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): March 11, 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 March 11, 2022, Clene Inc. (the "Company") issued a press release announcing its full year operating and financial results for its year ended December 31, 2021. 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 March 11, 2022 press release announcing the Company's full year operating and financial results for its year ended December 31, 2021, the Company released an updated corporate presentation (the "Corporate Presentation") on its website, www.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 March 11, 2022, announcing the Company's operating and financial results for its year ended December 31, 2021.
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: March 11, 2022

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

Exhibit 99.1

Clene Reports Full Year 2021 Financial Results and Recent Operating Highlights

- ***Cash and restricted cash of $50.3 million as of December 31, 2021***
- ***Visionary-MS Phase 2 Trial unblinded results expected 2H 2022***
- ***Healey ALS Platform Trial top-line data expected 2H 2022***
- ***COVID-19 Phase 2 Trial top-line results expected mid-year 2022***

SALT LAKE CITY, March 11, 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 full year 2021 operating and financial results, as well as an overview of fourth quarter 2021 and recent operating highlights.

"We exited 2021 with significant momentum, having made substantial clinical advancement across our portfolio of first-in-class nanotherapeutics," said Rob Etherington, President and CEO of Clene. "This progress now has Clene positioned to achieve multiple clinical milestones in 2022, highlighted by the upcoming results from the HEALEY ALS Platform Trial. Positive results for CNM-Au8® in this study would be transformative for Clene, and more importantly, for people living with ALS."

Fourth Quarter 2021 and Recent Operating Highlights

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

- Enrollment in the HEALEY ALS Platform Trial, led by the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital, was completed in November 2021, and top-line data are expected in the second half 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, including:
  - Results showed the slowing of disease progression and improvements to patients' quality of life. In addition, RESCUE-ALS demonstrated evidence for a potential long-term survival benefit from CNM-Au8®.
  - Data from RESCUE-ALS were presented in the fourth quarter of 2021 at the 4th Annual ALS ONE Research Symposium and at a late-breaking session at the 32nd International Symposium on ALS/MND.
- Additional data including the significant survival benefit from the RESCUE-ALS open label extension will be presented at the upcoming Muscular Dystrophy Association Clinical & Scientific Conference this month and at a late breaker session at the upcoming American Academy of Neurology Annual Meeting in April.
- Clene continues to support expanded access programs, providing CNM-Au8® treatment at four clinical sites to more than 50 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 the robust target engagement demonstrated in the first cohort of relapsing MS patients in this trial.
- The VISIONARY-MS Phase 2 clinical trial will conclude 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.
  - Unblinded VISIONARY-MS data are targeted for the second half of 2022.
  - 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 in February 2022.

CNM-ZnAg™ for the treatment of COVID-19

- The CNM-ZnAg COVID Phase 2 clinical trial achieved full enrollment in acutely symptomatic, non-hospitalized COVID-19 patients in Brazil. Top-line results are expected mid-year 2022.

Corporate Updates

- Morgan Brown was appointed Chief Financial Officer (CFO) effective February 1, 2022. Mr. Brown's extensive experience in executive finance roles includes four publicly traded life science companies, three as CFO, and experience as the CFO of a privately held clinical research organization.
- Two key patents were granted and validated in Europe that protect Clene's breakthrough processes, devices and methods for treating certain disease indications for its nanotherapeutic drugs. Clene was also granted a patent from the U.S. Patent and Trademark Office for CNM-Au8 for the treatment of MS.
- Clene announced a $1 million grant award from the Maryland Department of Housing and Community Development in support of the redevelopment of a 72,000 ft^2 manufacturing facility in Elkton, Maryland, in anticipation of product commercialization.

Full Year 2021 Financial Results

Clene's cash and restricted cash totaled $50.3 million as of December 31, 2021, compared to $59.3 million as of December 31, 2020. Clene expects that its resources as of December 31, 2021, will be sufficient to fund its operations into the second quarter of 2023.

Research and development expenses were $28.4 million for the year ended December 31, 2021, compared to $15.2 million for the same period in 2020. The year-over-year increase was primarily related to the development of CNM-Au8, rent expense for the newly-leased facility in Elkton, Maryland, and personnel and stock-based compensation due to increased headcount, partially offset by decreased manufacturing and materials expense.

General and administrative expenses were $22.0 million for the year ended December 31, 2021, compared to $5.2 million for the same period in 2020. The year-over-year increase was primarily attributable to costs related to being a public company and fees for professional services, technology services, and pre-commercialization activities for CNM-Au8, and personnel and stock-based compensation due to increased headcount.

Clene reported a net loss of $9.7 million, or $0.16 per share, for the year ended December 31, 2021, compared to a net loss of $19.3 million, or $1.10 per share, for the same period in 2020. Included in net loss for the year ended December 31, 2021, was an unrealized gain from the change in fair value of contingent earn-out liabilities of $37.5 million, compared to $14.1 million in the prior 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" which are intended to be covered by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Clene's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts,"

“potential,” “might” and “continues,” and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant known and unknown risks and uncertainties, many of which are beyond Clene’s control and could cause actual results to differ materially and adversely from expected results. Factors that may cause such differences include 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 marketed products and drug candidates, if approved; Clene’s ability to obtain and maintain protection of intellectual property for its technology and drugs; Clene’s reliance on third parties to conduct drug development, manufacturing and other services; Clene’s limited operating history and its ability to obtain additional funding for operations and to complete the licensing or development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on Clene’s clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled “Risk Factors” in Clene’s Annual Report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in Clene’s subsequent filings with the U.S. Securities and Exchange Commission. Clene undertakes no obligation to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, subject to applicable law. 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.

Media Contact
Erica Fiorini, Ph.D., or David Schull
Russo Partners, LLC
Erica.fiorini@russopartnersllc.com
David.schull@russopartnersllc.com
+1-212-845-4253

Investor Contact
John Woolford
Managing Director, Westwicke
clene@westwicke.com
+1-443-213-0506

Source: Clene Inc.

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

	Year Ended December 31,	
	2021	2020
Revenue:		
Product revenue	$ 570	$ 176
Royalty revenue	153	30
Total revenue	723	206
Operating expenses:		
Cost of revenue	289	65
Research and development	28,416	15,204
General and administrative	21,996	5,151
Total operating expenses	50,701	20,420
Loss from operations	(49,978)	(20,214)
Other income (expense), net:		
Interest expense	(870)	(950)
Gain on extinguishment of notes payable	648	—
Loss on extinguishment of convertibles notes payable	—	(540)
Gain on termination of lease	—	51
Change in fair value of preferred stock warrant liability	—	(14,615)
Change in fair value of common stock warrant liability	983	—
Change in fair value of derivative liability	—	29
Change in fair value of Clene Nanomedicine contingent earn-out	33,953	12,659
Change in fair value of Initial Stockholders contingent earn-out	3,589	1,465
Australia research and development credit	1,519	3,210
Other income (expense), net	(12)	34
Total other income (expense), net	39,810	1,343
Net loss before income taxes	(10,168)	(18,871)
Income tax benefit (expense)	428	(406)
Net loss	(9,740)	(19,277)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(92)	284
Total other comprehensive income (loss)	(92)	284
Comprehensive loss	$ (9,832)	$ (18,993)
Net loss per share-- basic and diluted	$ (0.16)	$ (1.10)
Weighted average common shares used to compute basic and diluted net loss per share	61,558,455	17,503,992

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

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash	$ 50,288	$ 59,275
Accounts receivable	49	21
Inventory	41	191
Prepaid expenses and other current assets	4,205	3,502
Total current assets	54,583	62,989
Restricted cash	58	—
Right-of-use assets	3,250	1,029
Property and equipment, net	5,172	4,225
TOTAL ASSETS	$ 63,063	$ 68,243
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,923	$ 1,124
Accrued liabilities	3,610	3,960
Income tax payable	—	164
Deferred revenue from related parties	—	112
Operating lease obligations, current portion	347	194
Finance lease obligations, current portion	146	190
Clene Nanomedicine contingent earn-out, current portion	—	5,924
Total current liabilities	6,026	11,668
Operating lease obligations, net of current portion	4,370	1,785
Finance lease obligations, net of current portion	97	205
Notes payable	14,484	1,949
Convertible notes payable	4,598	—
Deferred income tax	—	260
Common stock warrant liability	474	—
Clene Nanomedicine contingent earn-out, net of current portion	18,100	46,129
Initial Stockholders contingent earn-out	2,317	5,906
TOTAL LIABILITIES	50,466	67,902
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value: 150,000,000 and 100,000,000 shares authorized at December 31, 2021 and December 31, 2020, respectively; 62,312,097 and 59,526,171 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	6	6
Additional paid-in capital	175,659	153,571
Accumulated deficit	(163,301)	(153,561)
Accumulated other comprehensive income	233	325
TOTAL STOCKHOLDERS' EQUITY	12,597	341
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 63,063	$ 68,243


CLNN (NASDAQ)
clene.com
CLene
NANOMEDICINE

Forward Looking Statements

This presentation contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Clene's actual results may differ from its expectations, estimates, and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "might" and "continues," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant known and unknown risks and uncertainties, many of which are beyond Clene's control and could cause actual results to differ materially and adversely from expected results. Factors that may cause such differences include 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 marketed products and drug candidates, if approved; Clene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Clene's reliance on third parties to conduct drug development, manufacturing and other services; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the licensing or development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on Clene's clinical development, commercial and other operations, as well as those risks more fully discussed in the section the section entitled "Risk Factors" in Clene's recently filed Annual Report on Form 10-K (filed March 11, 2022), as well as discussions of potential risks, uncertainties, and other important factors in Clene's subsequent filings with the U.S. Securities and Exchange Commission. Clene undertakes no obligation to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, subject to applicable law. All information in this presentation is as of the date of presented or the date made publicly available. 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 | Leadership

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 · Credit Suisse · Actelion · Roche · Novartis · Pfizer · Parke-Davis · NPS Pharma

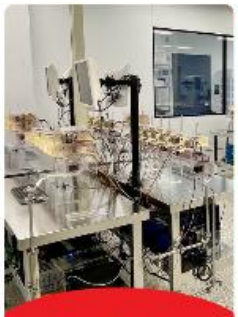
CLENE NANOMEDICINE

CLENE | Overview

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

ALS Registration Trial
Topline data in 2H 2022[2]

>300
patient years of CNM-Au8 clinical exposure



Manufacturing expansion in progress, preparing for possible commercialization in 2023

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

December 31, 2021 Cash and restricted cash on hand (audited):
$50.3M

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

clene NANOMEDICINE

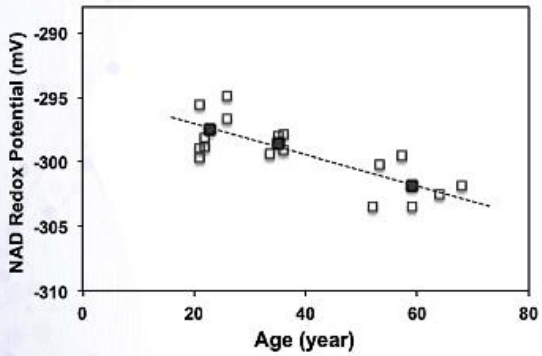
CLENE | Pipeline

CLENE NANOMEDICINE

Neurons With High Energetic Demand Are At Increased Risk For Neurodegenerative Disease

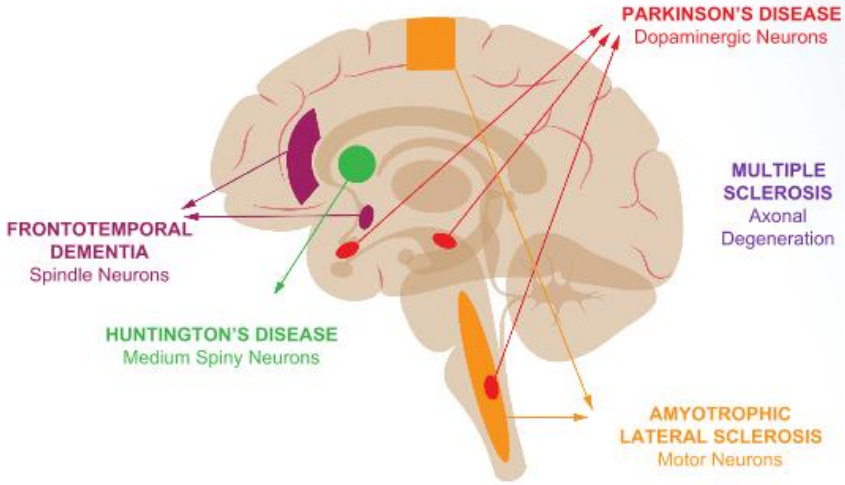
Brain Energy Potential Declines With Normal Aging

~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

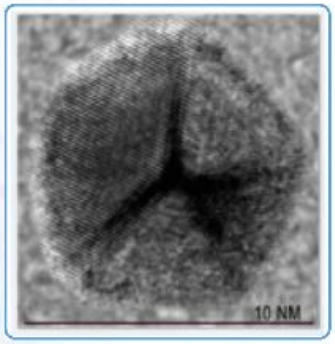


Fu, H., et al; Nature Neuroscience (2018) 21: 1350-1358. Zhu et al. Proc Natl Acad Sci USA . 2015 Mar 3;112(9):2876-81. Rone et al. J Neurosci. 2016 Apr 27;36(17):4698-707.

CNM-Au8® | Catalytically-Active Nanocrystals

Intersection of Physics and Biology

CNM-Au8 Nanocrystal



> 100 Trillion Nanocrystals per 60 mL Dose (At 30mg)

Clean Surfaced, Highly Faceted Shape Enhances Catalytic Activity

Electron Sharing Drives Catalytic Activity

Vertices, Edges, & Facets Key to Catalytic Activity

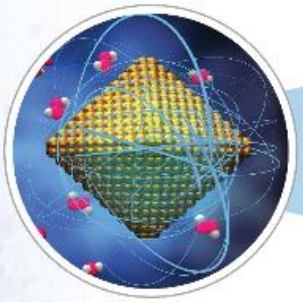
CNM-Au8 Catalytically Active Nanocrystal Suspension

60 mL per bottle (once daily)

clene NANOMEDICINE

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

CNM-Au8 Nanocrystal



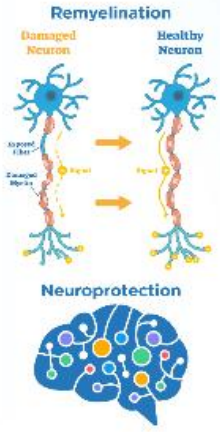
Mechanistic Effects

- ↑ 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



CLene NANOMEDICINE

CNM-Au8® | Preclinical Evidence for Energetic Improvement

Therapeutic Activity Across Remyelination + Neuroprotection Models

REMYELINATION[1]

Chronic Global CNS Demyelination

- Chronic Cuprizone (CPZ) Pilot
- Chronic CPZ Repeat Validation
- Prevent CPZ Damage
- Post-Chronic CPZ Myelin Recovery
- Chronic CPZ Functional Outcome

Focal Spinal Cord Remyelination

- Lysolecithin Focal Remyelination (I)
- Lysolecithin Focal Remyelination (II)

Perinatal Myelin Injury

- Cerebral Palsy Remyelination *Ex Vivo*

PUBLICATION

Robinson et al.
Sci Rep. 2020
Feb 11

SCIENTIFIC REPORTS

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

NEUROPROTECTION[2]

Neuroprotection: Motor Neuron

- MN Neuroprotection iPSC MN *In Vitro, Astrocyte*
- MN Glutamate Excitotoxicity *In Vitro*
- MN Amyloid beta *In Vitro*
- MN Neuroprotection *ALS SOD1, In Vivo*
- MN Neuroprotection *ALS SOD1, In Vitro*

Neuroprotection: Dopaminergic

- PD Neurotoxin MPP *In Vitro*
- PD Neurotoxin *6-OHDA In Vitro*
- PD Neurotoxin *6-OHDA In Vivo*

Neuroprotection: Other

- Hippocampal Neuron Glutamate Excitotoxicity *In Vitro*
- Cortical Neuron Glutamate Excitotoxicity *In Vitro*
- Forebrain Neuroprotection *C9ORF72 In Vitro*
- Alzheimer's Disease Induced Neurons *In Vitro*

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

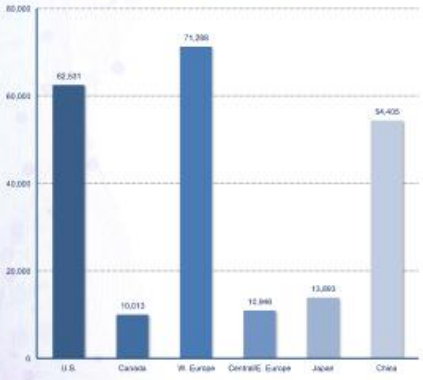
clene NANOMEDICINE

CNM-Au8® | Significant Global Opportunity

MOTOR NEURON DISEASE
(ALS, Other Orphan Disorders)

ALS sales >$1B globally by 2029[1]. Current drugs are largely ineffective, mostly generic

Est. Diagnosed MND Patients by Region

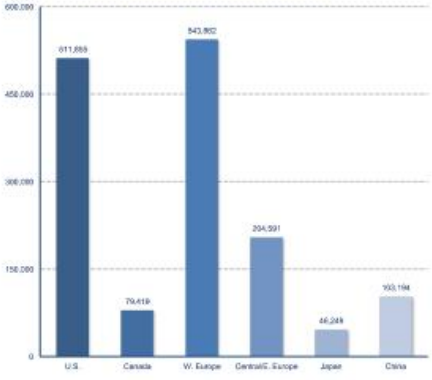


Source: Lancet Neurol. 2018 Dec;17(12):1083-1097.
MND includes amyotrophic lateral sclerosis, spinal muscular atrophy, hereditary spastic paraplegia, primary lateral sclerosis, progressive muscular atrophy, and pseudobulbar palsy

MULTIPLE SCLEROSIS
pts globally; $23B market[2]

Only approved treatments are immunomodulators

Est. Diagnosed MS Patients by Region

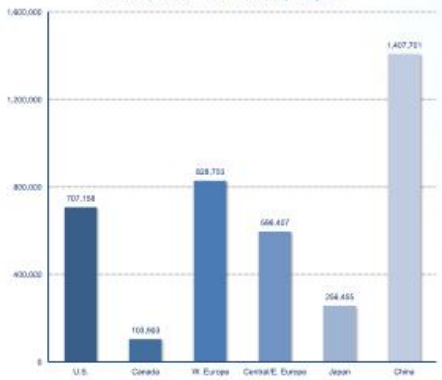


Source: Lancet Neurol. 2019 Mar;18(3):269-285; ~2.2 M patients globally, data as of 2016

PARKINSON'S DISEASE
~6.1M pts globally; $6B projected by 2026[3]

2ND most common neurodegenerative disorder; only symptomatic treatments

Est. Diagnosed PD Patients by Region



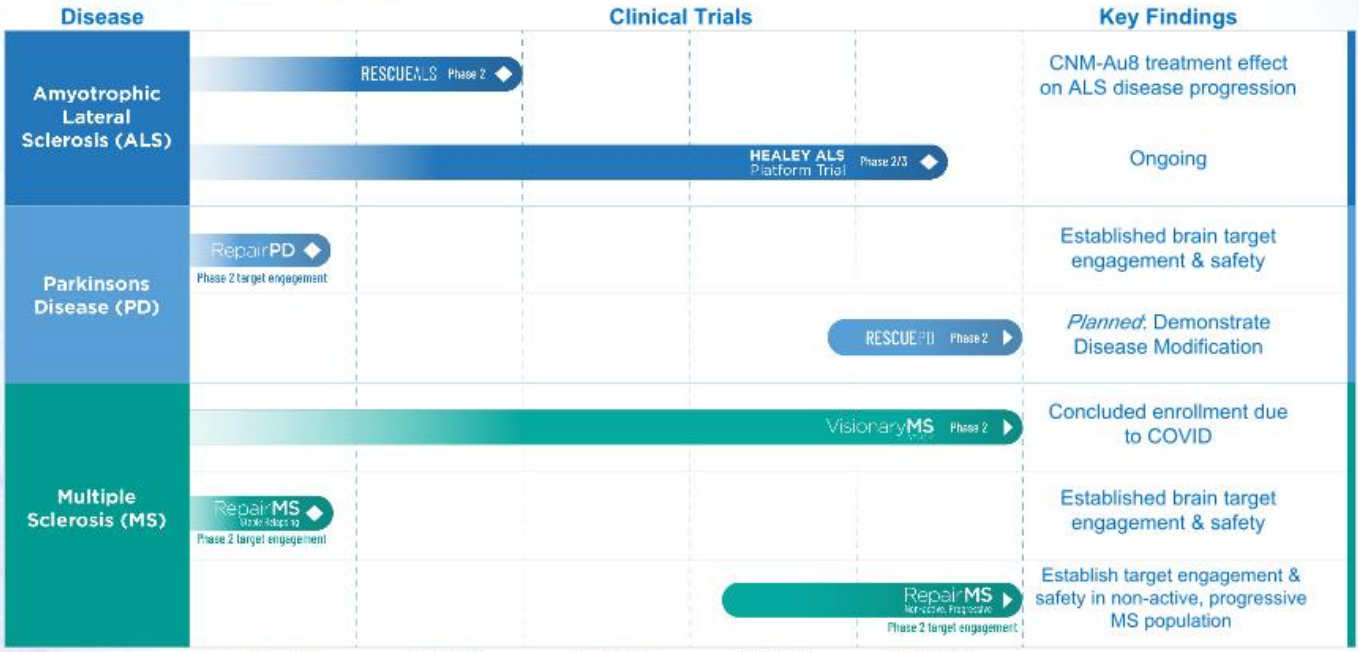
Source: Lancet Neurol. 2018 Nov;17(11):939-953. ~6.1M patients globally, data as of 2016.

[1] Clarivate, DRG, ALS 2020 [2] Westad et al. 2017, doi:10.1038/nrd.2017.107;. [3] Parkinson's Market Data Forecast, April 2021.

CLene NANOMEDICINE

CNM-Au8® | Neuroprotection & Remyelination

Phase 2 and Phase 3 Clinical Trials



Data on File, Clene Nanomedicine, Inc.

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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 related CNM-Au8 AEs leading to discontinuation of treatment
- No SAEs related to CNM-Au8 considered severe, life-threatening, or resulting in death

Patient Exposure Across PD, MS, & ALS

Over 300 Years of Subject Exposure Without Any Safety Signals

- Long-term dosing experience up to 125 weeks

Data on File, Clene Nanomedicine, Inc.

Phase 2

RepairPD

RepairMS

CNM-Au8 Effects on Brain Energetic Metabolites

A Phase 2, Open Label, Sequential Group, Investigator Blinded Study of Magnetic Resonance Spectroscopy (^{31}P-MRS) to Assess the Effects of CNM-Au8 for the Bioenergetic Improvement of Impaired Neuronal Redox State (REPAIR)

RepairPD

Early Parkinson's Disease

RepairMS

Stable Relapsing MS

RepairMS

Non-Active Progressive MS

(Underway)

Non-active, progressive MS patients is more severe than relapsing MS., and a high unmet need for disease modifying therapeutic options

1°

Change in Brain Bioenergetic Potential (NAD^+/NADH) vs. Baseline

N = Up to 15 per dosing cohort

(7.5, 15, 30, or 60 mg)

2°

Exploratory

- Difference in brain NAD^+ and NADH fraction at Week 12 (End of Treatment)
- Difference in bioenergetic metabolites (e.g., ATP, NAD) concentration at Week 12 – 16
- Difference in brain membrane markers (PE, PC, etc.) at Week 12 – 16

Data on File, Clene Nanomedicine, Inc.

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Phase 2 Results

RepairPD

RepairMS

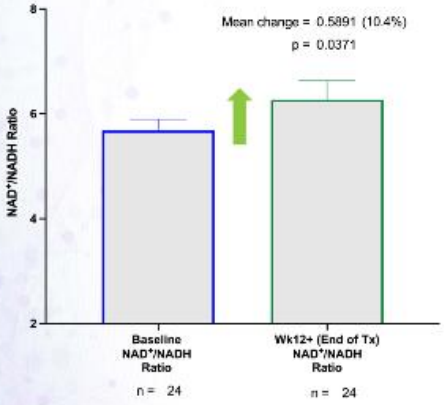
CNM-Au8 Improves Brain Energy Metabolism Increases NAD+/NADH Ratio in MS & PD

1° Endpoint

^{31}P-MRS Change in Brain NAD$^+$/NADH Ratio at End of Treatment

Partial Volume Coil; Ratio of NAD$^+$/NADH (% Fraction of NAD$^+$/ % Fraction NADH)

Primary Endpoint, Mean ± SEM (Paired t-test)



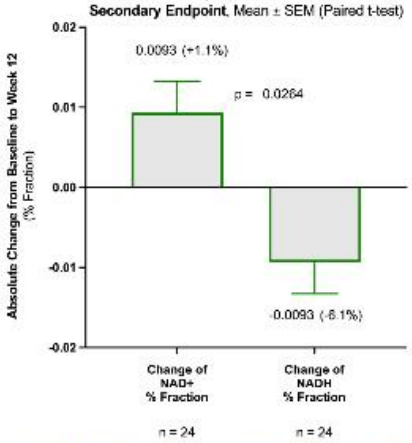
2° Endpoint

REPAIR Integrated Analysis

^{31}P-MRS Average Change in Brain NAD (% Fraction)

Partial Volume Coil; % Fraction of NAD$^+$ and NADH

Secondary Endpoint, Mean ± SEM (Paired t-test)



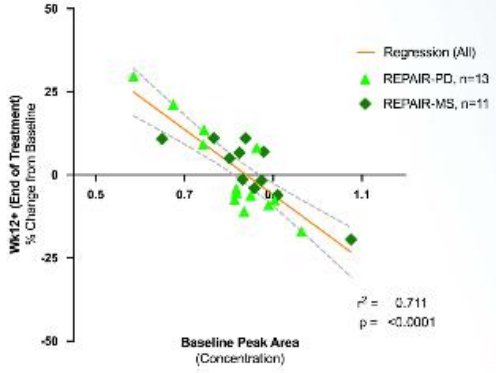
Exploratory (ATP Normalization)

REPAIR Integrated Analysis

^{31}P-MRS Change in β-ATP at End of Treatment

Full Volume Coil ^{31}P Signal Area (Integral)

Exploratory Endpoint, Percent (%) Change vs. Baseline Value



NAD is an essential molecule responsible for cellular energy production

Glanzman et al. 2021. International Parkinson and Movement Disorder Society (MDS) Virtual Congress 2021. September 17 – 22, 2021 . Data on File, Clene Nanomedicine, Inc.

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Phase 2

RESCUEALS

Randomized, Double-Blind, Placebo-Controlled Study in Early Symptomatic Amyotrophic Lateral Sclerosis Patients on Stable Background Therapy to Assess Bioenergetic Catalysis with CNM-Au8 to Slow Disease Progression in ALS

36-Week Treatment Period (n=42) 30mg, Placebo

Neurophysiology	Pulmonary Function	Function & QoL	Disease Progression & Survival
MUNIX[1]	Forced Vital Capacity	ALSFRS-R, ALSSQOL-SF	

[1] Study was powered for MUNIX primary endpoint

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

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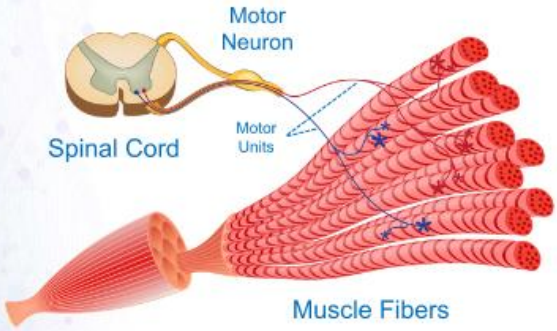
RESCUEALS | Pioneered Use of MUNIX Biomarker

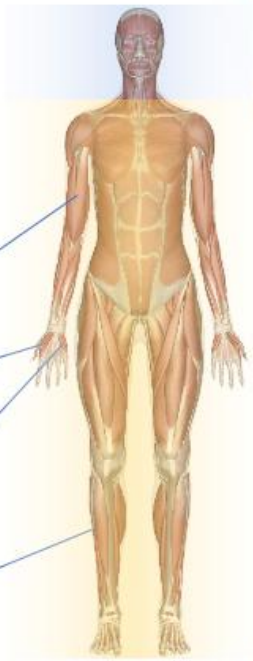
Primary Endpoint: Spinal Cord Lower Motor Neuron Protection

MUNIX biomarker estimates the number of functioning lower motor neurons serving specific muscles



Primary Endpoint: Spinal Cord Lower Motor Neuron Motor Unit Index (MUNIX) Sum

- Biceps brachii
- +
- Abductor Pollicis Brevis
- +
- Abductor Digiti Minimi
- +
- Tibialis Anterior



Bulbar Onset ALS (Brainstem)

Limb Onset ALS (Spinal Cord)

Vucic et al. BMJ Open. 2021 Jan 11;11(1):e041479.

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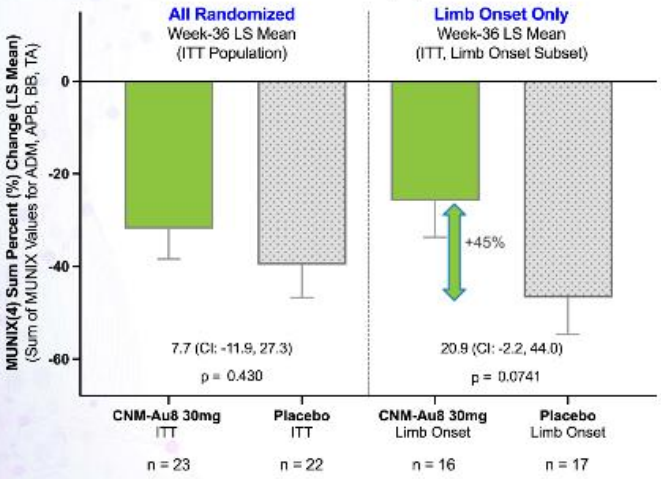
RESCUEALS | Evidence for Motor Neuron Protection

Primary Endpoint (MUNIX %, LS Mean Change)

All Randomized

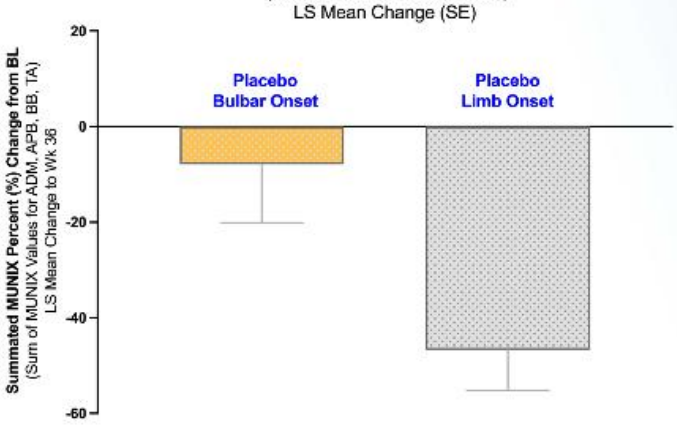
Summated MUNIX Percent Change from Baseline to Week 36
RESCUE-ALS Primary Endpoint
Mixed Model Repeat Measure (ITT Population & Limb Onset Subset)
LS Mean (SE)



All Placebo

Limited Rate of MUNIX Decline in Bulbar Onset

Summated MUNIX Percent Change from Baseline
Placebo Only Decline to Week 36
(Limb Onset vs. Bulbar Onset)
LS Mean Change (SE)



Insufficient Spinal Cord Lower Motor Neuron Progression in Early Bulbar Trial Participants

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

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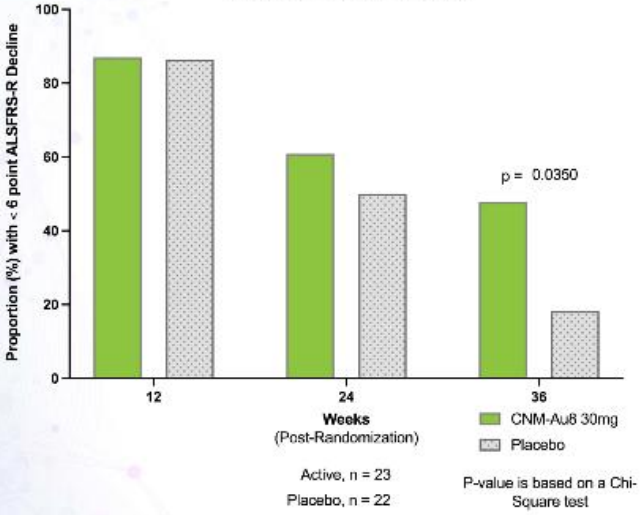
RESCUEALS | Significant Impact on ALSFRS-R Decline

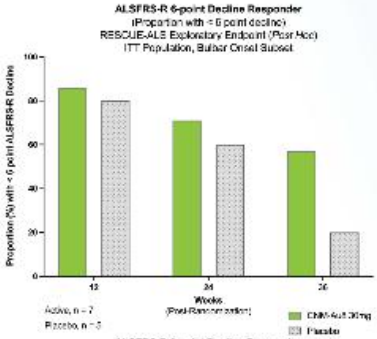
Exploratory (ALSFRS-R Responder Analysis, < 6-point decline)

All Randomized

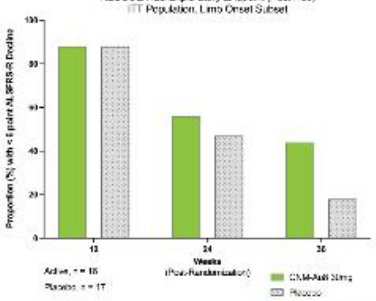


Sensitivity

All Bulbar



All Limb



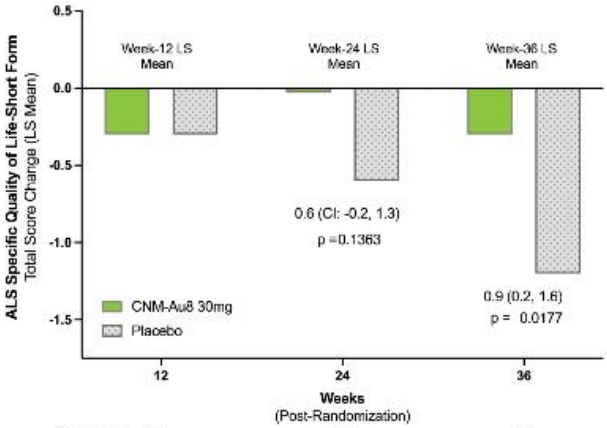
RESCUE-ALS: A Phase 2, randomized, double-blind, placebo-controlled study of CNM-Au8 to slow disease progression in ALS. MNDA Virtual Symposium, 2021 Data on File, Clene Nanomedicine, Inc.

RESCUEALS | Significant Quality of Life Improvement

Exploratory (ALS Specific QOL-SF)

All Randomized

ALS Specific Quality of Life-Short Form Total Score
RESCUE-ALS Exploratory Endpoint
Mixed Model Repeat Measure (ITT Population, All Randomized)
LS Mean Difference



Active, n =	23	23	22
Placebo, n =	21	20	19

P-value is based on MMRM model with treatment, visit, treatment by visit interaction as fixed effects, and baseline value, and ENCALS score as covariates. An unstructured covariance model was used.

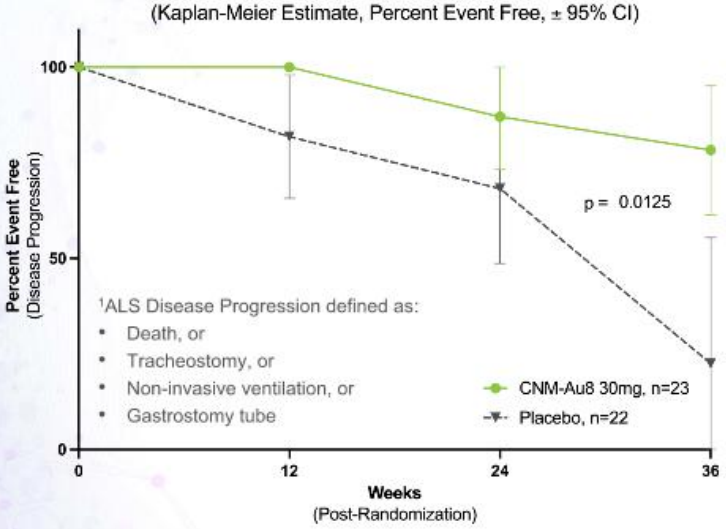
RESCUE-ALS: A Phase 2, randomized, double-blind, placebo-controlled study of CNM-Au8 to slow disease progression in ALS. MNDA Virtual Symposium, 2021 Data on File, Clene Nanomedicine, Inc.

RESCUEALS | Significant Impact on ALS Disease Progression

Exploratory Endpoint (Disease Progression)

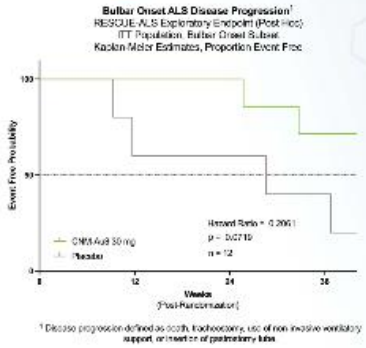
All Randomized

ALS Disease Progression[1]
RESCUE-ALS Exploratory Endpoint
ITT Population, All Randomized
(Kaplan-Meier Estimate, Percent Event Free, ± 95% CI)



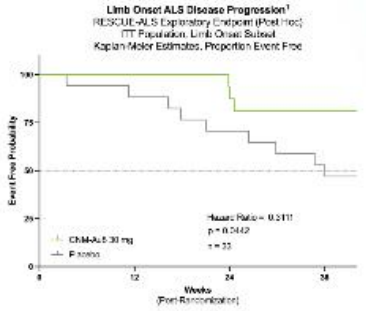
Sensitivity

All Bulbar



[1] Disease progression defined as death, tracheostomy, use of non-invasive ventilatory support, or insertion of gastrostomy tube.

All Limb



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

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RESCUEALS | Joint Rank: Survival & ALSFRS-R

Exploratory Endpoint Pre-specified (Combined Assessment of Survival and Function [CAFS])

Score participants based on relative function or time of death

Scoring

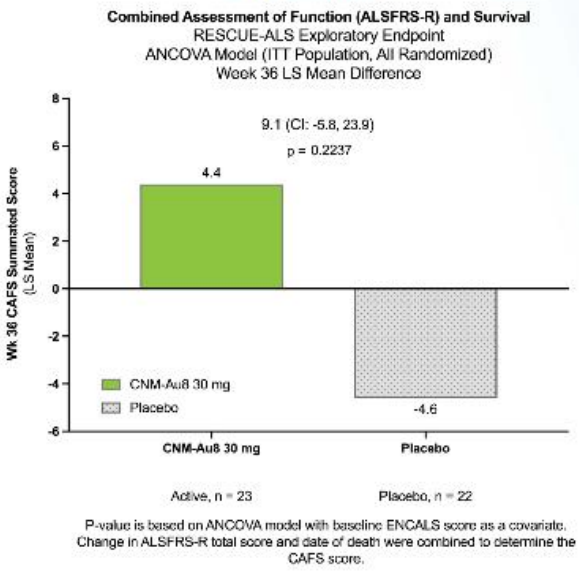
If...	Score
Better function or died later than comparison	+1
Same function or died at the same time as comparison	0
Worse function or died before comparison subject	-1

CAFS

Survival

ALSFRS-R Decline

All Randomized



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.

Berry et al. Amyotroph Lateral Scler Frontotemporal Degener. 2013 Apr;14(3):162-8.

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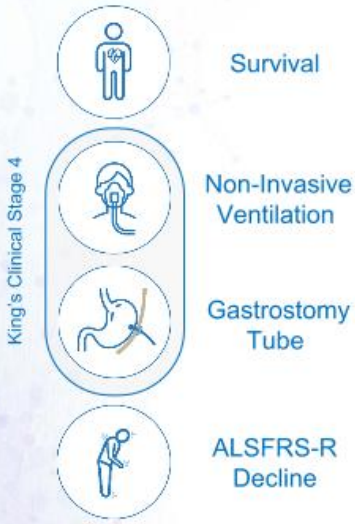
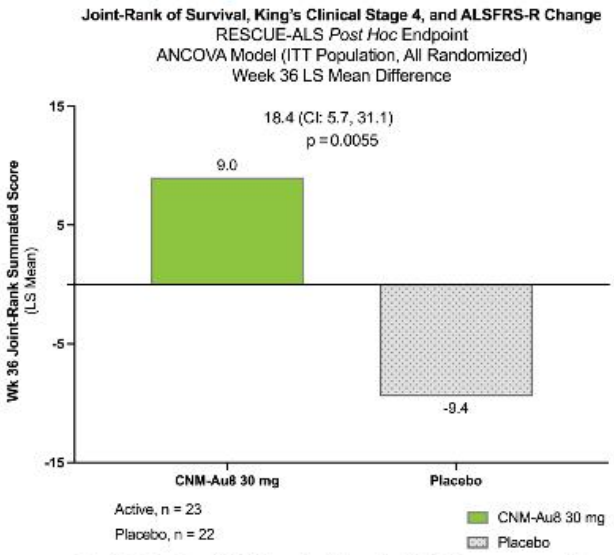
RESCUEALS | Impact on Joint Rank Score to Wk36

Post Hoc (Combined Assessment of (i) Survival, (ii) King's Clinical Stage 4, (iii) ALSFRS-R)



By Average of Summated Scores



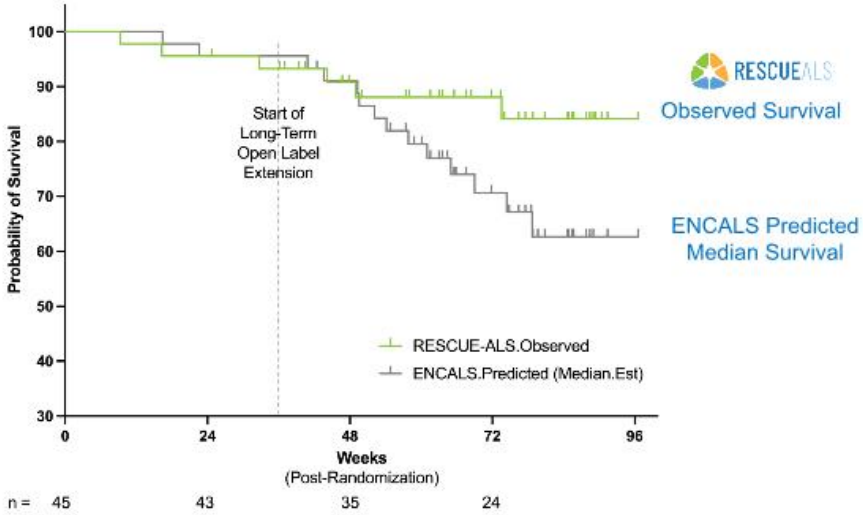
P-value is based on ANCOVA model with baseline ENCALS score as a covariate. Change in ALSFRS-R total score, date of non-invasive ventilation or gastrostomy, and date of death were combined to determine the joint-rank score.

Data on File, Clene Nanomedicine, Inc.

RESCUEALS | Potential Impact on Survival

Exploratory Endpoint (Observed Survival vs. Median Predicted)

Observed Survival vs. ENCALS Predicted Median Survival
RESCUE-ALS Exploratory Endpoint
ITT Population, All Randomized



All observations censored as of 22-November-2021. Participants who did not transition into the long-term open label extension (n=5) are censored at the safety follow-up visit.

Data on File, Clene Nanomedicine, Inc.

RESCUEALS | Well Tolerated & No Safety Signals

Safety Summary

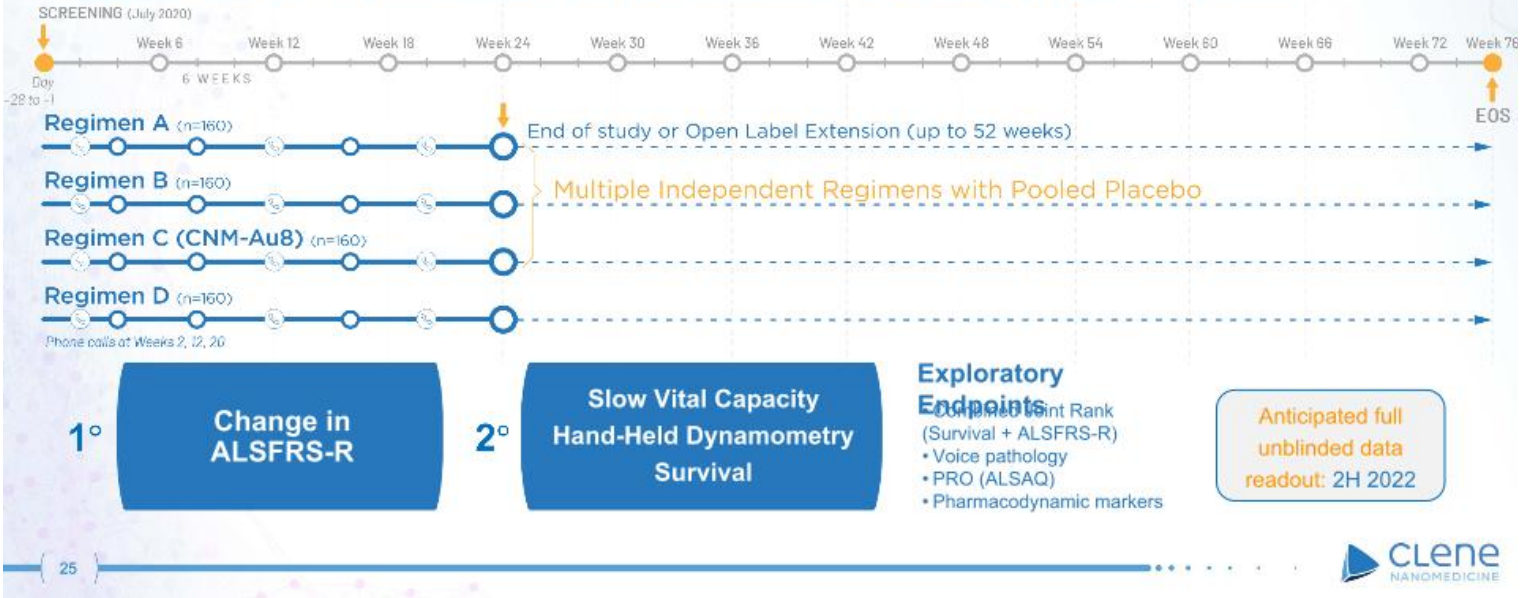
- No CNM-Au8 related serious adverse events (SAEs)
- No CNM-Au8 related drug discontinuations
- No imbalances in treatment emergent adverse event (TEAEs) by system organ class
- TEAEs were predominantly mild-to-moderate and transient
- Most common TEAEs associated with CNM-Au8
  (aspiration pneumonia, n=3; nausea, n=2; abdominal discomfort, n=2)

Data on File, Clene Nanomedicine, Inc.

Phase 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

2° Slow Vital Capacity
Hand-Held Dynamometry
Survival

Exploratory Endpoints
- Combined Joint Rank (Survival + ALSFRS-R)
- Voice pathology
- PRO (ALSAQ)
- Pharmacodynamic markers

Anticipated full unblinded data readout: 2H 2022

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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 top-line unblinded data:
2H 2022
Insights to inform new Phase 2/3 MS trial

*Subject to ongoing COVID-19 related site research restrictions generally implemented to protect MS patients taking standard-of-care immunosuppressive therapies

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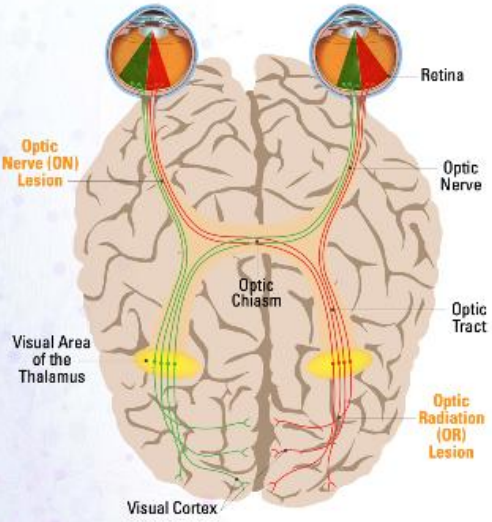
Measuring MS Functional Improvement

The Visual System is a Window into the Brain



LCLA

Phase 2 Primary: Functional Visual Improvement

LCLA Correlates with clinically meaningful deficits in QOL, EDSS and MSFC, MRI, and OCT[1]

MS Functional Endpoints

Phase 2 Exploratory: Neuroprotection/Remyelination Endpoints

9-Hole Peg Test

Symbol Digit Modalities

Timed 25-Ft Walk

[1]Balcer et la. Mult Scler. 2017 Apr;23(5):734-747. doi: 10.1177/1352458517690822.

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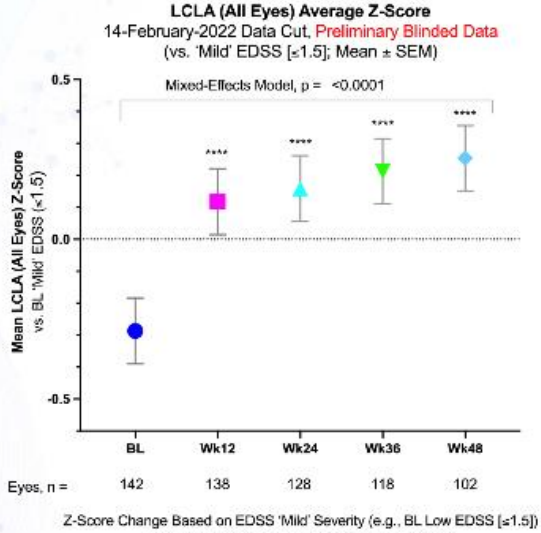
Phase 2 VISIONARY-MS STUDY

Significant Clinical Improvement Across Blinded Study Population

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

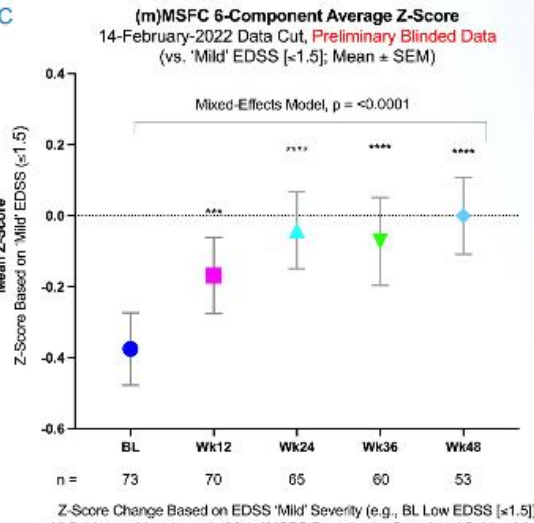
1° | LCLA



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



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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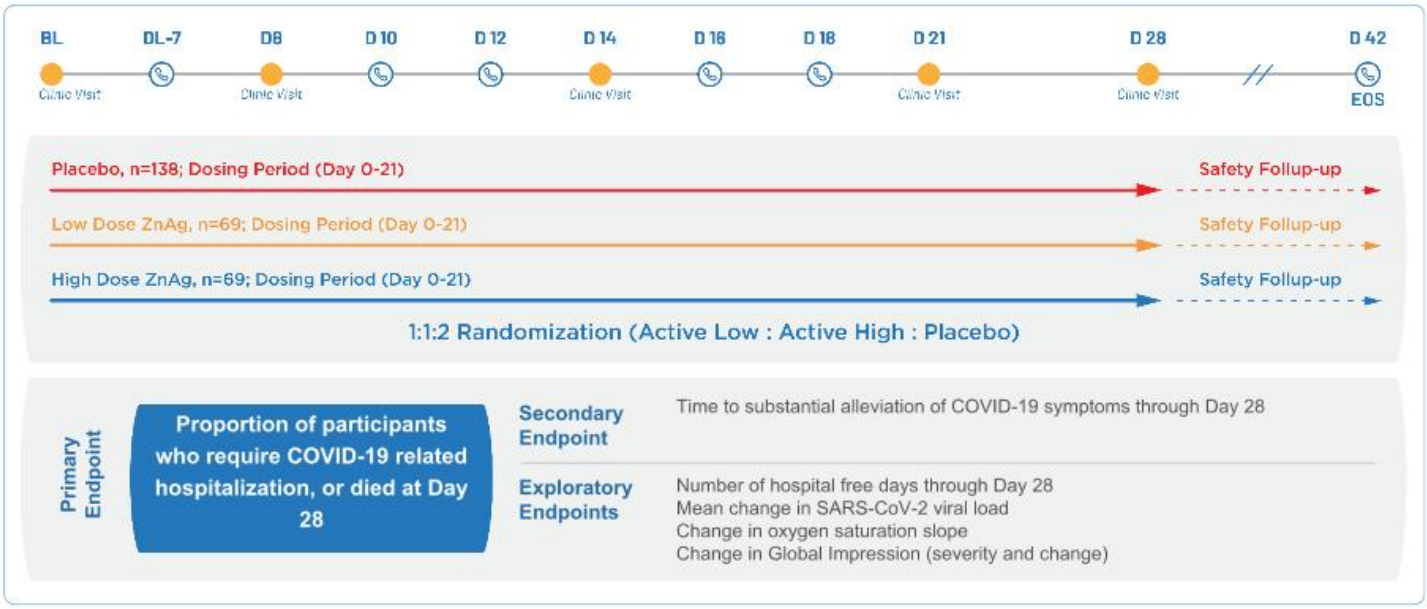
ZnAgSTUDY BRAZIL



Strong Intellectual Property

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

CSN®
Clean surface nanocrystal (CSN) therapeutics

Patent Status [b]	Patent Description	Trade Secrets
Issued & Allowed Patents 150+	Process And Method/Device (Clean Surface; Gold CSN)	Plasma Conditioning
Pending Applications ~20	State of Matter (CNM-Au8)	Electrode Design & Cycling
Total Patents/ Applications >170	Method of Use (Prevent Demyelination & MoA)	Trough Flow, Temp, Pressure
	Method of Use (Bi-Metallic Au/Pt; Antimicrobial)	Concentration & Filtration

[a] With Patent Restoration Term (assuming 5-year extension). [b] As of 30-September-2021.

Clene | Proprietary Nanocrystal Manufacturing

In-House ISO8 Clean Room Clinical Production in Maryland

Designed to be Scalable to Commercialization

- **Patented Hydro-electro-Crystallization**
- **Proprietary Trade Secrets**
- **Validated CMC Processes**

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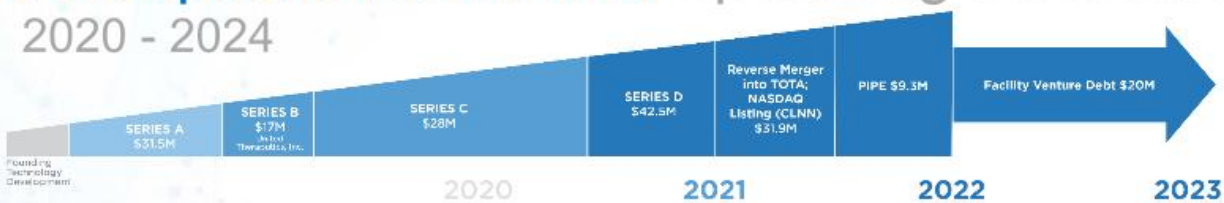
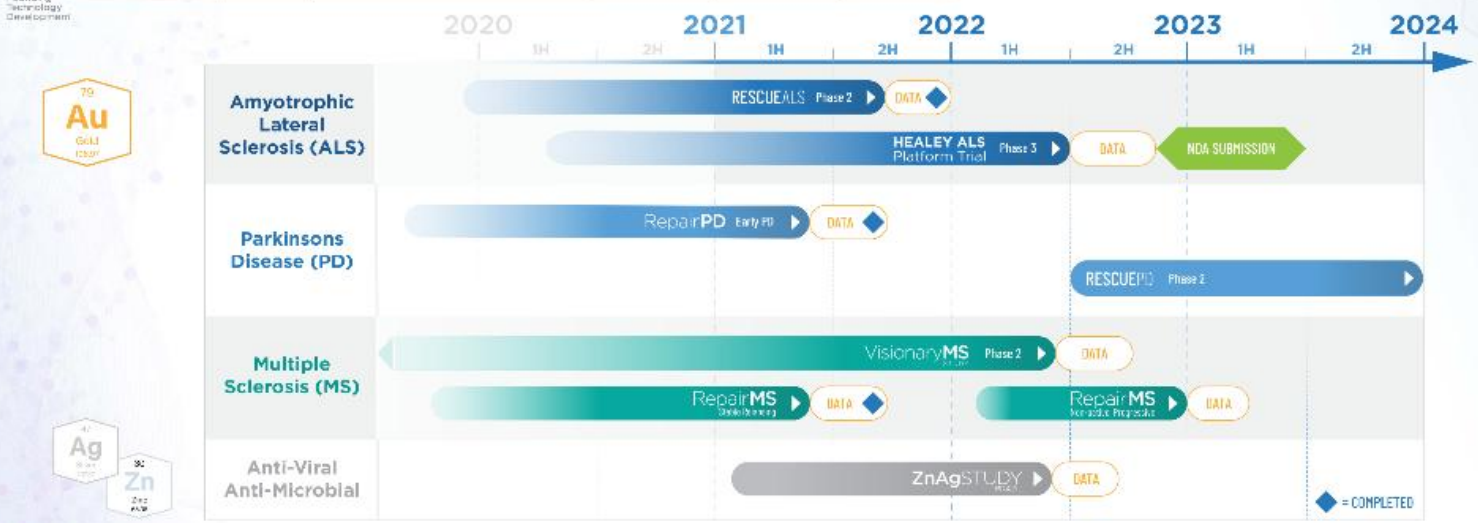
Anticipated Timeline & Upcoming Milestones

2020 - 2024





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CLENE | Company Highlights

Nanotherapeutics Platform

- Potential first-in-class nanotherapeutic with high catalytic activity to drive energy production and utilization in stressed CNS cells
- Applications across neurology, infectious disease, and oncology

Lead Asset: CNM-Au8 for Neurorepair

- CNM-Au8 improves cellular energy production and utilization to promote neuroprotection and remyelination
- Phase 2 ALS proof-of-concept evidence of clinical meaningful benefit
- Phase 3 Healey ALS platform trial results expected in 2H 2022
- Phase 2 VISIONARY-MS trial results expected 2H 2022

Strong Execution Capabilities

- Proprietary electrochemical manufacturing process produces nanotherapeutics, scalable to commercialization
- Strong IP, including 150+ granted patents, and trade secrets

Clene NANOMEDICINE

Clene Inc.
HQ & Clinical Development
6550 South Millrock Drive, Suite G50
Salt Lake City, UT 84121

R&D and Manufacturing
500 Principio Parkway, Suite 400
North East, MD 21901

Version: 11-March-2022