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): May 9, 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 2.02 Results of Operations and Financial Condition.

On May 9, 2022, Clene Inc. (the "Company") issued a press release announcing its first quarter operating and financial results for its quarter ended March 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report") 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 May 9, 2022 press release announcing the Company's first quarter operating and financial results for its quarter ended March 31, 2022, 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 this Current Report and is incorporated herein by reference. The Company plans to use its website to disseminate future updates to the Corporate Presentation and may not file or furnish a Current Report on Form 8-K alerting investors if the Corporate Presentation is updated.

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, 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 May 9, 2022, announcing the Company's operating and financial results for its quarter ended March 31, 2022.
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: May 9, 2022

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

Clene Reports First Quarter 2022 Financial Results and Recent Operating Highlights

- ***Cash, cash equivalents, restricted cash and marketable securities of $36.6 million as of March 31, 2022***
- ***Additional data from RESCUE-ALS presented at 2022 AAN Annual Meeting and MDA Clinical & Scientific Conference; Results show significant survival benefit in participants who entered open-label extension study***
- ***Top-line results from studies in ALS, MS and COVID-19 programs expected in third quarter***

SALT LAKE CITY, May 9, 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 reported its first quarter 2022 and recent operating highlights.

"As we approach the second half of 2022, we expect to report data readouts for our lead asset, CNM-Au8®, for the treatment of both ALS and MS," said Rob Etherington, President and CEO of Clene. "Positive results from the Healey ALS Platform Trial would bring this potential new treatment option one step closer for people living with ALS."

First Quarter 2022 and Recent Operating Highlights

CNM-Au8®, a gold nanocrystal suspension, for the treatment of amyotrophic lateral sclerosis (ALS)

- Top-line data from the HEALEY ALS Platform Trial, led by the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital, are expected in the third quarter of this year.
- Top-line results from the RESCUE-ALS Phase 2 clinical trial were reported in November 2021. Results demonstrated clinically meaningful benefits in people with early ALS.
    - Additional data from the RESCUE-ALS open-label extension were presented in a late breaker session at the American Academy of Neurology Annual Meeting (April 2022). The data demonstrate a 70% survival benefit among ALS patients who entered the open-label extension (n=36, 90% of those eligible). The presentation is available in the Scientific Posters & Presentations section of the Clene website.
    - Updated clinical trial results from RESCUE-ALS and REPAIR were presented at the Muscular Dystrophy Association Clinical & Scientific Conference (March 2022).
- Clene continues to support expanded access programs, providing CNM-Au8 treatment at four clinical sites for up to 55 total participants with ALS.

CNM-Au8 for the treatment of multiple sclerosis (MS)

- Clene has initiated a second cohort of the more severe non-active, progressive MS population in the REPAIR-MS Phase 2 clinical trial to confirm target engagement following the target engagement demonstrated in the first cohort of relapsing MS patients.
- Unblinded data from the VISIONARY-MS Phase 2 clinical trial data are targeted for the third quarter of 2022. VISIONARY-MS concluded early due to pandemic-related enrollment challenges. Clene will utilize the available data collected from up to 48 weeks of clinical visits to better understand the efficacy and safety profile of CNM-Au8 and to inform further clinical development in MS.
    - Updated blinded interim data from VISIONARY-MS and results from REPAIR-MS Phase 2 trials were presented at the Americas Committee for Treatment and Research in Multiple Sclerosis Forum 2022 (February 2022).

CNM-ZnAg for the treatment of COVID-19

- Top-line results for the ZnAg COVID Phase 2 clinical trial in acutely symptomatic, non-hospitalized COVID-19 patients in Brazil are expected in the third quarter of 2022.

First Quarter 2022 Financial Results

Clene's cash, cash equivalents, restricted cash and marketable securities totaled $36.6 million as of March 31, 2022, compared to $50.3 million as of December 31, 2021. Clene expects that its cash as of March 31, 2022, will be sufficient to fund its operations into the second quarter of 2023.

Research and development expenses were $8.6 million for the quarter ended March 31, 2022, compared to $6.3 million for the same period in 2021. The year-over-year increase is primarily attributable to the development of CNM-Au8 and CNM-ZnAg (including the rapid completion of the COVID study due to a viral wave leading to increased patient recruitment), rent expense for the newly-leased facility in Elkton, Maryland, and personnel expenses due to increased headcount as a result primarily of increased manufacturing hours, partially offset by decreased stock-based compensation expense.

General and administrative expenses were $4.8 million for the quarter ended March 31, 2022, compared to $5.4 million for the same period in 2021. The year-over-year decrease is primarily attributable to decreased finance, accounting and consulting fees after completing the Reverse Recapitalization and related activities in early 2021 and filing a registration statement on Form S-1, and decreased stock-based compensation, partially offset by an increase in personnel compensation due to increased headcount and increased public relations and investor relations efforts.

Clene reported a net loss of $13.4 million, or $0.21 per share, for the quarter ended March 31, 2022, compared to a net loss of $39.8 million, or $0.66 per share, for the same period in 2021. Included in net loss for the quarter ended March 31, 2022, is an unrealized loss from the change in fair value of contingent earn-out liabilities of $28.6 million, compared to $69,000 in the current year period.

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.

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.

About CNM-ZnAg
CNM-ZnAg, a proprietary zinc-silver ionic solution, has demonstrated broad antiviral and antimicrobial activity.

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 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 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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Source: Clene Inc.

CLENE INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Revenue:		
Product revenue	$ 7	$ 199
Royalty revenue	23	14
Total revenue	30	213
Operating expenses:		
Cost of revenue	—	243
Research and development	8,580	6,275
General and administrative	4,786	5,390
Total operating expenses	13,366	11,908
Loss from operations	(13,336)	(11,695)
Other income (expense), net:		
Interest expense	(782)	(551)
Gain on extinguishment of notes payable	—	647
Gain on termination of lease	420	—
Change in fair value of common stock warrant liability	(18)	—
Change in fair value of Clene Nanomedicine contingent earn-out	(57)	(25,610)
Change in fair value of Initial Stockholders contingent earn-out	(12)	(2,961)
Australia research and development credit	299	339
Other income, net	132	3
Total other income (expense), net	(18)	(28,133)
Net loss before income taxes	(13,354)	(39,828)
Income tax benefit	—	72
Net loss	(13,354)	(39,756)
Other comprehensive income (loss):		
Unrealized loss on available-for-sale securities	(50)	—
Foreign currency translation adjustments	50	24
Total other comprehensive income (loss)	—	24
Comprehensive loss	$ (13,354)	$ (39,732)
Net loss per share-- basic and diluted	$ (0.21)	$ (0.66)
Weighted average common shares used to compute basic and diluted net loss per share	62,852,863	60,670,932

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

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,930	$ 50,288
Marketable securities	23,586	—
Accounts receivable	—	49
Inventory	38	41
Prepaid expenses and other current assets	3,393	1,968
Metals to be used in research and development	2,502	2,237
Total current assets	42,449	54,583
Restricted cash	58	58
Right-of-use assets	4,940	3,250
Property and equipment, net	5,914	5,172
TOTAL ASSETS	$ 53,361	$ 63,063
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,313	$ 1,923
Accrued liabilities	1,541	3,610
Operating lease obligations, current portion	473	347
Finance lease obligations, current portion	139	146
Total current liabilities	5,466	6,026
Operating lease obligations, net of current portion	5,766	4,370
Finance lease obligations, net of current portion	72	97
Notes payable	14,712	14,484
Convertible notes payable	4,655	4,598
Common stock warrant liability	187	474
Clene Nanomedicine contingent earn-out	18,157	18,100
Initial Stockholders contingent earn-out	2,329	2,317
TOTAL LIABILITIES	51,344	50,466
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.0001 par value: 150,000,000 shares authorized; 63,246,545 and 62,312,097 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	178,433	175,659
Accumulated deficit	(176,655)	(163,301)
Accumulated other comprehensive income	233	233
TOTAL STOCKHOLDERS' EQUITY	2,017	12,597
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 53,361	$ 63,063

Exhibit 99.2

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 | Commitment and Experienced Leadership

COMMITTED TO **REVOLUTIONIZING** TREATMENT FOR PEOPLE WITH **NEURODEGENERATIVE DISEASES** TO RESTORE AND **PROTECT NEURONAL HEALTH**

BOARD CHAIR	CEO	CMO	CSO, FOUNDER	CDO	CFO	HR
						
David J. Matlin	Rob Etherington	Robert Glanzman	Mark Mortenson	Michael Hotchkin	Morgan Brown	Mary Anne McNeil

MatlinPatterson · Roche · ACTELION · Credit Suisse · NOVARTIS · Pfizer · PARKE-DAVIS · NPS Pharma

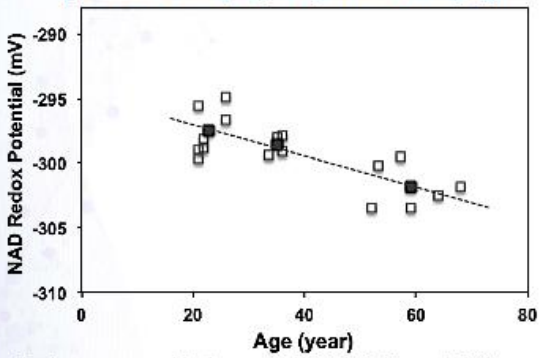
CLene NANOMEDICINE

Clene is Focused on Core Brain Energy Deficits in Neurodegenerative Diseases

Brain Energy Potential Declines With Normal Aging

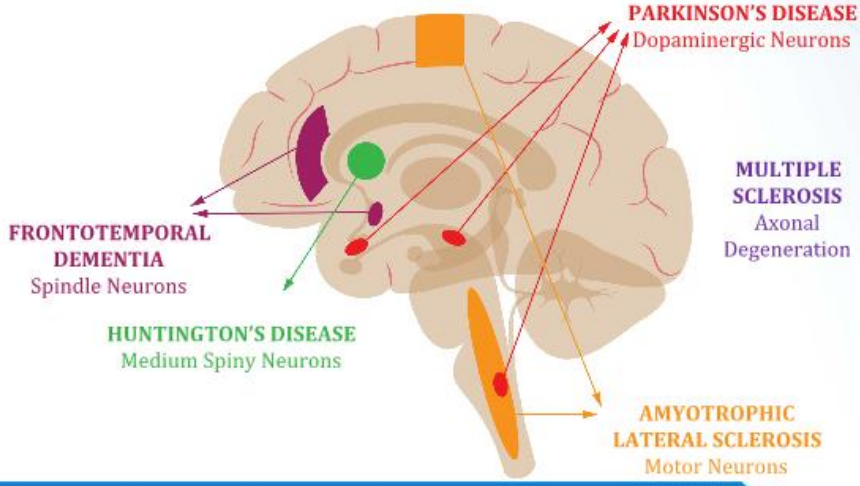
~0.5% NAD^+/NADH unit decline per decade

(~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



Neurons with high energetic demand are at increased risk for neurodegenerative disease

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. Rone et al. J Neurosci. 2016 Apr 27;36(17):4698-707.

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Significant Global Opportunity

Motor Neuron Disease (ALS, Other Orphan Disorders)

ALS PATIENTS IN US & EU ~40K

$1B GLOBAL SALES BY 2029[1]

Current drugs are largely ineffective, mostly generic.

3-5 YEARS LIFE EXPECTANCY

100% FATAL

Multiple Sclerosis

MS PATIENTS GLOBALLY 2.2M

$23B MARKET[2]

Existing treatments only target immunomodulation

EMERGING EVIDENCE THAT EARLY MS IS NEURODEGENERATIVE

Parkinsons Disease

2ND MOST COMMON DISORDER

$6B PROJECTED BY 2026[3]

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

30% OF DOPAMINERGIC NEURONS ARE LOST AT DIAGNOSIS[4]

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

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

CLene NANOMEDICINE

CNM-Au8® | Catalytically-Active Nanocrystals Improves Energy Production to Promote Neuroprotection and Remyelination

CNM-Au8 Nanocrystals

Clean Surfaced, Highly Faceted Shapes

CNM-Au8 Nanocrystal Suspension

Mechanistic Effects

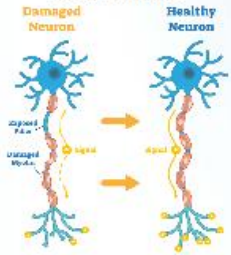
- ↑ Increased NAD
- ↑ Increased ATP
- ↓ Decreased reactive oxygen species
- ↑ Increased proteostasis

Improved Energy Production and Utilization

- ↑ Increased energetic potential
- ↑ Improved resistance to oxidative, mitochondrial, and excitotoxic stressors
- ↓ Reduction in levels of misfolded proteins

Promotes Neuroprotection and Remyelination

Remyelination



Neuroprotection

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

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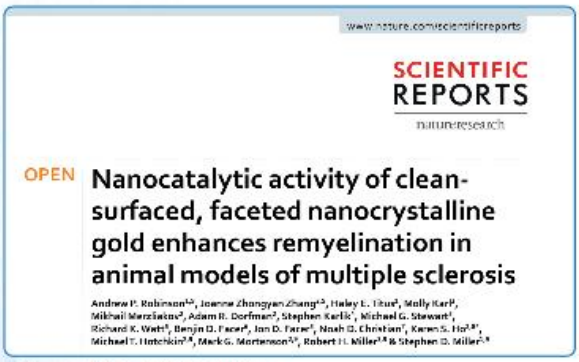
CNM-Au8® | Preclinical Evidence for Energetic Improvement

Supports Myelin Integrity & Remyelination



www.nature.com/scientificreports

SCIENTIFIC REPORTS
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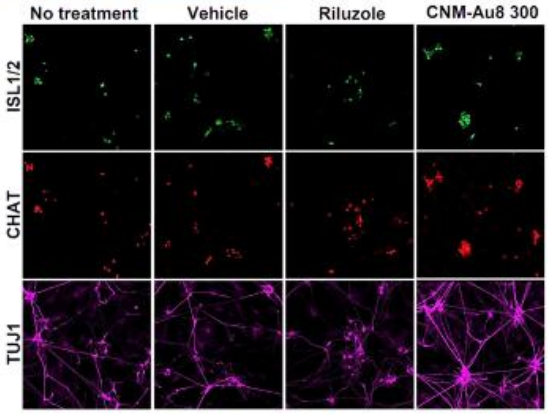
OPEN

Nanocatalytic activity of clean-surfaced, faceted nanocrystalline gold enhances remyelination in animal models of multiple sclerosis

Andrew P. Robinson[1,2], Joanne Zhongyan Zhang[1,2], Haley E. Titus[1], Molly Karl[1], Mikhail Merzlikine[1], Adam R. Dorfman[1], Stephen Karlik[3], Michael G. Stewart[1], Richard K. Watt[4], Benjn D. Farer[4], Jon D. Farer[4], Noah D. Christon[1], Karen S. Ho[1,5], Michael T. Hotchkin[1,6], Mark G. Mortenson[1,6], Robert H. Miller[1,5] & Stephen D. Miller[1,5]

Robinson et al. Sci Rep. 2020 Feb 11;10(1):1936.

CNM-Au8 Improves ALS Motor Neuron Survival & Neuron Connections



Induced Pluripotent Stem Cell *In Vitro* Results – Motor Neuron Markers

Karen S. Ho et al. "Redox-enhancing nanocatalysis improves motor neuron survival in vitro and SOD1 mouse motor function and survival in vivo." Presented at 30th International Symposium on ALS/MND 2019. December 4-6, 2019.

CNM-Au8 enables neuroprotection and remyelination by helping nervous system cells increase their resilience to the energetic deficits driving disease progression in ALS

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CNM-Au8® | Neuroprotection & Remyelination

Growing Evidence Supports CNM-Au8 Clinical Potential

RepairPD
RepairMS

- Established brain target engagement in early Parkinson's Disease (PD) and stable relapsing Multiple Sclerosis (MS)
- Phase 2 REPAIR non-active progressive MS underway

RESCUEALS
HEALEY ALS Platform Trial

- CNM-Au8 treatment effect on ALS disease progression and potential impact on survival
- Phase 2/3 HEALEY-ALS Platform Trial Ongoing
- Expected readout 3Q 2022

VISIONARY-MS STUDY

- Interim blinded observations: Stable relapsing multiple sclerosis (MS) participants suggests improved function (modified MSFC) including low contrast vision
- Expected readout 3Q 2022

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CNM-Au8® | Safety Summary

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 PD, MS, & ALS

Over 350 Years of Subject Exposure Without Identified Safety Signals

- Long-term dosing experience up to 125 weeks

Data on File, Clene Nanomedicine, Inc.

CNM-Au8® | REPAIR Program Demonstrated Target Engagement and Improved Brain Energy Metabolism

RepairPD
Early Parkinson's Disease

RepairMS
Stable Relapsing MS

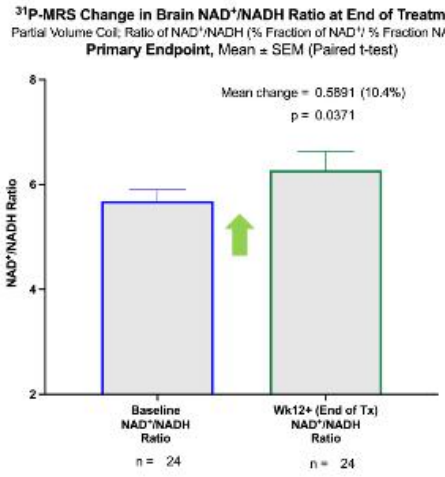
RepairMS
Non-Active Progressive MS
(Ongoing)

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

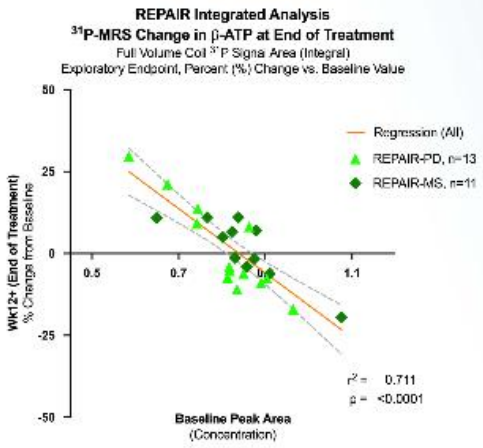
Brain Energy Potential Declines With Normal Aging
~0.5% NAD+/NADH unit decline per decade in healthy people (by ^{31}P-MRS Imaging)[1]

Results demonstrated 10% improvement in NAD+/NADH ratio, which may translate to decades of improvement in cellular energy production and utilization

1° Endpoint (integrated PD & MS)[2]



Exploratory
(ATP Normalization)



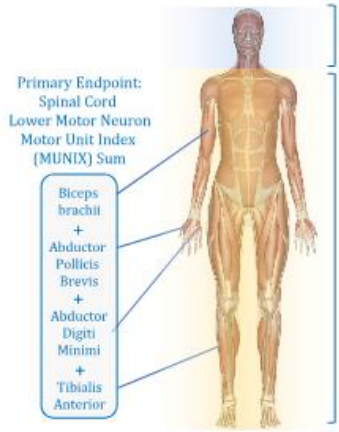
1. Zhu et al. Proc Natl Acad Sci USA 2015 Mar 3;112(9):2876-81. 2. Glanzman et al Improvement of Brain Energy Metabolism in Relapsing Multiple Sclerosis Patients – Results from Phase 2 REPAIR-MS Clinical Trial With CNM-Au8, ACTRIMS February 2022

CLene NANOMEDICINE

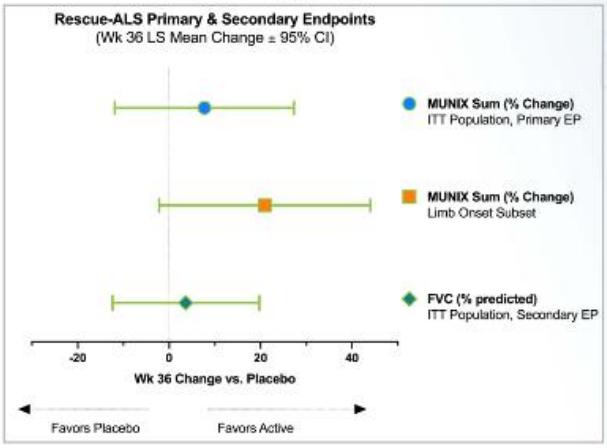
RESCUEALS CNM-Au8® | Evidence for Motor Neuron Protection

Study Objective:
Detect preservation of motor neuron function in people with early ALS as measured by MUNIX

Study Design:
36-week blinded treatment with ongoing long-term open-label follow-up



1° & 2° Endpoints



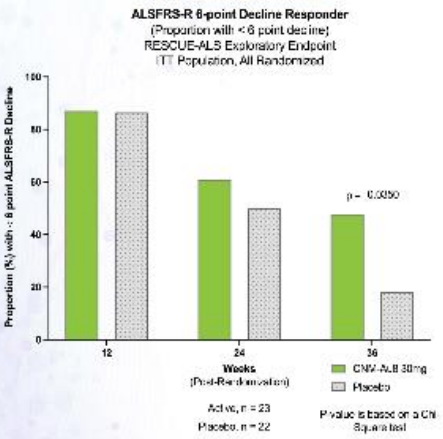
By targeting energy metabolism, CNM-Au8 may be able to protect motor neurons and restore ALS function

Results in favor of CNM-Au8 treatment but study underpowered

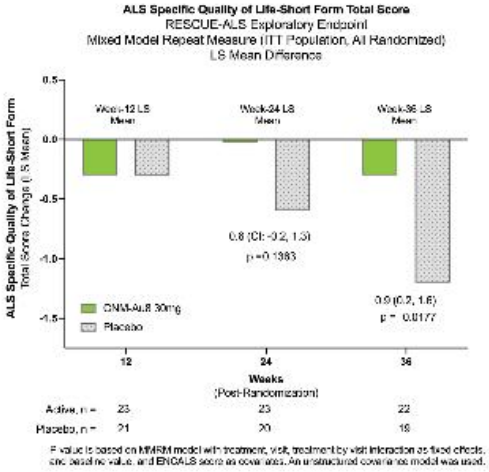
Vucic et al. BMJ Open. 2021 Jan 11;11(1):e041479. Data on File, Clene Nanomedicine, Inc.

RESCUEALS CNM-Au8® | Significant Impact on Key Functional ALS Measures (Exploratory Endpoint Pre-specified)

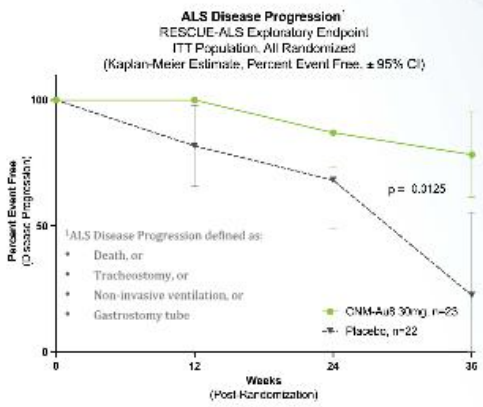
Proportion with <6 point decline



ALS Specific QOL



ALS Disease Progression



RESCUE-ALS: A Phase 2, randomized, double-blind, placebo-controlled study of CNM-Au8 to slow disease progression in ALS. MNDA Virtual Symposium, 2021.

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RESCUEALS CNM-Au8® | CAFS: Survival & ALSFRS-R

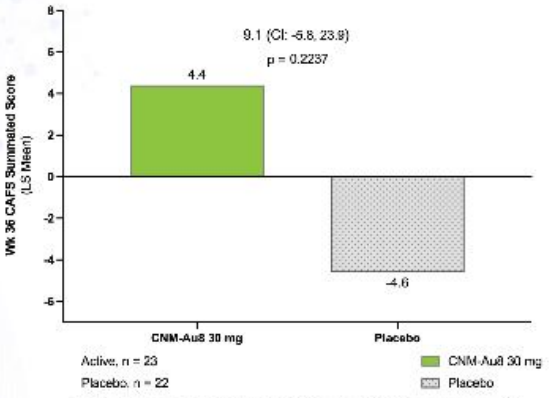
Exploratory Endpoint Pre-specified

CAFS

Survival

ALSFRS-R Decline

CAFS Joint Rank: (i) Survival and (ii) ALSFRS-R Change
RESCUE-ALS Exploratory Endpoint
ANCOVA Model (ITT Population, All Randomized)
Week 36 LS Mean Difference



Active, n = 23
Placebo, n = 22

CNM-Au8 30 mg
Placebo

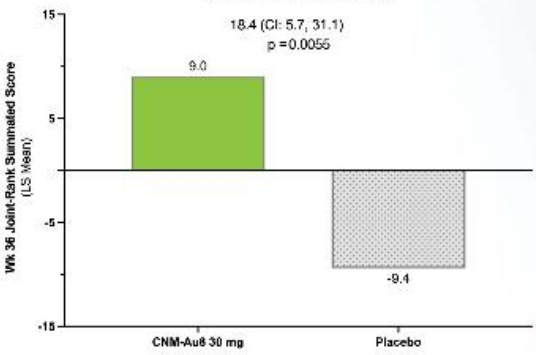
P-value is based on ANCOVA model with baseline ENCALS score as a covariate. Change in ALSFRS-R total score and date of death were combined to determine the CAFS score.

Exploratory Endpoint Post Hoc

Modified CAFS

King's Clinical Stage 4

Joint-Rank of (I) Survival, (II) King's Clinical Stage 4, and (III) ALSFRS-R Change
RESCUE-ALS *Post Hoc* Endpoint
ANCOVA Model (ITT Population, All Randomized)
Week 36 LS Mean Difference



Active, n = 23
Placebo, n = 22

CNM-Au8 30 mg
Placebo

P-value is based on ANCOVA model with baseline ENCALS score as a covariate. Change in ALSFRS-R total score, date of non-invasive ventilation or gastrostomy, and date of death were combined to determine the joint-rank score.

Berry et al. Amyotroph Lateral Scler Frontotemporal Degener. 2013 Apr;14(3):162-8. Data on File, Clene Nanomedicine, Inc.

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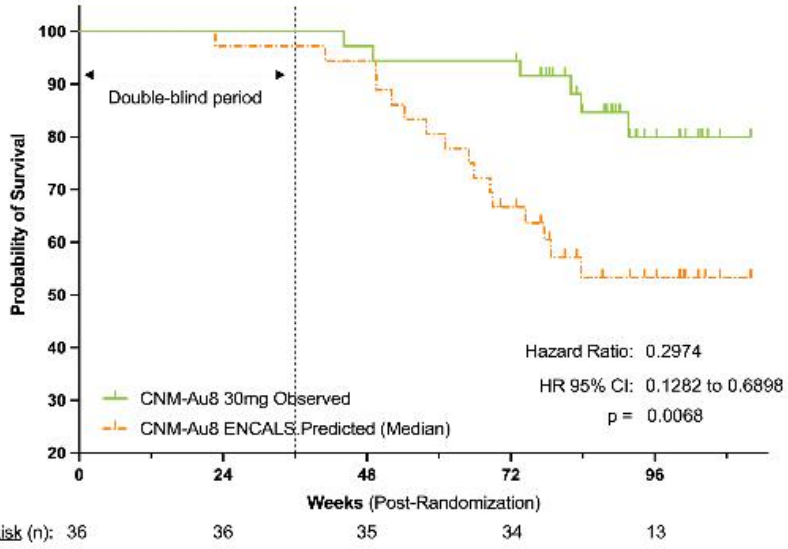
RESCUEALS CNM-Au8® | Impact on Long-Term Survival

70% Improvement vs. ENCALS Predicted Survival (Interim Analysis)

All OLE participants. Data censored as of 10-March-2022. Vital status and date of death (as applicable) captured for all subjects withdrawn from the study. ENCALS median survival estimate from baseline characteristics.

RESCUE-ALS Long-Term Observed Survival (OLE Participants)
vs. ENCALS Predicted Median Survival; All Open Label Participants, Interim Analysis



At Risk (n):					
	36	36	35	34	13

Kiernan et al. Kiernan MC. Long-Term Survival of Randomized Participants Enrolled in the Phase 2 RESCUE-ALS Trial of CNM-Au8, A Cellular Energetic Catalyst. Presented at: AAN Annual Meeting; April 2-7, 2022;

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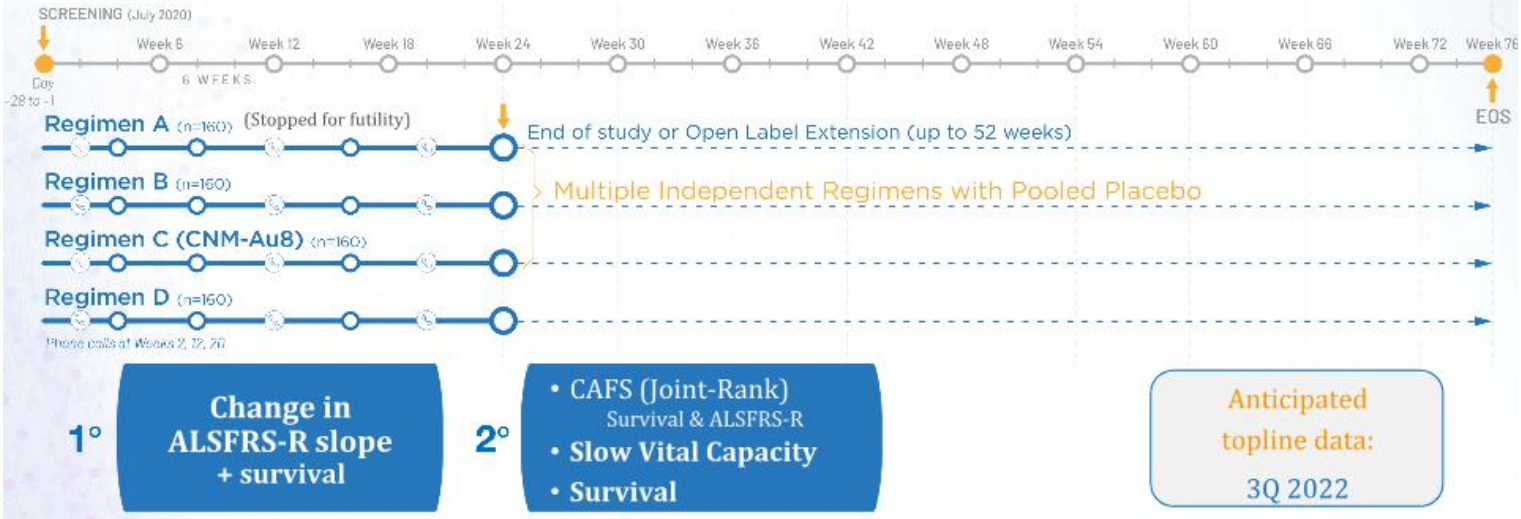
Phase 2/3
HEALEY ALS Platform Trial

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 + survival**

2°
- CAFS (Joint-Rank) Survival & ALSFRS-R
- **Slow Vital Capacity**
- **Survival**

Anticipated topline data: 3Q 2022

Paganoni et al. Ann Neurol. 2022 Feb;91(2):165-175. https://clinicaltrials.gov/ct2/show/NCT04414345.

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Phase 2/3
HEALEY ALS Platform Trial

Integrated Function & Survival
1° and Key 2° Endpoints

Primary Endpoint

Change in Slope of ALSFRS-R

+

Survival Improvement (Hazard Ratio)

Weighted Average of (1-slope change) and Hazard Ratio

(Weighting based on # of Mortality Events)

Key Secondary Endpoint
(Combined Assessment of Function & Survival)

Rank participants based on time to death or ALSFRS-R change

Individual Scoring

If...	Score
Better function or died later than comparison	+1
Same function or died at the same time as comparison	0
Worse function or died before comparison subject	-1

CAFS

Paganoni et al. Ann Neurol. 2022 Feb;91(2):165-175. Berry et al. Amyotroph Lateral Scler Frontotemporal Degener. 2013 Apr;14(3):162-8.

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Phase 2

VISIONARY-MS STUDY

Treatment of Visual Pathway Deficits In Chronic Optic Neuropathy for Assessment of Remyelination in Non-Active Relapsing MS

24-Week Blinded Fixed Treatment Period | **Up to 24-Week Blinded Extension Period** (Until LPLV 24Wk Visit)

Up to 48-Week Placebo-Control
2:1 Randomization (Active: Placebo)
15mg, 30mg, Placebo **(n=73 of 150)**

1° **Change in Low Contrast Letter Acuity (LCLA)**
At Week 24

2° **Change Composite Clinical Response**
9HPT / SDMT / T25FW / LCLA

Exploratory Endpoints

- Optical Coherence Tomography (OCT)
- Multi-focal VEP Amplitude & Latency
- Full field-VEP Amplitude & Latency
- MRI Endpoints
- Visual Function (High Contrast)
- QOL / EDSS

Anticipated topline data:
3Q 2022
Insights to inform new Phase 2/3 MS trial

https://clinicaltrials.gov/ct2/show/NCT03536559, Data on File, Clene Nanomedicine, Inc.

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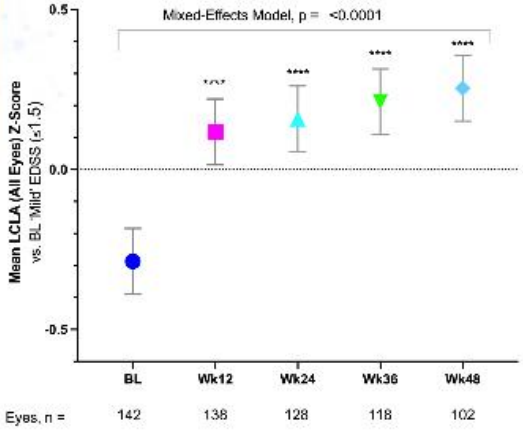
Phase 2 VISIONARY-MS STUDY

Significant Clinical Improvement Across Blinded Study Population

Primary Endpoint: LCLA (Best-Corrected) & Secondary Endpoint: (m)MSFC

1° | LCLA

LCLA (All Eyes) Average Z-Score
14-February-2022 Data Cut, Preliminary Blinded Data
(vs. 'Mild' EDSS [≤1.5]; Mean ± SEM)



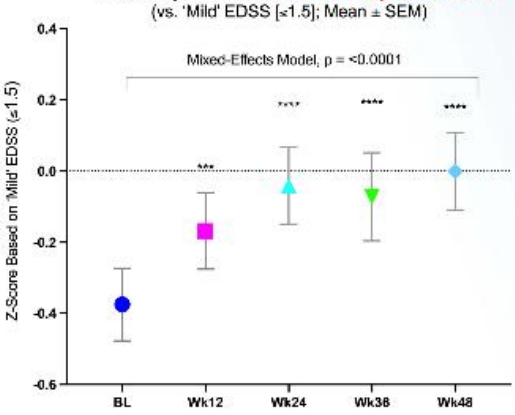
Eyes, n =	142	138	128	118	102

Z-Score Change Based on EDSS 'Mild' Severity (e.g., BL Low EDSS [≤1.5])
All Available Values (by Completed Subject Visit)

Mixed Effects Model, Dunnett's test for multiplicity:
* p<0.05, ** p<0.01, *** p<0.001, **** p<0.0001

2° | (m)MSFC

(m)MSFC 6-Component Average Z-Score
14-February-2022 Data Cut, Preliminary Blinded Data
(vs. 'Mild' EDSS [≤1.5]; Mean ± SEM)



n =	73	70	65	60	53

Z-Score Change Based on EDSS 'Mild' Severity (e.g., BL Low EDSS [≤1.5])
All Subjects with at least 4 of 6 (m)MSFC Domains by Completed Subject Visit.
(m)MSFC domains include LCLA (OD/OD), 9HPT (D/ND), T25FW, SDMT.

Mixed Effects Model, Dunnett's test for multiplicity:
^ p<0.05, ^^ p<0.01, ^^^ p<0.001, ^^^^ p<0.0001

Glanzman et al. VISIONARY-MS: Update to a Phase 2 Clinical Trial of CNM-Au8, Catalytically Active Gold Nanocrystals Suspension, for the Treatment of Chronic Optic Neuropathy ACTRIMS, February 2022.

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ZnAgSTUDY BRAZIL

Patient Population: Predominantly in vaccinated, symptomatic patients

Primary Endpoint: Time to substantial alleviation[1] of COVID-19 symptoms through Day 28

Secondary Endpoint: Time to complete alleviation[2] of COVID-19 symptoms through Day 28

Exploratory Endpoints:
- Number of hospital free days through Day 28
- Mean change in SARS-CoV-2 viral load
- Change in oxygen saturation slope
- Change in Global Impression (severity and change)

Anticipated topline data: 3Q 2022

1. **Substantial alleviation** is a patient global impression of severity scored as mild or normal.
2. **Complete alleviation** is a patient global impression of severity scored as normal

https://clinicaltrials.gov/ct2/show/NCT04610138

CLene NANOMEDICINE

Strong IP & MFG Capability

Extensive Patent Portfolio With Protection Through 2035[a] & Proprietary Trade Secrets; Plus 7-year Orphan Drug Designation, and Scalable to Commercialization

Patent Status [b]

- Issued & Allowed Patents 150+
- Pending Applications ~20
- Total Patents/ Applications >170

Patent Description

- Process And Method/Device (Clean Surface; Gold CSN)
- State of Matter (CNM-Au8)
- Method of Use (Prevent Demyelination & MoA)
- Method of Use (Bi-Metallic Au/Pt; Antimicrobial)

Trade Secrets

- Plasma Conditioning
- Electrode Design & Cycling
- Trough Flow, Temp, Pressure
- Concentration & Filtration

In-House ISO8 Clean Room Clinical Production in Maryland

[a] With Patent Restoration Term (assuming 5-year extension). [b] As of 31-December-2021.

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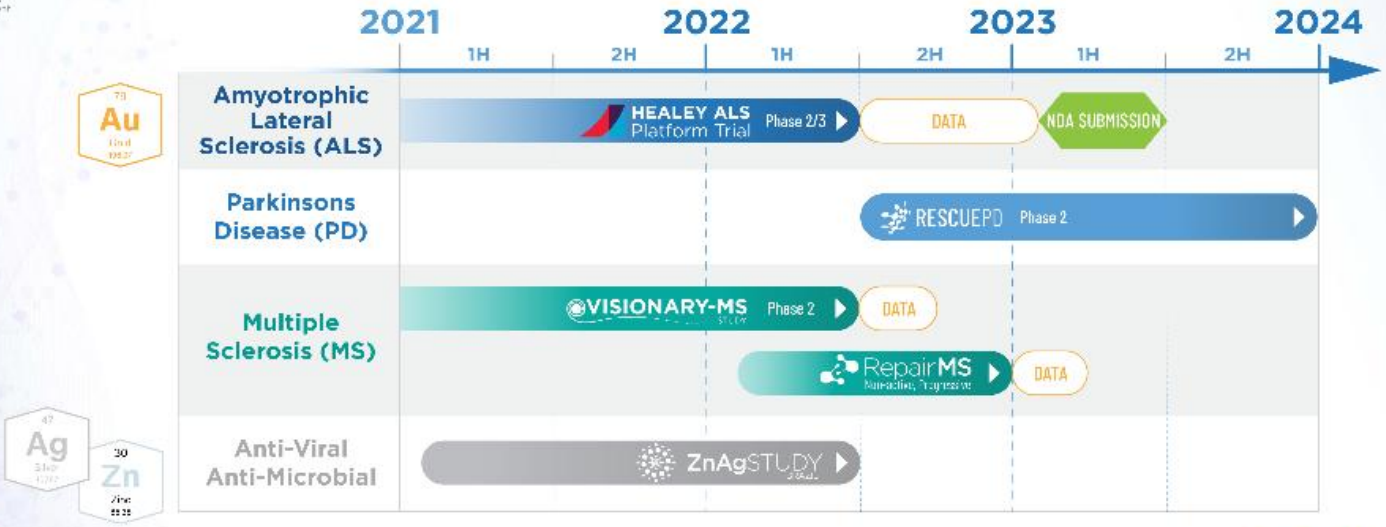
Anticipated Timeline & Upcoming Milestones

March 31, 2022
Cash and investments on hand (unaudited):
$36.6M



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CNM-Au8® | Growing Phase 2 Evidence Supports CNM-Au8 Commercial Potential

RepairMS
RepairPD

Established brain target engagement

RESCUEALS

Potential reduction in risk of disease progression and survival

HEALEY ALS Platform Trial
VISIONARY-MS

Topline data expected
3Q 2022

CLENE

Strong IP: 150+

patents and robust manufacturing trade secret portfolio

Manufacturing expansion in progress, preparing for possible commercialization

in 2023

>350

patient years of CNM-Au8® clinical exposure

CLENE NANOMEDICINE

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North East, MD 21901

Version: 9-May-2022