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): November 13, 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 2.02 Results of Operations and Financial Condition.

On November 13, 2024, Clene Inc. (the "Company") issued a press release announcing its third quarter 2024 financial results and recent operating highlights for its quarter ended September 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished in this Item 2.02, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933 (the "Securities Act"), 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 7.01 Regulation FD Disclosure.

In connection with the November 13, 2024 press release announcing the Company's third quarter 2024 financial results and recent operating highlights for its quarter ended September 30, 2024, 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 99.2 to the Current Report on Form 8-K and is incorporated herein by reference. The Company plans to use its website to disseminate future updates to the Corporate Presentation and may not file or furnish a Current Report on Form 8-K alerting investors if the Corporate Presentation is updated.

The information furnished in this Item 7.01, including Exhibit 99.2, shall not be deemed to be "filed" for purposes of Section 18 of 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, 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 November 13, 2024, announcing the Company's third quarter 2024 financial results and recent operating highlights.
99.2	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: November 13, 2024

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

Exhibit 99.1

CLENE REPORTS THIRD QUARTER 2024 FINANCIAL RESULTS AND RECENT OPERATING HIGHLIGHTS

- *Clene met with the U.S. Food and Drug Administration (FDA) on November 1, 2024 in a Type C meeting to discuss the potential for an accelerated approval pathway in ALS and are awaiting meeting minutes*
- *Cash, cash equivalents and marketable securities of $14.6 million as of September 30, 2024*
- *Amended debt agreement with Avenue Capital to defer principal payments and extend maturity of facility to second quarter of 2025*
- *Completed registered direct offering and concurrent private placements to raise $7.3 million in gross proceeds on October 1, 2024*

SALT LAKE CITY, November 13, 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 its third quarter 2024 financial results and provided recent updates on its CNM-Au8 programs.

Third Quarter 2024 and Recent Operating Highlights

CNM-Au8 for the treatment of ALS

On November 1, 2024, the Company met with the FDA in a Type C meeting to discuss the potential for an accelerated approval pathway in ALS for CNM-Au8, including biomarker and related clinical and survival data, and are currently awaiting meeting minutes from this meeting.

Corporate Update

In July, Clene announced a 1-for-20 reverse stock split. Clene's common stock now trades on the Nasdaq Capital Market on a split-adjusted basis under a new CUSIP number 185634201 and the Company's existing trading symbol "CLNN." The reverse stock split enabled Clene to regain compliance with the $1.00 minimum closing bid price required for continued listing on the Nasdaq Capital Market. All outstanding stock options, warrants, rights to restricted stock awards, convertible debt, and contingent earn-out shares entitling their holders to purchase or receive shares of Common Stock were adjusted as a result of the reverse stock split as required by the terms of each security.

In September, Clene amended its existing debt facility with Avenue Venture Opportunities Fund, L.P. in which the parties agreed to reduce or defer future monthly principal payments and extend the principal amortization period and maturity date into the second quarter of 2025.

In October, Clene announced the closing of a registered direct offering and concurrent private placements of common stock and warrants with a healthcare-focused institutional investor and existing shareholders, including insiders, with total gross proceeds of $7.3 million and the potential for additional capital in the future through the exercise of warrants. The offering was led by a healthcare-focused institutional investor with participation from SymBiosis; founding investor Kensington Capital Holdings; Clene's Chairman of the Board of Directors, Chief Executive Officer and Chief Scientific Officer and Founder; along with support from several other previously existing shareholders.

The October offering, combined with the amendment to the debt facility with Avenue, is expected to enable the Company to fund its operations into the first quarter of 2025. We believe that this funding enables runway for key inflection points.

In October, Clene presented the design for RESTORE-ALS, its potentially confirmatory international Phase 3 clinical trial of CNMAu8 30 mg, at the 2024 Annual Northeast Amyotrophic Lateral Sclerosis Consortium.

Third Quarter 2024 Financial Results

Clene's cash, cash equivalents and marketable securities totaled $14.6 million as of September 30, 2024, compared to $35.0 million as of December 31, 2023. Clene expects that its resources as of September 30, 2024 combined with gross proceeds raised in the October offering, will be sufficient to fund its operations into the first quarter of 2025.

Research and development expenses were $4.5 million for the quarter ended September 30, 2024, compared to $6.0 million for the same period in 2023. The year-over-year decrease was primarily related to a decrease in expenses in the HEALEY ALS Platform Trial, RESCUE-ALS, REPAIR-MS, and VISIONARY-MS clinical trials due to the previous completion of the blinded period of each trial; a decrease in expenses for the VISIONARY-MS LTE due to its completion; and a decrease in non-clinical and pre-clinical activities; partially offset by an increase in expenses related to our two ALS EAPs with Massachusetts General Hospital due to increased enrollment and expansion of one EAP.

General and administrative expenses were $3.4 million for the quarter ended September 30, 2024, compared to $3.7 million for the same period in 2023. The year-over-year decrease was primarily related to decreases in directors' and officers' insurance premiums, decreases in finance and accounting fees, primarily due to a decrease in fees from consultants, advisors, and other financial vendors, and decreases in stock-based compensation expense; partially offset by an increase in legal fees, primarily related to regulatory activities, and an increase in other general and administrative fees associated primarily with lobbying activities.

Total other expense was $0.2 million for the quarter ended September 30, 2024, compared to total other income of $7.1 million for the same period in 2023. During 2023, Clene recorded significant non-cash gains from the change in the fair value of the common stock warrant liability related to the 2023 Avenue Warrants and Tranche A Warrants as well as significant non-cash gains from the change in fair value of the Clene Nanomedicine Contingent Earn-out liability and the Initial Stockholders Contingent Earn-out liability. Similar large non-cash gains were not recorded in 2024. Additionally, interest expense was less in 2024 due to reduced interest rates and outstanding principal balances.

Clene reported a net loss of $8.0 million, or $1.22 per share, for the quarter ended September 30, 2024, compared to a net loss of $2.4 million, or $0.38 per share, for the same period in 2023.

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 that its resources are sufficient to fund operations into the first quarter of 2025, and the availability of an accelerated approval regulatory pathway. 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 that its resources are sufficient to fund operations into the first quarter of 2025 and the availability of an accelerated approval regulatory pathway 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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CLENE INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue	$ 65	$ 65	$ 173	$ 355
Royalty revenue	22	43	78	129
Total revenue	87	108	251	484
Operating expenses:				
Cost of revenue	18	12	52	83
Research and development	4,471	5,972	14,490	19,982
General and administrative	3,413	3,666	10,147	11,029
Total operating expenses	7,902	9,650	24,689	31,094
Loss from operations	(7,815)	(9,542)	(24,438)	(30,610)
Other income (expense), net:				
Interest income	127	546	755	931
Interest expense	(1,022)	(1,188)	(3,548)	(3,358)
Commitment share expense	—	—	—	(402)
Issuance costs for common stock warrant liabilities	—	—	—	(333)
Loss on initial issuance of equity	—	—	—	(14,840)
Change in fair value of common stock warrant liabilities	697	6,341	956	5,958
Change in fair value of Clene Nanomedicine contingent earn-out liability	—	1,004	75	2,114
Change in fair value of Initial Stockholders contingent earn-out liability	—	129	10	272
Research and development tax credits and unrestricted grants	27	247	339	902
Other income, net	—	45	—	35
Total other income (expense), net	(171)	7,124	(1,413)	(8,721)
Net loss before income taxes	(7,986)	(2,418)	(25,851)	(39,331)
Income tax expense	—	—	—	—
Net loss	(7,986)	(2,418)	(25,851)	(39,331)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	1	(4)	(1)	16
Foreign currency translation adjustments	52	(81)	25	(130)
Total other comprehensive income (loss)	53	(85)	24	(114)
Comprehensive loss	$ (7,933)	$ (2,503)	$ (25,827)	$ (39,445)
Net loss per share – basic and diluted	$ (1.22)	$ (0.38)	$ (4.00)	$ (8.11)
Weighted average common shares used to compute basic and diluted net loss per share	6,557,839	6,420,274	6,467,771	4,851,348

CLENE INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,645	$ 28,821
Marketable securities	—	6,179
Accounts receivable	—	143
Inventory	128	37
Prepaid expenses and other current assets	4,925	3,672
Total current assets	19,698	38,852
Restricted cash	58	58
Operating lease right-of-use assets	3,776	4,168
Property and equipment, net	8,037	9,263
TOTAL ASSETS	$ 31,569	$ 52,341
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,678	$ 1,504
Accrued liabilities	6,733	3,720
Share subscriptions payable	3,810	—
Operating lease obligations, current portion	732	576
Finance lease obligations, current portion	—	27
Notes payable, current portion	10,875	14,627
Convertible notes payable, current portion	—	4,876
Total current liabilities	23,828	25,330
Operating lease obligations, net of current portion	4,335	4,903
Notes payable, net of current portion	1,668	1,894
Convertible notes payable, net of current portion	5,271	5,258
Common stock warrant liabilities	592	1,481
Clene Nanomedicine contingent earn-out liability	—	75
Initial Stockholders contingent earn-out liability	—	10
TOTAL LIABILITIES	35,694	38,951
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 600,000,000 and 300,000,000 shares authorized at September 30, 2024 and December 31, 2023, respectively; 6,857,170 and 6,421,084 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	264,225	255,913
Accumulated deficit	(268,574)	(242,723)
Accumulated other comprehensive income	223	199
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(4,125)	13,390
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 31,569	$ 52,341


clene.com
clene
NASDAQ: CLNN

Forward Looking Statements

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

THE PROBLEM

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

A NEW APPROACH

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

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Building the Clinical Case for Neuroprotection & Remyelination

HEALEY ALS Platform Trial

RESCUEALS

VISIONARY-MS STUDY

RepairPD

RepairMS

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

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

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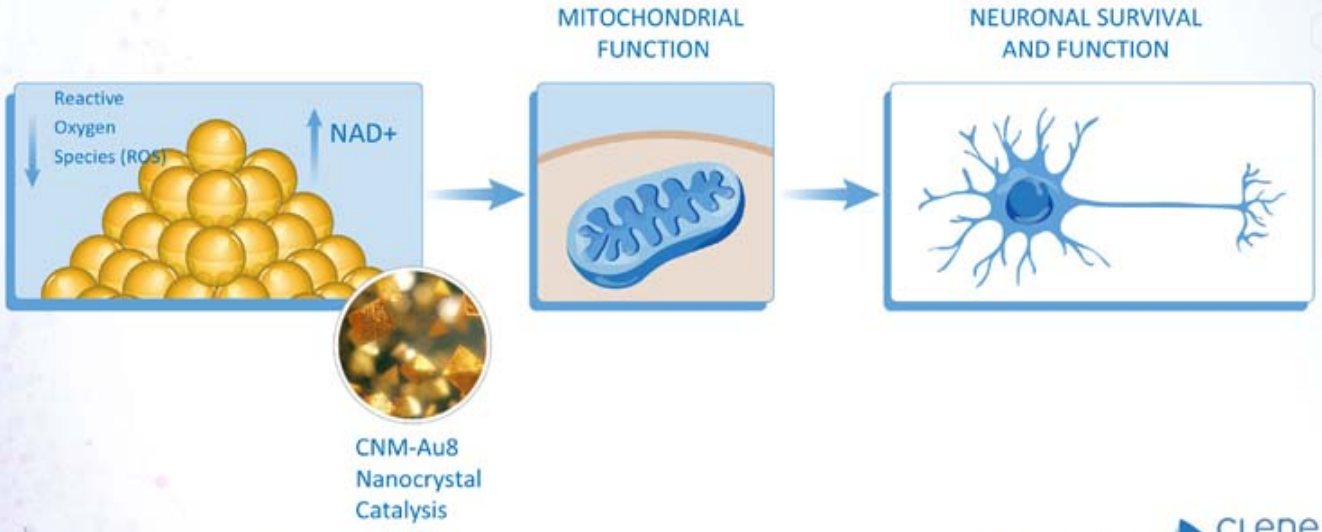
CNM-Au8® | Surface Catalysis Improves Mitochondrial Function



Robinson et al. Sci Rep. 2020 Feb 11;10(1):2936. Wang et al 2023, Small. 2023 Sep 28:e2304082.

CLene NANOMEDICINE

Over 700 Years of Subject Exposure Without Identified Safety Signals Across ALS, MS, and PD

Clean Toxicology Findings

All Animal Toxicology Studies Resulted in No-Adverse Effect Level (NOAEL) Findings

- Multiple species up to 9-months treatment
- Up to maximum feasible dosing without any toxicology findings related to CNM-Au8

Well Tolerated Adverse Event (AE) Profile

Assessed as Predominantly Mild-to-Moderate Severity and Transient

- **No SAEs related to CNM-Au8** considered severe, life-threatening, or resulting in death
- **AEs transient/mild-to-moderate** severity (GI/Headache)

Patient Exposure Across ALS, MS & PD

Over 700 Years of Subject Exposure Without Identified Safety Signals

- Long-term dosing experience **over 5 years**

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

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

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

	RESCUE-ALS	RESCUE-OLE	HEALEY ALS Platform	HEALEY OLE	EAP
ALS Patient Demographics	Early-to-Mid-Stage (45)	Early-to-Mid-Stage	Mid-to-Late-Stage (161 Regimen C)	Mid-to-Late-Stage	Real-World Experience (256)
Duration	36-weeks	Up to 173 weeks	24-weeks	Up to 133 weeks	Over 5.0 years
Survival	--	✓	✓	✓ PRO-ACT	✓
Delayed Time to Clinical Worsening	✓	✓	✓	Pending data 1Q 2024	Not routinely collected
Preserved Function (ALSFRS-R)	--	✓	--		
Progression Biomarkers	p75 trend	↓ UCHL1 *	✓ NfL ↓	✓ NfL ↓	
Safety	>700 Years of Subject Exposure Without Identified Safety Signals Across ALS, MS, and PD				

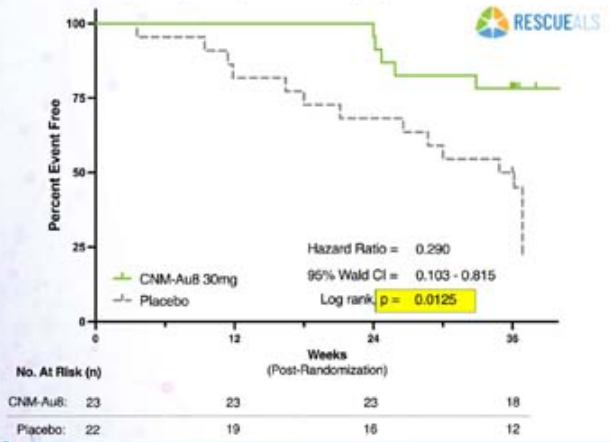
Consistent Evidence for CNM-Au8 30mg Dose Across Broad ALS Patient Population

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

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

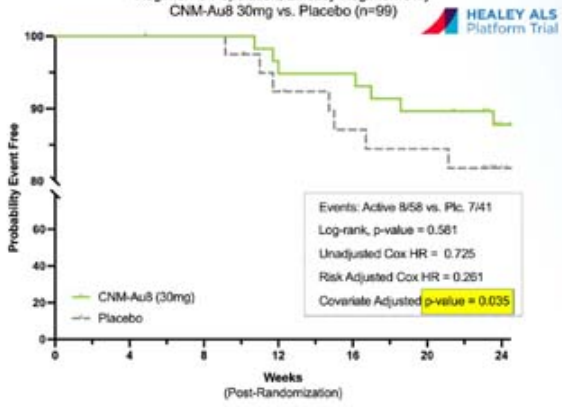
Evidence for Decreased Clinical Worsening Events Across Two Phase 2 Studies

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



No. At Risk (n)				
CNM-Au8:	23	23	23	18
Placebo:	22	19	16	12

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



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

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

RESCUEALS

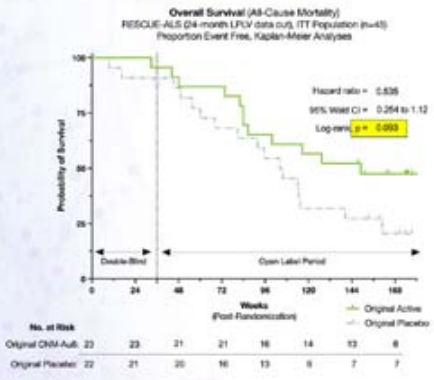
Up to 75% decreased risk of death through 168 weeks

HEALEY ALS Platform Trial

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

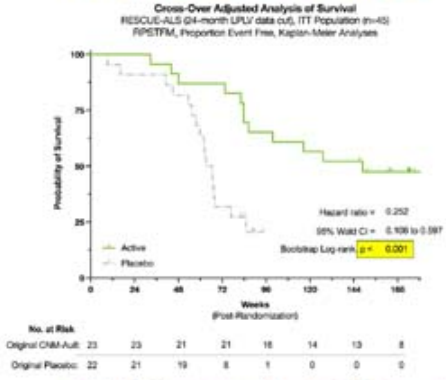
Unadjusted Survival

10.1 Months Survival Difference



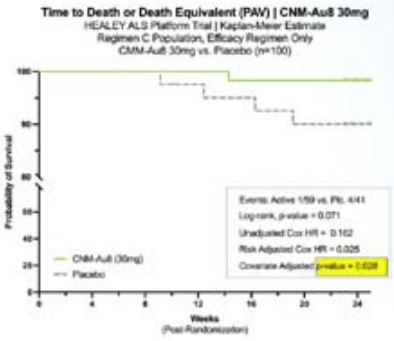
Cross-Over Adjusted Survival

Up to 19.3 Month Survival Benefit vs. Original Pbo



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

Survival During Blinded Period

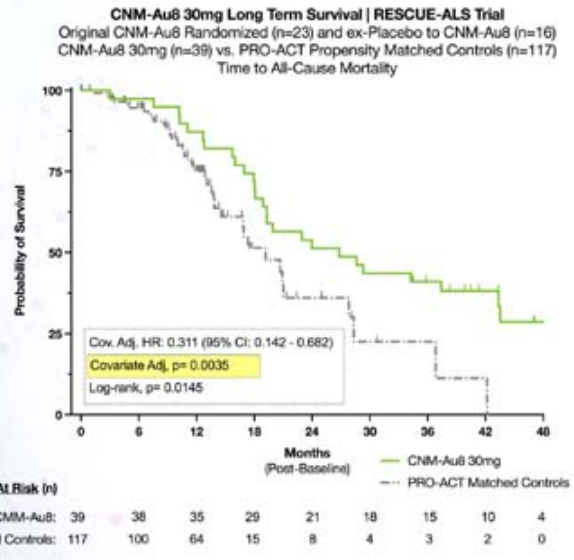


Data on File, Clene Nanomedicine, Inc.

clene NANOMEDICINE

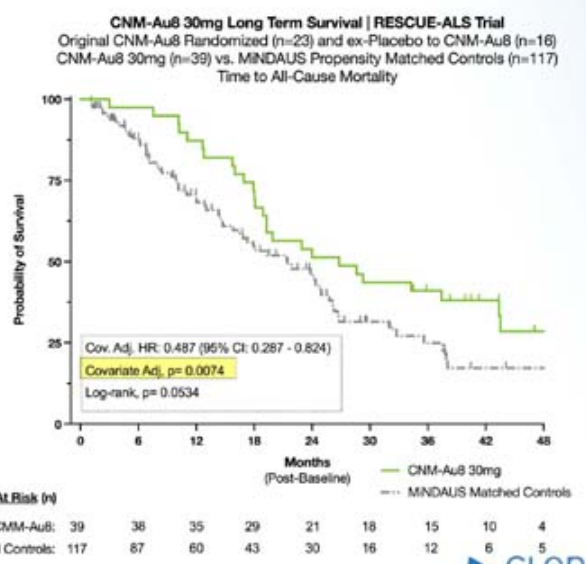
CNM-Au8 30mg Treatment Improved Long-Term Survival vs. Propensity Matched PRO-ACT & MiNDAUS (Australian) Controls

PRO-ACT Controls



At Risk (n)									
CMM-Au8:	39	38	35	29	21	18	15	10	4
Matched Controls:	117	100	64	15	8	4	3	2	0

MiNDAUS Controls



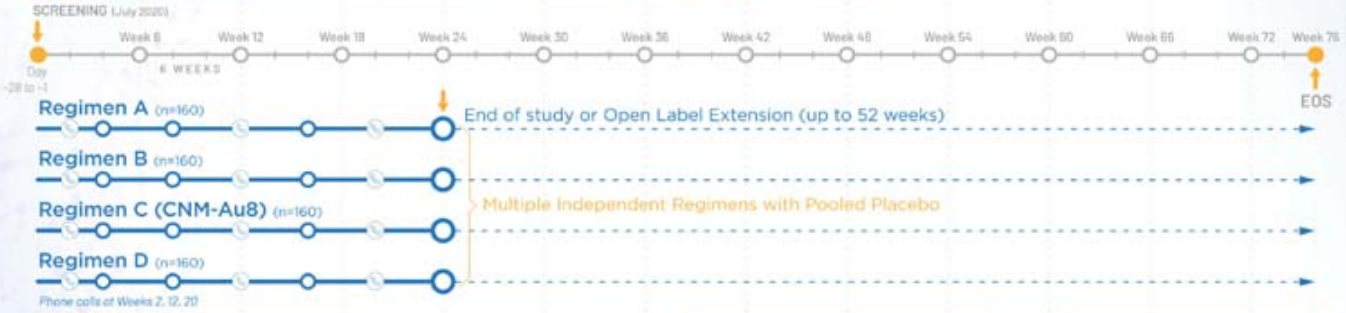
At Risk (n)									
CMM-Au8:	39	38	35	29	21	18	15	10	4
Matched Controls:	117	87	60	43	30	16	12	6	5

Data on File, Clene Nanomedicine, Inc.

HEALEY ALS Platform Trial

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

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



1° Change in ALSFRS-R slope adjusted by mortality

Weighted Average of Slope Change & Hazard Ratio

Weighting based on # of Mortality Events

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

Exploratory Endpoints

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

Pagoni et al. Adaptive Platform Trials to Transform Amyotrophic Lateral Sclerosis Therapy Development. Ann Neurol. 2022; 91:160-175.

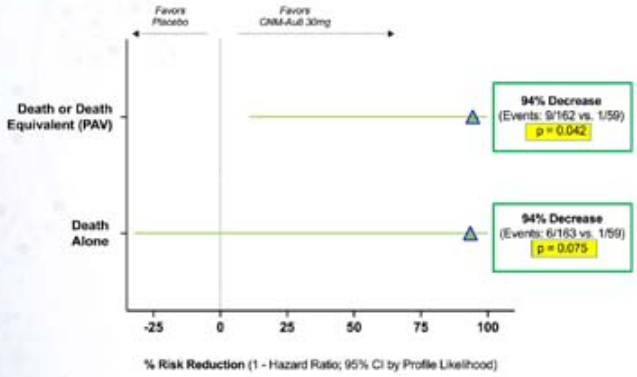
CLene NANOMEDICINE

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

HEALEY ALS Platform Trial

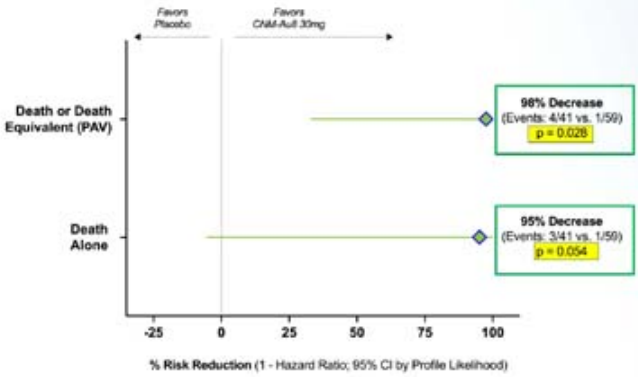
Shared Placebo Across Regimens

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



CNM-Au8 Regimen Only (Regimen C)

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



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

Data on File, Clene Nanomedicine, Inc.

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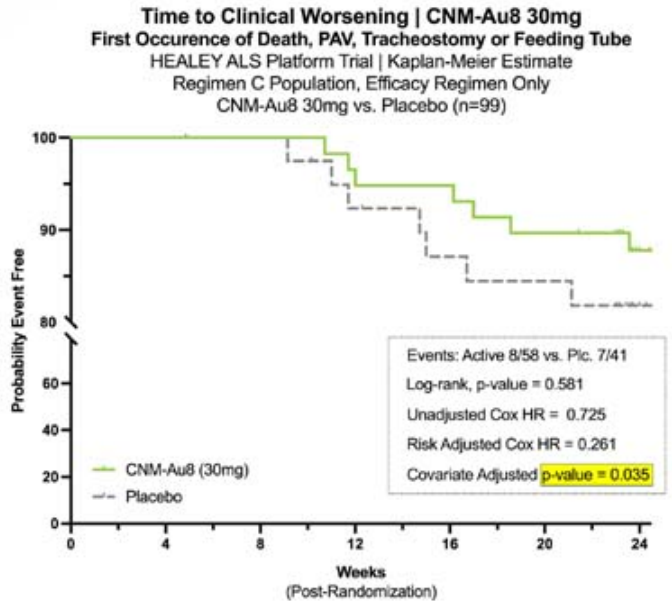
Delayed Time to ALS Clinical Worsening

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

HEALEY ALS Platform Trial



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

Data on File, Clene Nanomedicine, Inc.

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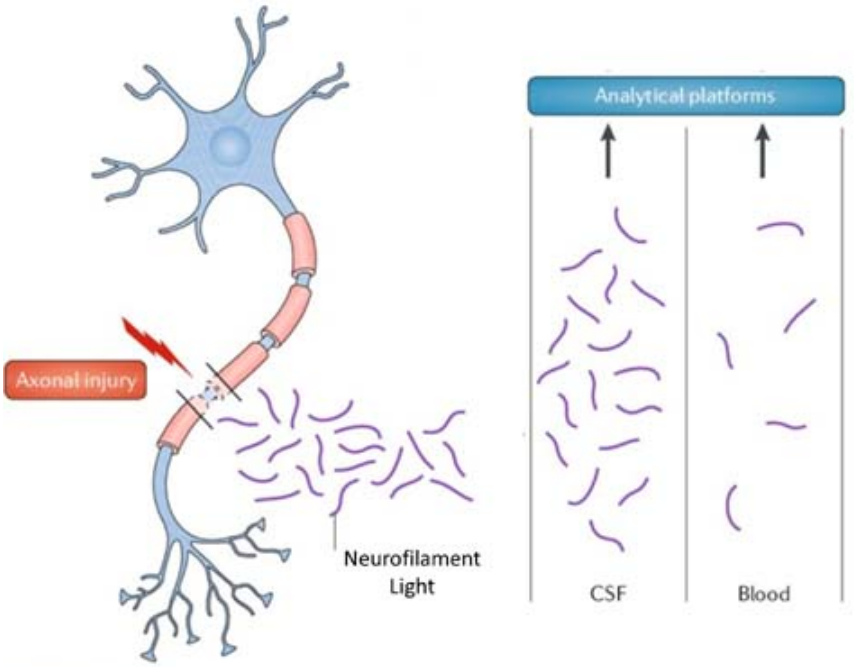
Origination of NfL in Bloodstream



Neurofilament Proteins

- Cytoskeletal proteins highly specific for neurons.
- Comprising 85% of neuronal structural proteins.
- Determine axon diameter.
- Any disorder/disease shows NfL damage.

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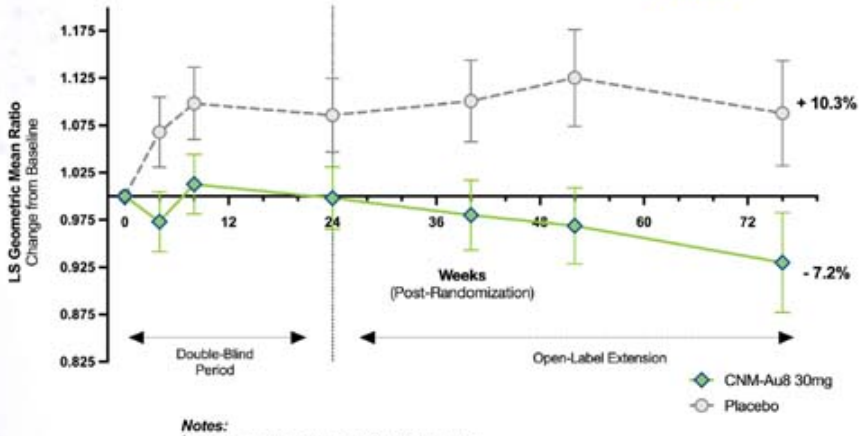
Continued Long Term Plasma NfL Decline in the OLE

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

HEALEY ALS Platform Trial

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

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



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

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

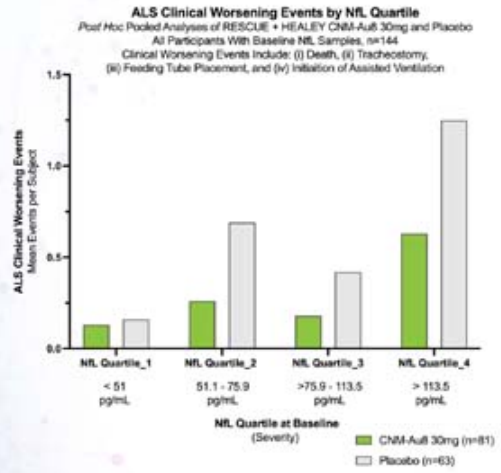
Data on File, Clene Nanomedicine, Inc.

CLENE NANOMEDICINE

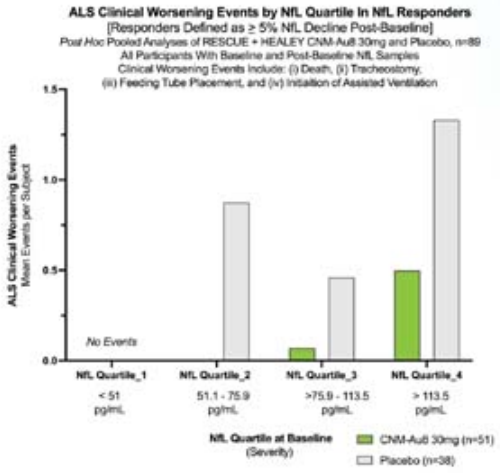
Validation of NfL Association with Clinical Outcomes

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

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



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



Data on File, Clene Nanomedicine, Inc.

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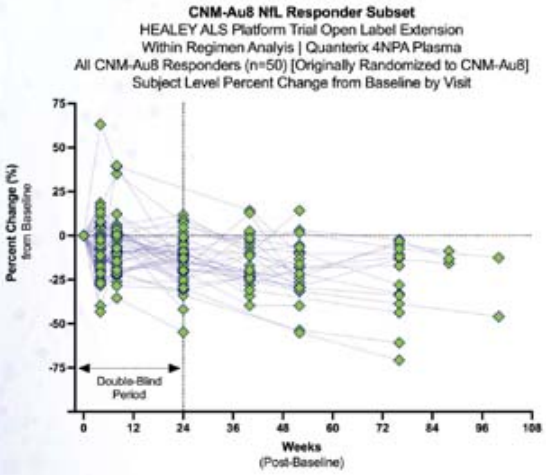
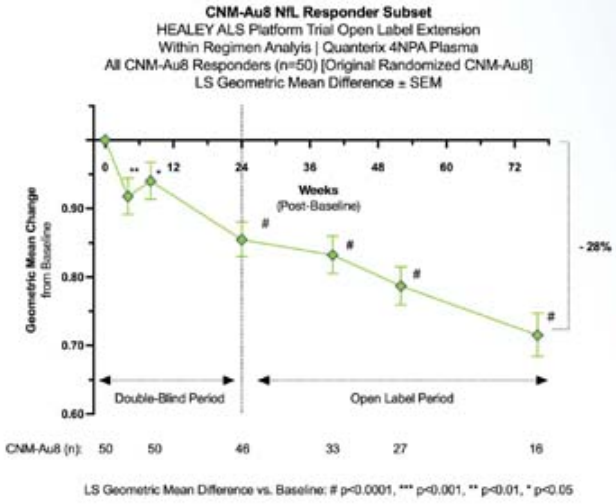
CNM-Au8 NfL Responders Demonstrated Robust NfL Declines

HEALEY ALS Platform Trial

NfL Decline by Participant



NfL Decline Across Responders



LS Geometric Mean Difference vs. Baseline: # p<0.0001, *** p<0.001, ** p<0.01, * p<0.05

NfL Responders include all CNM-Au8 30mg and 60mg originally randomized participants with consistent and sustained NfL declines.

Data on File, Clene Nanomedicine, Inc.

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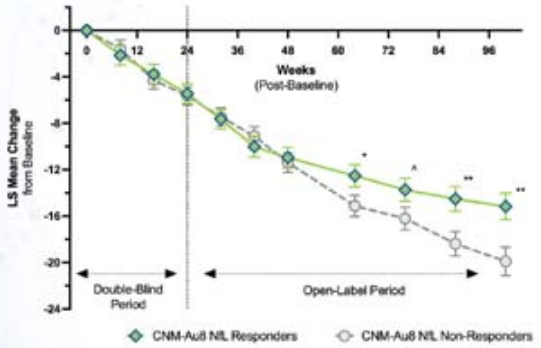
CNM-Au8 NfL Responders Showed Slowed ALSFRS-R Decline

NfL Responders vs. NfL Non-Responders

HEALEY ALS Platform Trial

ALSFRS-R Decline

Long-Term ALSFRS-R Total Score Change by NfL Responder Status
HEALEY ALS Platform Trial | All CNM-Au8 with Baseline Covariates (n=116 of 120)
CNM-Au8 Plasma NfL Responders vs. Non-Responders
MMRM; LS Mean Change from Baseline ± SEM



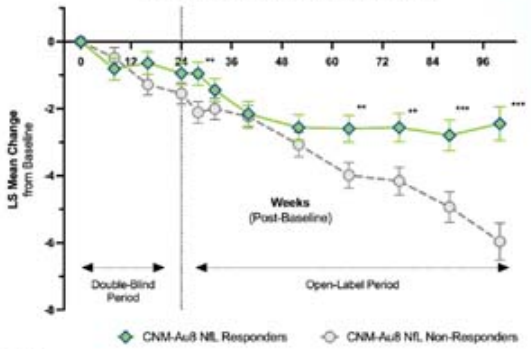
◆ CNM-Au8 NfL Responders ○ CNM-Au8 NfL Non-Responders

No. Evaluable											
NfL Responder:	50	50	45	47	41	32	35	27	23	17	14
Non-Responder:	66	60	59	59	52	41	38	29	22	18	9

LS Mean Difference: *** p<0.001, ** p< 0.01, * p<0.05, ^ p<0.10

ALSFRS-R Respiratory Subdomain

Long-Term ALSFRS-R Respiratory Subscore Change by NfL Responder Status
HEALEY ALS Platform Trial | All CNM-Au8 with Baseline Covariates (n=116 of 120)
CNM-Au8 Plasma NfL Responders vs. Non-Responders
MMRM; LS Mean Change from Baseline ± SEM



◆ CNM-Au8 NfL Responders ○ CNM-Au8 NfL Non-Responders

No. Evaluable											
NfL Responder:	50	50	45	47	41	32	32	27	23	17	14
Non-Responder:	66	60	59	59	52	41	34	29	22	18	9

LS Mean Difference: *** p<0.001, ** p< 0.01, * p<0.05, ^ p<0.10

Data on File, Clene Nanomedicine, Inc. NfL Responders include all CNM-Au8 30mg and 60mg originally randomized participants with consistent and sustained NfL declines.

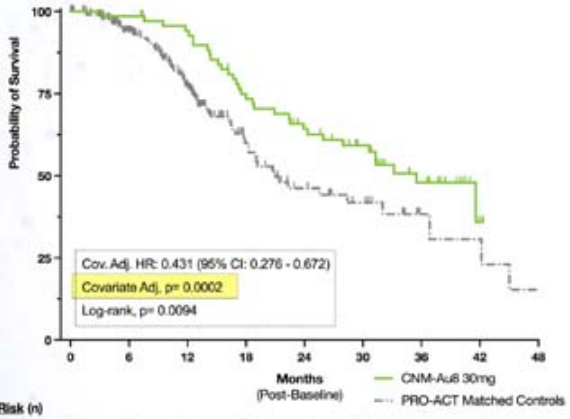
Clene NANOMEDICINE

CNM-Au8 30mg Treatment Improved Long-Term Survival vs. Propensity Matched PRO-ACT & NHC Controls

HEALEY ALS Platform Trial

PRO-ACT Controls

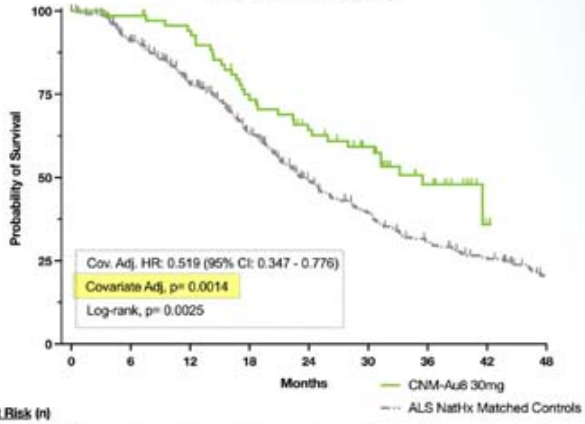
CNM-Au8 30 mg Long Term Survival | HEALEY ALS Platform Trial
Original CNM-Au8 (n=59) and ex-Placebo to CNM-Au8 (n=11)
CNM-Au8 30mg (n=70) vs. PRO-ACT Propensity Matched Controls (n=322)
Time to All-Cause Mortality



At Risk (n)									
CMM-Au8:	70	70	65	51	41	32	18	3	0
Matched Controls:	322	259	174	43	25	16	6	5	3

Natural History Consortium Controls

CNM-Au8 30 mg Long Term Survival | HEALEY ALS Platform Trial
Original CNM-Au8 (n=59) and ex-Placebo to CNM-Au8 (n=11)
CNM-Au8 30mg vs. ALS Natural History Study Propensity Matched Controls
Time to All-Cause Mortality



At Risk (n)									
CMM-Au8:	70	70	65	50	41	32	18	3	0
Matched Controls:	322	277	220	164	115	87	65	50	31

Data on File, Clene Nanomedicine, Inc.

CLENE NANOMEDICINE

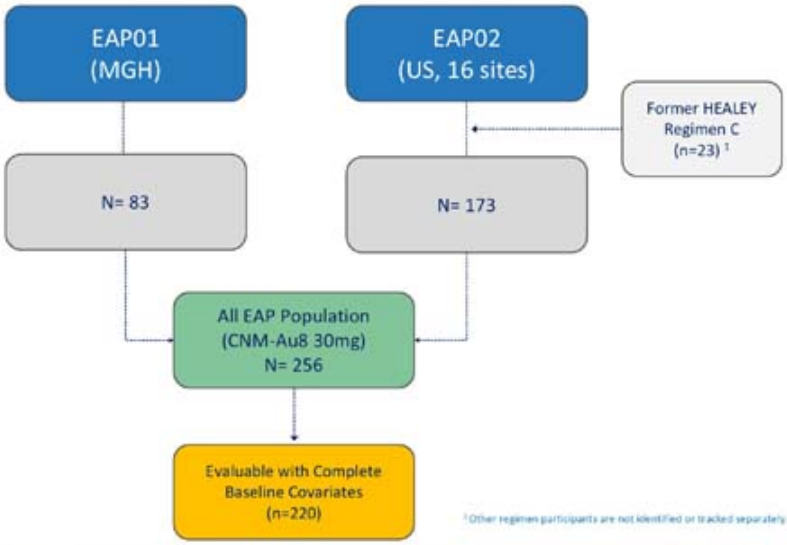
EAP Participant Enrollment

- All EAP participants (CNM-Au8 30mg) enrolled through 15-December-2023 with EDC data entry
- Survival updated through the 14-January-2024 data cut

EAP01 in collaboration with the:

Healey Center
Sean M. Healey & AMG Center for ALS at Mass General

The Healey center covered all site costs and EDC management through philanthropic donations; Clene provided CNM-Au8 and conducted analyses

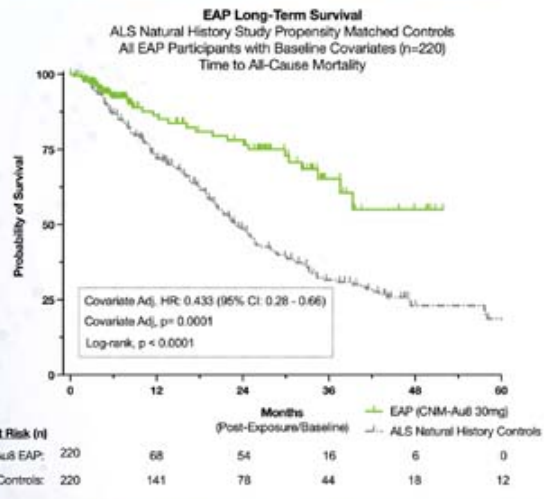


[1] Other regimen participants are not identified or tracked separately.

Data on File, Clene Nanomedicine, Inc.

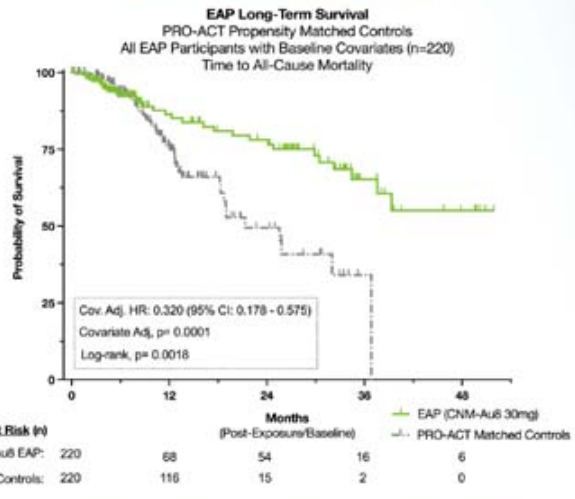
EAP Survival vs. ALS Natural History and PRO-ACT Matched Controls | Control-Matched EAP and All EAP

ALS Natural History Study | EAP Matched (n=220)



At Risk (n)						
CMM-Au8 EAP:	220	68	54	16	6	0
Controls:	220	141	78	44	18	12

PRO-ACT | EAP Matched (n=220)



At Risk (n)					
CMM-Au8 EAP:	220	68	54	16	6
Controls:	220	116	15	2	0

Baseline covariates include: (i) onset age, (ii) sex, (iii) BMI, (iv) pre-treatment ALSFRS-R slope, (v) ALSFRs-R, (vi) vital capacity (% predicted), (vii) vital capacity pre-treatment slope, and (viii) TRICALS risk score. Propensity matching caliper minimized at 0.41. All EAP participants alive are right censored as of the January 18, 2024 data cut.

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, Clene Nanomedicine, Inc.

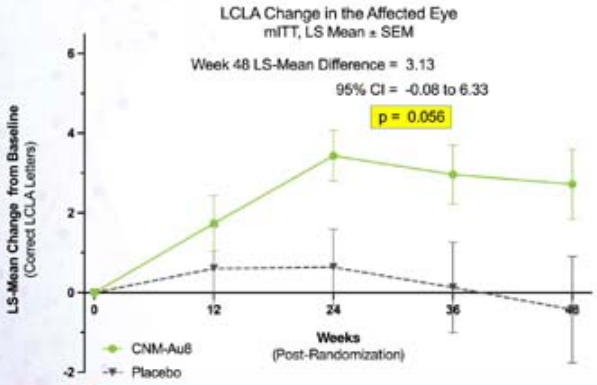
clene NANOMEDICINE

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

VISIONARY-MS STUDY

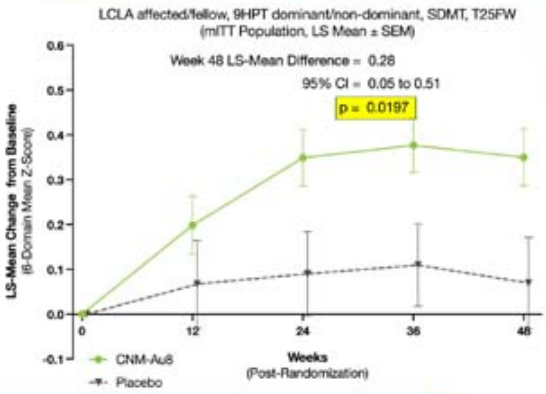
Significantly Improved Vision

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

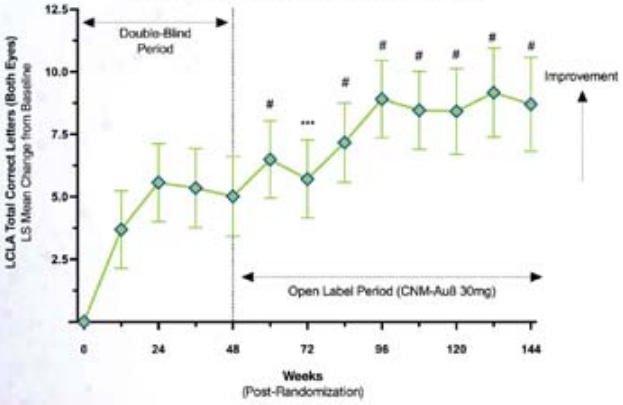
Long-Term LCLA Improvement in LTE Participants

Low Contrast Letter Acuity

VISIONARY-MS

Original Active (CNM-Au8)

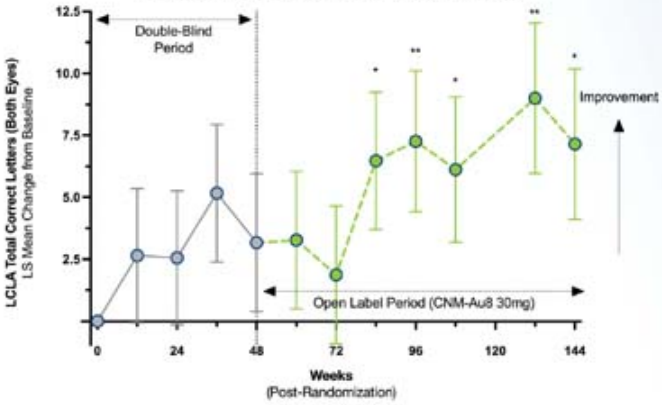
Longitudinal LCLA | Change from Baseline (Total Correct, Both Eyes) | All Active
In LTE Participants Originally Randomized to CNM-Au8 (n=35), mITT Population
LS Mean ± SEM, Change from Baseline (Preliminary)



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

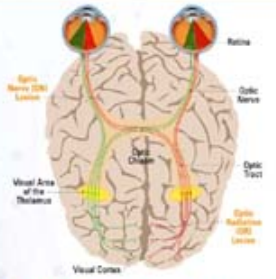
Data on File, Clene Nanomedicine, Inc.

CLENE NANOMEDICINE

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

VISIONARY-MS STUDY

Visual Evoked Potentials

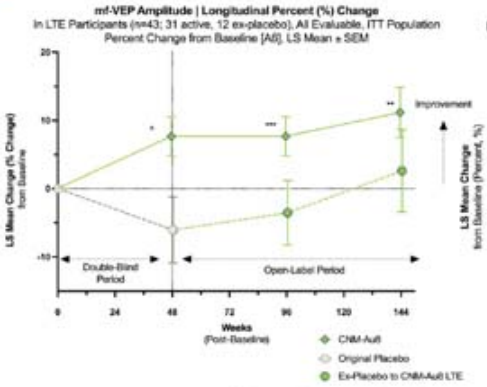


Amplitude = Signal Strength

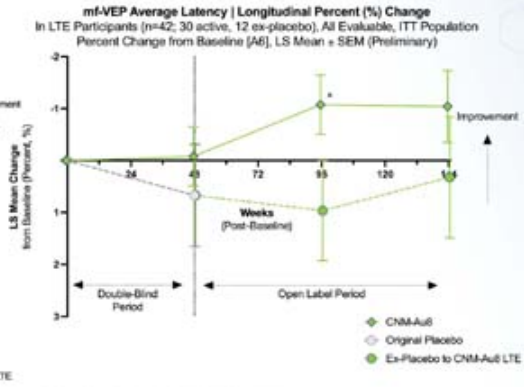
Latency = Signal Speed

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, Clene Nanomedicine, Inc.

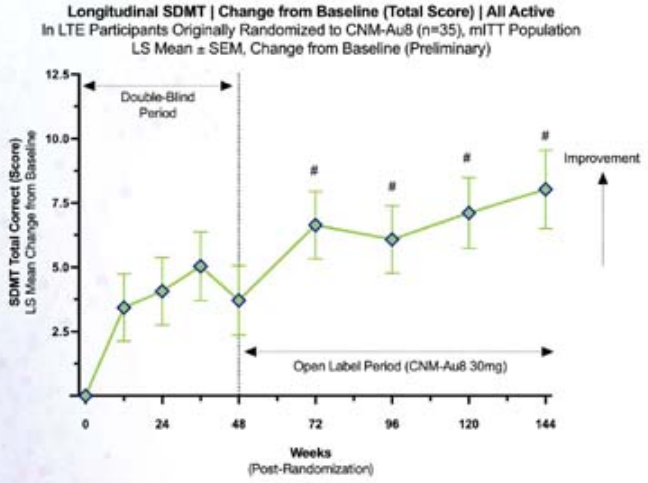
CLENE NANOMEDICINE

Long-Term SDMT Improvement in LTE Participants

Symbol Digit Modality Test | Working Memory & Cognition

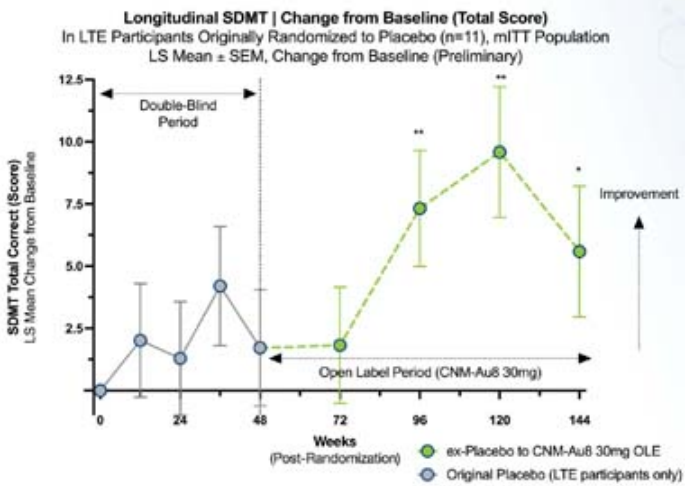
VISIONARY-MS

Original Active (CNM-Au8)



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

Original Placebo



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

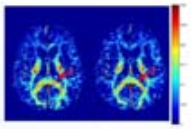
Data on File, Clene Nanomedicine, Inc.

CLENE NANOMEDICINE

CNM-Au8 Treatment Demonstrated MS Lesion Repair and Promoted Remyelination

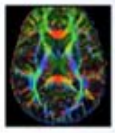
VISIONARY-MS STUDY

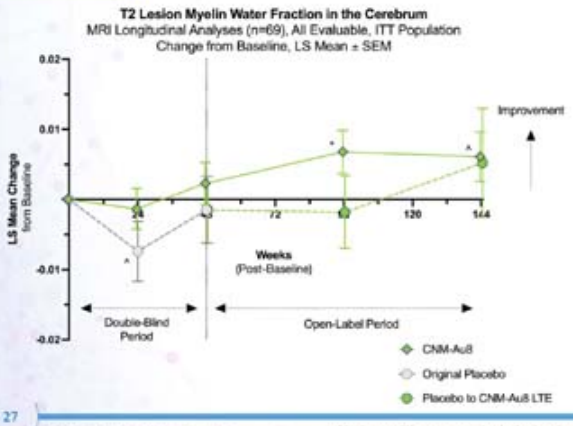
Advanced MRI Techniques

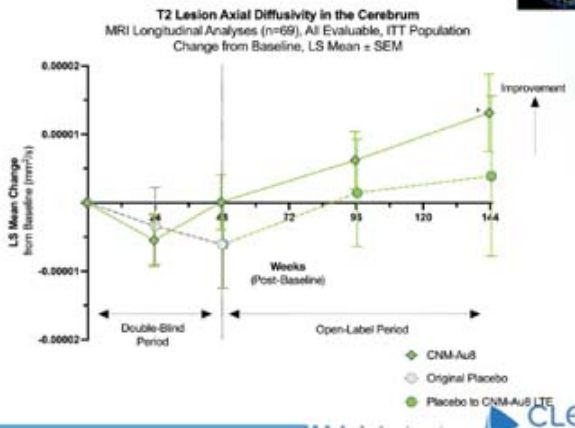


T2 Lesion Myelin Water Fraction (Remyelination)

T2 Lesion Axial Diffusivity (Axonal Integrity)







Data on File, Clene Nanomedicine, Inc.

LTE: LS mean difference vs. randomization baseline: # pg0.0001, *** pg0.001, ** pg0.01, *pg0.05, ^pg0.10

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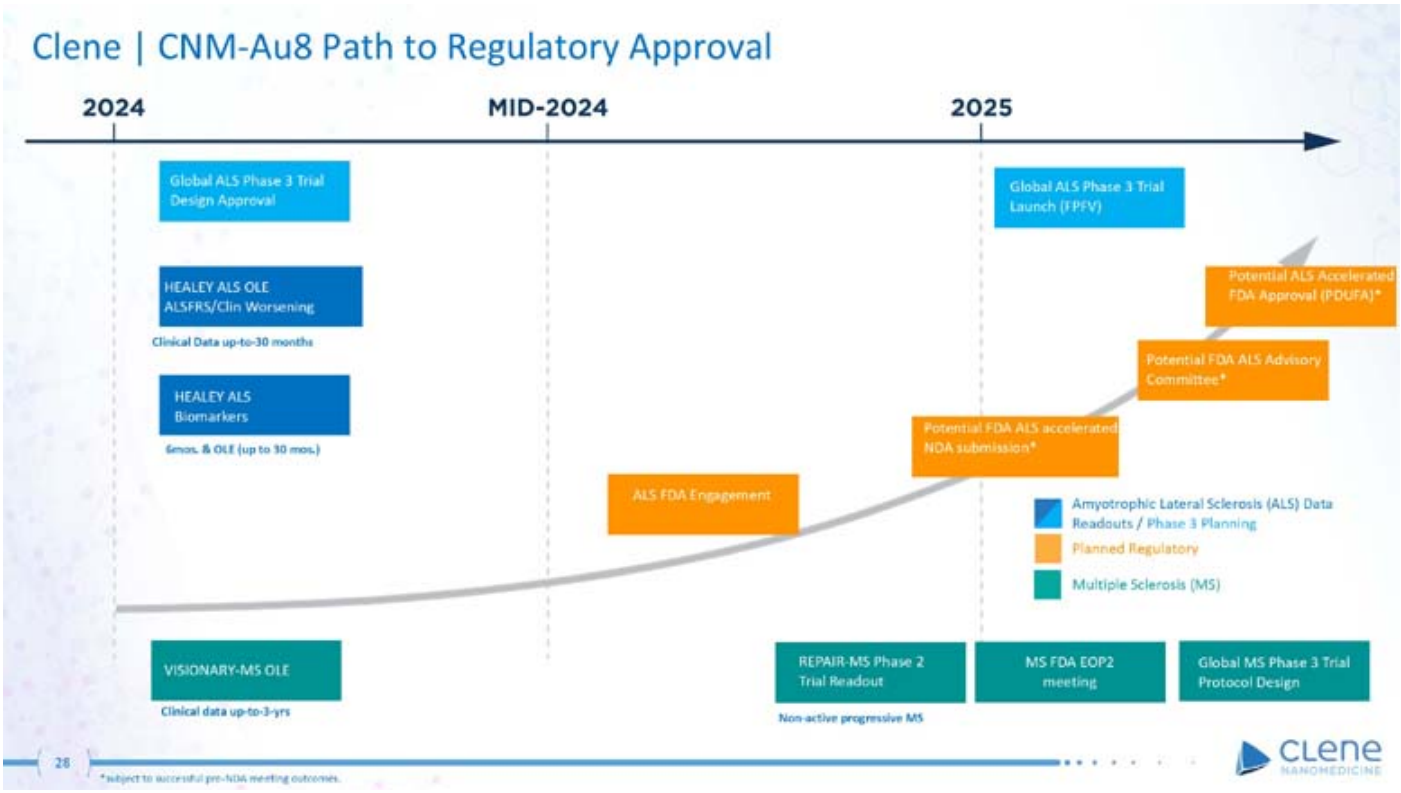
Clene | CNM-Au8 Path to Regulatory Approval
2024
MID-2024
2025
Global ALS Phase 3 Trial Design Approval
HEALEY ALS OLE ALSFRS/Clin Worsening
Clinical Data up-to-30 months
HEALEY ALS Biomarkers
6mos. & OLE (up to 30 mos.)
ALS FDA Engagement
Global ALS Phase 3 Trial Launch (FPFV)
Potential FDA ALS accelerated 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)
VISIONARY-MS OLE
Clinical data up-to-3-yrs
REPAIR-MS Phase 2 Trial Readout
Non-active progressive MS
MS FDA EOP2 meeting
Global MS Phase 3 Trial Protocol Design
28
*subject to successful pre-NDA meeting outcomes.
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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

RESCUEALS

75% decreased risk of death in ALS through 168 weeks

HEALEY ALS Platform Trial

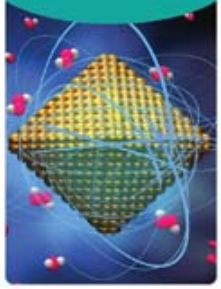
>90% decreased risk of death with 30 mg in ALS

VISIONARY-MS

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

>700
patient 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*

Data on File, Clene Nanomedicine, Inc. [1]Robinson et al. Sci Rep. 2020 Feb 11;10(1):1936. [2]https://clinicaltrials.gov/ct2/show/NCT04434345.

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