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): October 3, 2022

Clene Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39834**	**85-2828339**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
6550 South Millrock Drive, Suite G50 Salt Lake City, Utah		**84121**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's telephone number, including area code: (801) 676-9695

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

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

☐ 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.

Healey ALS Platform Trial Topline Results

On October 3, 2022, Clene Inc. (the "Company") issued a press release announcing topline results for CNM-Au8® in the HEALEY ALS Platform Trial. The Company also hosted a conference call and webcast on October 3, 2022 to discuss the topline results. A copy of the press release and presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K (the "Current Report") and are incorporated herein by reference.

Corporate Presentation

In connection with the press release announcing topline results for CNM-Au8 in the Healey ALS Platform Trial, 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 99.3 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 alerting investors if the Corporate Presentation is updated.

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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release, dated October 3, 2022, announcing topline results demonstrating survival signal for CNM-Au8 in the HEALEY ALS Platform Trial.
99.2	Presentation, dated October 3, 2022.
99.3	Corporate Presentation.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CLENE INC.

Date: October 3, 2022

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

Clene Reports Topline Results Demonstrating Survival Signal for CNM-Au8® in Healey ALS Platform Trial

- ***The primary endpoint of adjusted ALSFRS-R and secondary endpoints of CAFS and SVC were not met at 24 weeks***
- ***Prespecified exploratory analyses of the secondary survival endpoint for the 30 mg dose demonstrated a >90% reduction in risk of death or risk of death/permanently assisted ventilation at 24 weeks***
- ***Survival signal consistent with prior results from the Phase 2 RESCUE-ALS trial***
- ***Clene will continue the open-label extension of CNM-Au8 in the Healey ALS Platform Trial and is in discussions with the Healey & AMG ALS Center to design and offer an Expanded Access Protocol (EAP) of CNM-Au8 30mg for eligible participants of closed regimens and others***
- ***Clene is pursuing multiple paths, including ongoing discussions with potential strategic partners, in its goal of marketing authorization***
- ***Clene to host investor call and webcast at 8:30 am EDT today***

SALT LAKE CITY, Oct. 3, 2022 -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease, today announced topline study results showing a survival benefit in the Healey ALS Platform trial of CNM-Au8®, an investigational gold nanocrystal suspension, in participants with amyotrophic lateral sclerosis (ALS).

The primary endpoint of slope of change in ALS Functional Rating Scale Revised (ALSFRS-R) scores adjusted for mortality was not significant (2% slowing, 95% CI: -20% to +19%) at 24 weeks. Secondary endpoints of Combined Assessment of Function and Survival (CAFS) and slow vital capacity (SVC) were also not met at 24 weeks across the combined 30 mg and 60 mg CNM-Au8 doses.

The prespecified exploratory analyses of the secondary survival endpoint demonstrated a >90% reduction in risk of death alone or in risk of death/permanently assisted ventilation at 24 weeks, when adjusted for baseline imbalances in risk (p=0.028 to p=0.075, unadjusted for multiple comparisons) with the CNM-Au8 30 mg dose. These survival results were statistically consistent for the 30 mg dose between the regimen only and full analysis sets, which included shared placebo from other regimens participating in the Healey ALS Platform trial (Regimens A, B, and D). This survival signal is consistent with results previously reported by Clene in the Phase 2 RESCUE-ALS trial with CNM-Au8.

The full analyses, including data on biomarkers of neurodegeneration and exploratory efficacy results, are expected later in 2022. The open-label extension will continue to follow participants and provide data updates in the future. Clene is in discussions with the Healey & AMG ALS Center to offer a broader EAP of CNM-Au8 30 mg for eligible participants of closed regimens and others.

Based on these topline findings, Clene has selected the CNM-Au8 30 mg dose for continued development in ALS. The CNM-Au8 60 mg dose did not demonstrate a survival benefit.

CNM-Au8 was well-tolerated, and there were no drug-related serious adverse events or significant safety findings reported.

"There remains a high unmet medical need for treatments for people living with ALS. The potential survival benefit with CNM-Au8 at 30 mg is encouraging. Additional pre-specified exploratory analyses of both the RCT and open-label extension part of the study will be shared once available," said Merit Cudkowicz, M.D., MSc, principal investigator and sponsor of the Healey ALS Platform Trial, director of the Sean M. Healey & AMG Center for ALS, chief of the Department of Neurology at Massachusetts General Hospital, and the Julieanne Dorn Professor of Neurology at Harvard Medical School. "We are thankful to the many people who participated in this study. We will learn from these results and continue to use these data to inform future advances in ALS trial design," she concluded.

Robert Glanzman, M.D., FAAN, Clene's Chief Medical Officer, said, "We are very pleased to see a survival benefit in a broad population of people who had already been living with ALS for up to three years. Importantly, this is the second Phase 2 study

demonstrating a survival benefit following CNM-Au8 treatment. CNM-Au8's mechanism of enabling energy metabolism and efficiency may not be reflected in the slope of ALSFRS-R change after only 24 weeks of treatment. These Healey ALS Platform Trial results support advancement of the CNM-Au8 30 mg dose. We look forward to discussions with U.S. regulatory authorities at an End of Phase 2 meeting for our CNM-Au8 development program in ALS."

Rob Etherington, Clene's President and CEO, added, "The survival results from this trial together with the consistent benefit seen in the open-label extension of the Phase 2 RESCUE-ALS trial, based on up to 31.5 months of long-term follow-up, support the rationale for treating neuronal and glial energetic failure with CNM-Au8. We have now completed multiple Phase 2 studies in ALS and MS, building a body of evidence demonstrating that CNM-Au8 supports cellular energy production, improving myelination and neuronal viability. We believe supporting brain energetic capacity translates to patient benefit, including survival. We will work closely with regulatory health authorities, ALS experts, and patient representatives to determine the proper path for FDA and EMA approval. Clene remains committed to advancing CNM-Au8 clinical programs to the ultimate goal of FDA approval. To support this effort, Clene is pursuing paths, including strategic partnerships, and is in dialogue with various potential partners."

Michael Hotchkin, Clene's Chief Development Officer, concluded, "We thank the ALS community for its support of the Healey ALS Platform trial. Furthermore, we thank the site investigators for their research excellence and dedication to patients, and we thank Dr. Cudkowicz and the team at the Healey & AMG ALS center for their leadership and for the development of the platform trial. Most importantly, we thank people living with ALS who participated in the study and their families for their effort and willingness to engage in clinical research."

Conference Call and Webcast Information

Clene will host a conference call and webcast at 8:30 am EDT to discuss the Healey ALS Platform trial topline results for CNM-Au8. Members of Clene's executive team will lead the discussion.

Time and Date: 8:30 a.m. EDT on Oct. 3, 2022
Investors: 1 (888) 660-6179 (toll-free) or 1 (929) 203-1946 (toll)
Conference ID: 5318408
*Press *1 to ask or withdraw a question, or *0 for operator assistance.*

To access the live webcast, please register online at this link. Participants are requested to register at a minimum 15 minutes before the start of the call. A replay of the call will be available two hours after the call and archived on the same web page for six months. A live audio webcast of the call will be available on the Investors section of the Company's website Events page. An archived webcast will be available on the Company's website approximately two hours after the event.

About the Healey ALS Platform Trial
The Healey ALS Platform Trial is a perpetual multi-center, randomized, double-blind, placebo-controlled program designed to evaluate the efficacy and safety of multiple investigational products utilizing a shared placebo group in people living with amyotrophic lateral sclerosis (ALS). In the CNM-Au8 regimen, 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. 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.

About CNM-Au8®
CNM-Au8 is Clene's lead asset in mid- and late-stage clinical development for the treatment of multiple sclerosis and amyotrophic lateral sclerosis. An oral suspension of gold nanocrystals, CNM-Au8 was developed to protect 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.

About Clene

Clene is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease by targeting energetic failure, an underlying cause of many neurological diseases. 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 Twitter, LinkedIn and Facebook.

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; uncertainty regarding whether potential strategic partnerships will result in any agreements or transactions, or, if completed, any agreements or transactions will be successful or on attractive terms; 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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617-283-2856

Source: Clene Inc.

Exhibit 99.2


Healey ALS Platform Trial
CNM-Au8 Results Webcast
October 2022
clene.com
clene
NASDAQ: CLNN

Healey ALS Platform Trial Results Webcast

01	**Introduction & CLNN Program Update**	Rob Etherington, President and Chief Executive Officer | Clene Inc.
02	**HEALEY ALS Platform Trial Results for CNM-Au8**	Merit Cudkowicz, M.D., MSc | Chief of Neurology at Massachusetts General Hospital Director of the Sean M. Healey & AMG Center for ALS
03	**Clene Milestones Q&A session**	Rob Etherington, President and Chief Executive Officer | Clene Inc. Robert Glanzman M.D., FAAN, Chief Medical Officer | Clene Inc. Michael Hotchkin, Chief Development Officer | Clene Inc. Merit Cudkowicz, M.D., MSc | Massachusetts General Hospital

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Forward Looking Statements

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CLENE | Growing Clinical Evidence Across ALS and MS Supports CNM-Au8 Therapeutic Potential

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

RESCUEALS

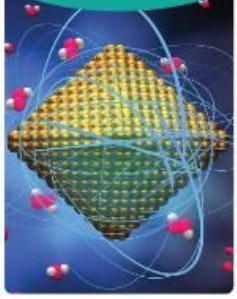
70% decreased risk of death in ALS

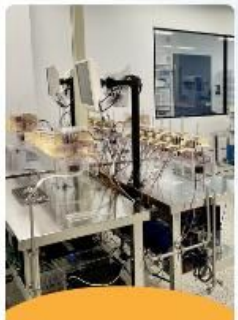
VISIONARY-MS STUDY

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

>400
patient years of CNM-Au8 clinical exposure

Strong IP:
150+
patents on Clean-Surface-Nanocrystal technology (CSN®) platform





Proprietary Nanotherapeutic Manufacturing

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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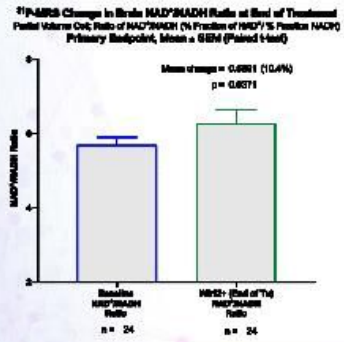
Building the Clinical Case for Neuroprotection & Remyelination

RepairPD
RepairMS

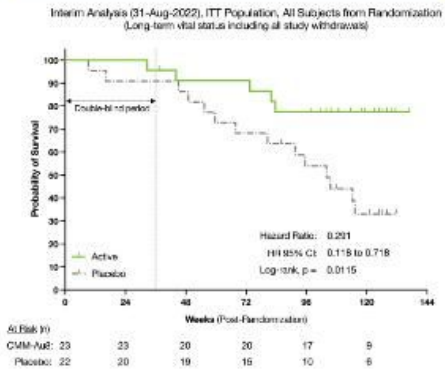
Established brain target engagement in early PD and stable relapsing MS patients

1° Endpoint (integrated PD & MS)[2]



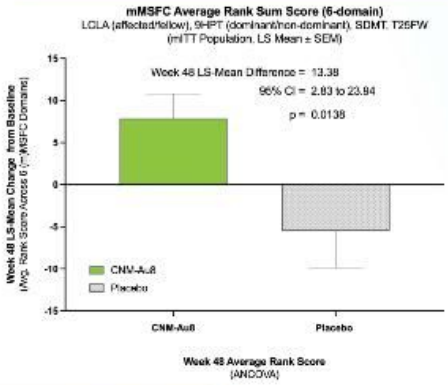
RESCUEALS

Demonstrated statistically significant survival; 70% decreased risk of death



VISIONARY-MS STUDY

First therapy to demonstrate global neurological improvement in MS patients on top of background DMT standard of care



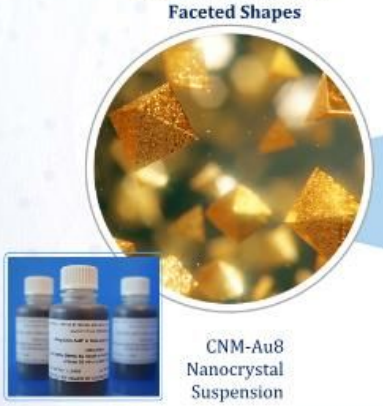
Growing Body of Clinical Evidence Across ALS and MS Supports CNM-Au8 Therapeutic Potential

CLene NANOMEDICINE

CNM-Au8® | Pioneering A New Drug Class To Improve Cellular Energy Production And Utilization

CNM-Au8 Nanocrystals

Clean Surfaced, Highly Faceted Shapes



CNM-Au8 Nanocrystal Suspension

Mechanistic Effects

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

=

Improved Energy Production and Utilization

By targeting energy metabolism, CNM-Au8 may protect neuronal health

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

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Over 400 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 predominantly mild-to-moderate

Patient Exposure Across ALS, MS & PD

Over 400 Years of Subject Exposure Without Identified Safety Signals

- Long-term dosing experience up to 150 weeks

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

HEALEY ALS Platform Trial

Results for CNM-Au8 Regimen

Merit Cudkowicz, M.D., MSc

- Director of the Sean M. Healey & AMG Center for ALS
- Chief of the Department of Neurology at MGH, and the Julieanne Dorn Professor of Neurology at Harvard Medical School
- Principal Investigator and Sponsor of the Healey ALS Platform Trial

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HEALEY ALS Platform Trial

A Multi-center, Randomized Double-Blind, Placebo-Controlled Clinical Trial Assessing the Efficacy, Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of CNM-Au8 in Participants with Amyotrophic Lateral Sclerosis

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

1° **Change in ALSFRS-R slope adjusted by mortality**

Weighted Average of Slope Change & Hazard Ratio

Weighting based on # of Mortality Events

2°

- CAFS (Joint-Rank)
- **Slow Vital Capacity (SVC)**
- **Survival (Death + PAV)**

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

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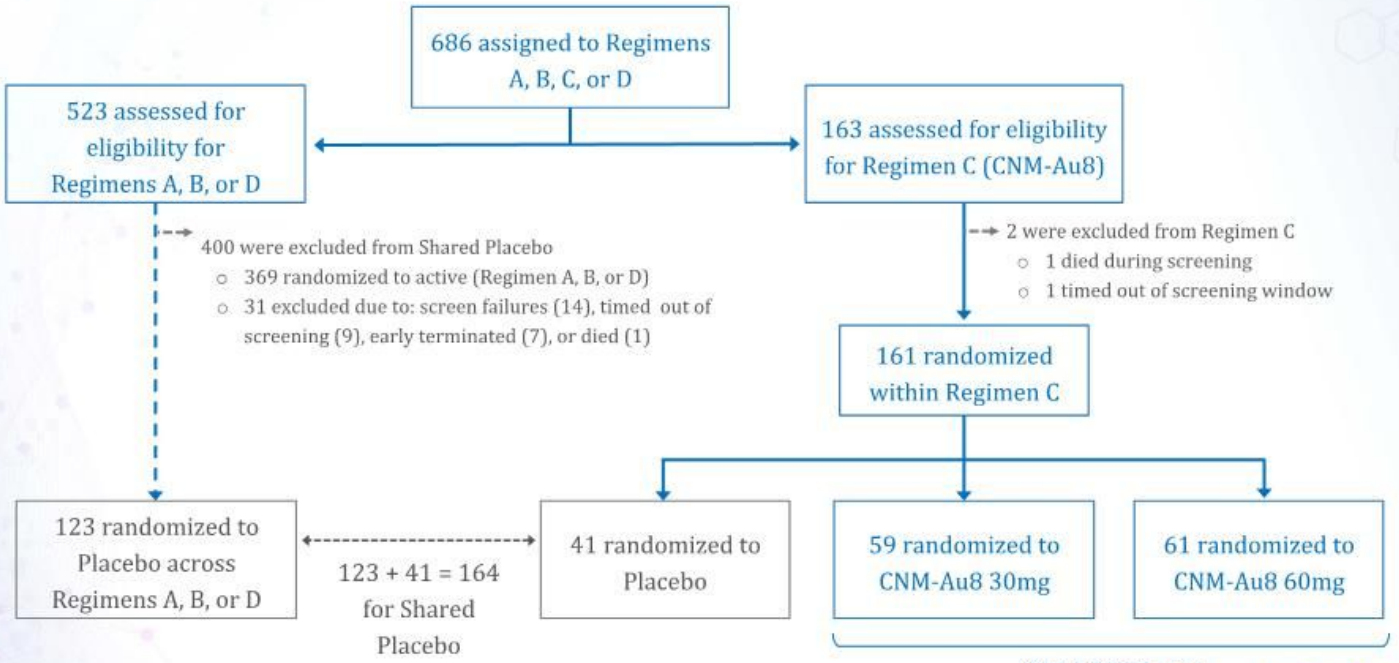
Participant Disposition | With Shared Placebo

HEALEY ALS Platform Trial



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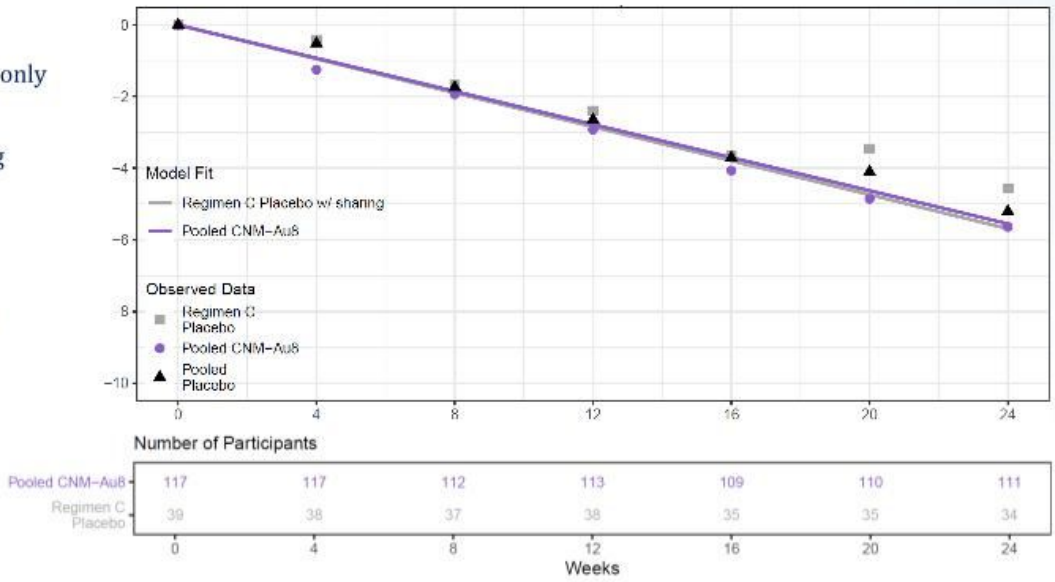
Primary | No Effect on Mortality Adjusted ALSFRS-R Change at 24 Weeks (30mg & 60mg combined)

- All shared controls
- ALSFRS-R component includes only survivors
- Mortality is accounted for using common treatment effect
- Model adjusts for covariates:
  - Time since symptom onset
  - Pre-baseline ALSFRS-R slope
  - Edaravone use
  - Riluzole use

Effect	CI*
-2%	-20% to +19%

*Credible interval

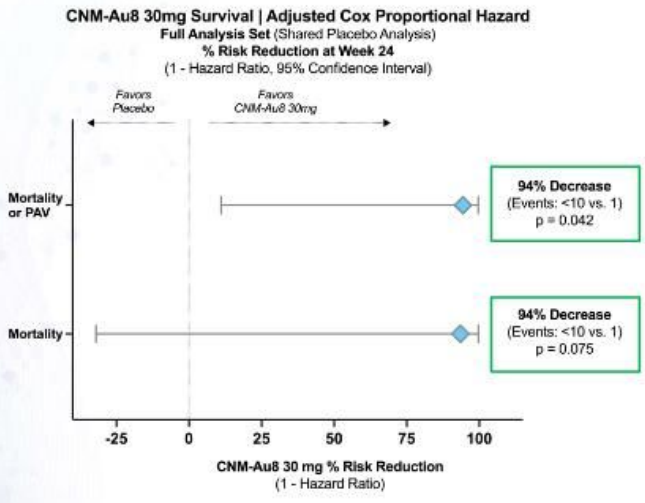


No Effect on Key Secondary Endpoints at 24 Weeks (30mg & 60mg combined)

- Combined Assessment of Function and Survival (CAFS) change at 24 weeks was not significant
- No effect on Slow Vital Capacity (SVC) at 24 weeks

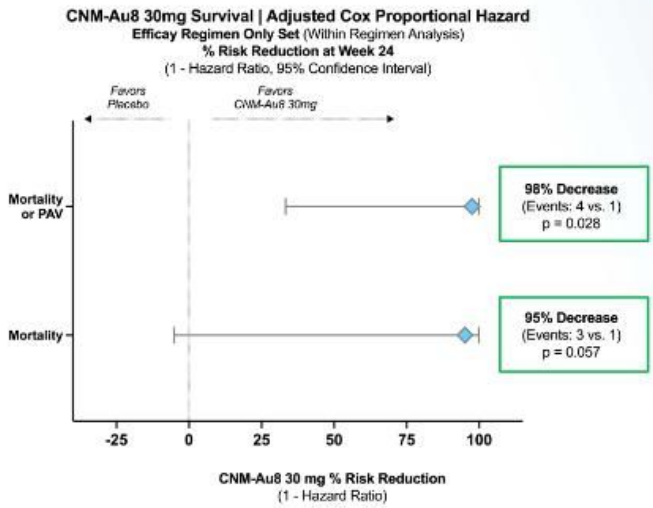
24-Week Survival Signal | >90% Risk Reduction at 30mg

*Shared Placebo Across Regimens



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.

*CNM-Au8 Regimen Only



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.

* p-values are not adjusted for multiple comparisons; exploratory analyses by dose

Safety

- Occurrence of TEAEs were balanced between CNM-Au8 and placebo
- No SAEs were assessed as related to CNM-Au8
- Higher incidence of SAEs at 60mg dose

Treatment Emergent Adverse Events (TEAEs)	Placebo (%)	CNM-Au8 30 mg (%)	CNM-Au8 60 mg(%)
Subjects with Any TEAE	90%	92%	93%
Subjects with Related TEAEs	39%	29%	43%
Subjects with SAE	9%	10%	16%
Subjects Withdrawn due to TEAE	7%	7%	7%

Healey ALS Platform Trial CNM-Au8 Summary

- No evidence for treatment effect at 24 weeks for either adjusted ALSFRS-R, CAFS, or SVC (combined doses)
- Potential survival signal: >90% decreased risk at 30mg
  - Mortality/PAV, p=0.028; Mortality = 0.057 (Regimen only)
  - Mortality/PAV, p=0.042; Mortality = 0.075 (Shared placebo)
- Well tolerated with no definitive safety signals

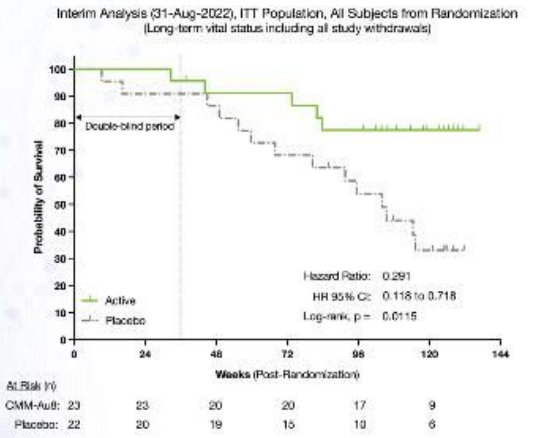
Robert Glanzman, M.D., FAAN

Clene Chief Medical Officer

CNM-Au8 Has Demonstrated ALS Survival Benefit at 30 mg Dose in Two Phase 2 Studies

RESCUEALS

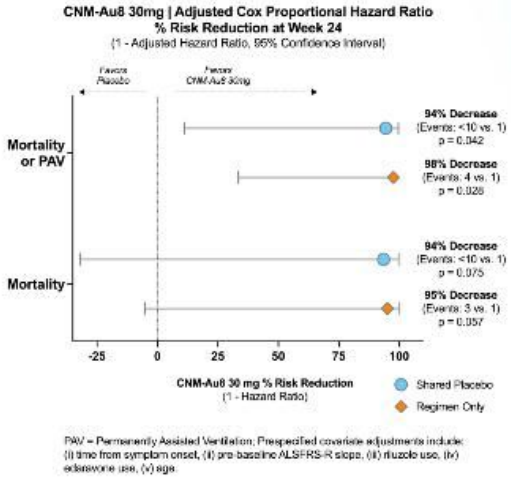
CNM-Au8 demonstrated 70% decreased risk of death



Long-term follow-up up to 2.5 years show 70% decreased risk of death (original active vs original placebo randomization), P=0.0115

HEALEY ALS Platform Trial

CNM-Au8 demonstrated a >90% risk reduction of death at 30 mg



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

(i) Risk of Death or (ii) Risk of Death or Permanently Assisted Ventilation at 24 weeks in Regimen-Only and in Full Analysis (Shared Placebo) (P=0.028 to 0.075)

Data on File, Clene Nanomedicine, Inc.

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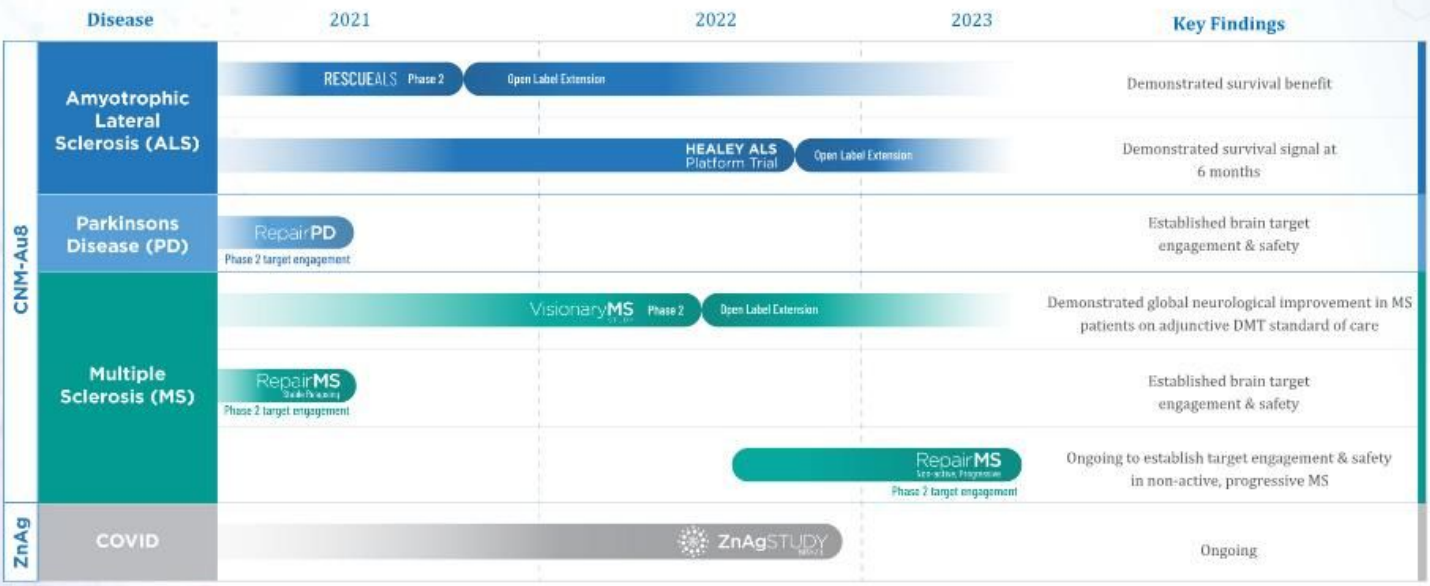
Growing Body of Evidence for Clene Nanotherapeutics



Data on File, Clene Nanomedicine, Inc.

CNM-Au8 Question and Answers

Merit Cudkowicz, M.D., MSc
Chief, Department of Neurology at MGH
Director of the Sean M. Healey & AMG Center for ALS

Rob Etherington
Chief Executive Officer
Clene Nanomedicine, Inc.

Robert Glanzman, M.D., FAAN
Chief Medical Officer
Clene Nanomedicine, Inc.

Michael Hotchkin
Chief Development Officer
Clene Nanomedicine, Inc.

Exhibit 99.3


Corporate Presentation
October 2022
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.

CLENE | Building Clinical Neuroprotective Evidence

Significant Opportunity

- Targeting neurodegenerative diseases such as ALS and Multiple Sclerosis
- >$1B commercial opportunity in each indication

CNM-Au8® Clinical Results

- Long-term follow-up of RESCUE-ALS Phase 2 participants demonstrated statistically significant survival benefit; 70% decreased risk of death
- Positive Topline Results from the Phase 2 VISIONARY-MS Trial: CNM-Au8 demonstrated global neurological improvements in stable relapsing MS as adjunctive therapy to immunomodulatory DMTs
- CNM-Au8 demonstrated a >90% reduction in risk of death or permanently assisted ventilation for the 30 mg dose at 24 weeks in pre-specified exploratory results in the HEALEY ALS Platform Trial

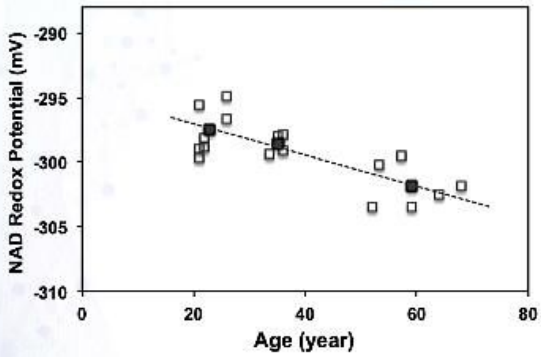
Proprietary Platform

Strong IP

- Proprietary nanotherapeutic manufacturing
- Strong IP, including 150+ granted patents and manufacturing trade secrets

Neurodegenerative Diseases Share A Common Mechanism: A Decline In The Brain's Ability To Produce Energy

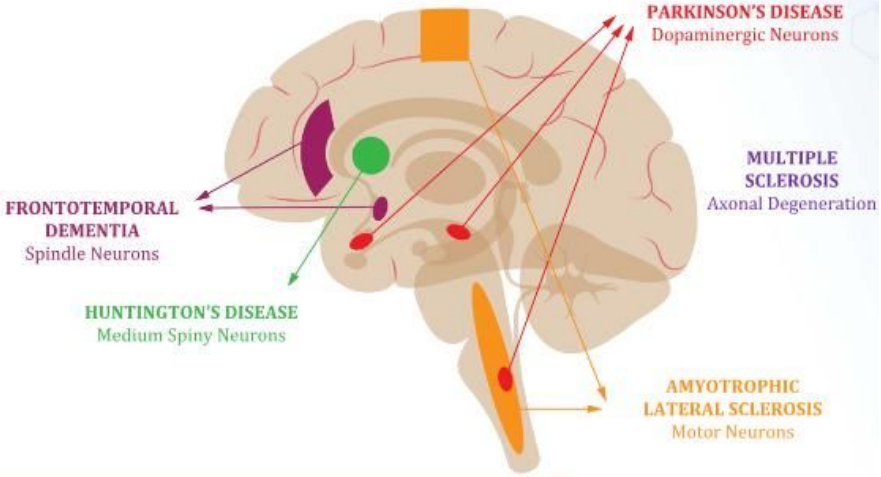
Brain Energy Potential Declines With Normal Aging



~0.5% NAD^+/NADH unit decline per decade
(~0.13 mV units per year by ^{31}P-MRS Imaging)

Closed squares = averaged data by age group: 21–26 yrs, 33–36 yrs, and 59–68 yrs old; Open squares = individual subject values

Specific Neuronal Populations Are Vulnerable to Energetic Failure



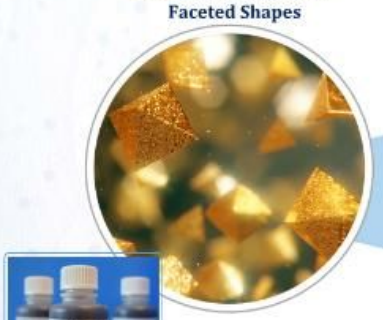
Energetic impairments in the CNS both pre-dispose and drive progression in neurodegenerative diseases

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

CNM-Au8® | Pioneering A New Drug Class To Improve Cellular Energy Production And Utilization

CNM-Au8 Nanocrystals

Clean Surfaced, Highly Faceted Shapes



CNM-Au8 Nanocrystal Suspension

Mechanistic Effects

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

=

Improved Energy Production and Utilization

By targeting energy metabolism, CNM-Au8 may protect neuronal health

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

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Significant Global Opportunity for Treatment in Combination with Standard of Care

Motor Neuron Disease (ALS, Other Orphan Disorders)

ALS PATIENTS IN US & EU ~40K[1]

$1B GLOBAL SALES BY 2028[1]

Current drugs are largely ineffective, mostly generic.

2-5 YEARS[2] LIFE EXPECTANCY

100% FATAL

Multiple Sclerosis (MS)

MS PATIENTS GLOBALLY 2.2M

$23B MARKET[3]

Existing treatments only target immunomodulation

EMERGING EVIDENCE THAT EARLY MS IS NEURODEGENERATIVE

Parkinsons Disease (PD)

2ND MOST COMMON DISORDER

$6B PROJECTED BY 2026[4]

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

30% OF DOPAMINERGIC NEURONS ARE LOST AT DIAGNOSIS[5]

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

[1] Clarivate, DRG, ALS 2020 2. https://pubmed.ncbi.nlm.nih.gov/17974351/ 3. Westad et al. 2017, doi:10.1038/nrd.2017.107;-4. Parkinson's Market Data Forecast, April 2021.. 5. Cheng HC, Ulane CM, Burke RE. Clinical progression in Parkinson disease and the neurobiology of axons. Ann Neurol 2010;67:715-725.

Building the Clinical Case for Neuroprotection & Remyelination

RepairPD
RepairMS

RESCUEALS

VISIONARY-MS STUDY

Established brain target engagement in early PD and stable relapsing MS patients

CNM-Au8 demonstrated statistically significant survival benefit

70% decreased risk of death

CNM-Au8 demonstrated neurological improvements in people with stable relapsing MS as adjunctive therapy to immunomodulatory DMTs

Growing Body of Clinical Evidence Across ALS and MS Supports CNM-Au8 Therapeutic Potential

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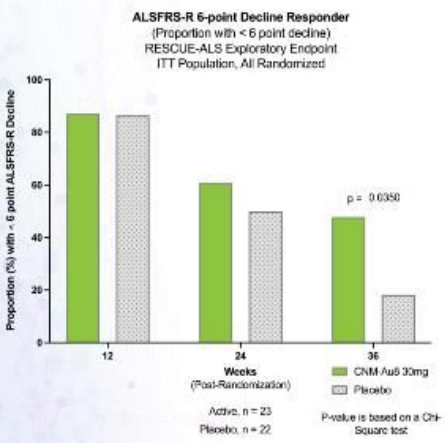
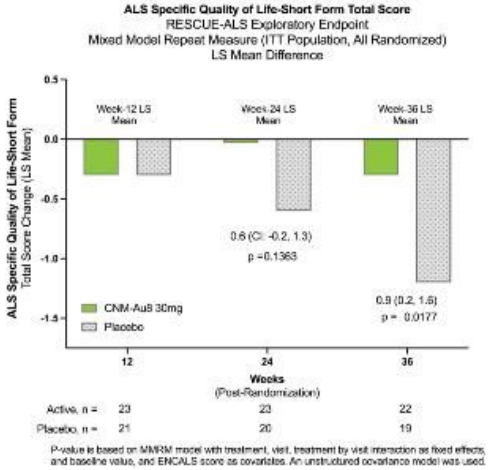
RESCUEALS CNM-Au8 Improved Patient Function and QOL, and Slowed ALS Disease Progression

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

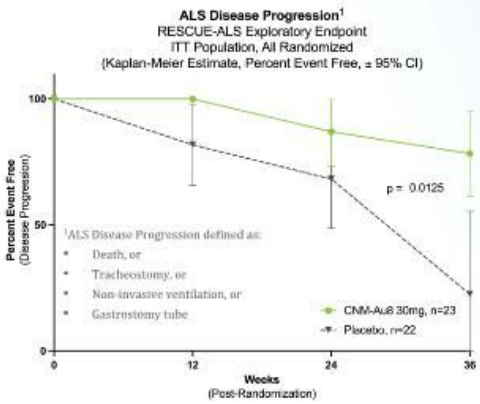
Proportion with <6 point decline



ALS Specific QOL



ALS Disease Progression



Vucic et al. RESCUE-ALS Trial Results: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of CNM-Au8 to Slow Disease Progression in Amyotrophic Lateral Sclerosis; Presented at International Symposium on ALS/MND; 7-10 December 2021

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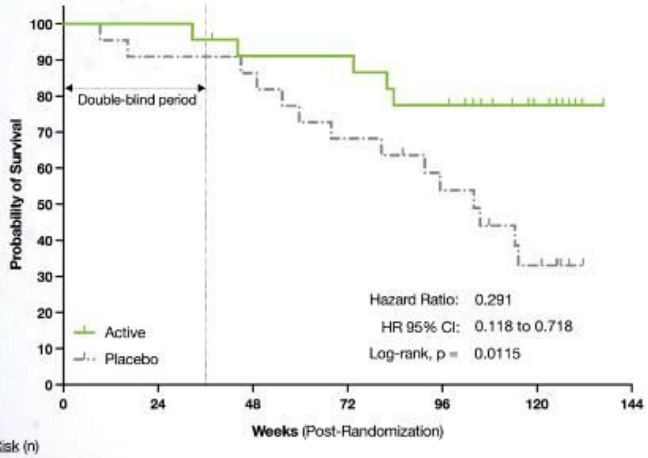
RESCUEALS Demonstrated Significant Impact on Long-Term Survival with 70% Decreased Risk of Death

RESCUE-ALS Active vs. Placebo Randomization

Long-Term Observed Survival (Interim Analysis)

Interim Analysis (31-Aug-2022), ITT Population, All Subjects from Randomization
(Long-term vital status including all study withdrawals)



At Risk (n)						
CMM-Au8:	23	23	20	20	17	9
Placebo:	22	20	19	15	10	6

Early CNM-Au8 treatment demonstrated a significant survival benefit:

- Follow-up of active compared to initial placebo randomization*
- 70% decreased risk of death

*9-month delayed treatment start (ex-placebo) or no treatment

Time to all-cause mortality amongst participants originally randomized to CNM-Au8 compared to participants originally randomized to placebo through 31-Aug-2022. Vital status and date of death (as applicable) were captured for all subjects withdrawn from the study. Lost-to-follow-up (active, n=1; placebo, n=1) censored as of the date of last study contact (Active: Feb-2021; Placebo: Feb-2022). All OLE ex-placebo CNM-Au8 transitioned participants within the placebo group. All alive subjects are right censored as of 31-Aug-2022.

Data on File, Clene Nanomedicine, Inc.

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

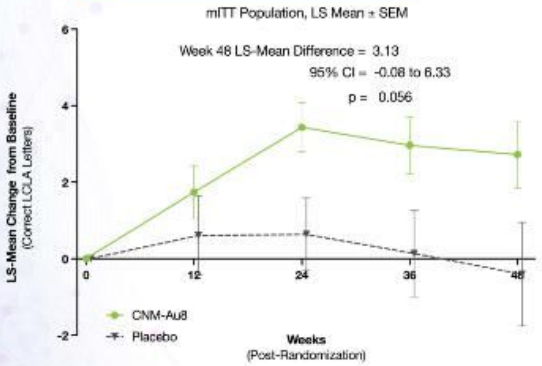
VISIONARY-MS

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

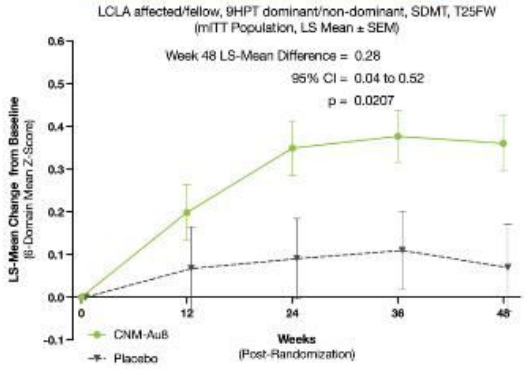
Enrolled stable relapsing remitting MS participants with chronic optic neuropathy on background DMTs

n=73 of 150 planned – study ended prematurely due to COVID-19 pandemic-related enrollment challenges

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



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



Data on File, Clene Nanomedicine, Inc.

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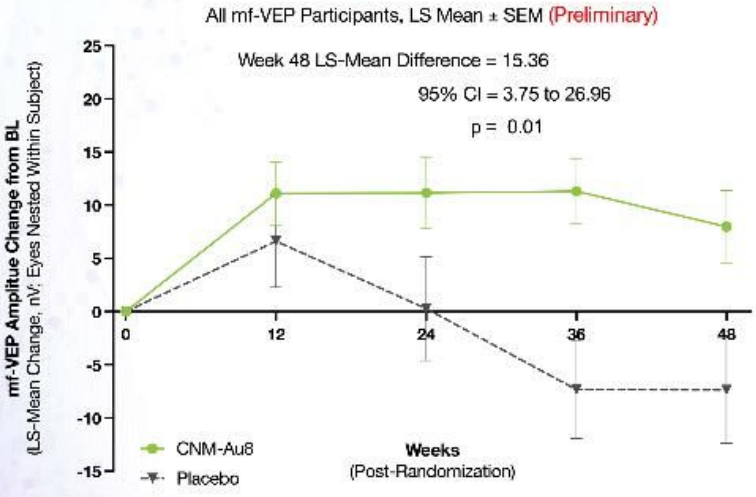
CNM-Au8 Improved Axonal Integrity and Retinal Structure

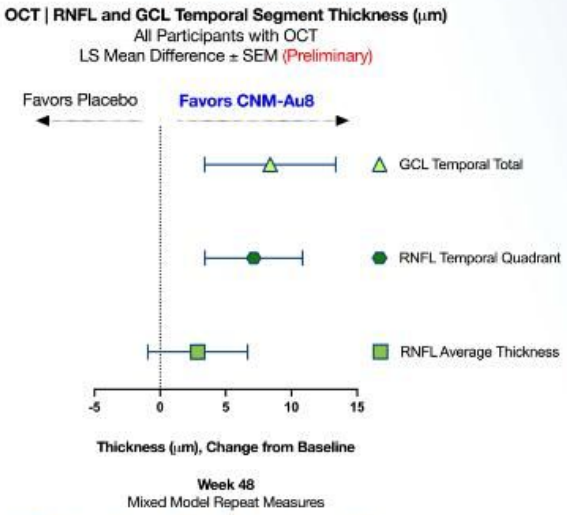
VISIONARY-MS

Increased Amplitude (Signal Strength) Exploratory Endpoint



mf-VEP amplitude

Improved Temporal Segment GCL & RNFL Exploratory Endpoint



OCT retinal nerve fiber & ganglion cell layers

Data on File, Clene Nanomedicine, Inc.

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HEALEY ALS Platform Trial

A Multi-center, Randomized Double-Blind, Placebo-Controlled Clinical Trial Assessing the Efficacy, Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of CNM-Au8 in Participants with Amyotrophic Lateral Sclerosis

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

1° **Change in ALSFRS-R slope 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)**

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

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Healey ALS Platform Trial CNM-Au8 Results

HEALEY ALS Platform Trial

- No evidence for treatment effect at 24 weeks for either adjusted ALSFRS-R, CAFS, or SVC (combined 30 & 60 mg doses)
- Potential survival signal: >90% decreased risk of death at 30mg
  - Mortality/PAV, p=0.028; Mortality = 0.057 (Regimen only)
  - Mortality/PAV, p=0.042; Mortality = 0.075 (Shared placebo)
- Well tolerated with no definitive safety signals

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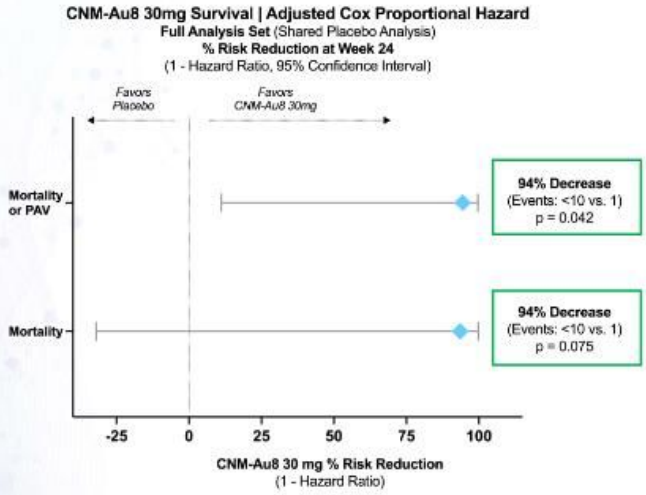
24-Week Survival Signal | >90% Reduced Risk of Death at 30 mg

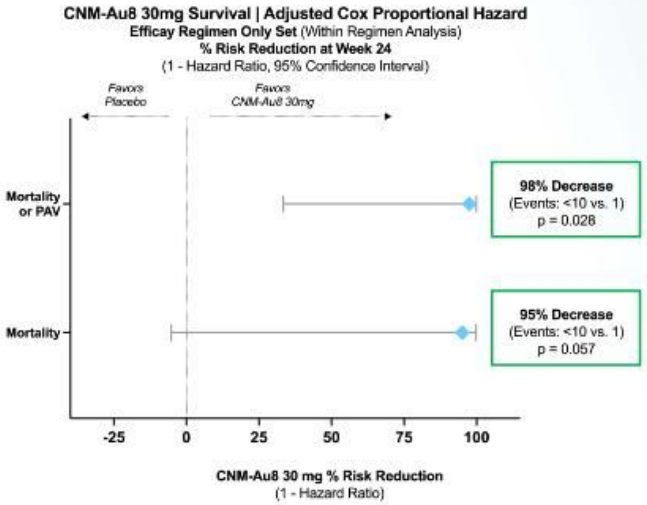
HEALEY ALS Platform Trial

*Shared Placebo Across Regimens



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.

*CNM-Au8 Regimen Only



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* p-values are not adjusted for multiple comparisons; exploratory analyses by dose

Data on File, Clene Nanomedicine, Inc.

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Over 400 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 predominantly mild-to-moderate

Patient Exposure Across ALS, MS & PD

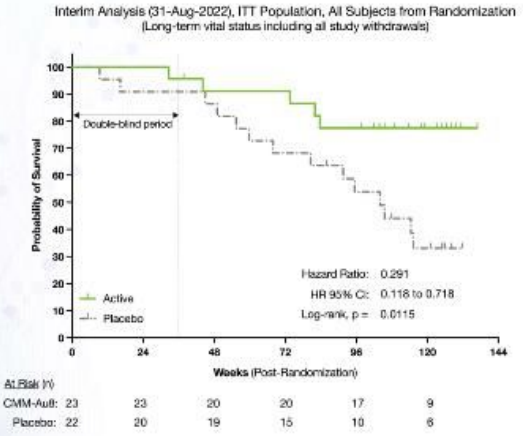
Over 400 Years of Subject Exposure Without Identified Safety Signals

- Long-term dosing experience up to 150 weeks

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

CNM-Au8 Has Demonstrated ALS Survival Benefit at 30 mg Dose in Two Phase 2 Studies

RESCUEALS CNM-Au8 demonstrated 70% decreased risk of death



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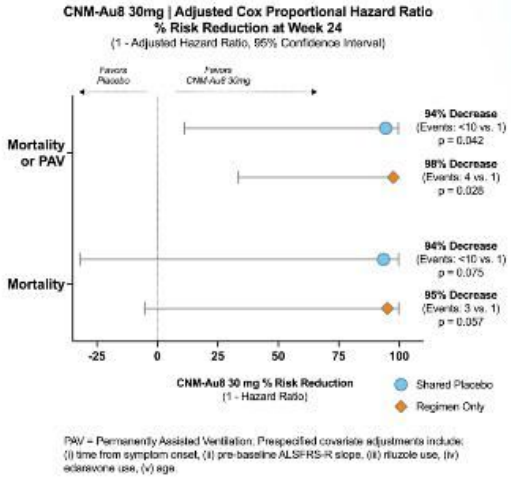

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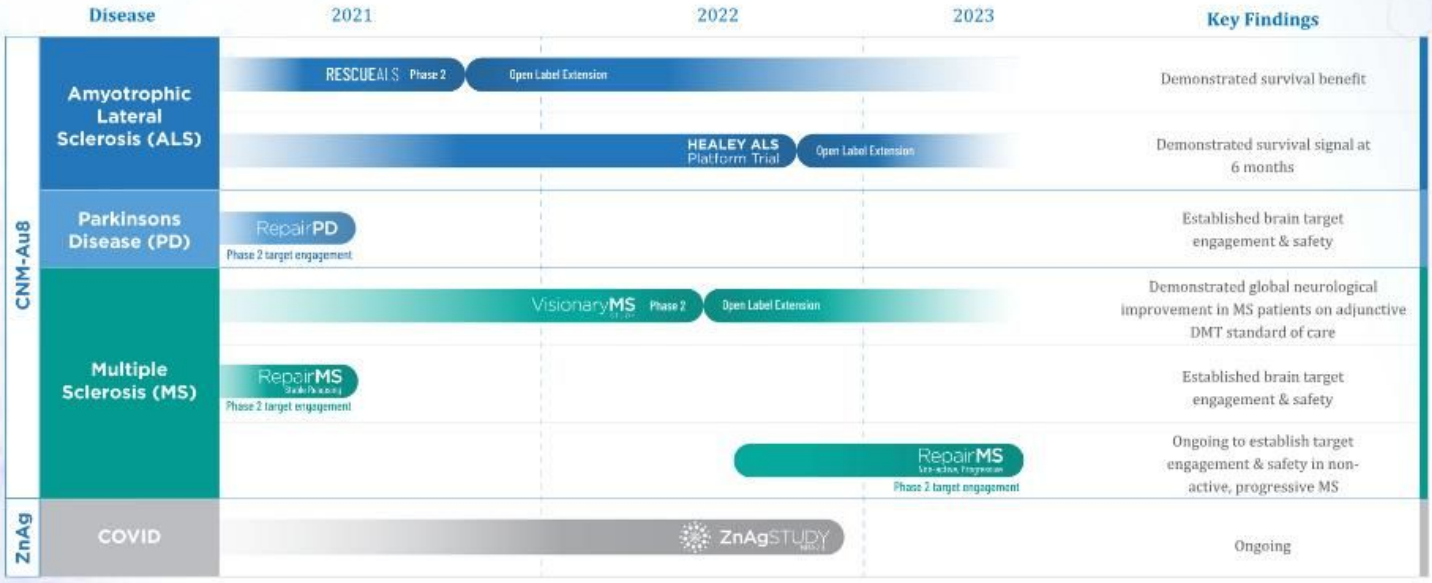
Growing Body of Evidence for Clene Nanotherapeutics



Data on File, Clene Nanomedicine, Inc.

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

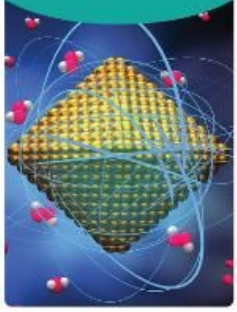
RESCUEALS
70% decreased risk of death in ALS

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

>400
patient years of CNM-Au8 clinical exposure

Strong IP:
150+
patents on nanotherapeutic platform



As of June 30, 2022, cash and investments on hand (unaudited):

$26.3M

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: 3-Oct-2022