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): August 10, 2021

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

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 (see General Instruction A.2. below):

☐ 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, par value US$0.0001 per share	CLNN	The Nasdaq Stock Market LLC
Warrants, to acquire one-half of one share of Common Stock for $11.50 per share	CLNNW	The Nasdaq Stock Market LLC

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 August 10, 2021, Clene Inc. (the "Company") issued a press release announcing its operating and financial results for its second quarter ended June 30, 2021. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished in this Item 2.02, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933 (the "Securities Act"), as amended, regardless of any general incorporation language in any such filings, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

In connection with the August 10, 2021 press release announcing the Company's operating and financial results for its second quarter ended June 30, 2021, the Company released an updated corporate presentation (the "Corporate Presentation") on its website, www.clene.com. A copy of the Corporate Presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company plans to use its website to disseminate future updates to the Corporate Presentation and may not file or furnish a Current Report on Form 8-K alerting investors if the Corporate Presentation is updated.

The information furnished in this Item 7.01, including Exhibit 99.2, shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act, regardless of any general incorporation language in any such filings, except as shall be expressly set forth by specific reference in such a filing.

Forward-Looking Statements

This report, the press releases and the presentation may contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. The forward-looking statements include, but are not limited to, our expectations, hopes, beliefs, intentions, strategies, estimates and assumptions concerning events and financial trends that may affect our future results of operations or financial condition. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements are based on information available as of the date of this report and our management's current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. As a result of a number of known and unknown risks and uncertainties, our actual results and the timing of events may differ materially from those expressed or implied by these forward-looking statements due to a number of factors. Applicable risks and uncertainties include those related to the possibility that any results of operations and financial condition or the Company are preliminary and subject to final audit, and the risks listed under the heading "Risk Factors" and elsewhere in our Annual Report on Form 10-K filed on March 29, 2021, and our subsequent filings with the U.S. Securities and Exchange Commission. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. We disclaim any 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 specifically required under applicable securities laws.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated August 10, 2021 announcing the Company's operating and financial results for its second quarter ended June 30, 2021
99.2	Corporate Presentation dated August 10, 2021
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: August 10, 2021

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

Exhibit 99.1

Clene Reports Second Quarter 2021 Operating and Financial Highlights

Phase 2 REPAIR program demonstrated statistically significant improvements in brain energetic metabolism with CNM-Au8®, a gold nanocrystal suspension

Phase 2, placebo-controlled RESCUE-ALS trial remains on track for top-line data in 2H 2021

Interim blinded RESCUE-ALS efficacy data suggest CNM-Au8®, a gold nanocrystal suspension, may have neuro-reparative potential in people with amyotrophic lateral sclerosis

Cash of $63 million as of June 30, 2021

SALT LAKE CITY, August 10, 2021 -- Clene Inc. (NASDAQ: CLNN) along with its subsidiaries "Clene" and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company dedicated to the treatment of neurodegenerative disease using nanotechnology to treat energetic failure, today reported its second quarter 2021 operating and financial results.

"Our recent progress has substantially bolstered our clinical data set and has us poised to achieve multiple milestones by the end of 2021, the most notable being the expected top-line data release from the placebo-controlled RESCUE-ALS trial," said Rob Etherington, President and CEO of Clene. "Our Phase 2 REPAIR program in multiple sclerosis and Parkinson's disease has shown that CNM-Au8 significantly improves energy metabolism in the brains of MS and PD patients. This is an exciting finding, as it clinically demonstrates CNM-Au8's mechanism of action is broadly applicable and strongly supports the entirety of our clinical pipeline. We also presented highly encouraging blinded results from RESCUE-ALS last quarter, further adding to the robust set of clinical and preclinical data demonstrating CNM-Au8's potential to become a breakthrough for patients with neurodegenerative disease."

Second Quarter 2021 and Recent Highlights

CNM-Au8 for the treatment of multiple sclerosis (MS) and Parkinson's disease (PD)

Reported positive top-line results from the Phase 2 REPAIR clinical trials

The objective of the REPAIR clinical trial program was to demonstrate the effects of Clene's energy-enhancing nanotherapeutic, CNM-Au8, on brain energy metabolites in two sister studies of patients with Parkinson's disease (REPAIR-PD) and multiple sclerosis (REPAIR-MS). Patients were imaged using ^{31}phosphorous magnetic resonance spectroscopy, an innovative non-invasive brain imaging technique, before and after 12 weeks of daily oral dosing with CNM-Au8. The results for the primary endpoint, the mean change in the brain NAD^+/NADH ratio (the ratio of the oxidized to reduced form of nicotinamide adenine dinucleotide), demonstrated a statistically significant increase by an average of 0.589 units (10.4%) following 12-weeks of treatment with CNM-Au8 ($p=0.037$, paired t-test), in the pre-specified integrated analysis of the REPAIR-PD and REPAIR-MS studies. Key secondary endpoints, mean change from baseline in the NAD+ fraction and NADH fraction of the total NAD pool, were concordant with the primary endpoint, demonstrating the NAD+ fraction increased ($p=0.026$), while the NADH fraction decreased ($p=0.026$). The individual results for these sister studies demonstrated consistent statistical trends toward improvement in the NAD+/NADH ratio with results of $p=0.11$ and $p=0.14$, for REPAIR-PD and REPAIR-MS, respectively. Collectively, these results provide clinical proof-of-mechanism and support the potential of CNM-Au8 to drive meaningful neurological functional improvements in the treatment of neurodegenerative disorders.

These data, together with concordant data on key secondary and exploratory endpoints, provide clinical proof-of-mechanism and support the potential of CNM-Au8 to drive meaningful functional improvements in the treatment of neurodegenerative diseases.

CNM-Au8 for the treatment of amyotrophic lateral sclerosis (ALS):

Presented interim blinded efficacy data from the Phase 2 RESCUE-ALS study at the ENCALS 2021 Annual Meeting

RESCUE-ALS is a randomized, placebo-controlled Phase 2 study evaluating CNM-Au8 in patients with early ALS. The study's primary endpoint utilizes Motor Unit Number Index (MUNIX). MUNIX is an electrophysiology technique which measures the estimated number of functioning motor neurons serving specific muscles and has been shown to be a sensitive predictor of clinical decline in ALS. In the overall study population (n = 45; randomized 1:1 active CNM-Au8 30 mg daily to placebo), 34%, 26%, and 18% of patients who completed weeks 12, 24, and 36, respectively, showed increases (improvements) in MUNIX(4)sum values (equal to the sum of MUNIX values for the *abductor digiti minimi, abductor pollicis brevis, tibialis anterior*, and *biceps brachii* muscles) from baseline. This differs from the expected continuous decline seen in published data from prior observational studies[1]. Additionally, the mean reduction in forced vital capacity (FVC) for the overall study population was approximately 11% (absolute change of the % predicted) at Week 24 (n=42), which is generally less decline than anticipated based on published data sets[2]. Though blinded, these data suggest that CNM-Au8 may have neuro-reparative potential in ALS patients.

Evaluation of CNM-Au8 in indications beyond ALS, multiple sclerosis, and Parkinson's disease:

Received a Healthy Longevity Catalyst Award from the U.S. National Academy of Medicine

The award will provide funding to support the accelerated preclinical development of CNM-Au8 as a treatment for neuronal aging-related deficits and Alzheimer's disease. Preclinical studies designed to identify key mechanisms by which CNM-Au8 may impact age-related neurogenerative diseases will be led by Dr. Karen Ho, Head of Translational Medicine at Clene, in collaboration with Assistant Professor Jerome Mertens of the University of Innsbruck (Austria).

Corporate Highlights:

Intellectual Property

In April 2021, Clene received Notices of Allowance from the U.S. Patent and Trademark Office (USPTO) for two patent applications covering device and process claims for its platform technology and advanced stage clean-surfaced nanocrystal therapeutic candidates. These have since issued as patents, adding to Clene's robust intellectual property portfolio that includes more than 130 patents issued and allowed and approximately 30 more applications pending.

Appointments

In May 2021, Clene appointed David J. Matlin as a Chairman of the Company's Board of Directors. Mr. Matlin has served as a Director of Clene since 2020 and is currently the Chief Executive Officer of MatlinPatterson Global Advisers, a global private equity firm he co-founded in 2002. Mr. Matlin is succeeding Shalom Jacobovitz, who stepped down from his prior role as Chairman but continues to serve on the Company's Board.

In August 2021, Clene appointed Vallerie V. McLaughlin, MD, to its Board as its seventh independent director. Dr. McLaughlin is the Kim A. Eagle MD Endowed Professor of Cardiovascular Medicine, Associate Chief Clinical Officer for Cardiovascular Services of the University of Michigan Medical Group, Associate Chief, Division of Cardiovascular Medicine, and Director of the Pulmonary Hypertension Program at the University of Michigan in Ann Arbor.

Manufacturing Facility

Clene is currently in negotiations to lease an approximately 75,000 square foot facility in Elkton, Maryland. Subject to the successful consummation of those negotiations, the facility will be redeveloped to enable an increase in Clene's manufacturing capacity in preparation for the expected data release in H1 2022 from its Phase 3 registration trial evaluating CNM-Au8 as a treatment for ALS.

Financing Agreements

In connection with its planned efforts to expand its manufacturing capacity, Clene added net proceeds of approximately $24 million to its cash position through a private placement (PIPE) financing that resulted in gross proceeds of approximately $9.25 million, and a Loan and Security Agreement with Avenue Venture Opportunities Fund, L.P., a fund of the Avenue Capital Group. The Loan Agreement provides for term loans in an aggregate principal amount up to $30 million, with up to $20 million committed between May 24, 2021, and December 31, 2021, and up to a further $10 million funded between January 1, 2022, and June 30, 2022. To date, Clene has received $15 million of gross proceeds under the Loan Agreement.

FTSE Russell Indexes

As of the market open on June 28, 2021, Clene was included as a member of the U.S. small-cap Russell 2000® Index and the all-cap Russell 3000® Index. Clene's common stock was also added to the appropriate growth and value indexes.

Expert Perspectives Webinar

On July 14, 2021, Clene hosted an expert perspectives webinar entitled: "Cellular Energetic Failure: Addressing Unmet Needs and a New Investigational Treatment for ALS and MS." The webinar featured presentations by two experts: Professor of Neurology Matthew Kiernan, PhD, DSc, FRACP, FAHMS, AM, MBBS and Professor of Neurology Benjamin Greenberg, MD, MHS, FANA, FAAN, CRND, who discussed the current treatment landscape and unmet medical needs in ALS and multiple sclerosis. A replay of the presentation is available here.

Anticipated 2021 Milestones:

- HEALEY ALS Platform Trial full enrollment: 2H 2021
- Phase 2 RESCUE-ALS topline data: 2H 2021
- Phase 2 CNM-ZnAg COVID-19 topline data: 2H 2021
- Initiation of Phase 2 RESCUE-PD efficacy trial: 2H 2021

Second Quarter 2021 and Financial Results

Cash Position:

Clene's cash totaled approximately $63.0 million as of June 30, 2021, compared to approximately $59.3 million as of December 31, 2020. The increase in cash through the second quarter ended June 30, 2021 was primarily due to approximately $17.7 million of net cash used in operating activities; $0.4 million of net cash used in investing activities; and $21.9 million of net cash provided by financing activities. Included in net cash provided by financing activities is $9.3 million of net proceeds from a PIPE offering and $14.5 million of net proceeds from a venture loan agreement which occurred concurrently in May 2021. Clene expects that its cash as of June 30, 2021 will be sufficient to fund its operations for a period extending beyond twelve months from the date the June 30, 2021 condensed consolidated financial statements are issued.

R&D Expenses:

Research and development ("R&D") expenses were approximately $6.5 million for the second quarter ended June 30, 2021, compared to $3.6 million for the same period in 2020. The year-over-year increase is primarily attributable to (i) the progression of Clene's drug candidates through the clinical development process, including increased enrollment into the REPAIR-PD and the REPAIR-MS studies, and calendar payments due for Clene's participation in the HEALEY-ALS Platform Trial; and (ii) $1.6 million of share-based expense related to stock option and restricted stock unit ("RSU") awards included in R&D expenses.

G&A Expenses:

General and administrative ("G&A") expenses were $6.9 million for the second quarter ended June 30, 2021, compared to $1.0 million for the same period in 2020. The year-over-year increase is primarily attributable to (i) increased professional expenses, public company expenses, legal fees, accounting fees, tax fees, and insurance expenses as a result of Clene becoming a public company on December 30, 2020; and (ii) $2.6 million of share-based expense related to stock option and RSU awards included in G&A expenses.

Net Loss:

Clene's loss from operations was $13.8 million and $4.6 million for the quarters ended June 30, 2021 and 2020, respectively. Clene's net loss was $3.4 million, or $0.05 per share, for the second quarter ended June 30, 2021, compared to a net loss of $5.8 million, or $0.34 per share, for the second quarter ended June 30, 2020. Included in the net loss for the second quarter ended June 30, 2021 is an unrealized gain from the change in fair value of contingent earn-out liabilities of $9.9 million.

About RESCUE-ALS

RESCUE-ALS is a Phase 2 multi-center, randomized, double-blind, parallel-group, placebo-controlled study examining the efficacy, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in patients with early amyotrophic lateral sclerosis (ALS). The trial completed enrollment in 2H 2020. 45 subjects were randomized 1:1 to receive either active treatment with CNM-Au8 (30 mg) or placebo in addition to their current standard of care over a 36-week treatment period. The objective of the study is to assess the impact of improving cellular energy production, reducing oxidative stress, and enhancing energetic homeostasis with CNM-Au8 on disease progression in patients with early-stage ALS. CNM-Au8 was selected by FightMND of Australia and Clene was provided a substantial grant to investigate efficacy in ALS utilizing novel neurophysiological endpoints at two expert clinical sites in Australia. Topline data are expected in 2H 2021. For more information, please see ClinicalTrials.gov Identifier: NCT04098406.

About the HEALEY ALS Platform Trial

The HEALEY ALS Platform trial is a perpetual multi-center, randomized, double-blind, placebo-controlled Phase 3 registration program designed to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of multiple investigational products in early symptomatic amyotrophic lateral sclerosis (ALS) patients. Funded by philanthropic donors and led by Harvard's Massachusetts General Hospital, HEALEY is the first-ever ALS platform trial designed to reduce trial time, costs, and increase patient participation in developing novel therapies. This landmark platform trial tests multiple treatments utilizing a combined placebo group. CNM-Au8 was selected as one of the first three drugs to be evaluated. Full enrollment of 160 patients into the CNM-Au8 portion of the study through more than 50 expert ALS U.S. clinical trial sites is expected by the end of 2021. Subjects are randomized 3:1 to receive one of three active treatments or placebo daily for a 24-week treatment period. The primary endpoint is rate of change in disease severity over time as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R). Secondary endpoints include change in respiratory function over time as measured by slow vital capacity and change in muscle strength over time as measured isometrically using hand-held dynamometry. Topline data are expected in 1H 2022. For more information, please see ClinicalTrials.gov Identifier: NCT04297683.

About VISIONARY-MS

VISIONARY-MS is a Phase 2 multi-center, double-blind, randomized, placebo-controlled trial evaluating the efficacy and safety of CNM-Au8 for remyelination and neurorepair in stable relapsing multiple sclerosis (MS) patients with chronic visual impairment. 150 participants are being enrolled at expert MS clinical trial sites within Australia, Canada, and the United States. Subjects are randomized 1:1:1 (high-dose:low-dose:placebo). The primary endpoint is improvement in Low Contrast Letter Acuity (LCLA) from baseline to week-24. Key secondary endpoints include improvements from baseline to week-24 in the remaining modified-Multiple Sclerosis Functional Composite (MSFC) subscales (Symbol Digit Modalities Test, 9-Hole Peg Test, and Timed 25-Foot Walk). Interim blinded data presented at the ACTRIMS Forum 2021 demonstrated exposure-dependent, statistically significant improvements in both LCLA scores and across the averaged components of the modified MSFC scale for the study population in comparison to baseline values from the mildest sub-population ($p<0.001$). Subject to ongoing pandemic-related research restrictions at MS clinical trial sites, enrollment will advance through 2021. For more information, see ClinicalTrials.gov Identifier: NCT03536559.

About REPAIR-MS and REPAIR-PD

REPAIR-MS and REPAIR-PD are Phase 2 single-center, active-only, sequential group studies examining the brain metabolic effects, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in patients who have been diagnosed with MS within 15 years of screening or in patients with PD who have been diagnosed within three years of screening. Investigators and participants are blinded to dose. Participants received orally delivered CNM-Au8 daily each morning for 12 weeks. Participants undergo ^{31}P-MRS brain imaging scans to semi-quantitatively measure central nervous system (CNS) energetic metabolites at baseline, prior to administration of drug, and at the end-of-study following at least 12 weeks of exposure to CNM-Au8. The objective of these studies is to demonstrate target engagement for CNM-Au8 on CNS biomarkers related to energetics and neuronal membrane stability in patients with MS and PD. The studies are taking place at the University of Texas Southwestern Medical Center with a team of internationally recognized experts in brain imaging and treatment of disorders of the CNS. For more information see ClinicalTrials.gov Identifiers: NCT03993171 and NCT03815916.

About CNM-Au8

Clene's lead drug candidate, CNM-Au8, is an aqueous suspension of catalytically-active, clean-surfaced, faceted gold nanocrystals. Resulting from a patented manufacturing breakthrough, the catalytically active nanocrystals of CNM-Au8 drive critical cellular energy producing reactions in the brain that enable neurorepair and remyelination by increasing neuronal and glial resilience to disease-relevant stressors. CNM-Au8 crosses the blood-brain barrier and is not associated with the toxicities related to synthetic gold compounds or nanoparticles manufactured via alternative methods. CNM-Au8 has demonstrated safety in Phase 1 studies in healthy volunteers and has shown both remyelination and neuroprotective effects in multiple preclinical (animal) models. Preclinical data, both published in peer-reviewed journals and presented at scientific congresses, demonstrate that treatment of neuronal cultures with CNM-Au8 improves survival of neurons, protects neurite networks, decreases intracellular levels of reactive oxygen species and improves mitochondrial capacity in response to cellular stresses induced by numerous disease-relevant neurotoxins. Oral treatment with CNM-Au8 improved functional behaviors in rodent models of ALS, MS, and PD versus vehicle (placebo). CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc.

About Clene

Clene, a clinical-stage biopharmaceutical company focused on neurodegenerative disease treatments, is leading the way by using nanotechnology to treat energetic failure, which underlies many neurological diseases. Clene has innovated a novel nanotherapeutic platform to create a new class of drugs. Clene's lead drug candidate, CNM-Au8, is an aqueous suspension of catalytically-active, clean-surfaced, faceted gold nanocrystals that drive critical cellular energetic metabolism in the central nervous system (CNS). CNM-Au8 increases cellular energy production to accelerate neurorepair and improve neuroprotection. CNM-Au8 is currently being evaluated in a Phase 3 registration trial in amyotrophic lateral sclerosis (ALS), a Phase 2 trial examining disease progression via a novel electromyography technique in patients with early ALS, a Phase 2 trial for the treatment of chronic optic neuropathy in patients with stable relapsing multiple sclerosis (MS), and Phase 2 brain target engagement studies in patients with Parkinson's disease (PD) and MS. Clene has also advanced into the clinic an aqueous solution of ionic zinc and silver for anti-viral and anti-microbial uses. 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.

References

[1] Neuwirth et al. J Neurol Neurosurg Psychiatry. 2015 Nov;86(11):1172-9.
[2] Andrews et al. JAMA Neurol. 2018 Jan 1;75(1):58-64.

Forward-Looking Statements

This press release 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 entitled "Risk Factors" in Clene's Annual Report filed on Form 10K, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue	138	9	337	79
Royalty revenue	63	-	77	-
Total revenue	201	9	414	79
Operating expenses:				
Cost of revenue	555	-	798	58
Research and development	6,472	3,554	12,747	6,756
General and administrative	6,949	1,016	12,339	1,828
Total operating expenses	13,976	4,570	25,884	8,642
Loss from operations	(13,775)	(4,561)	(25,470)	(8,563)
Other income (expense), net:				
Interest expense	(26)	(190)	(577)	(241)
Gain on extinguishment of notes payable	-	-	647	-
Gain on termination of lease	-	51	-	51
Change in fair value of preferred stock warrant liability	-	(2,419)	-	(2,307)
Change in fair value of derivative liability	-	10	-	14
Change in fair value of Clene Nanomedicine contingent earn-out	8,640	-	(16,970)	-
Change in fair value of Initial Shareholders contingent earn-out	1,232	-	(1,729)	-
Change in fair value of common stock warrant liability	133	-	133	-
Australia research and development credit	375	1,268	714	1,268
Other income (expense), net	(2)	22	1	18
Total other income (expense), net	10,352	(1,258)	(17,781)	(1,197)
Net loss before income taxes	(3,423)	(5,819)	(43,251)	(9,760)
Income tax benefit	72	-	144	-
Net loss	(3,351)	(5,819)	(43,107)	(9,760)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(61)	10	(37)	16
Total other comprehensive income (loss)	(61)	10	(37)	16
Comprehensive loss	(3,412)	(5,809)	(43,144)	(9,744)
Net loss per share-- basic and diluted	(0.05)	(0.34)	(0.71)	(0.56)
Weighted average common shares used to compute basic and diluted net loss per share	61,165,018	17,357,505	60,919,340	17,357,505

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash	$ 63,007	$ 59,275
Accounts receivable	68	21
Inventory	53	191
Prepaid expenses and other current assets	5,030	3,502
Total current assets	68,158	62,989
Right-of-use assets	983	1,029
Property and equipment, net	4,143	4,225
TOTAL ASSETS	$ 73,284	$ 68,243
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,143	$ 1,124
Accrued liabilities	2,731	3,960
Income tax payable	164	164
Deferred revenue from related parties	112	112
Operating lease obligations, current portion	210	194
Finance lease obligations, current portion	159	190
Clene Nanomedicine contingent earn-out, current portion	-	5,924
Total current liabilities	4,519	11,668
Operating lease obligations, net of current portion	1,658	1,785
Finance lease obligations, net of current portion	152	205
Convertible notes payable	4,380	-
Notes payable	10,378	1,949
Deferred income tax	140	260
Warrant liability	1,324	-
Clene Nanomedicine contingent earn-out, net of current portion	69,023	46,129
Initial Shareholders contingent earn-out	7,635	5,906
TOTAL LIABILITIES	99,209	67,902
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 150,000,000 and 100,000,000 shares authorized at June 30, 2021 and December 31, 2020, respectively; 60,681,591 and 59,526,171 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	6	6
Additional paid-in capital	170,449	153,571
Accumulated deficit	(196,668)	(153,561)
Accumulated other comprehensive income	288	325
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(25,925)	341
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 73,284	$ 68,243

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Source: Clene Inc.


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 entitled "Risk Factors" in Clene's recently filed registration statement on Form S-4/A 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.

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- Credit Suisse

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- Purdue
- Roche
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Dupont Lanxide Composites

Lanxide Armor Company

Lanxide Performance Materials

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- NeuroBo Pharmaceuticals
- rexahn Pharmaceuticals
- HVIC
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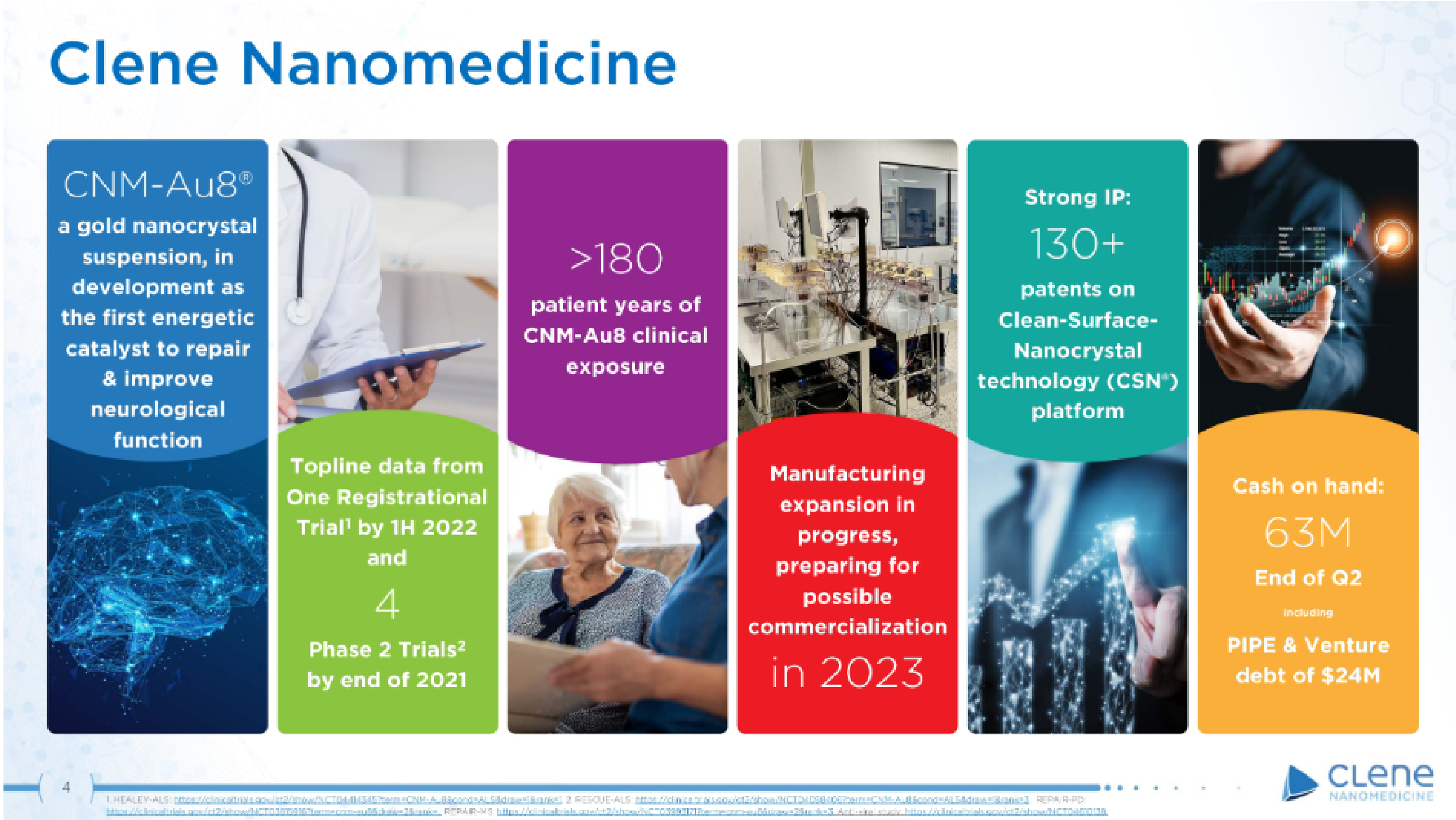
Clene Nanomedicine
CNM-Au8®
a gold nanocrystal suspension, in development as the first energetic catalyst to repair & improve neurological function
Topline data from One Registrational Trial¹ by 1H 2022
and
4
Phase 2 Trials²
by end of 2021
>180
patient years of CNM-Au8 clinical exposure
Manufacturing expansion in progress, preparing for possible commercialization
in 2023
Strong IP:
130+
patents on Clean-Surface-Nanocrystal technology (CSN®) platform
Cash on hand:
63M
End of Q2
including
PIPE & Venture debt of $24M
4
1. HEALEY-ALS:
2. RESCUE-ALS:
REPAIR-PD:
REPAIR-MS
Anti-vire study
CLENE
NANOMEDICINE

CLENE | Platform & Pipeline

Clean Surface Nanocrystal Therapeutics (CSN®)

CSN® PLATFORM — 130+ Granted Patents

Novel electro-chemistry platform produces catalytic Clean Surface Nanocrystal drugs designed to avoid toxicities associated with synthetic chemistry

*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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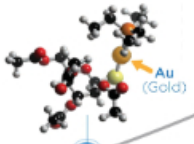
Evolution of Gold
as a Therapeutic Modality

Chinese & Ayurvedic Gold Preparations
(China, Arabia, India)

2500–1000 BC

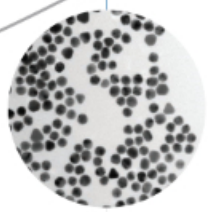


1930–1980s

Monoatomic Gold Salts for Rheumatoid Arthritis
(IM Sodium Aurothiomalate;
IM Aurothioglucose;
Oral Auranofin)

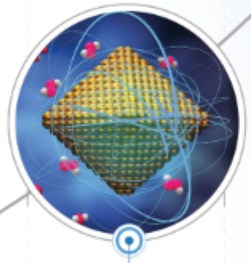
gold 3,4,5-triacetyloxy-6-(acetyloxymethyl) oxane-2-thiolate; triethylphosphanium

1950s–2000s



Surface Modified and Functionalized Colloidal Gold Particles
Drug Carriers;
Photothermal Therapy

Clene's Patented Breakthrough



2020+

Catalytic Clean Surfaced Faceted Gold Nanocrystals

Pioneering Bioenergetic Nanocatalysis

clene NANOMEDICINE

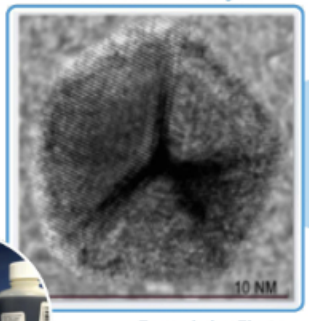
CNM-Au8® | Energy Enhancing Nanotherapeutic

Improved Cellular Energy Production & Utilization

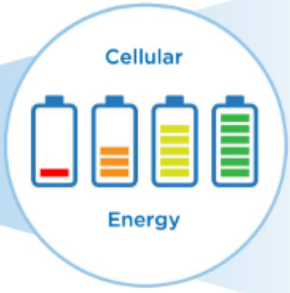
Novel mechanism of action to address a range of CNS diseases

- **Clean Surfaced Faceted Nanocrystal**
- **13 nm Median Diameter** (Ribosome = 20-30 nm)
- **> 100 Trillion Nanocrystals per 60 mL Dose** (At 30mg)
- **Oral Suspension; Once Daily**

CNM-Au8 Nanocrystal



Transmission Electron Micrograph



Remyelination Failure In MS

Parkinson's Disease

Amyotrophic Lateral Sclerosis

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CNM-Au8 | Integrating Physics With Biology

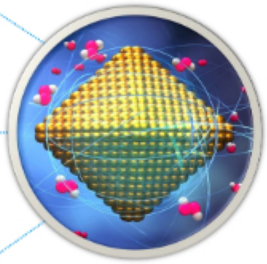
Electron Transfer Is Fundamental to Energy Production

Surface Based Catalytic Activity

Electrons (e-) Move Freely Across Nanocrystal Surface

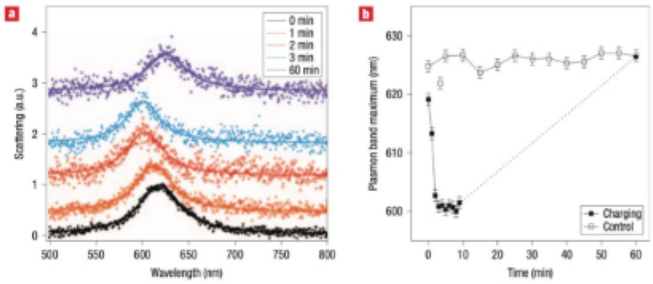
Vertices, Edges, & Faces Key to Catalytic Activity

Clean-Surfaced Nanocrystals



Up to 4,600 e^- per second per nanocrystal[1]

AuNP Catalyzed Oxidation of Ascorbic Acid[1]



a. Rayleigh scattering measured by dark field microscopy of surface plasmon resonance of scattering spectra of the AuNP decahedron before and at 1, 2, 3 and 60 min after electron injection by ascorbate ions.

b. Spectral shift as a function of time for the catalysis reaction and for the control experiment..

[1] Novo et al. Nature Nanotech 3, 598-602 (2008).

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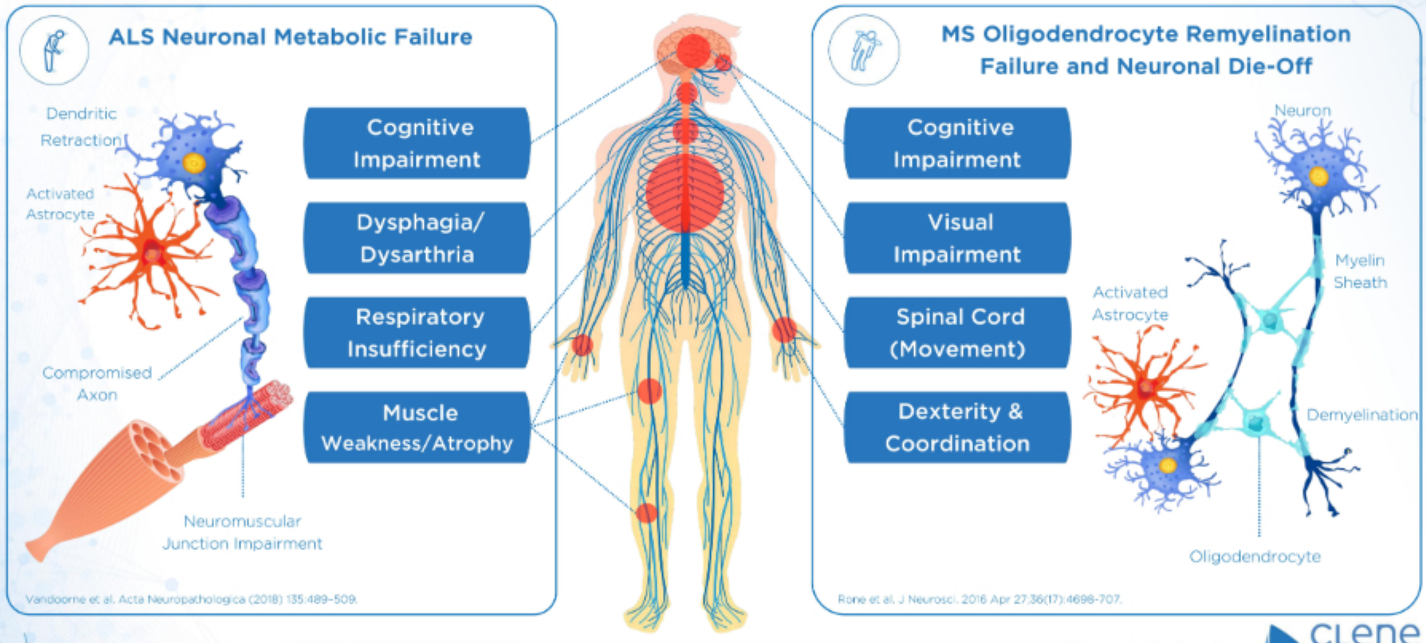
Treating Energetic Failure | Common Pathological Mechanism In Neurodegenerative Disorders (MS, ALS, PD)



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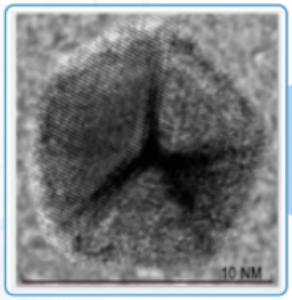
CNM-Au8 | MOA → Therapeutic Effects

Catalytic Gold Nanocrystals



Bioenergetic Mechanism

- ↑ Increased NAD [a]
- ↑ Increased ATP
- ↓ Decreased reactive oxygen species
- ↑ Increased proteostasis

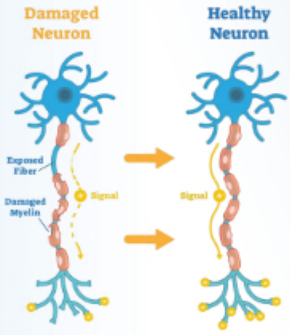
[a] Nicotinamide Adenine Dinucleotide

Enhanced Disease Response

- ↑ Increased energetic capacity

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

Remyelination



Neuro Repair

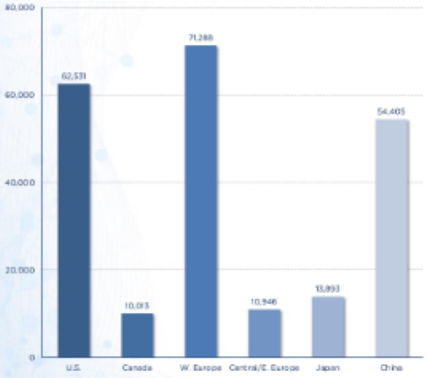
CLene NANOMEDICINE

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

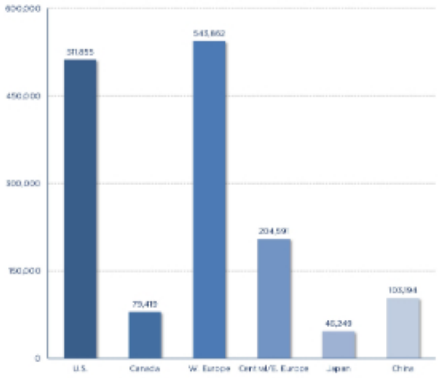


Source: Lancet Neurol. 2018 Dec;17(12):1083-1097.
MND includes amyotrophic lateral sclerosis, spinal muscular atrophy, hereditary spastic paraplegia, primary lateral sclerosis, progressive muscular atrophy, and pseudobulbar palsy

MULTIPLE SCLEROSIS
~2.5M pts globally; $23B market[2]

Only approved treatments are immunomodulators

Est. Diagnosed MS Patients by Region

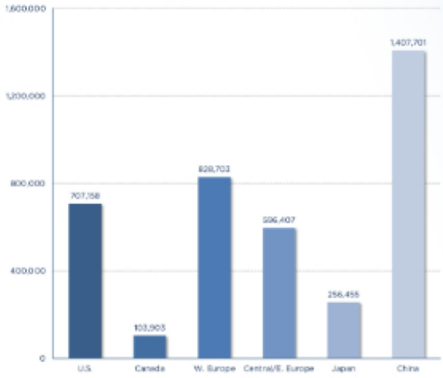


Source: Lancet Neurol. 2019 Mar;18(3):269-285

PARKINSON'S DISEASE
~7M pts globally; $6B projected by 2025[3]

2ND most common neurodegenerative disorder; only symptomatic treatments

Est. Diagnosed PD Patients by Region



Source: Lancet Neurol. 2018 Nov;17(11):939-953.

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

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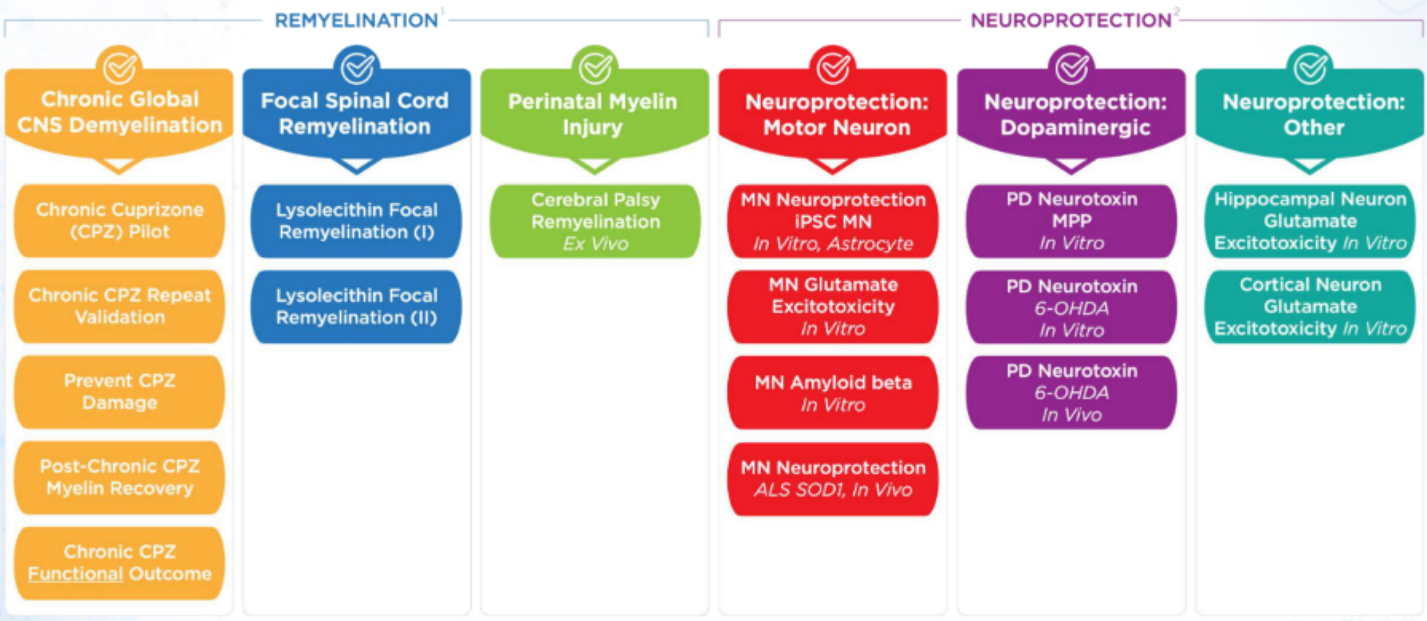
CNM-Au8 | Evidence for Energetic Improvement

Therapeutic Activity Across Remyelination + Neuroprotection Models



[1]Robinson et al. Sci Rep. 2020; DOI: 10.1038/s41598-020-58709-w. [2]Ho et al. Society for Neuroscience Meeting, 2019. Ho et al. Motor Neuron Disease Associating Meeting, 2019. Data on File, Clene Nanomedicine, Inc.

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CNM-Au8 | MOA & Remyelination Data Published

www.nature.com/scientificreports

SCIENTIFIC REPORTS

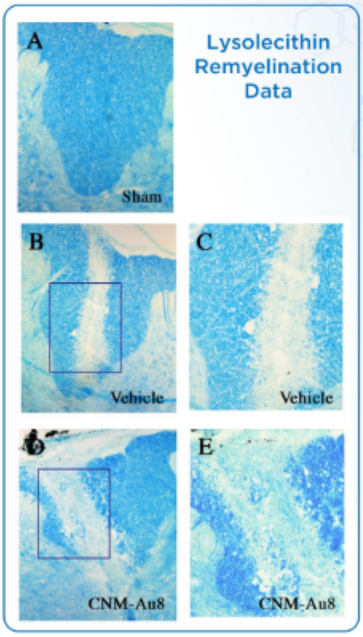
nature research

OPEN

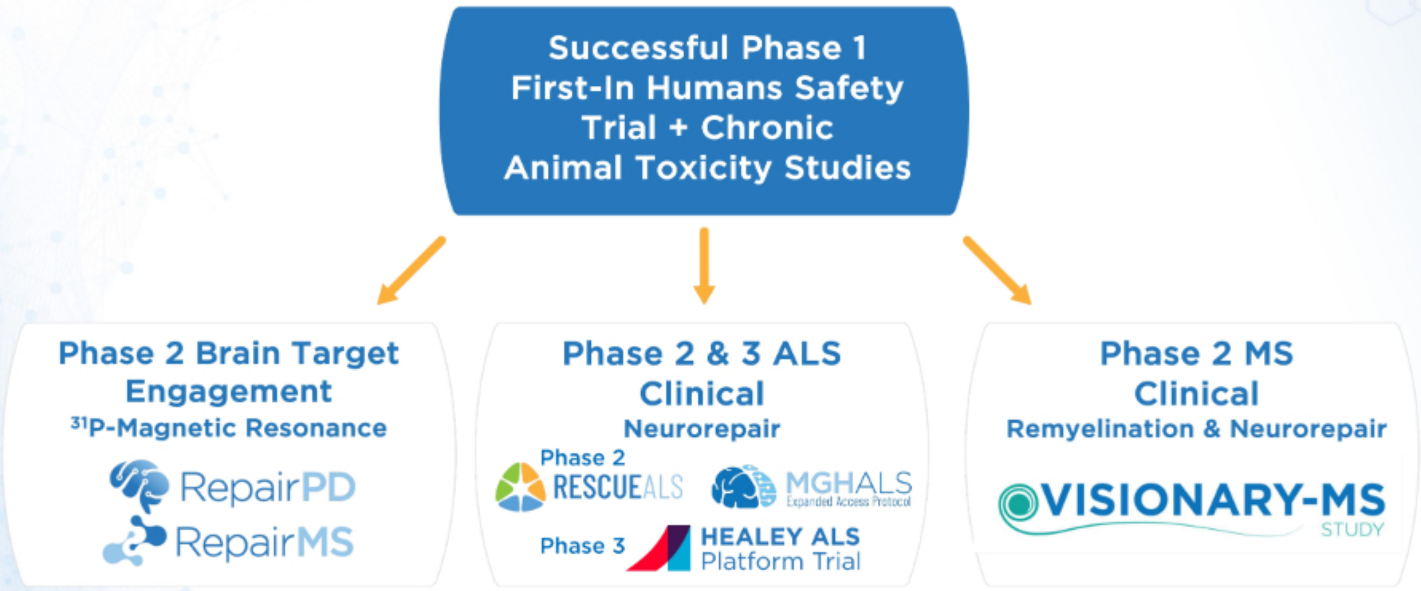
Nanocatalytic activity of clean-surfaced, faceted nanocrystalline gold enhances remyelination in animal models of multiple sclerosis

Andrew P. Robinson[1,9], Joanne Zhongyan Zhang[2,9], Haley E. Titus[1], Molly Karl[3], Mikhail Merzliakov[2], Adam R. Dorfman[2], Stephen Karlik[4], Michael G. Stewart[5], Richard K. Watt[5], Benjin D. Facer[6], Jon D. Facer[5], Noah D. Christian[7], Karen S. Ho[2,8*], Michael T. Hotchkin[2,9], Mark G. Mortenson[2,9], Robert H. Miller[3,9] & Stephen D. Miller[1,9]

Robinson et al. Sci Rep. 2020 Feb 11;10(1):1936. doi: 10.1038/s41598-020-58709-w



CNM-Au8 | Clinical Program Overview



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CNM-Au8 | Clean Toxicology Findings

All Studies Resulted in No Adverse Effect Level (NOAEL)[a]

Standard ICH M3(R2) Toxicology Program

Genotoxicity *In Vitro & In Vivo (Rodent)*	**Single Dose Toxicokinetics** *Canine*	**Max Feasible Toxicokinetics** *Rodent (1-Wk, SQ)*	**Chronic Toxicity Rodent** *Rodent (6-Month)*
Safety Pharmacology *CNS, CV, Renal*	**Multi-Dose Toxicokinetics** *Canine (7-Day)*	**Max Feasible Toxicokinetics** *Canine (3-Wk)*	**Chronic Toxicity Canine** *Canine (9-Month)*
Dose Range Finding *Rodent, Minipig*	**MTD Toxicokinetics** *Canine (4-Wk)*	**High Dose Toxicokinetics** *Rodent (3-Wk)*	**Carcinogenicity Dose Range Finding** *rasH2 (1-Month)*

[a] NOAEL = No Dose Limiting Toxicities Observed

CNM-Au8 | Well Tolerated; No Dose-Limiting Safety Issues

Phase 1 First In Human Study Completed (n=86)

- **Single-ascending dose**
  - 4 cohorts of 8 subjects plus one repeat (n=40)
  - 15, 30, 60, 90 mg
  - 3:1 randomized (active:control)
  - 1 dose; 17-day follow-up
- **Multi-ascending dose**
  - 4 cohorts of ~12 subjects (n=46)
  - 15, 30, 60, 90 mg
  - 3:1 randomized (active:control)
  - 21 days daily dosing + follow-up (Up to 50 days)

- **Most frequent TEAEs by System Organ Class: Nervous/GI**
  - Nearly all of the TEAEs were Grade 1 severity (mild)
- **No serious TEAEs, TEAEs leading to discontinuation of treatment, or TEAEs considered severe, life-threatening, or resulting in death**
- **No dose responsive TEAEs observed in SAD or MAD**

Phase 2 & 3 Clinical (>180 Years Exposure)

Up to 89 Weeks Exposure in Clinical Trials;
Up to 96 Weeks in ALS Expanded Access

VISIONARY-MS STUDY
+ Long-Term Extension

RESCUEALS
+ Long-Term Extension

HEALEY ALS Platform Trial
+ Long-Term Extension

MGHALS Expanded Access Protocol

RepairPD

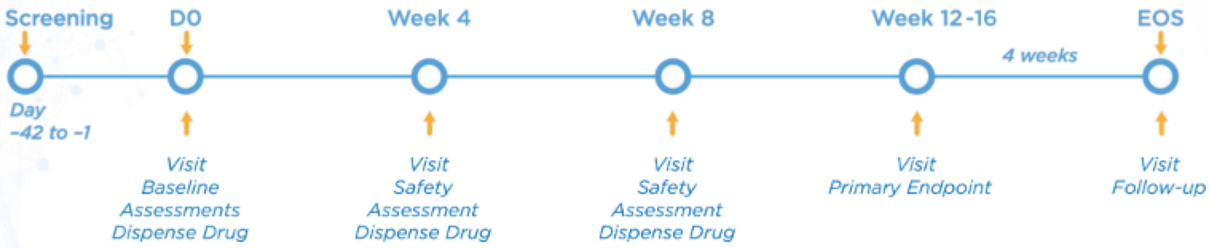
RepairMS

CLene NANOMEDICINE

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)



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 12-16
- Difference in bioenergetic metabolites (e.g., ATP, PCr, NAD) concentration at Week 12 – 16
- Difference in brain membrane markers (PE, PC, etc.) at Week 12 – 16

Top-Line Results
Repair-PD: 2H 2021
Repair-MS: 2H 2021

*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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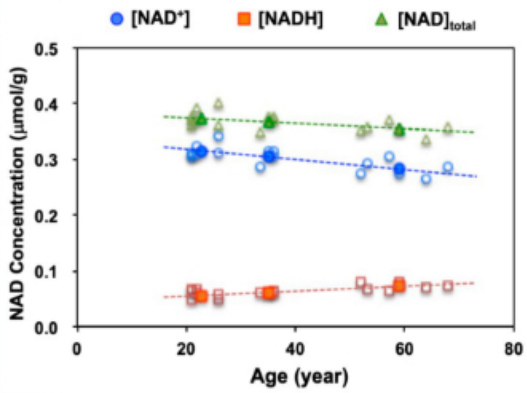
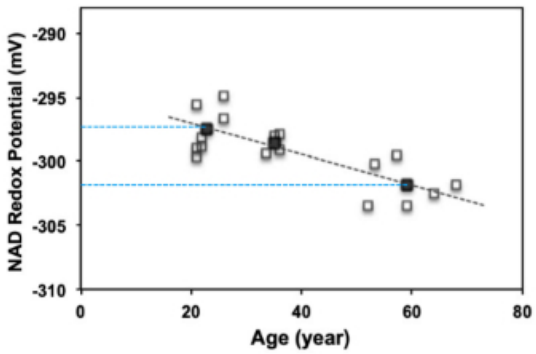
NAD+/NADH | Age Related Decline
By ^{31}P-MRS Imaging

NAD+ Decline &. NADH Increase
(Aging Change by Decade)



~0.5% NAD+/NADH unit decline per decade
(-0.13 mV units per year)



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

Zhu et al. Proc Natl Acad Sci USA . 2015 Mar 3;112(9):2876-81.

CLene NANOMEDICINE

Phase 2
RepairPD
RepairMS

CNM-Au8 Improved Brain Energetic Metabolism

Increased NAD+/NADH Ratio (Primary Endpoint)

CLENE NANOMEDICINE

Clene Reports Positive Top-line Results from its Phase 2 REPAIR Clinical Trials in Parkinson's Disease and Multiple Sclerosis

Achieved a statistically significant increase in the Phase 2 program's primary endpoint (mean change in brain NAD+/NADH ratio)

CNM-Au8® significantly improved brain energetic metabolism

Trial results demonstrate consistent brain target engagement in PD and MS patients

Data provide clinical proof-of-mechanism and support the potential of CNM-Au8 to drive meaningful neurological functional improvements in the treatment of neurodegenerative disorders

SALT LAKE CITY, August 5, 2021 -- Clene Inc. (NASDAQ: CLNN) along with its subsidiaries ("Clene"), and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company dedicated to the treatment of neurodegenerative disease using nanotechnology to treat energetic failure, today reported positive top-line results from the Phase 2 **REPAIR** clinical trials investigating the improvement of brain energetic metabolism in Parkinson's disease (PD) and multiple sclerosis (MS).

The objective of the REPAIR clinical trial program was to demonstrate the effects of Clene's energy-enhancing nanotherapeutic, CNM-Au8® on brain energy metabolites in two sister studies of patients with Parkinson's disease (REPAIR-PD) and multiple sclerosis (REPAIR-MS). Patients were imaged using ^{31}phosphorous magnetic resonance spectroscopy, an innovative non-invasive brain imaging technique, before and after 12 or more weeks of daily oral dosing with CNM-Au8. End of treatment results at week 12 were compared to baseline in 24 patients, 13 patients in REPAIR-PD and 11 patients in REPAIR-MS (all study participants with repeat imaging data).

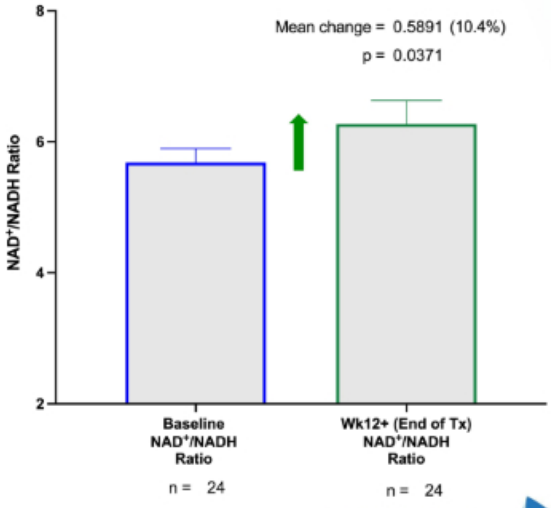
The results for the primary endpoint, the mean change in the brain NAD^+/NADH ratio (the ratio of the oxidized to reduced form of nicotinamide adenine dinucleotide), demonstrated a statistically significant increase by an average of 0.589 units (10.4%) following 12-weeks of treatment with CNM-Au8 ($p=0.037$, paired t-test), in the pre-specified integrated analysis of the REPAIR-PD and REPAIR-MS studies. Key secondary endpoints, mean change from baseline in the NAD^+ fraction and NADH fraction of the total NAD pool, were concordant with the primary endpoint, demonstrating the NAD^+ fraction increased ($p=0.026$), while the NADH fraction decreased ($p=0.026$). The individual results for these sister studies demonstrated consistent statistical trends toward improvement in the NAD+/NADH ratio with results of $p=0.11$ and $p=0.14$, for REPAIR-PD and REPAIR-MS, respectively.

REPAIR Integrated Analysis

^{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)



Data on File, Clene Nanomedicine, Inc.

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Phase 2
RepairPD
RepairMS

CNM-Au8 Increased NAD⁺ & Decreased NADH

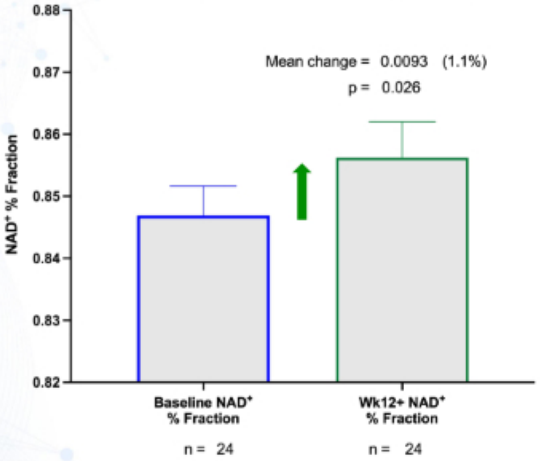
Secondary Endpoints

REPAIR Integrated Analysis

^{31}P-MRS Change in Brain NAD⁺ % Fraction at End of Treatment

Partial Volume Coil; % Fraction of NAD⁺, (NAD⁺, NADH Couple)

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

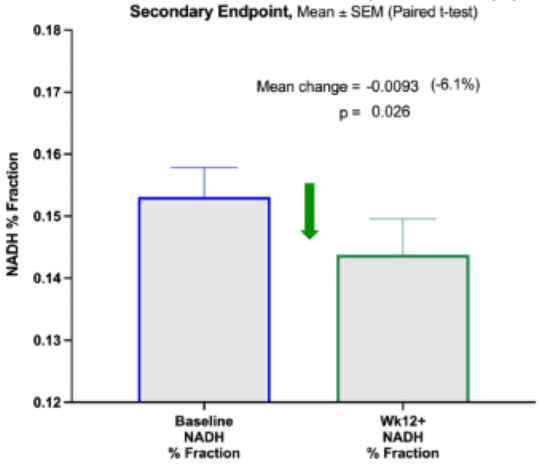


REPAIR Integrated Analysis

^{31}P-MRS Change in Brain NADH % Fraction at End of Treatment

Partial Volume Coil; % Fraction of NADH, (NAD⁺, NADH Couple)

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



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

SCREENING (January 2020); FPFV 16-Jan-2020; 45 of 42 enrolled (Nov-2020)

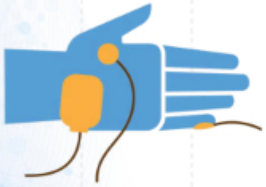
Day -28 to -1 | Week 6 | Week 12 | Week 18 | Week 24 | Week 30 | Week 36 | Week 42 | Week 48 | Week 54 | Week 60 | Week 66 | Week 72 | Week 76

6 WEEKS

EOS

Open Label Extension

Phone calls at Weeks 3, 6, 18, 30



1° Change in Sum of Motor Unit Index
For the Abductor Digiti Minimi (ADM), Abductor Pollicis Brevis (APB), Biceps Brachii (BB), Tibialis Anterior (TA)

2° Key Secondary: Forced Vital Capacity

Exploratory Endpoints

- Other Electromyography (SH_I, NP_I, MUSIX, MScan)
- ALSFRS-R
- Change in Rate of ALSFRS-R progression
- QOL
- Combined Joint-Rank (Survival + ALSFRS-R)

Anticipated full unblinded data readout: 2H 2021

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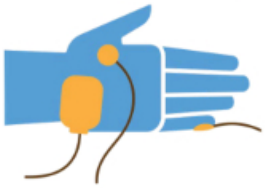
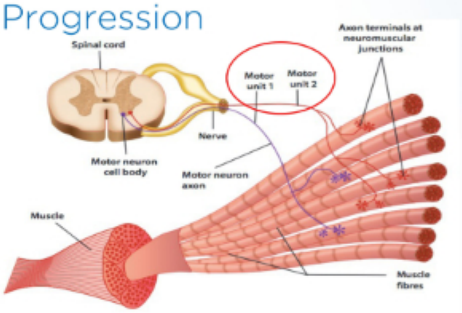
Measuring ALS Disease Progression

Electromyography: Predictive Biomarker of Clinical Progression

Predictive Endpoints of Disease Progression

- **Loss of Motor Units**
  Motor Unit Index (MUNIX)

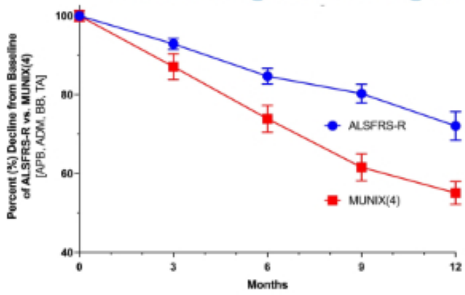




Clinical Endpoints

- **ALSFRS-R**
- **Pulmonary Function**
  (Vital Capacity)
- **Mortality**

MUNIX Longitudinal Progression



Neuwirth et al. JNNP 2015 Nov;86(11):1172-9.

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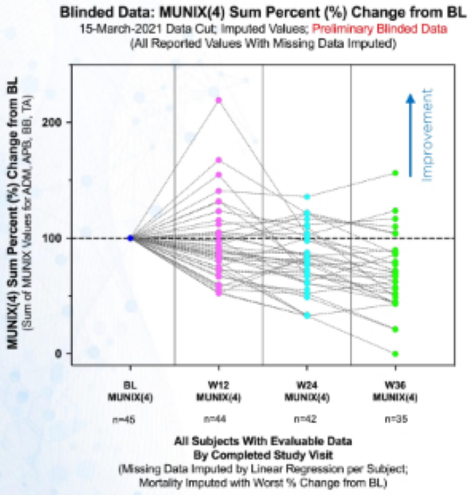
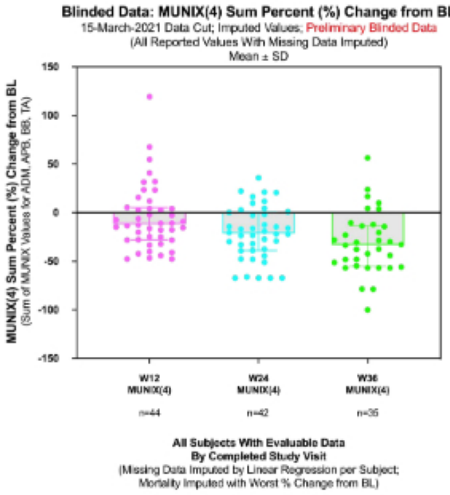
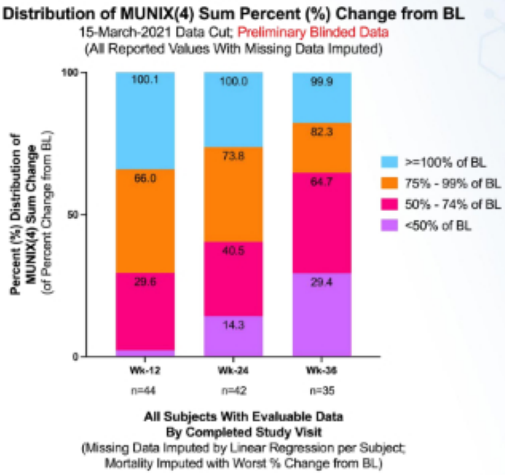
Phase 2 RESCUEALS

Primary Endpoint: Emerging Evidence of MUNIX Benefit







Robert Glanzman MD FAAN, et al. "A Blinded Interim Update on RESCUE-ALS: A Randomized, Placebo-Controlled, Phase 2 Study to Determine the Effects of CNM-Au8 to Slow Disease Progression in Amyotrophic Lateral Sclerosis" Presented at: ENCALS 2021 Virtual Meeting, 12-May-2021.

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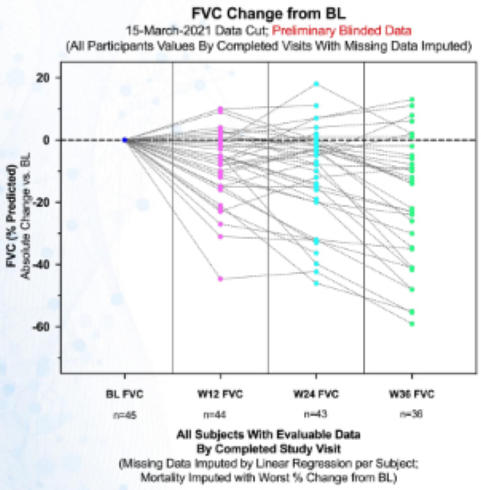
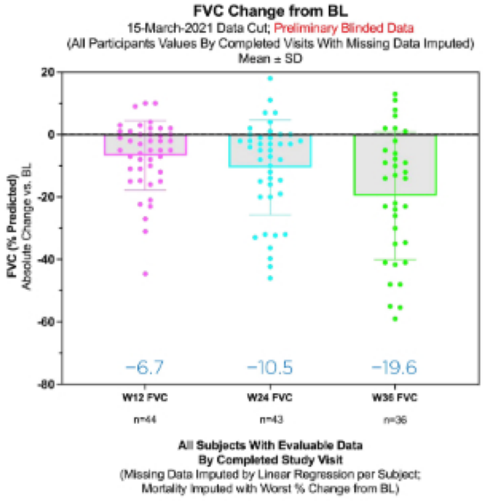
Phase 2 RESCUEALS

Secondary Endpoint: Emerging Evidence of Clinical Benefit | Forced Vital Capacity





SVC Avg. Slope Decline (% points/month)	Slope Est. (9-months)
Empower (−2.73%)	-24.6%
Benefit (−2.74%)	-24.7%
PRO-ACT (-2.90%)	-26.1%

Andrews et al. JAMA Neurol. 2018;75(1):58-64.

Robert Glanzman MD FAAN, et al. "A Blinded Interim Update on RESCUE-ALS: A Randomized, Placebo-Controlled, Phase 2 Study to Determine the Effects of CNM-Au8 to Slow Disease Progression in Amyotrophic Lateral Sclerosis" Presented at: ENCALS 2021 Virtual Meeting, 12-May-2021.

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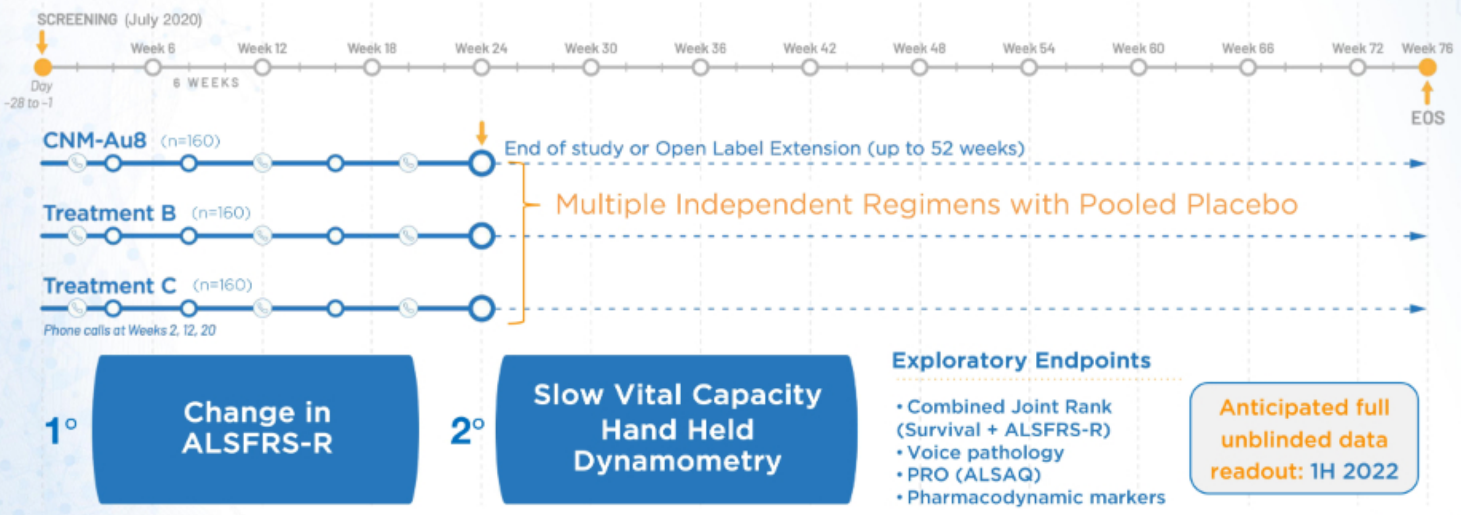
Phase 3
HEALEY ALS Platform Trial

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

Exploratory Endpoints

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

Anticipated full unblinded data readout: 1H 2022

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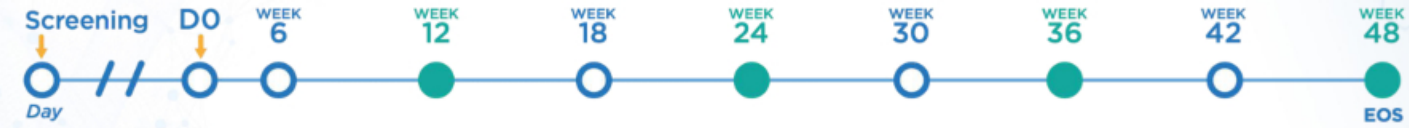
Phase 2

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)

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

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

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*

*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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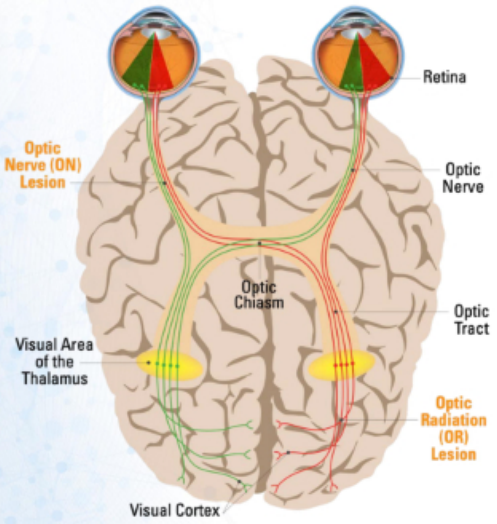
Measuring MS Functional Improvement

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

MS Functional Endpoints

Phase 2 Exploratory:
Neuroprotection/Remyelination Endpoints

9-Hole Peg Test

Symbol Digit Modalities

Timed 25-Ft Walk

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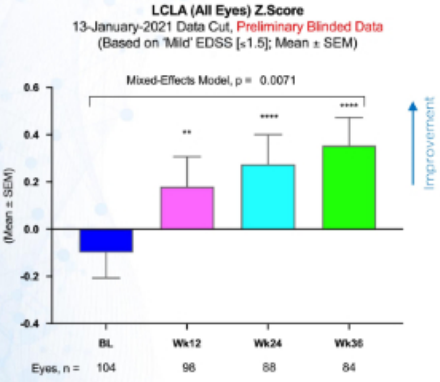
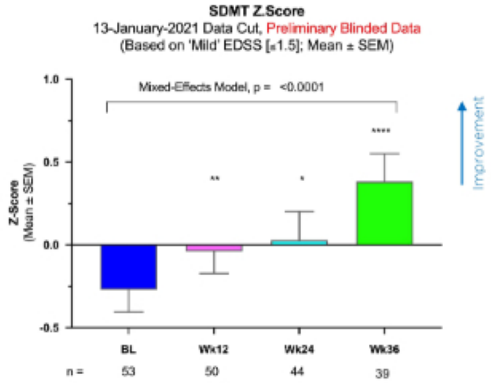
Phase 2 VISIONARY-MS STUDY

Emerging Evidence of Clinical Improvement

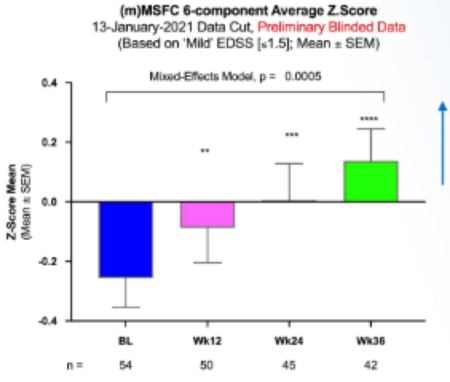
LCLA (Best-Corrected)



SDMT



6-Component Integrated (m)MSFC



Z-Score change compared to the least-affected patients at Baseline (with 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

Glanzman, R., H. Beadnall, M. T. Hotchkin, A. Klistorner, M. Barnett, R. Sergott, A. Rynders, K. S. Ho, and Mark G. Mortenson, "Update to a Phase 2 clinical trial of catalytic gold nanocrystals, CNM-Au8, for the treatment of chronic optic neuropathy," Presented at the ACTRIMS Forum 2021, February 26, 2021.

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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	Patent Description	Trade Secrets
Issued & Allowed Patents 130+	Process And Method/Device (Clean Surface; Gold CSN)	Plasma Conditioning
Pending Applications >30	State of Matter (CNM-Au8)	Electrode Design & Cycling
Total Patents/ Applications >160	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).

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Clene | Proprietary Nanocrystal Manufacturing

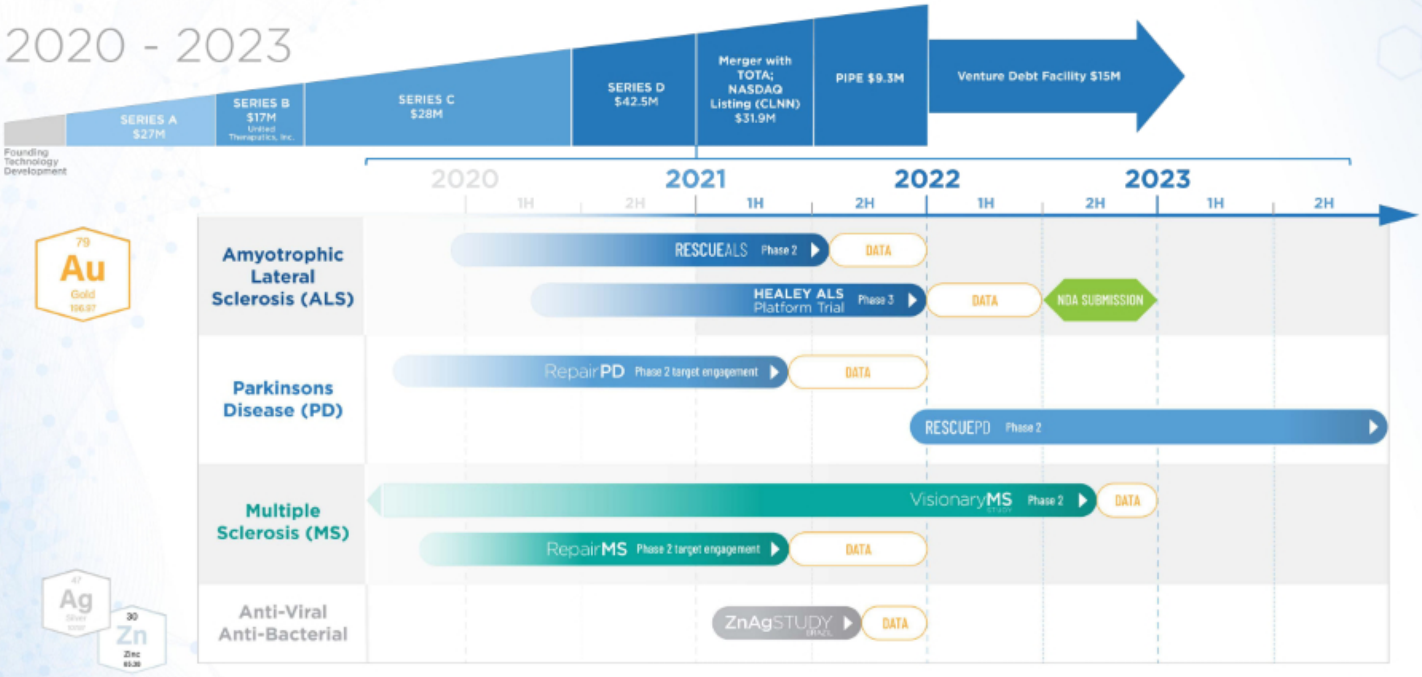
In-House ISO8 Clean Room Clinical Production in North East, MD

Designed to be Scalable to Commercialization

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

Anticipated Timeline & Investor Catalysts

2020 - 2023



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CLENE | Investment Highlights

Lead Asset: CNM-Au8 for Neuro Repair

- Energy enhancing nanotherapeutic
- Robust Preclinical Remyelination & Neuroprotection Data Across Multiple Animal Models in:
  - MS,
  - ALS, and
  - Parkinson's Disease
- NOAEL Findings From All Toxicity Studies
- Acceptable Phase 1 Safety Profile
- Up to 89 Weeks Exposure in Clinical Trials; Up to 97 Weeks in ALS Expanded Access (EAP)

Unmet Medical Need & Market Opportunity

- No Effective Disease-Modifying Drugs for ALS or PD
- No MS Therapies Clinically Impact Remyelination & Neurorepair
- Remyelination and Neurorepair Sales Could Exceed $10B per annum[1]
  - ALS is a Lethal Motor Neuron Disease With Suboptimal Therapies
  - PD is Highly Prevalent With No Disease Modifying Treatments

Clinical Development Pipeline

- Two Phase 2 Brain Target Engagement Studies in PD and MS with Top Line Results Reported Aug 2021
- Three Phase 2 POC Studies in ALS, MS, and COVID with Results Anticipated in the next 12-18 Months
- Phase 3 ALS Registrational Trial in with Full Results Anticipated in 1H 2022
- Ongoing ALS Early Access Program
- USA FDA Granted ALS Orphan Drug Designation

CNM-ZnAg for COVID-19

- Zinc-Silver Antiviral + Immune Support
- Phase 2 Trial in Brazil To Treat Acutely Symptomatic Non-Hospitalized COVID-19 Patients Underway
  - 1st Endpoint: Prevention of Hospitalization
  - 2nd Endpoint: Time to Symptomatic Improvement (Up to 28 Days)
- Results Anticipated 2H 2021

Strong IP Portfolio

- 130+ Issued Patents Worldwide; 30+ Pending Patent Applications
- State of Matter Claims Cover Myelin Protection Mechanisms, Remyelination, and Neuroprotection to 2035 (with Patent Restoration Term)
- Manufacturing Device and Process Patents to 2030 and Beyond

Financials

- **CLNN** (NASDAQ)
- $31.9M USD (Gross) Raised via SPAC merger + PIPE (2020)
- Cash on Hand at end of Q2 2021 of $63.0M (Unaudited)
- Anticipated Cash Runway to EOY 2022
- $114M USD Raised Privately (Series A-D)
- +$16.7M in Additional Grant and Indirect Financial Support for ALS and MS Phase 2 & 3 Clinical Programs
- $24.3M USD (Gross) Raised via PIPE + Venture debt for MFG (2021)

[1] Data on file, Clene Nanomedicine, Inc.

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Version: 9-August-2021