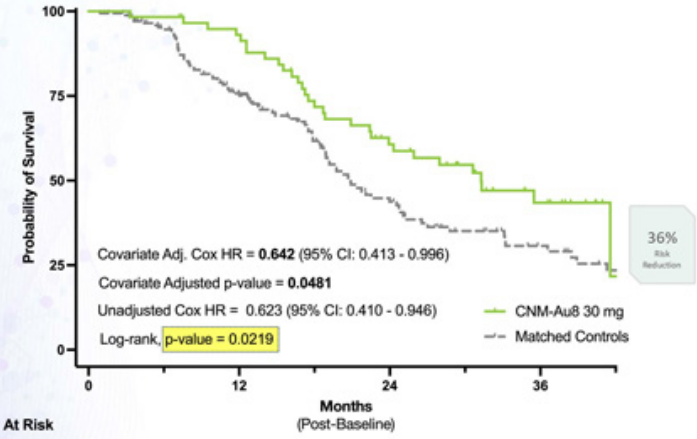
Improved Long-Term Survival | HEALEY ALS Platform & Pooled ALS Trials

CNM-Au8 30 mg Original Randomization vs. Propensity Matched Controls

HEALEY ALS Platform Trial

HEALEY | Optimal Variable Ratio Matching
Prespecified Matching Methodology

Original CNM-Au8 30 Randomized mg vs. Propensity Matched Controls
HEALEY ALS Platform Trial | Optimal Variable Matching
Pooled Matched Controls (PRO-ACT, ALS NHC, ANSWER-ALS)

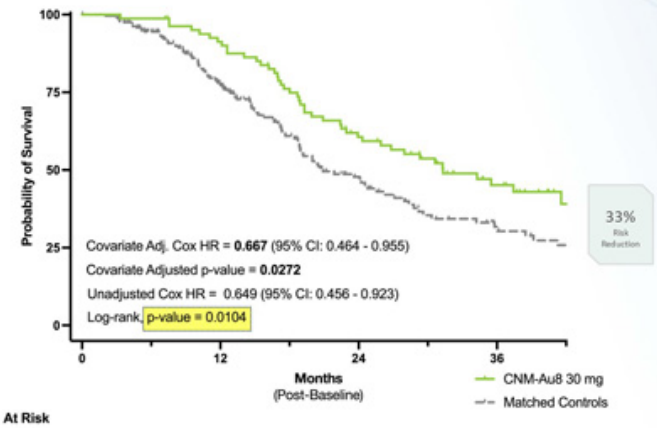


At Risk								
CNM-Au8 30 mg:	59	58	53	41	31	23	12	1
Placebo:	177	153	112	65	43	28	19	12

HEALEY ALS Platform Trial
RESCUE ALS

Pooled ALS Trials | Optimal Variable Ratio Matching

Original CNM-Au8 30 Randomized mg vs. Propensity Matched Controls
Pooled HEALEY ALS Platform Trial & RESCUE-ALS | Optimal Variable Matching
Pooled Matched Controls (PRO-ACT, ALS NHC, ANSWER-ALS)



At Risk								
CNM-Au8 30 mg:	82	81	73	60	45	35	23	10
Placebo:	246	211	147	78	52	31	23	17

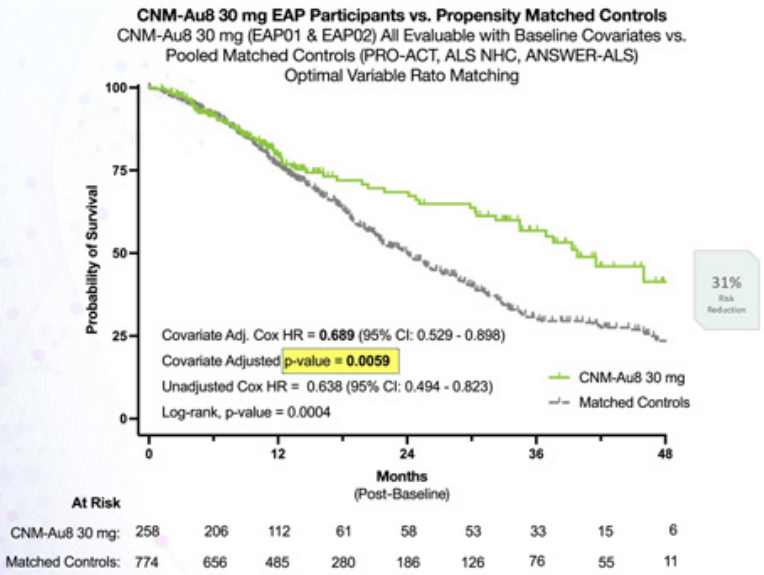
Data on File, Clene Nanomedicine, Inc.

Clene NANOMEDICINE

Long-Term Survival | Real-World Expanded Access Protocols

CNM-Au8 30 mg vs. Propensity Matched Controls (Pooled PRO-ACT, ALS NHC, ANSWER-ALS)

EAP Matching | Optimal Variable Ratio
(Prespecified)



At Risk									
CNM-Au8 30 mg:	258	206	112	61	58	53	33	15	6
Matched Controls:	774	656	485	280	186	126	76	55	11

- Propensity Matching: Variable Optimal Ratio Matching

  Minimizes global distance of the logit score by assessing the overall set of matches when choosing individual matches

- Pooled Control Set: PRO-ACT, ALS Natural History Consortium (ALS NHC), ANSWER-ALS
  - Widest possible universe for control matches
  - 1:3 (active:control) match
- Narrow Logit Caliper Width: 0.1
- Matching Covariates:

  BMI, Sex, Bulbar Onset, Months from Symptom Onset, Onset Age, Diagnostic Delay (Months), ALSFRS-R Pre-Treatment Slope, ALSFRS-R Total Score, Vital Capacity (% predicted), VC (% predicted) Pre-Treatment Slope, TRICALS Risk Score

- Survival Cox Proportional HR Model Covariates:

  Bulbar Onset, (ii) Onset Age, (iii) Sex, (iv) BMI, (v) Pre-treatment ALSFRS-R slope, (vi) ALSFRS-R Total Score, (vii) Diagnostic Delay (in months), (viii) Vital Capacity (% predicted), (ix) Pre-Treatment Vital Capacity Slope, and (x) TRICALS Risk Score

Data on File, Clene Nanomedicine, Inc.

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, Ciene Nanomedicine, Inc.

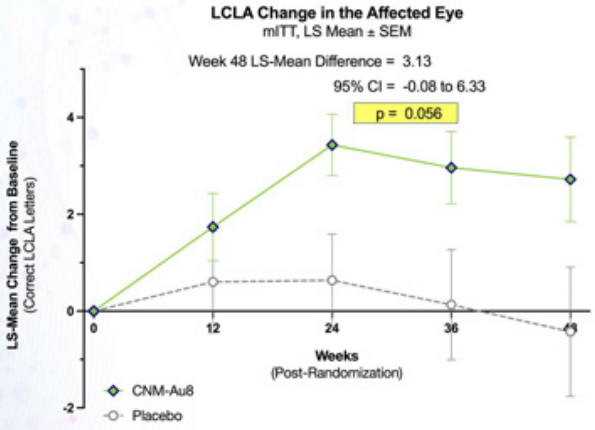
Ciene NANOMEDICINE

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

VISIONARY-MS STUDY

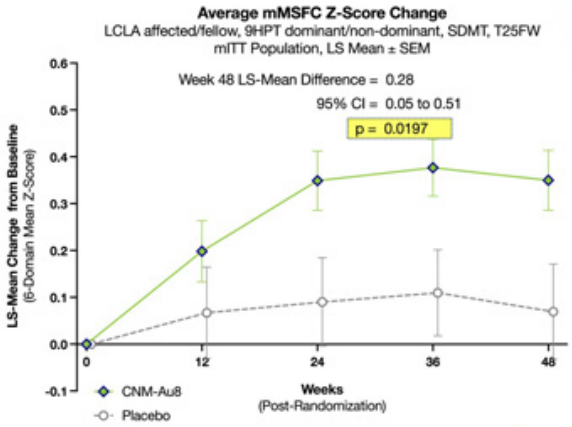
Significantly Improved Vision

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.

clene NANOMEDICINE

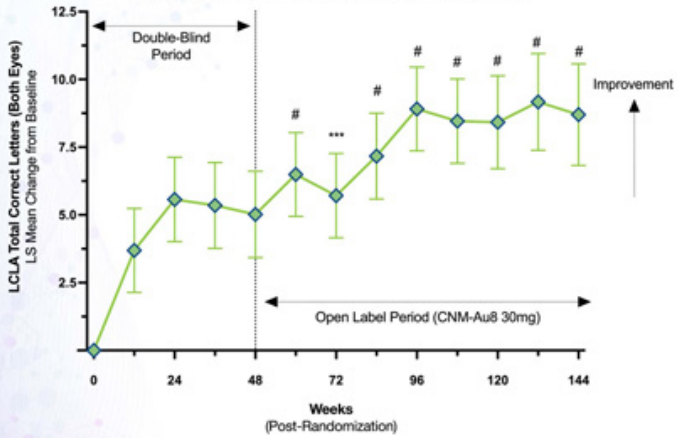
Long-Term LCLA Improvement in LTE Participants

Low Contrast Letter Acuity

VISIONARY-MS STUDY

Original Active (CNM-Au8)

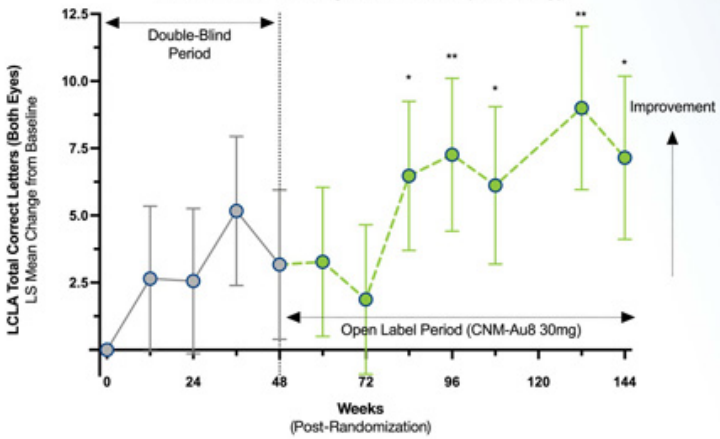
Longitudinal LCLA | Change from Baseline (Total Correct, Both Eyes) | All Active
In LTE Participants Originally Randomized to CNM-Au8 (n=35), mITT Population
LS Mean ± SEM, Change from Baseline (Preliminary)



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

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.

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

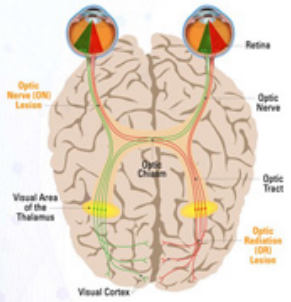
Data on File, Ciene Nanomedicine, Inc.

CIene NANOMEDICINE

CNM-Au8 Improved Information Signal Strength & Speed in the Visual Pathway

VISIONARY-MS STUDY

Visual Evoked Potentials

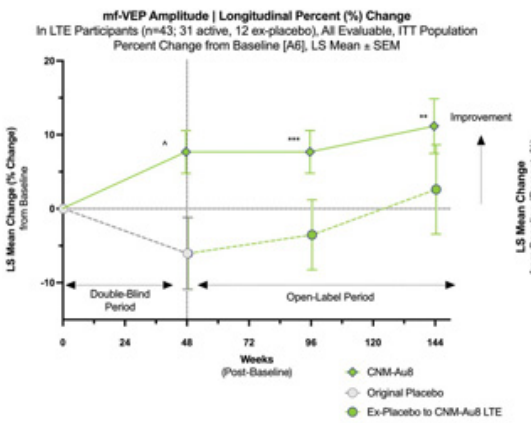


Amplitude = Signal Strength

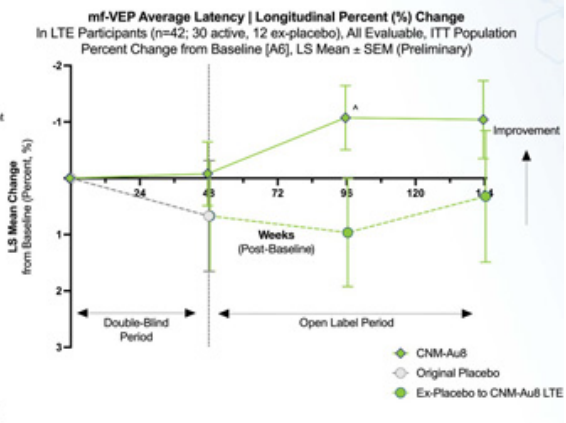
Latency = Signal Speed

From the Eye to Visual Cortex

Improved Amplitude



Improved Latency



LTE: LS mean difference vs. randomization baseline: # p≤0.0001, *** p≤0.001, ** p≤0.01, *p≤0.05, ^p≤0.10

Increased VEP amplitude is associated with improved axonal integrity (more signal);
Improved latency is associated with evidence of remyelination (faster conduction velocity)

Data on File, Ciene Nanomedicine, Inc.

CIene NANOMEDICINE

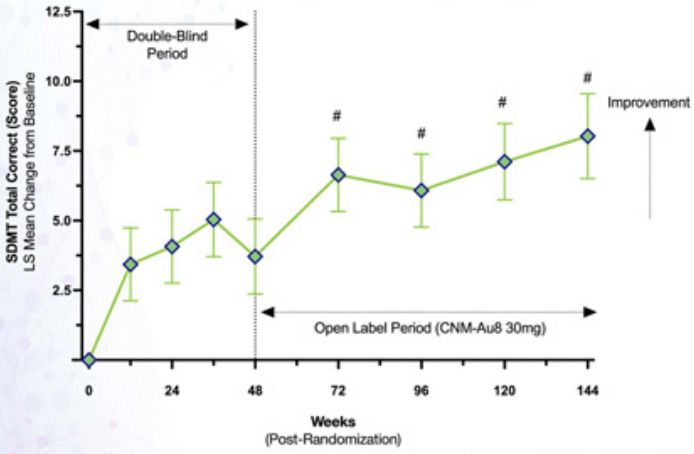
Long-Term SDMT Improvement in LTE Participants

Symbol Digit Modality Test | Working Memory & Cognition

VISIONARY-MS STUDY

Original Active (CNM-Au8)

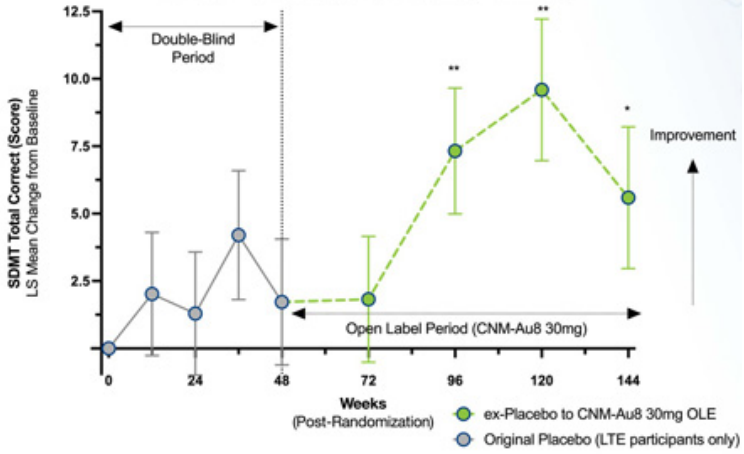
Longitudinal SDMT | Change from Baseline (Total Score) | All Active
In LTE Participants Originally Randomized to CNM-Au8 (n=35), mITT Population
LS Mean ± SEM, Change from Baseline (Preliminary)



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

Original Placebo

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



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

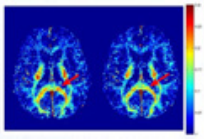
Data on File, Clene Nanomedicine, Inc.

CLENE NANOMEDICINE

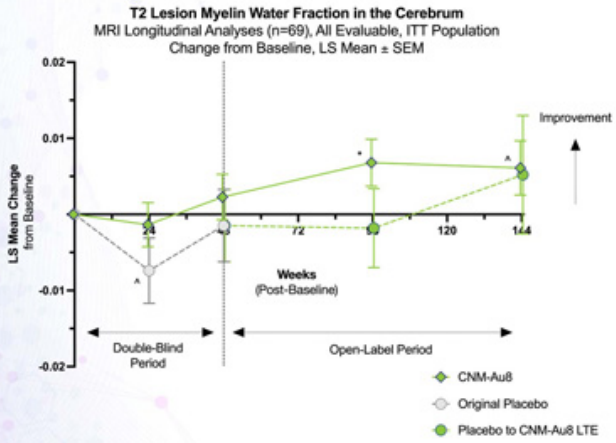
CNM-Au8 Treatment Demonstrated MS Lesion Repair and Promoted Remyelination

VISIONARY-MS STUDY

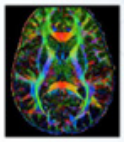
Advanced MRI Techniques

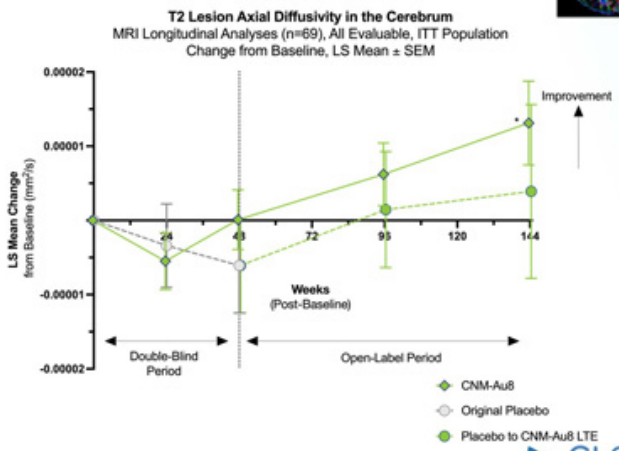


T2 Lesion Myelin Water Fraction (Remyelination)



T2 Lesion Axial Diffusivity (Axonal Integrity)





Data on File, Ciene Nanomedicine, Inc.

LTE: LS mean difference vs. randomization baseline: # p≤0.0001, *** p≤0.001, ** p≤0.01, * p≤0.05, ^p≤0.10

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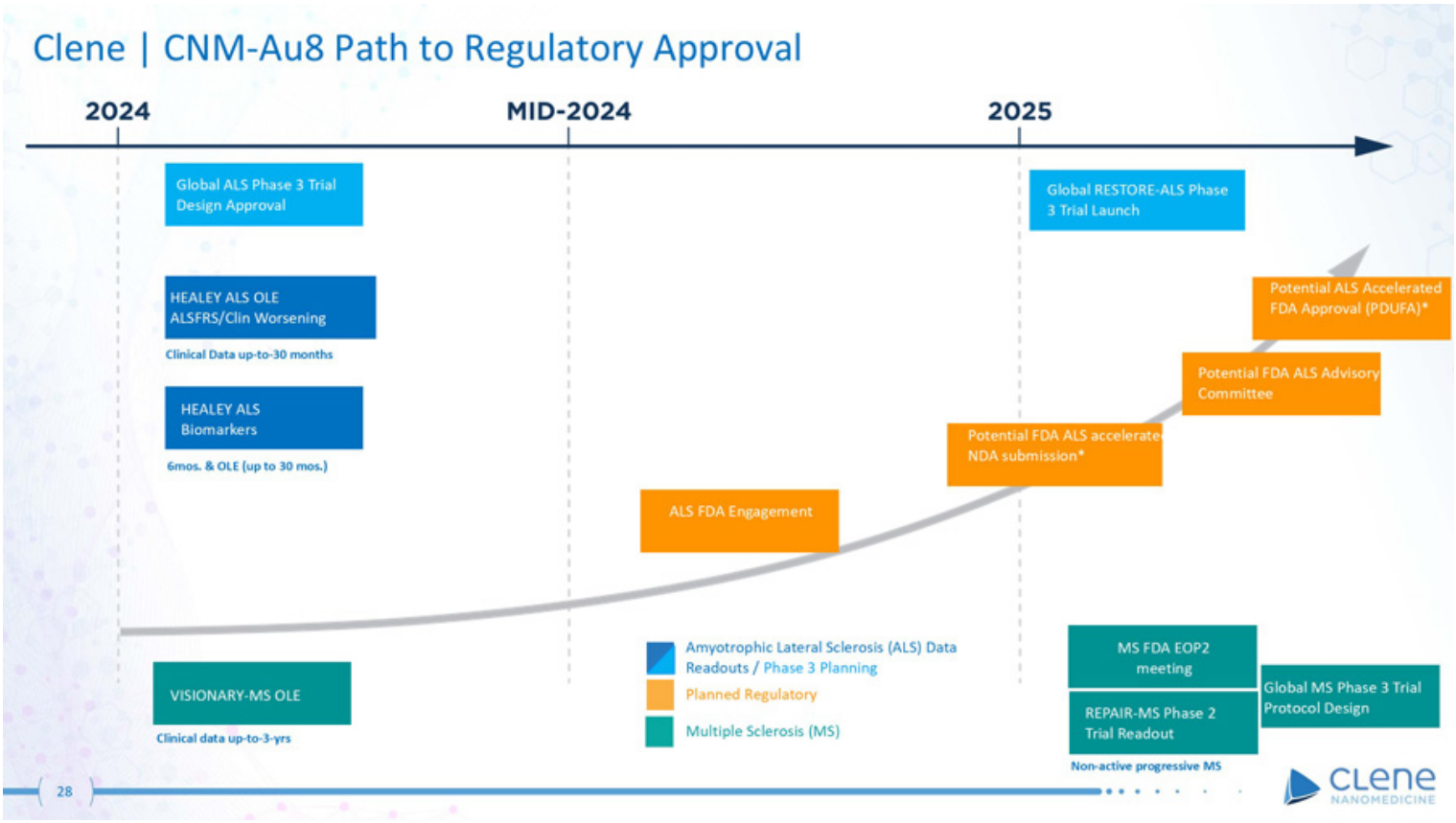
Clene | CNM-Au8 Path to Regulatory Approval
2024
MID-2024
2025
Global ALS Phase 3 Trial Design Approval
HEALEY ALS OLE ALSFRS/Clin Worsening
Clinical Data up-to-30 months
HEALEY ALS Biomarkers
6mos. & OLE (up to 30 mos.)
VISIONARY-MS OLE
Clinical data up-to-3-yrs
ALS FDA Engagement
Global RESTORE-ALS Phase 3 Trial Launch
Potential FDA ALS accelerated NDA submission*
Potential FDA ALS Advisory Committee
Potential ALS Accelerated FDA Approval (PDUFA)*
Amyotrophic Lateral Sclerosis (ALS) Data Readouts / Phase 3 Planning
Planned Regulatory
Multiple Sclerosis (MS)
MS FDA EOP2 meeting
REPAIR-MS Phase 2 Trial Readout
Non-active progressive MS
Global MS Phase 3 Trial Protocol Design
28
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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

HEALEY ALS Platform Trial

RESCUEALS

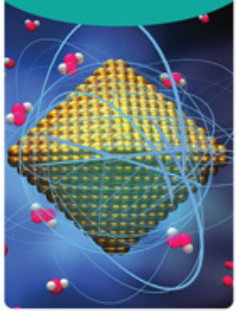
Concordant Survival in two Phase2 trials, with NfL Biomarker in HEALEY

VISIONARY-MS

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

>700
participant years of CNM-Au8 clinical exposure

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



As of September 30 2024, cash and equivalents on hand (unaudited):
$14.6
+ $3.5
Raised in an RDO on 10/1/2024

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

clene NANOMEDICINE

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R&D and Manufacturing
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North East, MD 21901

Version: 10 Dec 2024

Evidence of Long-term Survival Benefit in ALS with CNM-Au8 30 mg Treatment Across Three Study Populations

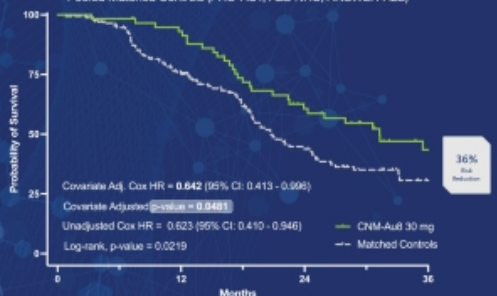
Marjan Sepassi, PharmD; James D. Berry, MD, MPH; Nicholas Maragakis, MD; Sabrina Paganoni, MD, PhD; Melanie Quintana, PhD; Eric A. Macklin, PhD; Benjamin R. Saville, PhD; Jinsy Andrews, MD; Jeremy Shefner, MD, PhD; Michelle A. Detry, PhD; Elijah Stommel MD, Parvathi Menon PhD, FRACP, William Huynh PhD, FRACP, Colin Mahoney, PhD, MB, MRCPI; Meghan Hall; Mariah Connolly; Gale Kittle; Marianne Chase; Alex Sherman; Hong Yu; Lindsay Pothier; Kristin Drake, MBA; Lori Chibnik, PhD, MPH; Marie-Abele Bind, PhD; Matteo Vestrucci, PhD; Austin Rynders, RN; Jacob Evan; Jeremy Evan, PA-C; Karen S. Ho, PhD, MSc; Alan Hartford, PhD; Ben Greenberg, MD; Steve Vucic Dsc, PhD, FRACP, FAHMS; Matthew C. Kiernan, DSc, PhD, MBBS, FRACP, FAHMS; Merit E. Cudkowicz, MD; and Michael T. Hotchkin for the HEALEY ALS Platform Trial Study Group and RESCUE-ALS Investigators

RESULTS: Long-term follow-up from RESCUE-ALS and the HEALEY ALS Platform Trial provide evidence of improved survival with CNM-Au8 30mg, reinforced by real-world data from expanded access programs

HEALEY ALS Platform Trial

Optimal Variable Ratio Matching
Prespecified Matching Methodology

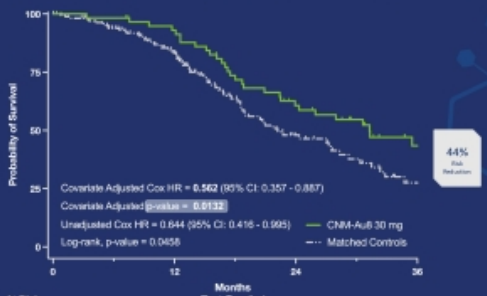
Original Randomized CNM-Au8 30 mg vs. Propensity Matched Controls
HEALEY ALS Platform Trial | Optimal Variable Matching
Pooled Matched Controls (PRO-ACT, ALS NHC, ANSWER-ALS)



At Risk							
CNM-Au8 30 mg:	59	58	53	41	31	23	12
Matched Controls:	177	153	112	65	43	28	19

Nearest Neighbor (Greedy) Matching
Sensitivity Matching Methodology

Original Randomized CNM-Au8 30 mg vs. Propensity Matched Controls
HEALEY ALS Platform Trial | Greedy Nearest Neighbor Match
Pooled Matched Controls (PRO-ACT, ALS NHC, ANSWER-ALS)

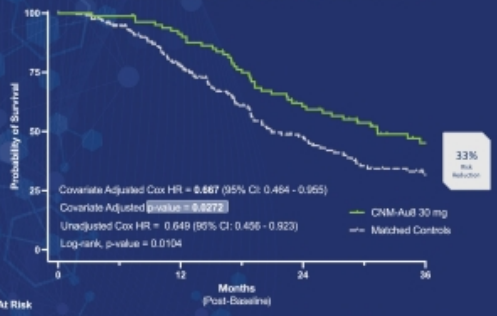


At Risk							
CNM-Au8 30 mg:	59	58	53	41	31	23	12
Matched Controls:	172	144	110	52	31	21	10

HEALEY ALS Platform Trial
RESCUEALS

Optimal Variable Ratio Matching
Prespecified Matching Methodology

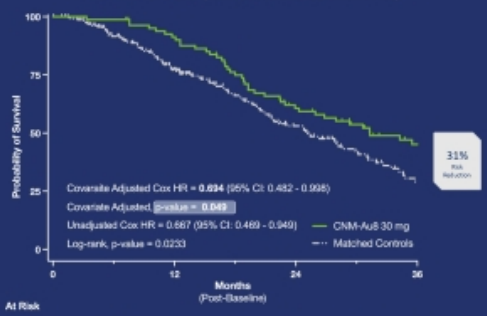
Original Randomized CNM-Au8 30 mg vs. Propensity Matched Controls
Pooled HEALEY ALS Platform Trial & RESCUE-ALS | Optimal Variable Matching
Pooled Matched Controls (PRO-ACT, ALS NHC, ANSWER-ALS)



At Risk							
CNM-Au8 30 mg:	82	81	73	59	45	36	23
Matched Controls:	246	211	147	78	52	31	23

Nearest Neighbor (Greedy) Matching
Sensitivity Matching Methodology

Original Randomized CNM-Au8 30 mg vs. Propensity Matched Controls
HEALEY ALS Platform Trial & RESCUE-ALS | Greedy Nearest Neighbor Match
Pooled Matched Controls (PRO-ACT, ALS NHC, ANSWER-ALS)

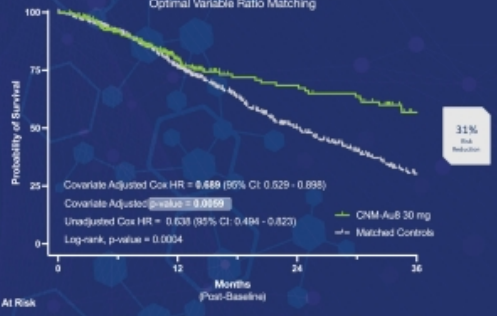


At Risk							
CNM-Au8 30 mg:	82	81	73	59	45	35	23
Matched Controls:	241	197	144	83	59	36	21

ALS EXPANDED ACCESS PROTOCOLS (EAP)

Optimal Variable Ratio Matching
Prespecified Matching Methodology

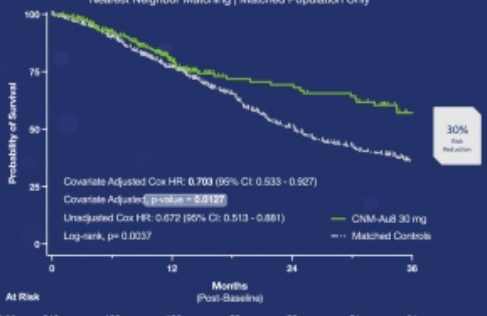
CNM-Au8 30 mg EAP Participants vs. Propensity Matched Controls
CNM-Au8 30 mg (EAP01 & EAP02) All Evaluable with Baseline Covariates vs.
Pooled Matched Controls (PRO-ACT, ALS NHC, ANSWER-ALS)
Optimal Variable Ratio Matching



At Risk							
CNM-Au8 30 mg:	258	206	112	61	58	53	33
Matched Controls:	774	656	485	280	186	126	76

Nearest Neighbor (Greedy) Matching
Sensitivity Matching Methodology

CNM-Au8 30 mg EAP Participants vs. Propensity Matched Controls
CNM-Au8 30 mg (EAP01 & EAP02) All Evaluable with Baseline Covariates vs.
Pooled Matched Controls (PRO-ACT, ALS NHC, ANSWER-ALS)
Nearest Neighbor Matching | Matched Population Only



At Risk							
CNM-Au8 30 mg:	240	190	106	58	56	51	31
Matched Controls:	557	463	356	219	148	108	73

Methods

Propensity Matching: Optimal Variable Ratio (Prespecified) and Nearest Neighbor (Sensitivity); Pooled Control Set: PRO-ACT, ALS Natural History Consortium (ALS NHC), ANSWER-ALS (i.e., widest possible pool for matching); Matching Allocation: 1:3 (active:control) match; Logit Caliper Width: 0.2; Matching Covariates: (i) BMI, (ii) Sex, (iii) Bulbar Onset, (iv) Months from Symptom Onset, (v) Onset Age, (vi) Diagnostic Delay (Months), (vii) ALSFRS-R Pre-Treatment Slope, (viii) ALSFRS-R Total Score, (ix) Vital Capacity (% predicted), (x) VC (% predicted) Pre-Treatment Slope, (xi) TRICALS Risk Score; Survival Cox Proportional Hazard Ratio Model Baseline Covariates: (i) Bulbar Onset, (ii) Onset Age, (iii) Sex, (iv) BMI, (v) Pre-treatment ALSFRS-R slope, (vi) ALSFRS-R Total Score, (vii) Diagnostic Delay (in months), (viii) Vital Capacity (% predicted), (ix) Pre-Treatment Vital Capacity Slope, and (x) TRICALS Risk Score. Notes: Includes all evaluable participants with complete baseline covariates for matching. Participants are right censored at last observation (death or any reported clinical or laboratory value). When less than ~10% follow-up information is available in both groups (active and matched controls), Kaplan-Meier figures are truncated thereafter (Hazard Ratios include all follow-up data in all participants). Survival (time to all-cause mortality) does not include permanent assisted ventilation, which was not tracked consistently in the control datasets.

Acknowledgements: We are indebted to the participants and investigators of the HEALEY ALS Platform Trial, the RESCUE-ALS trial, and the U.S. Expanded Access Protocols (EAPs).

CLene NANOMEDICINE

ALS Biomarkers of Neurodegeneration, Astrogliosis, and Inflammation

Original Placebo Randomization vs. CNM-Au8 30 mg Treatment

Results from the HEALEY ALS Platform Trial Long-Term Open Label Extension

HEALEY ALS Platform Trial

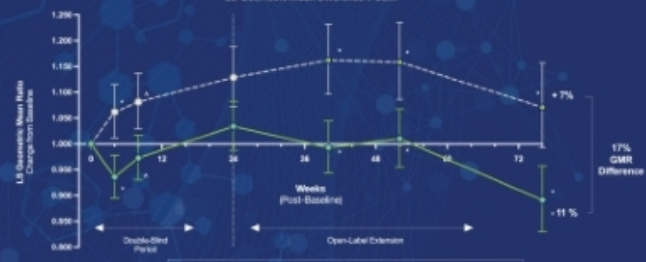
Marjan Sepassi, PharmD; James D. Berry, MD, MPH; Nicholas Maragakis, MD; Sabrina Paganoni, MD, PhD; Melanie Quintana, PhD; Eric A. Macklin, PhD; Benjamin R. Saville, PhD; Jinsy Andrews, MD; Jeremy Shefner, MD, PhD; Michelle A. Detry, PhD; Elijah Stommel MD; Meghan Kell; Mariah Connolly; Gale Kittle; Marianne Chase; Alex Sherman; Hong Yu; Lindsay Pothier; Kristin Drake, MBA; Lori Chibnik, PhD, MPH; Marie-Abele Bind, PhD; Matteo Vestrucci, PhD; Austin Ryders, RN; Jacob Evan; Jeremy Evan, PA-C; Karen S. Ho, PhD, MSc; Alan Hartford, PhD; Ben Greenberg, MD; Merit E. Cudkowicz, MD; and Michael T. Hutchkin for the HEALEY ALS Platform Trial Study Group

RESULTS: Long-Term Treatment with CNM-Au8 Resulted in Significant Differences in Decline of of NfL, GFAP, and CHI3L1 (YKL-40) Levels versus Original Randomization to Placebo

Neurofilament Light (NfL)

(All Evaluable, Pre-planned Analysis)

Plasma NfL Geometric Mean Change (CNM-Au8 30mg)
Within Regimen Analysis | Quanterix 4NPA
All Evaluable with Baseline and Post-Baseline Data (n=99)
LS Geometric Mean Difference ± SEM



Evaluable (n)						
CNM-Au8 30 mg:	58	55	50	36	31	15
Placebo:	41	36	35	26	20	14

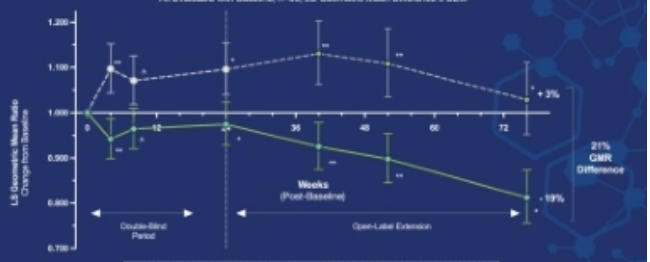
MMRM included all evaluable clinical visits. All visits with ≥ 10 participants (for either group) are graphed.

LS Geometric mean difference: *** p<0.001, ** p<0.01, * p < 0.05, ^ p<0.10

Neurofilament Light (NfL)

(Limb Onset, *Post Hoc*)

Plasma NfL Geometric Mean Change (CNM-Au8 30mg)
Limb Onset Subset
Within Regimen Analysis | Quanterix 4NPA
All Evaluable with Baseline, n=83; LS Geometric Mean Difference ± SEM



Evaluable (n)						
CNM-Au8 30mg:	48	46	42	29	28	14
Placebo:	35	32	30	22	17	13

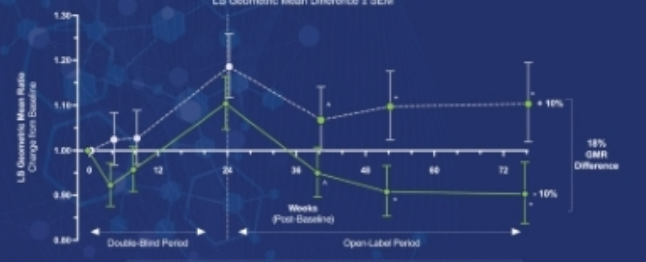
MMRM included all evaluable clinical visits. All visits with ≥ 10 participants (for either group) are graphed.

LS Geometric mean difference: *** p<0.001, ** p<0.01, * p < 0.05, ^ p<0.10

Glial Fibrillary Acidic Protein (GFAP)

(All Evaluable, *Post Hoc*)

Plasma GFAP Geometric Mean Change (CNM-Au8 30 mg)
Within Regimen Analysis | Quanterix 4NPA
All Evaluable with Baseline and Post-Baseline Data (n=99)
LS Geometric Mean Difference ± SEM



No. Evaluable						
CNM-Au8 30 mg:	58	55	50	36	31	15
Placebo:	41	36	35	26	20	14

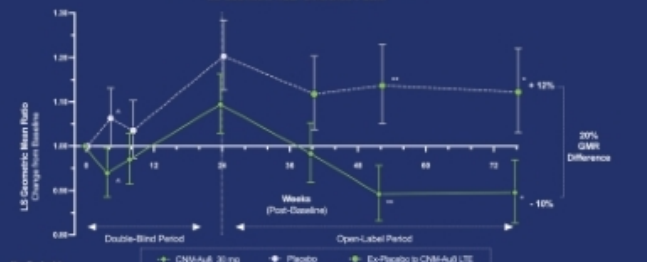
MMRM included all evaluable clinical visits. All visits with ≥ 10 participants (for either group) are graphed.

LS Geometric mean difference: *** p ≤ 0.001, ** p ≤ 0.01, * p < 0.05, ^ p ≤ 0.10

Glial Fibrillary Acidic Protein (GFAP)

(Limb Onset, *Post Hoc*)

Plasma GFAP Geometric Mean Change (CNM-Au8 30 mg)
Limb Onset Subset
Within Regimen Analysis | Quanterix 4NPA
All Evaluable with Baseline and Post-Baseline Data (n=82)
LS Geometric Mean Difference ± SEM



No. Evaluable						
CNM-Au8 30mg:	48	46	42	29	28	14
Placebo:	34	33	30	21	17	13

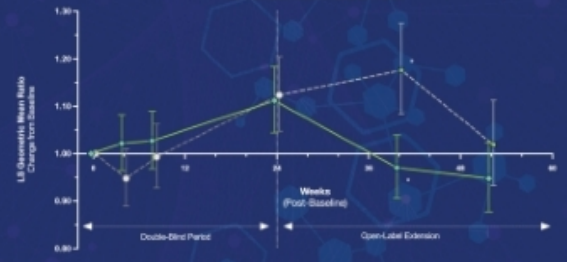
MMRM included all evaluable clinical visits. All visits with ≥ 10 participants (for either group) are graphed.

LS Geometric mean difference: *** p ≤ 0.001, ** p ≤ 0.01, * p < 0.05, ^ p ≤ 0.10

Chitinase-3-Like Protein 1 (YKL-40)

(All Evaluable, *Post Hoc*)

Plasma CHI3L1 (YKL-40) Geometric Mean Change (CNM-Au8 30mg)
Within Regimen Analysis | nVector
All Evaluable with Baseline and Post-Baseline Data (n=94)
LS Geometric Mean Difference ± SEM



No. Evaluable						
CNM-Au8 30 mg:	56	51	47	35	29	
Placebo:	38	32	30	23	19	

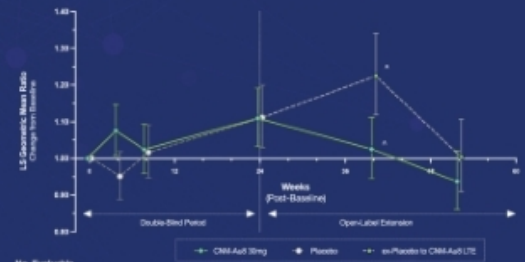
MMRM included all evaluable clinical visits. All visits with ≥ 10 participants (for either group) are graphed.

LS Geometric mean difference: *** p<0.001, ** p<0.01, * p < 0.05, ^ p<0.10

Chitinase-3-Like Protein 1 (YKL-40)

(Limb Onset, *Post Hoc*)

Plasma CHI3L1 (YKL-40) Geometric Mean Change (CNM-Au8 30 mg)
Limb Onset Subset
Within Regimen Analysis | nVector
All Evaluable with Baseline and Post-Baseline Data (n=80)
LS Geometric Mean Difference ± SEM



No. Evaluable						
CNM-Au8 30 mg:	47	43	40	28	26	
Placebo:	33	29	28	20	16	

MMRM included all evaluable clinical visits. All visits with ≥ 10 participants (for either group) are graphed.

LS Geometric mean difference: *** p<0.001, ** p<0.01, * p < 0.05, ^ p<0.10

Methods

Mixed Model Repeat Measure (MMRM) included baseline covariates: time from symptom onset, pre-treatment ALSFRS-R slope, background edaravone and riluzole treatment, and covariate interaction by week. Analyses includes all participants with evaluable baseline and post-baseline values.

Acknowledgements: We are indebted to the participants and investigators of the HEALEY ALS Platform Trial.

CLene NANOMEDICINE

Exhibit 99.4

FDA PROVIDES ROADMAP FOR ACCELERATED APPROVAL PATHWAY THROUGH SUBMISSION OF ADDITIONAL CNM-Au8® BIOMARKER DATA IN ALS

- *FDA recommends that Clene leverage additional Neurofilament Light (NfL) data from its three Expanded Access Protocols (EAPs) and the HEALEY ALS Platform Trial to support earlier presented findings*
- *FDA recommends a follow-up meeting to discuss in more detail the analyses needed to support the accelerated approval pathway*
- *Additional NfL biomarker collection and analyses are underway and planned to be completed during the second quarter of 2025*
- *Clene is proceeding with its New Drug Application (NDA) for ALS with a planned submission in mid-2025 following incorporation of the EAP NfL biomarker analyses*
- *Clene plans to commence the confirmatory Phase 3 trial (RESTORE-ALS) evaluating the survival benefit of CNM-Au8 with initial participant enrollment prior to the NDA submission*

SALT LAKE CITY, December 10, 2024 -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., a late clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today announced that it recently received written guidance from the Division of Neurology 1 (DN1), of the U.S. Food and Drug Administration (FDA) regarding a potential accelerated approval pathway for CNM-Au8® in ALS.

As announced previously on September 16, 2024, Clene was initially advised that the data presented in its briefing package for CNM-Au8 was not adequate to support an NDA submission under the accelerated approval pathway. However, following Clene's November 1, 2024 meeting with DN1 and presentation of additional data and analyses, the FDA has provided guidance on a potential path to meet the regulatory standard for substantial evidence of effectiveness supporting accelerated approval. The FDA recommended that Clene investigate whether additional data from the ongoing compassionate use EAPs could be leveraged to substantiate the effect of CNM-Au8 on NfL decline.

Clene intends to follow the FDA's recommendation to provide data from the ongoing EAPs and believes that it can address the FDA's requests. This additional NfL biomarker collection and analyses to support NDA submission is planned to be completed during second quarter of 2025, as summarized below:

- **NfL Biomarker Analyses:** Provide supportive evidence of NfL declines in participants from the three ongoing FDA-authorized compassionate use EAPs. Clene will meet with the FDA in early 2025 to review and finalize its statistical analysis plan for the EAP NfL biomarker analyses.
- **Survival Pharmacometric Modeling:** Provide analyses of NfL and related disease-specific biomarkers linked to clinical survival benefit and clinical changes from the Phase 2 trial data.
- **Additional ALS-specific biomarkers:** Provide analyses of additional ALS-disease specific biomarkers to support the pharmacodynamic activity of CNM-Au8 for treatment of ALS.

The FDA noted that whether NfL can serve as a reasonably likely surrogate endpoint for the effects of CNM-Au8 in ALS and whether the magnitude of change observed on NfL in patients treated with CNM-Au8 is reasonably likely to predict clinical benefit for ALS would be a matter of review.

Clene plans to commence the confirmatory Phase 3 RESTORE-ALS trial with participant enrollment beginning prior to the submission of the NDA. The study is designed to investigate the effects of CNM-Au8 on improved survival (primary endpoint) and delayed time to ALS clinical worsening events (secondary efficacy endpoint).

"We are incredibly grateful for the FDA's willingness to consider how the available data from our expanded access programs may be able to support the existing clinical study data to allow for the review of an application for approval of CNM-Au8 for ALS via an accelerated regulatory pathway, and for the valuable feedback we have received to date," said Rob Etherington, President and CEO of Clene. "Together with the survival and supportive biomarker data generated thus far, the drug's benign safety profile, and the emerging EAP NfL data, we look forward to continued discussions with the Agency. Clene plans to include the additional data in an NDA submission under the accelerated approval pathway in mid-2025. We remain dedicated to the ALS community and honored to help critically ill patients and their families."

Jinsy A. Andrews, MD, MSc, FAAN, Associate Professor of Neurology and the Director of Neuromuscular Clinical Trials at Columbia University, and Primary Investigator of the CNM-Au8 Clene NIH EAP Compassionate Use Protocol, said, “Having seen first-hand the potential benefits of CNM-Au8 in both its clinical and compassionate use EAP programs, I am grateful that the FDA has recognized the power of real-world experience for a drug in ALS, and is willing to consider how EAP data can help ALS drugs advance on regulatory pathways.”

Merit Cudkowicz, MD, Chair, Neurology Department, Massachusetts General Hospital, Director, Sean M Healey & AMG Center for ALS, and the Principal Investigator of the HEALEY ALS Platform Trial, said, “It was my pleasure to assist Clene in these varied supportive analyses, including NfL biomarker data from participants in our trials. Given the limited therapeutic options for ALS and a high sense of urgency, I am grateful to participate in considering multiple paths forward in ALS.”

Presentation at the November 1, 2024 FDA In-person Meeting: As previous noted, at the FDA in-person meeting on November 1, 2024, Clene and recognized ALS experts presented new supportive prespecified and *post hoc* analyses of its Phase 2 data, which included:

- **78% Risk Reduction in Time to Death (Improved Survival) during the Open Label Extension** to Month 12 from the HEALEY ALS Platform Trial (CNM-Au8 30 mg vs. original placebo randomization; covariate adjusted Cox Hazard Ratio (HR) = 0.224, 95% CI: 0.053 – 0.949, p-value = 0.042)
- **Evidence Linking Baseline NfL Burden with a CNM-Au8 Survival Benefit** *(post hoc)* included:
    - **83% Risk Reduction of Time to Death or PAV** (Permanently Assisted Ventilation) observed in CNM-Au8 participants with the highest baseline Upper NfL Tertile from the HEALEY ALS Platform Trial through Month 12 (CNM-Au8 30 mg vs. original placebo randomization; covariate adjusted Cox HR = 0.174, 95% CI: 0.036 – 0.830, p-value = 0.0283)
    - **84% Risk Reduction of Time to Death or PAV** seen in CNM-Au8 Participants with baseline NfL ≥ Median from the HEALEY ALS Platform Trial through Month 12 (CNM-Au8 30 mg vs. original placebo randomization; covariate adjusted Cox HR = 0.155, 95% CI: 0.035 – 0.693, p-value = 0.0147)
- **Evidence Linking NfL Decline with a CNM-Au8 Survival Benefit** *(post hoc)* included:
    - **57% of CNM-Au8 30 mg treated participants demonstrated NfL decline at week 24** (the end of the HEALEY-ALS Platform double-blind trial).
    - **91% Risk Reduction in Time to Death or PAV** observed in participants with any level of NfL decline (or missing NfL data) at week 24 in the HEALEY ALS Platform Trial with follow-up through Month 12; (CNM-Au8 30 mg vs. original placebo randomization; covariate adjusted Cox HR = 0.0925, 95% CI: 0.22 – 0.382, p-value = 0.001)
- **Long-Term Survival from Real-World Expanded Access Compassionate-use Protocols** showing a 31% risk reduction in CNM-Au8 participants who were unable to enter other ALS clinical trials due to advanced disease severity, when compared to propensity matched controls pooled from three different natural history and clinical trial datasets (covariate adjusted Cox HR = 0.689, 95% CI: 0.529 – 0.898, p-value = 0.0059)

In over 700 patient years of use of CNM-Au8, no significant safety concerns or safety trends have been identified. No serious adverse events (SAEs) have been identified as related to CNM-Au8 treatment by any investigator to date.

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 CNM-Au8®
CNM-Au8 is an oral suspension of gold nanocrystals developed to restore neuronal health and function by increasing energy production and utilization. The catalytically active nanocrystals of CNM-Au8 drive critical cellular energy producing reactions that enable neuroprotection and remyelination by increasing neuronal and glial resilience to disease-relevant stressors. CNM-Au8® is a federally registered trademark of Clene Nanomedicine Inc.

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 Clene's expectations regarding the availability of an accelerated approval regulatory pathway, the timing of clinical trials and the submission of an NDA, Clene's intention to follow the FDA's recommendation to provide data from the ongoing EAPs and address the FDA's requests, and that Clene can provide the additional evidence to meet the FDA's data requests. In addition, any statements that refer to 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, Clene's expectations regarding the availability of an accelerated approval regulatory pathway, the timing of clinical trials and the submission of an NDA, Clene's intention to follow the FDA's recommendation to provide data from the ongoing EAPs and address the FDA's requests, and that Clene can provide the additional evidence to meet the FDA's data requests may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include general market conditions; whether clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or do not otherwise produce positive results, which may cause us to incur additional costs or experience delays in completing, or ultimately be unable to complete; Clene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; Clene's ability to achieve commercial success for its drug candidates, if approved; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the development and commercialization of its 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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