

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 11, 2021

Clene Inc.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-39834</u> (Commission File Number)	<u>85-2828339</u> (IRS Employer Identification No.)
<u>6550 South Millrock Drive, Suite G50 Salt Lake City, Utah</u> (Address of principal executive offices)		<u>84121</u> (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 May 11, 2021, Clene Inc. (the “Company”) issued a press release announcing its operating and financial results for its first quarter ended March 31, 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 a presentation by the Company at the 2021 meeting of the European Network to Cure ALS (“ENCALS 2021”) on May 12, 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 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 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 release 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 May 11, 2021 announcing the Company’s operating and financial results for its first quarter ended March 31, 2021
99.2	Corporate Presentation dated May 12, 2021

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.

Date: May 12, 2021

Clene Inc.

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

Clene Reports First Quarter 2021 Operating and Financial Highlights

Interim Phase 2 data indicate that CNM-Au8 has a homeostatic effect on brain bioenergetics and support its potential to drive meaningful neurological functional improvements in MS patients

Awarded Michael J. Fox Foundation (MJFF) grant to accelerate development of CNM-Au8 as a treatment for Parkinson's disease

Phase 2 RESCUE-ALS trial and Phase 2 target engagement trials in MS and PD remain on track for topline data in 2H 2021

Cash of \$48.0 million as of March 31, 2021

SALT LAKE CITY, May 11, 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 revolutionizing the treatment of neurodegenerative disease using bioenergetic nanocatalysis, today reported its first quarter 2021 operating and financial results.

"Clene is off to a strong start in 2021, having made great progress across its programs," said Rob Etherington, president and chief executive officer of Clene. "During the first quarter, we announced compelling interim data in MS patients indicating that CNM-Au8 has a homeostatic effect on brain bioenergetics, which may allow it to ultimately slow or halt disease progression. We also received important external validation for our Parkinson's Disease program in the form of a grant from the Michael J. Fox Foundation that will enable us to accelerate CNM-Au8's development in this high unmet need indication. Looking ahead, we are on track to achieve multiple key inflection points across our pipeline over the remainder of the year, the most notable being the announcement of topline data from our placebo-controlled, Phase 2 RESCUE-ALS study in the second half of 2021. With our strong cash position, we will continue to work expeditiously on our mission to change the treatment paradigm for patients with neurodegenerative diseases."

First Quarter 2021 and Recent Highlights

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

Phase 3 registrational trial in ALS on track for full enrollment in second half of 2021

In the first quarter of 2021, the HEALEY ALS Platform trial, a multi-center, multi-regimen, placebo-controlled, Phase 3 / registrational clinical program evaluating the safety and efficacy of multiple investigational products for the treatment of ALS, reached 50% of its target enrollment for the first three of the ongoing studies, including CNM-Au8. This first-ever ALS platform trial is designed to reduce trial time, reduce costs, and increase patient participation in developing novel therapies for ALS. It includes substantial financial support from philanthropic donors and foundations and provides access to more than 50 expert ALS clinical trial sites across the U.S. Full enrollment of 160 patients into the CNM-Au8 portion of the trial is anticipated before the end of 2021, with topline data expected in the first half of 2022.

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

Presented blinded interim data from the Phase 2 VISIONARY-MS trial at ACTRIMS Forum 2021

Updated blinded interim data from VISIONARY-MS continue to support the potential of CNM-Au8 to drive meaningful neurological improvements in people with MS. Interim blinded data from all enrolled participants (randomized 2:1, active CNM-Au8 to placebo) showed clinically relevant mean improvements in key MSFC sub-scales, as well as a composite score including all of the MSFC sub-scales. The overall study population's progress on study was compared to the mildest sub-population (EDSS \leq 1.5) scores at Baseline (mixed-effects model; $p < 0.0001$ vs. baseline). These findings support CNM-Au8's potential to drive meaningful neurological improvements in MS patients. Subject to ongoing pandemic-related research restrictions at MS clinical trial sites, enrollment will advance through 2021.

Presented interim data from the Phase 2 REPAIR-MS trial at ACTRIMS Forum 2021:

REPAIR-MS utilizes high-field strength magnetic resonance spectroscopy (^{31}P -MRS) to evaluate the effects of orally administered CNM-Au8 on the brain metabolic profile in people with MS. Updated interim data from the trial show significant CNS target engagement of CNM-Au8 with catalytic bioenergetic improvements in NAD⁺/NADH ratio and normalization of adenosine triphosphate (ATP) levels, two key CNS metabolic markers. Together, these data indicate that orally administered CNM-Au8 has positive effects on brain bioenergetics in MS patients. Clene expects to complete REPAIR-MS and report topline data in the second half of 2021.

CNM-Au8 for the treatment of Parkinson's disease (PD):

Awarded Michael J. Fox Foundation (MJFF) grant to accelerate the development of CNM-Au8 in PD

The MJFF funding will support preclinical studies in two complementary models of PD that will be led by Dr. Karen Ho, head of translational medicine at Clene in partnership with academic and CRO collaborators. The project will further evaluate the effects of CNM-Au8 on the survival and bioenergetic profiles of human PD patient dopaminergic neurons in the presence of PD-related neurotoxins and characterize the effects of CNM-Au8 on motor behaviors and neuronal survival in an animal model of PD, both of which will facilitate the advancement of CNM-Au8 into Phase 2 efficacy trials in PD patients.

CNM-ZnAg for the treatment of infectious diseases, including COVID-19:

Initiated a Phase 2 study of CNM-ZnAg for patients with COVID-19 in Brazil:

CNM-ZnAg is Clene's second key asset intended for broad anti-viral and anti-microbial use. Clene has received official ANVISA approval in Brazil to commence its multicenter, randomized, double-blind, placebo-controlled study assessing the efficacy and safety of CNM-ZnAg liquid solution in acutely symptomatic, non-hospitalized COVID-19 patients. The primary endpoint will evaluate the incidence of hospitalization at day 28, with secondary endpoints assessing time to symptom resolution. The trial is expected to enroll approximately 276 patients randomized 1:1:2 to receive either a low or high dose of CNM-ZnAg or placebo in a double-blind fashion, in addition to standard supportive care. Clene expects to report topline results from the trial in the second half of 2021.

Corporate Highlights:

Intellectual Property:

Clene recently received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for methods of using CNM-Au8 for the treatment of patients with MS, as well as two additional Notices of Allowances from the USPTO for patent applications covering device and process claims for its platform technology and advanced stage clean-surfaced nanocrystal therapeutic candidates. The resulting patents will add to Clene's robust intellectual property portfolio in the field of clean-surfaced nanocrystal therapeutics, which includes over 130 issued and allowed patents and approximately 30 additional applications pending.

Anticipated 2021 Milestones:

- HEALEY ALS Platform Trial full enrollment: 2H 2021
- Phase 2 RESCUE-ALS topline data: 2H 2021
- Phase 2 REPAIR-MS topline data: 2H 2021
- Phase 2 REPAIR-PD topline data: 3Q 2021
- Phase 2 CNM-ZnAg COVID-19 topline data: 2H 2021
- Initiation of Phase 2 RESCUE-PD efficacy trial: 2H 2021

First Quarter 2021 Financial Results**Cash Position:**

Clene's cash totaled approximately \$48.0 million as of March 31, 2021, compared to approximately \$59.3 million as of December 31, 2020. The decrease in cash during the first quarter ended March 31, 2021 was primarily due to approximately \$9.2 million of net cash used in operating activities, \$0.2 million of net cash used in investing activities, and \$1.9 million of net cash used in financing activities. We expect that our cash as of March 31, 2021 will be sufficient to fund our operating expenses into mid-2022.

R&D Expenses:

Research and development ("R&D") expenses were approximately \$6.3 million for the first quarter ended March 31, 2021, compared to \$3.2 million for the same period in 2020. The year over year increase is primarily attributable to (i) the progression of our drug candidates through the clinical development process, including increased enrollment into the REPAIR-PD and the REPAIR-MS studies, and calendar payments due for our participation in the HEALEY-ALS Platform Trial; and (ii) \$1.3 million of share-based expense related to restricted stock unit ("RSU") awards included in R&D expenses.

G&A Expenses:

General and administrative ("G&A") expenses were \$5.4 million for the first quarter ended March 31, 2021, compared to \$0.8 million for the same period in 2020. The year over year increase is primarily attributable to (i) increased professional expenses, legal fees, accounting fees, tax fees, and insurance expenses as a result of becoming a public company on December 30, 2020; and (ii) \$1.9 million of share-based expense related to RSU awards included in G&A expenses.

Net Loss:

Clene's loss from operations was \$11.7 million and \$4.0 million for the quarters ended March 31, 2021 and 2020, respectively. Clene's net loss was \$39.8 million, or \$0.66 per share, for the first quarter ended March 31, 2021, compared to a net loss of \$3.9 million, or \$0.23 per share, for the first quarter ended March 31, 2020. Included in the net loss for the first quarter ended March 31, 2021 is an unrealized loss from the change in fair value of contingent earn-out liabilities of \$28.6 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 neuronal bioenergetics, reducing reactive oxygen species, and promoting protein homeostasis with CNM-Au8 on disease progression in patients with early ALS. CNM-Au8 was selected by FightMND of Australia and Clene was provided a substantial grant to investigate efficacy in ALS utilizing novel electromyography endpoints at two expert sites in Australia. Topline data are expected in 2H 2021. For more information, please see [ClinicalTrials.gov Identifier: NCT04098406](https://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 drugs to be evaluated. Full enrollment of 160 patients into the CNM-Au8 study through 54 expert ALS U.S. clinical trial sites is expected by end of 2021. Subjects are randomized 3:1 to receive either active treatment 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 1H 2022. For more information, please see [ClinicalTrials.gov Identifier: NCT04297683](https://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 as a remyelinating and neuro-reparative treatment in stable relapsing multiple sclerosis (MS) patients with chronic visual impairment. 150 participants are being enrolled through 10 expert MS clinical trial sites in Australia. 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 from the Phase 2 VISIONARY-MS trial presented at ACTRIMS Forum 2021 Meeting 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](https://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, the concentrated nanocrystalline gold (Au) suspension, daily each morning for 12 weeks. Participants undergo ^{31}P -MRS brain imaging scans to semi-quantitatively measure CNS bioenergetic 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 bioenergetics 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](https://ClinicalTrials.gov/Identifier/NCT03993171) and [NCT03815916](https://ClinicalTrials.gov/Identifier/NCT03815916).

About CNM-Au8

Clene's lead drug candidate, CNM-Au8, a bioenergetic nanocatalyst, is a stable, aqueous suspension of catalytically active gold (Au) nanocrystals. Resulting from a patented manufacturing breakthrough, the self-organized, clean surfaced nanocrystals of CNM-Au8 drive critical cellular bioenergetic reactions in the brain that increase cellular energy, enhance neurorepair, and improve neuroprotection. 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 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. 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).

About Clene

Clene, a clinical-stage biopharmaceutical company focused on neurodegenerative disease, is leading the way by using nanotechnology to treat bioenergetic failure, which underlies many neurological diseases. Clene has innovated a novel nanotherapeutic platform to create a new class of drugs—bioenergetic nanocatalysts. Clene's lead drug candidate, CNM-Au8, is a concentrated nanocrystalline gold (Au) suspension that drives critical cellular bioenergetic reactions in the CNS. CNM-Au8 increases cellular energy to accelerate neurorepair and improve neuroprotection. Currently, CNM-Au8 is being investigated for efficacy and safety in a Phase 3 registration trial for ALS and in Phase 2 trials for multiple sclerosis and Parkinson's disease. 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.

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 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.

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

	Three Months Ended March 31,	
	2021	2020
Revenue:		
Product revenue	\$ 199	\$ 70
Royalty revenue	14	-
Total revenue	<u>213</u>	<u>70</u>
Operating expenses:		
Cost of revenue	243	58
Research and development	6,275	3,202
General and administrative	5,390	812
Total operating expenses	<u>11,908</u>	<u>4,072</u>
Loss from operations	(11,695)	(4,002)
Other income (expense), net:		
Interest expense	(551)	(51)
Gain on extinguishment of notes payable	647	-
Change in fair value of preferred stock warrant liability	-	112
Change in fair value of derivative liability	-	4
Change in fair value of Clene Nanomedicine contingent earn-out	(25,610)	-
Change in fair value of Initial Shareholders contingent earn-out	(2,961)	-
Australia research and development credit	339	-
Other income (expense), net	3	(4)
Total other income (expense), net	<u>(28,133)</u>	<u>61</u>
Net loss before income taxes	(39,828)	(3,941)
Income tax benefit	72	-
Net loss	(39,756)	(3,941)
Other comprehensive income:		
Foreign currency translation adjustments	24	6
Total other comprehensive income	<u>24</u>	<u>6</u>
Comprehensive loss	<u>\$ (39,732)</u>	<u>\$ (3,935)</u>
Net loss per share-- basic and diluted	(0.66)	(0.23)
Weighted average common shares used to compute basic and diluted net loss per share	<u>60,670,932</u>	<u>17,357,505</u>

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

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
ASSETS		
Current assets:		
Cash	\$ 48,041	\$ 59,275
Accounts receivable	123	21
Inventory	355	191
Prepaid expenses and other current assets	4,824	3,502
Total current assets	<u>53,343</u>	<u>62,989</u>
Right-of-use assets	1,006	1,029
Property and equipment, net	4,182	4,225
TOTAL ASSETS	<u>\$ 58,531</u>	<u>\$ 68,243</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 739	\$ 1,124
Accrued liabilities	2,730	3,960
Income tax payable	164	164
Deferred revenue from related parties	112	112
Operating lease obligations, current portion	202	194
Finance lease obligations, current portion	139	190
Clene Nanomedicine contingent earn-out, current portion	-	5,924
Total current liabilities	<u>4,086</u>	<u>11,668</u>
Operating lease obligations, net of current portion	1,723	1,785
Finance lease obligations, net of current portion	210	205
Notes payable	1,844	1,949
Deferred income tax	214	260
Clene Nanomedicine contingent earn-out, net of current portion	77,663	46,129
Initial Shareholders contingent earn-out	8,867	5,906
TOTAL LIABILITIES	<u>94,607</u>	<u>67,902</u>
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value: 100,000,000 shares authorized; 59,574,382 and 59,526,171 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	6	6
Additional paid-in capital	156,886	153,571
Accumulated deficit	(193,317)	(153,561)
Accumulated other comprehensive income	349	325
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>(36,076)</u>	<u>341</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 58,531</u>	<u>\$ 68,243</u>

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Source: Clene Inc.



CLNN (NASDAQ)
clene.com



Forward Looking Statements

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CLENE | Investment Highlights

Lead Asset: CNM-Au8 for Neuro Repair

- Nanocatalyst of Intracellular Biological Reactions
- 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 76 Weeks Exposure in Clinical Trials; Up to 85 Weeks in ALS Expanded Access

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 annum¹
 - ☑ 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 anticipated in 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 Q1 2021 of \$48.0M (Unaudited)
- Anticipated Cash Runway into mid-2022
- \$114M USD Raised Privately (Series A-D)
- +\$18M in Additional Grant and Indirect Financial Support for ALS and MS Phase 2 & 3 Clinical Programs

CLENE | Management Team

BOARD CHAIR



Shalom Jacobovitz



CEO



Rob Etherington



CMO



Robert Glanzman, MD, FAAN



CSO, FOUNDER



Mark Mortenson



CDO



Michael Hotchkin



CFO



Ted Jeong, DM



CLENE | Platform & Pipeline



Clean Surface Nanocrystal Therapeutics (CSN[®])

CSN[®] PLATFORM

130+ Granted Patents

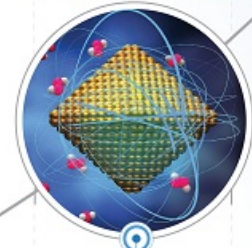
Novel electro-chemistry platform produces catalytic **Clean Surface Nanocrystal** drugs designed to avoid toxicities associated with synthetic chemistry

CSN [®] THERAPEUTIC	INDICATION	RESEARCH	PRECLINICAL	IND FILING	PHASE 1	PHASE 2 or EAP	PHASE 3	ANTICIPATED RESULTS
CNM-Au8 (CSN [®] gold) Bioenergetic Nanocatalyst	Amyotrophic Lateral Sclerosis	Healey ALS Platform Trial RESCUEALS		Harvard MGH (Registration Trial)				1H 2022
	ALS Expanded Access	MGHALS Harvard (MGH) Expanded Access Program						2H 2021
	Multiple Sclerosis	VISIONARY-MS RepairMS		Phase 2	Phase 2			2H 2022*
	Parkinson's Disease	RepairPD RESCUEPD		Phase 2	Phase 2	Brain Imaging Biomarker Study		2H 2021*
CNM-ZnAg (CSN [®] zinc-silver)	Anti-viral Anti-bacterial	ZnAgSTUDY						2H 2021
CNM-AgZn17 (CSN [®] silver-zinc gel)	Wound Healing, Burn Treatment							
CNM-PtAu7 (CSN [®] platinum-gold)	Oncology							

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

Evolution of Gold as a Therapeutic Modality

Clene's Patented Breakthrough

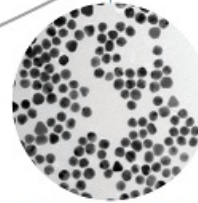


2020+

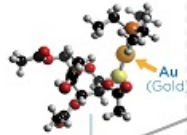
Catalytic Clean Surfacd Faceted Gold Nanocrystals

Pioneering Bioenergetic Nanocatalysis

1950s-2000s



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



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; triethylphosphonium



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

2500-1000 BC

CNM-Au8 | Bioenergetic Nanocatalyst

Improved Cellular Energetic Support

Novel mechanism of action to address a range of CNS diseases

Clean Surfaced Faceted Nanocrystal



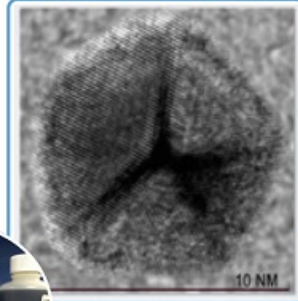
13 nm Median Diameter
(Ribosome = 20-30 nm)

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

Oral Suspension;
Once Daily



CNM-Au8 Nanocrystal



Transmission Electron Micrograph

Cellular



Energy



Remyelination
Failure In MS



Parkinson's
Disease



Amyotrophic
Lateral Sclerosis

clene
NANOMEDICINE

CNM-Au8 | Integrating Physics With Biology

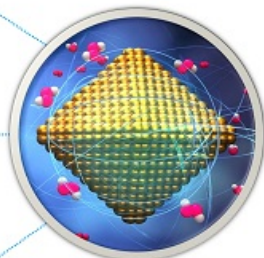
Electron Transfer Is Fundamental to Energy Production

Surface Based
Catalytic Activity

Electrons (e^-)
Move Freely Across
Nanocrystal Surface

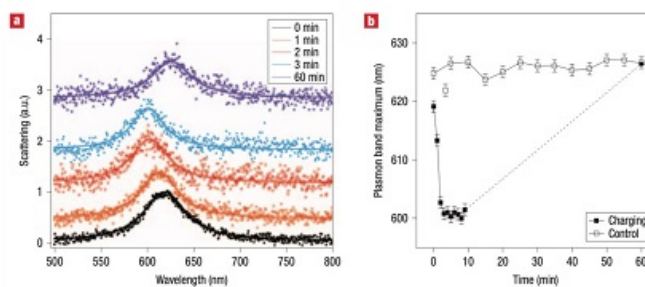
Vertices, Edges,
& Faces Key to
Catalytic Activity

Clean-Surfaced
Nanocrystals



Up to 4,600 e^- per
second per nanocrystal¹

AuNP Catalyzed Oxidation of Ascorbic Acid¹

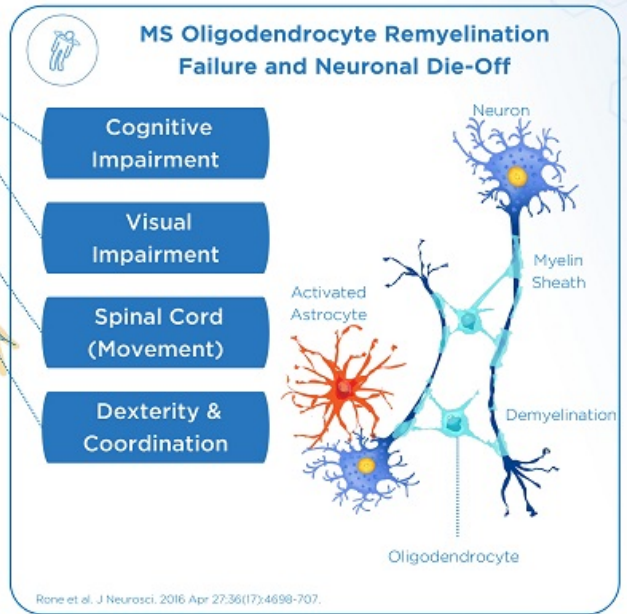
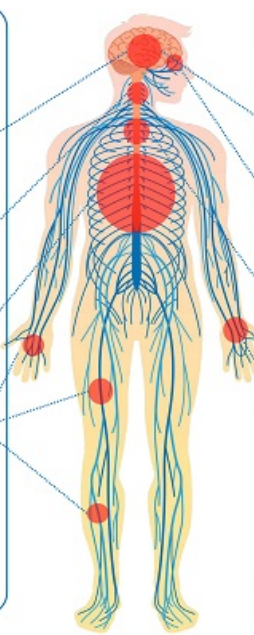
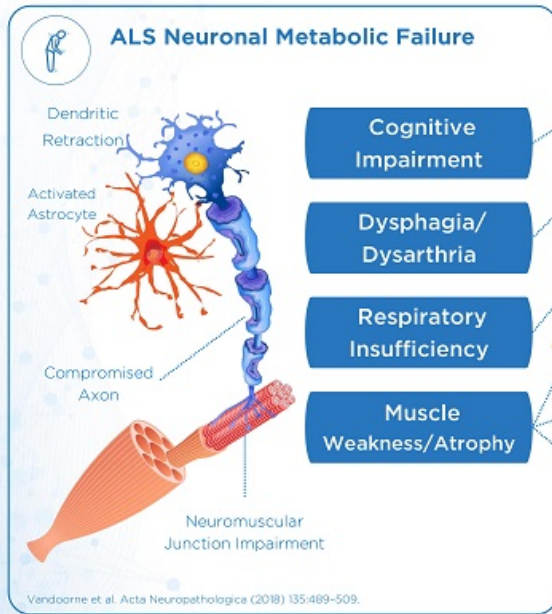


a. Rayleigh scattering measured by dark field microscopy of surface plasmon resonance of scattering spectra of the AuNP decahedron before and at 1, 2, 3 and 60 min after electron injection by ascorbate ions.

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

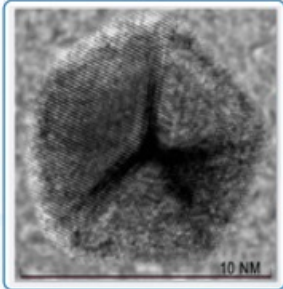
¹Novo et al. Nature Nanotech 3, 598-602 (2008).

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



CNM-Au8 | MOA → Therapeutic Effects

Catalytic Gold Nanocrystals



Bioenergetic Mechanism

↑ Increased NAD⁺

↑ Increased ATP

↓ Decreased reactive oxygen species

↑ Increased proteostasis

* Nicotinamide Adenine Dinucleotide

Enhanced Disease Response

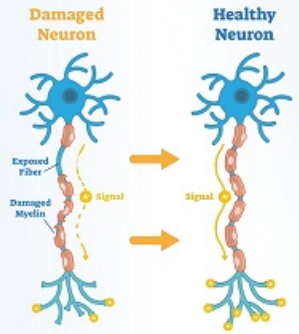
↑ Increased energetic capacity



Improved resistance to oxidative, mitochondrial, and excitotoxic stressors

↓ Reduction in levels of misfolded proteins

Remyelination



Neuro Repair



CNM-Au8 | Significant Global Opportunity



MOTOR NEURON DISEASE (ALS, Other Orphan Disorders)

ALS sales >\$1B globally by 2029¹. Current drugs are largely ineffective, mostly generic.



MULTIPLE SCLEROSIS ~2.5M pts globally; \$23B market²

Only approved treatments are immunomodulators.

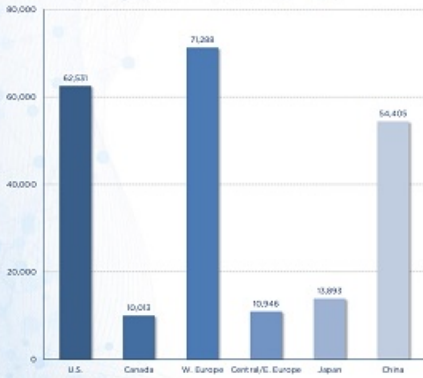


PARKINSON'S DISEASE

~7M pts globally; \$6B projected by 2025³

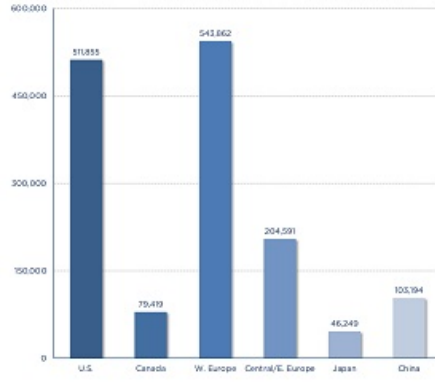
2ND most common neurodegenerative disorder; only symptomatic treatments

Est. Diagnosed MND Patients by Region



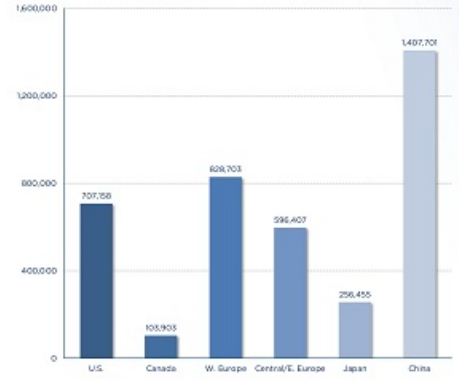
Source: Lancet Neurol. 2018 Dec;17(12):1083-1097.
MND includes amyotrophic lateral sclerosis, spinal muscular atrophy, hereditary spastic paraplegia, primary lateral sclerosis, progressive muscular atrophy, and pseudobulbar palsy

Est. Diagnosed MS Patients by Region



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

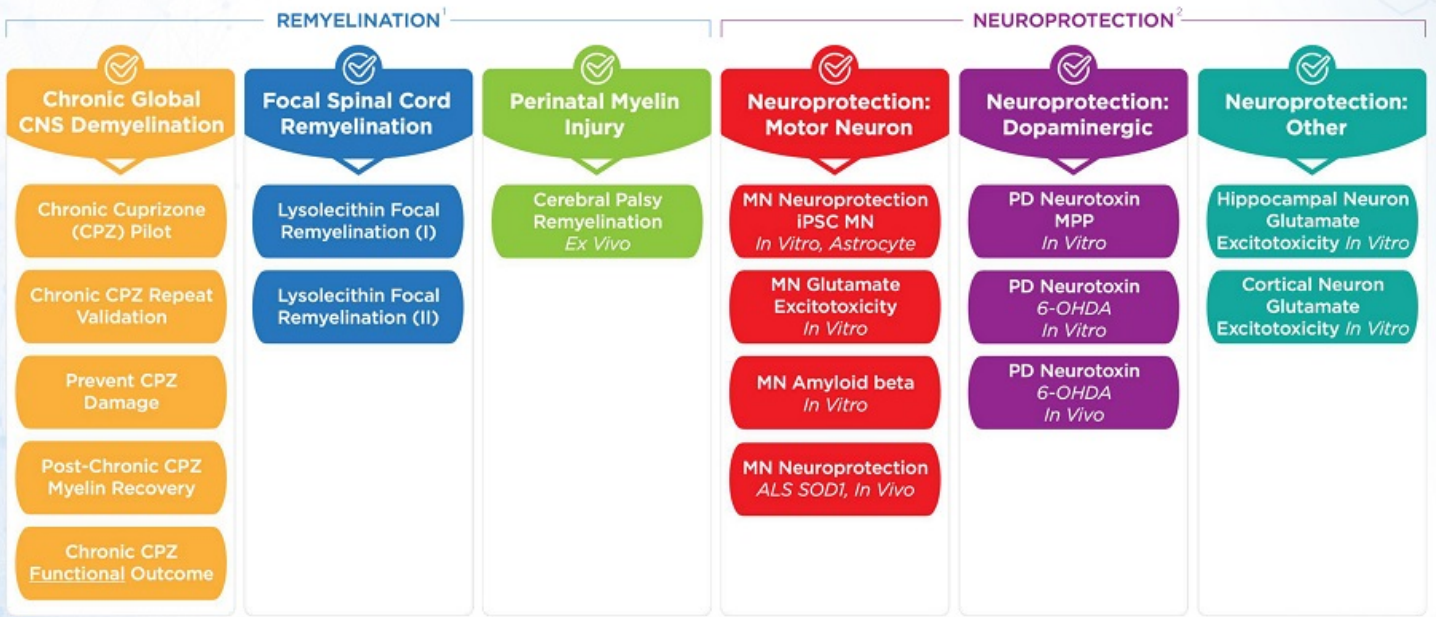
Est. Diagnosed PD Patients by Region



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

CNM-Au8 | Evidence for Bioenergetic Improvement

Therapeutic Activity Across Remyelination + Neuroprotection Models



www.nature.com/scientificreports

**SCIENTIFIC
REPORTS**

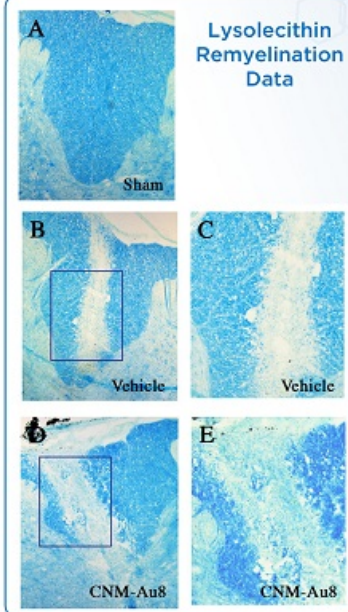
nature research

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. Titus¹, Molly Karl³, Mikhail Merzliakov², Adam R. Dorfman², Stephen Karlik⁴, Michael G. Stewart⁵, Richard K. Watt⁵, Benjin D. Facer⁶, Jon D. Facer⁵, Noah D. Christian⁷, Karen S. Ho^{2,8*}, Michael T. Hotchkiss^{2,9}, Mark G. Mortenson^{2,9}, Robert H. Miller^{2,9} & 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

Successful Phase 1
First-In Humans Safety
Trial + Chronic
Animal Toxicity Studies

Phase 2 Brain Target
Engagement

³¹P-Magnetic Resonance



Phase 2 & 3 ALS
Clinical
Neurorepair



Phase 2 MS
Clinical
Remyelination & Neurorepair



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 (>140 Years Exposure)

Up to 76 Weeks Exposure in Clinical Trials;
Up to 85 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

CNM-Au8 Effects on Brain Bioenergetic Metabolites

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



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°

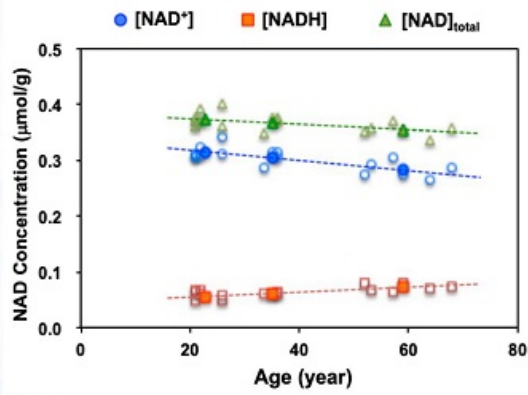
- Difference in NAD⁺ and NADH fraction at Week 12-16
- Difference in other bioenergetic metabolites (e.g., ATP, PCr, NAD) concentration at Week 12 - 16
- Difference in brain membrane markers (PE, PC, etc.) at Week 12 - 16

Anticipated Top-Line Results (Cohort 1):
Repair-PD: 2H 2021
Repair-MS: 2H 2021*

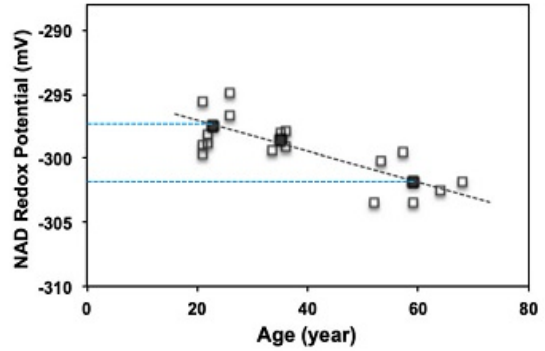
NAD⁺/NADH | Age Related Decline

By ³¹P-MRS Imaging

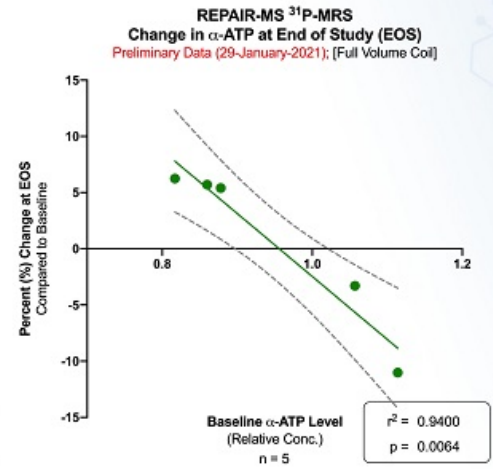
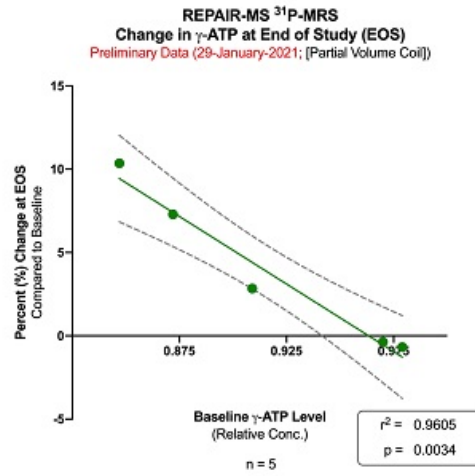
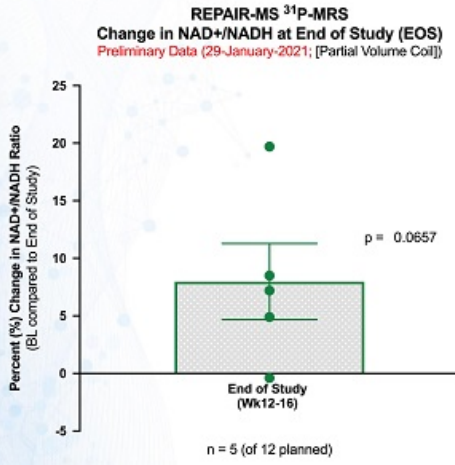
NAD⁺ Decline & NADH Increase (Aging Change by Decade)



-0.05% NAD⁺/NADH unit decline per year (-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

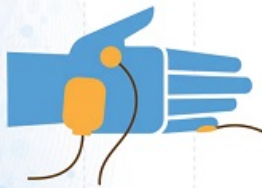


Glanzman, R., J. Ren, A. Rynders, B. Greenberg, R.B. Dewey, K. S. Ho, and M. T. Hotchkiss. "Effects of Nanocatalysis on CNS Bioenergetic Markers in Patients Treated with CNM-Au8: Interim Results from a Phase 2 ³¹P-Magnetic Resonance Imaging Study in Relapsing MS." Presented at the ACTRIMS Forum 2021, February 26th, 2021.

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



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)

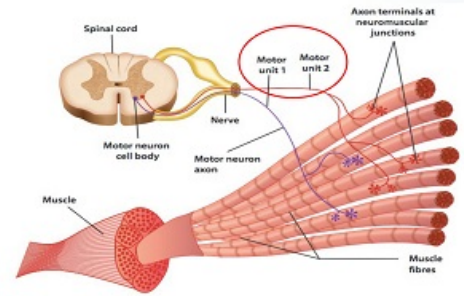
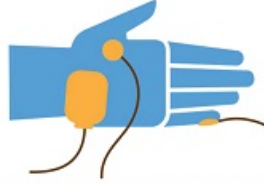
Anticipated full unblinded data readout: 2H 2021

Measuring ALS Disease Progression

Electromyography Predicts Clinical Progression

Predictive Endpoints of Disease Progression

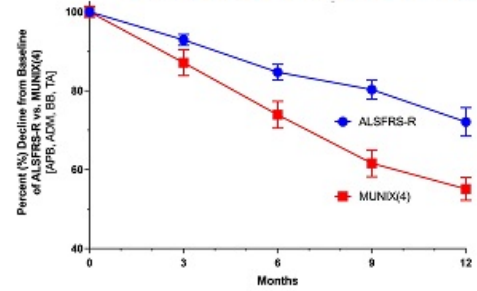
- **Loss of Motor Units**
Motor Unit Index (MUNIX)



Clinical Endpoints

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

Historical Longitudinal Controls

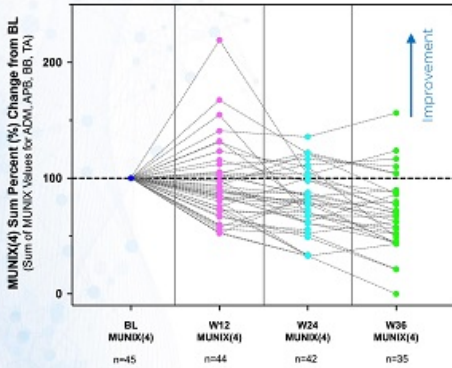


Neuwirth et al., JNNP 2015 Nov;86(11):1172-9.



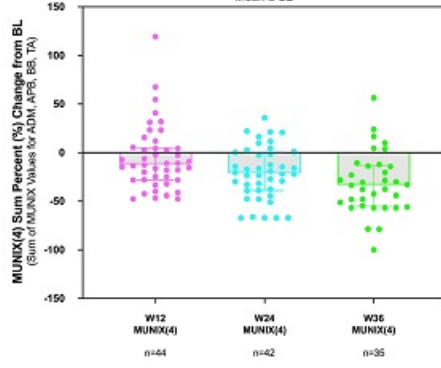
Emerging Evidence of Primary Endpoint MUNIX(4) Improvement

Blinded Data: MUNIX(4) Sum Percent (%) Change from BL
15-March-2021 Data Cut; Imputed Values; Preliminary Blinded Data
(All Reported Values With Missing Data Imputed)



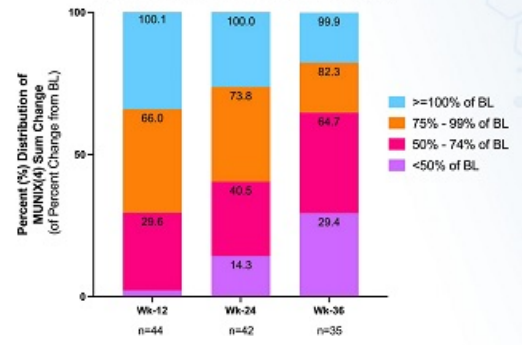
All Subjects With Evaluable Data
By Completed Study Visit
(Missing Data Imputed by Linear Regression per Subject;
Mortality Imputed with Worst % Change from BL)

Blinded Data: MUNIX(4) Sum Percent (%) Change from BL
15-March-2021 Data Cut; Imputed Values; Preliminary Blinded Data
(All Reported Values With Missing Data Imputed)
Mean ± SD



All Subjects With Evaluable Data
By Completed Study Visit
(Missing Data Imputed by Linear Regression per Subject;
Mortality Imputed with Worst % Change from BL)

Distribution of MUNIX(4) Sum Percent (%) Change from BL
15-March-2021 Data Cut; Preliminary Blinded Data
(All Reported Values With Missing Data Imputed)

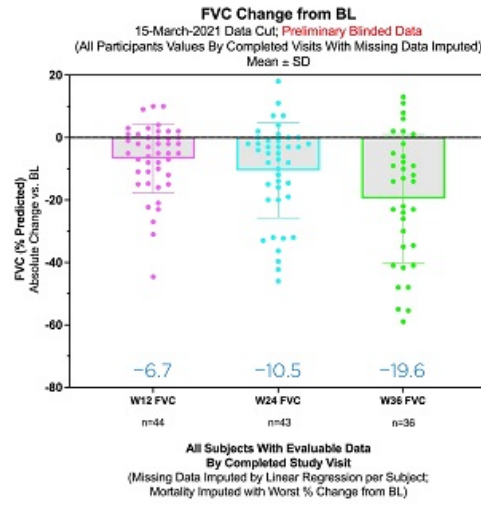
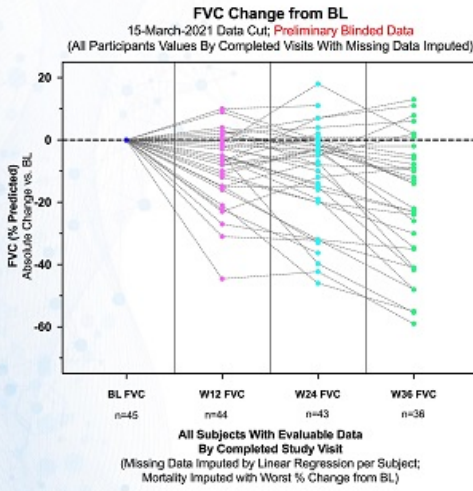


All Subjects With Evaluable Data
By Completed Study Visit
(Missing Data Imputed by Linear Regression per Subject;
Mortality Imputed with Worst % Change from BL)

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.



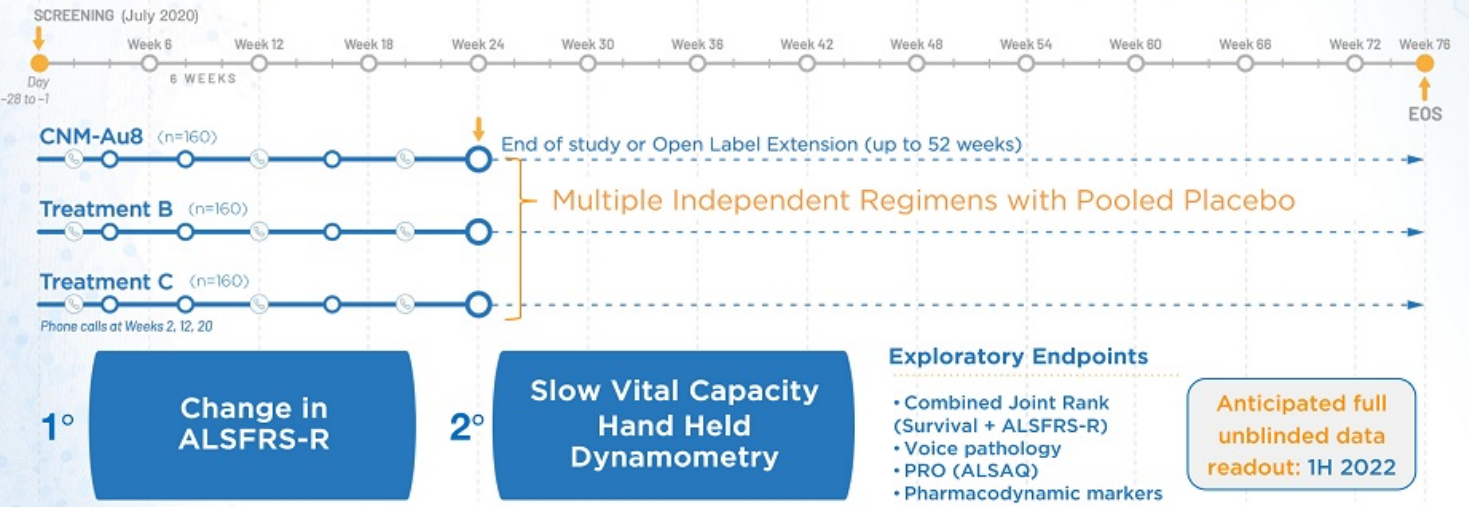
Emerging Evidence of Clinical Improvement | Forced Vital Capacity



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.

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



Phase 2
VISIONARY-MS
STUDY

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



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*

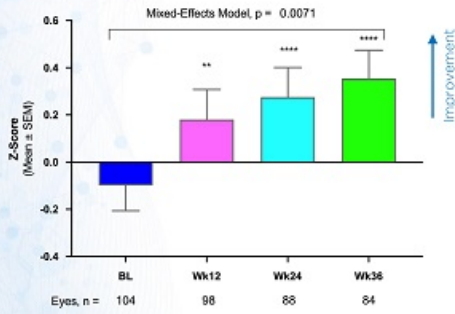
*Subject to ongoing COVID-19 related site research restrictions generally implemented to protect MS patients taking standard-of-care immunosuppressive therapies



LCLA (Best-Corrected)



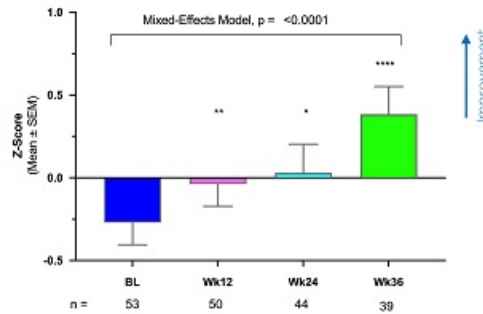
LCLA (All Eyes) Z-Score
13-January-2021 Data Cut, Preliminary Blinded Data
(Based on 'Mild' EDSS [≤ 1.5]; Mean \pm SEM)



SDMT



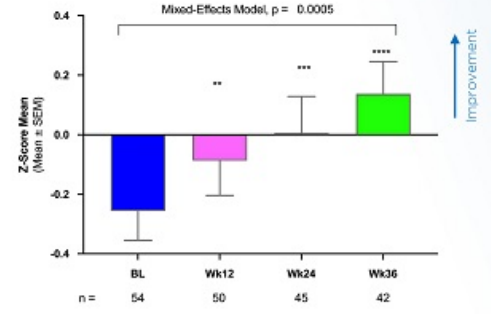
SDMT Z-Score
13-January-2021 Data Cut, Preliminary Blinded Data
(Based on 'Mild' EDSS [≤ 1.5]; Mean \pm SEM)



6-Component Integrated (m)MSFC



(m)MSFC 6-component Average Z-Score
13-January-2021 Data Cut, Preliminary Blinded Data
(Based on 'Mild' EDSS [≤ 1.5]; Mean \pm SEM)



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. Hotchkiss, A. Klisterner, 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-AuB, for the treatment of chronic optic neuropathy." Presented at the ACTRIMS Forum 2021, February 26, 2021.

Strong Intellectual Property

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



Patent Status

Issued & Allowed Patents
130+

Pending Applications
>30

**Total Patents/
Applications**
>160

Patent Description

Process And Method/Device
(Clean Surface; Gold CSN)

State of Matter
(CNM-Au8)

Method of Use
(Prevent Demyelination & MoA)

Method of Use
(Bi-Metallic Au/Pt; Antimicrobial)

Trade Secrets

Plasma Conditioning

Electrode Design & Cycling

Trough Flow, Temp, Pressure

Concentration & Filtration

^a With Patent Restoration Term (assuming 5-year extension).

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

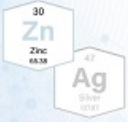
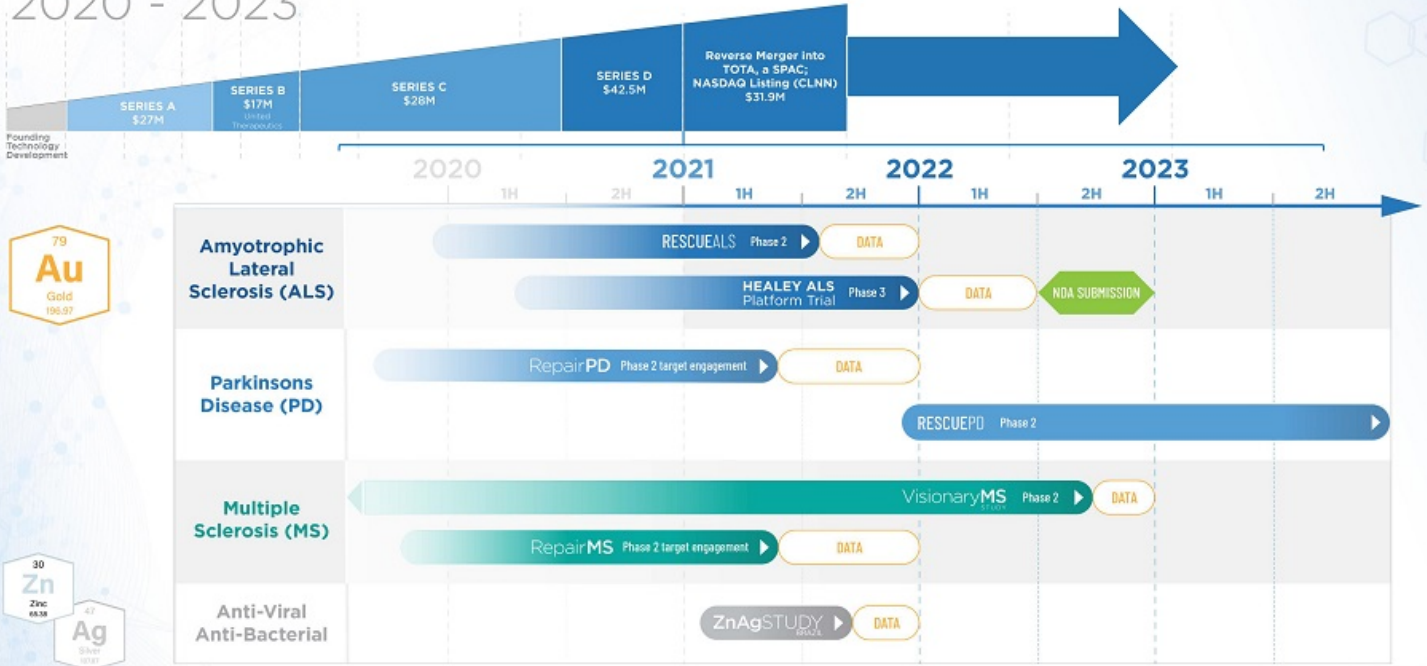
Proprietary Trade
Secrets

Validated CMC
Processes



Anticipated Timeline & Investor Catalysts

2020 - 2023



CLENE | Investment Highlights

Lead Asset: CNM-Au8 for Neuro Repair

- Nanocatalyst of Intracellular Biological Reactions
- 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 76 Weeks Exposure in Clinical Trials; Up to 85 Weeks in ALS Expanded Access

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 annum¹
 - ☑ 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 anticipated in 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 Q1 2021 of \$48.0M (Unaudited)
- Anticipated Cash Runway into mid-2022
- \$114M USD Raised Privately (Series A-D)
- +\$18M in Additional Grant and Indirect Financial Support for ALS and MS Phase 2 & 3 Clinical Programs



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