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): December 1, 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

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (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 Capital Market
Warrants, to acquire one-half of one share of Common Stock for $11.50 per share	CLNNW	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 1, 2021, Clene Inc. (the "Company") issued a press release announcing presentation of updated data from the RESCUE-ALS Phase 2 study in amyotrophic lateral sclerosis ("ALS") at the 4th Annual ALS ONE Research Symposium which took place on November 30, 2021. A copy of the press release and presentation are furnished as Exhibit 99.1 and Exhibit 99.2 to this Current Report on Form 8-K and are incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 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, regardless of any general incorporation language in any such filings, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated December 1, 2021 announcing the presentation of updated data from RESCUE-ALS Phase 2 study at 4th Annual ALS ONE Research Symposium.
99.2	Presentation dated November 30, 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: December 1, 2021

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

Exhibit 99.1

Clene Nanomedicine Presents Updated Data from RESCUE-ALS Phase 2 Study at 4th Annual ALS ONE Research Symposium

- *CNM-Au8 has favorable impact on progression of ALS as measured by joint rank comparison of combined survival and ALSFRS-R change – a clinically meaningful endpoint recommended by the FDA*

- *CNM-Au8 showed consistent efficacy across limb and bulbar onset participants for ALS disease progression and the proportion with less than a 6-point decline on the ALSFRS-R scale.*

SALT LAKE CITY, December 1, 2021 -- -- Clene Inc. (NASDAQ: CLNN) along with its subsidiaries "Clene" and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease, presented new data from the RESCUE-ALS Phase 2 study of CNM-Au8®, a catalytically active gold nanocrystal suspension, in the treatment of amyotrophic lateral sclerosis (ALS) at the 4th Annual ALS ONE Research Symposium which took place virtually on November 30, 2021. The presentation can be viewed on Clene's website at: https://invest.clene.com/overview/default.aspx

New data presented included analyses of CNM-Au8's efficacy in limb and bulbar onset participants across key endpoints of slowing ALS clinical worsening:

- Consistent clinical benefit was shown in both limb and bulbar onset participants for the pre-specified endpoint of ALS disease progression defined as death, or the need for tracheostomy, non-invasive ventilation, or gastrostomy.

- Similarly, CNM-Au8 treated participants showed consistent clinical benefit in the proportion without a 6-point decline on the ALSFRS-R across both limb and bulbar onset participants in a *post hoc* analysis.

In a pre-specified joint-rank analysis of survival and ALSFRS-R decline, the Combined Assessment of Function and Survival (CAFS), CNM-Au8 showed directional benefit. The CAFS combines the change in ALS Functional Rating Scale-Revised (ALSFRS-R) score with participant survival time. The rating for each participant in the study group is compared to every other participant and a higher CAFS score indicates a better outcome for the group. Despite the small sample size of 45 subjects at 36 weeks, participants treated with CNM-Au8 had an improved average CAFS summated score of +4.4 compared to -4.6 decline for the placebo group (LS Mean Difference; 9.1, 95% CI: -5.8, 23.9; p=0.22).

Updated long-term survival from the RESCUE-ALS open-label extension study was presented, which continues to suggest a potential survival benefit compared to estimated median survival from the validated ENCALS prediction model across the study population.

"We were pleased to continue sharing our findings from the RESCUE-ALS trial with the ALS community at this symposium. We continue to remain excited about these clinically meaningful findings, which given the remarkable safety and tolerability of CNM-Au8 seen so far in the development program, speak to the potential for a positive benefit-risk assessment," stated Dr. Robert Glanzman, Chief Medical Officer at Clene.

About ALS ONE

ALS ONE is a partnership bringing together world-leading ALS researchers, doctors, and care practitioners focused on finding treatments for ALS and novel approaches to improve care and quality of life for those battling the disease. The unprecedented linking of minds and resources from Massachusetts General Hospital (MGH), University of Massachusetts Medical Center, ALS Therapy Development Institute (ALS TDI), and Compassionate Care ALS (CCALS) is unique for its leadership in efficiency, dedication to innovative research, and commitment to increasing access to care and treatment.

About RESCUE-ALS

RESCUE-ALS is a Phase 2 multi-center, randomized, double-blind, parallel-group, placebo-controlled trial examining the efficacy, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in patients with early amyotrophic lateral sclerosis (ALS). The trial completed enrollment in the second half of 2020. In the trial, 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 trial is to assess the impact of CNM-Au8 on disease progression in patients with early-stage ALS through changes in motor unit index MUNIX. MUNIX values were evaluated for four muscles in the hand, arm, and leg: the abductor digiti minimi, abductor pollicis brevis, tibialis anterior and biceps brachii from baseline through 36 weeks of treatment. 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 clinical sites in Australia. For more information, please see ClinicalTrials.gov Identifier: NCT04098406.

About CNM-Au8®, a gold nanocrystal suspension

Clene's lead drug candidate, CNM-Au8, a catalytically active gold nanotherapeutic, is the result of a patented manufacturing breakthrough. The catalytically active nanocrystals of CNM-Au8 drive critical cellular energy producing reactions in the brain that enable neuroprotection 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 is being evaluated in a Phase 3 registration trial for the treatment of amyotrophic lateral sclerosis (ALS). In the REPAIR Program Phase 2 open-label biomarker clinical trials, CNM-Au8 demonstrated target engagement in the treatment of Parkinson's disease (PD) and multiple sclerosis (MS). REPAIR-PD has concluded, and REPAIR-MS will continue with the initiation of a second MS dosing cohort. 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 is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease with potential first-in-class nanotherapeutics to treat energetic failure, an underlying cause of many neurological diseases. Our lead drug candidate, CNM-Au8, is an oral suspension of gold nanocrystals that drive critical cellular energetic metabolism in the central nervous system (CNS). CNM-Au8 increases energy production and utilization to accelerate neurorepair and improve neuroprotection. CNM-Au8 is currently being evaluated in a Phase 3 registration trial in amyotrophic lateral sclerosis (ALS) and a Phase 2 trial for the treatment of chronic optic neuropathy in patients with stable relapsing multiple sclerosis (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.

Forward-Looking Statements

This press release contains "forward-looking statements" which are intended to be covered by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Clene's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "might" and "continues," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant known and unknown risks and uncertainties, many of which are beyond Clene's control and could cause actual results to differ materially and adversely from expected results. Factors that may cause such differences include Clene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; Clene's ability to achieve commercial success for its marketed products and drug candidates, if approved; Clene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Clene's reliance on third parties to conduct drug development, manufacturing and other services; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the licensing or development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on Clene's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in Clene's Annual Report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in Clene's subsequent filings with the U.S. Securities and Exchange Commission. Clene undertakes no obligation to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, subject to applicable law. All information in this press release is as of the date of this press release. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this press release.

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Exhibit 99.2

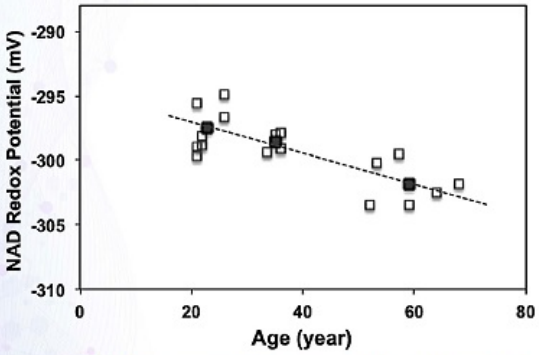
Forward Looking Statements

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-1 (filed July 22, 2021), 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.

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

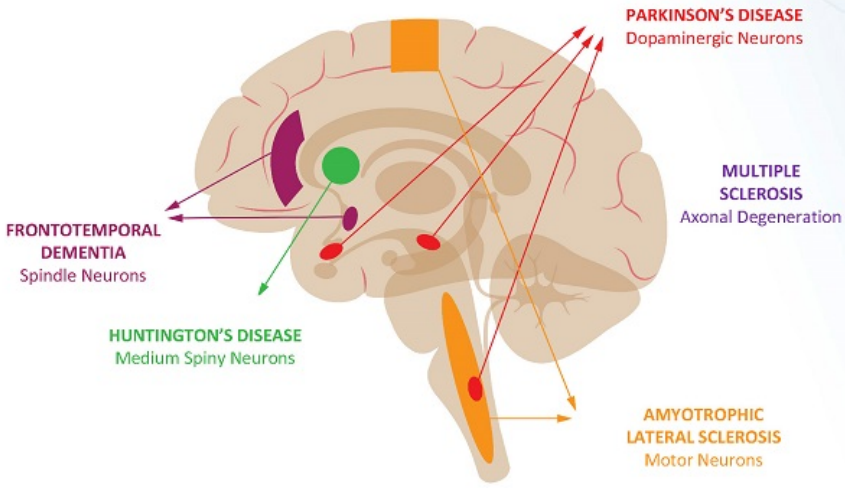
Brain Energy Potential Declines With Normal Aging

~0.5% NAD^+/NADH unit decline per decade
(~0.13 mV units per year by ^{31}P-MRS Imaging)



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

Specific Neuronal Populations Are Vulnerable to Energetic Failure



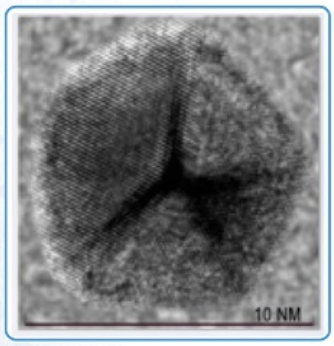
Fu, H., et al; Nature Neuroscience (2018) 21: 1350-1358. Zhu et al. Proc Natl Acad Sci USA . 2015 Mar 3;112(9):2876-81. Rone et al. J Neurosci. 2016 Apr 27;36(17):4698-707.

CLene NANOMEDICINE

CNM-Au8® | Catalytically-Active Nanocrystals

Intersection of Physics and Biology

CNM-Au8 Nanocrystal



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

Clean Surfaced, Highly Faceted Shape Enhances Catalytic Activity

Electron Sharing Drives Catalytic Activity

Vertices, Edges, & Facets Key to Catalytic Activity

CNM-Au8 Catalytically Active Nanocrystal Suspension

Once Daily Oral Suspension

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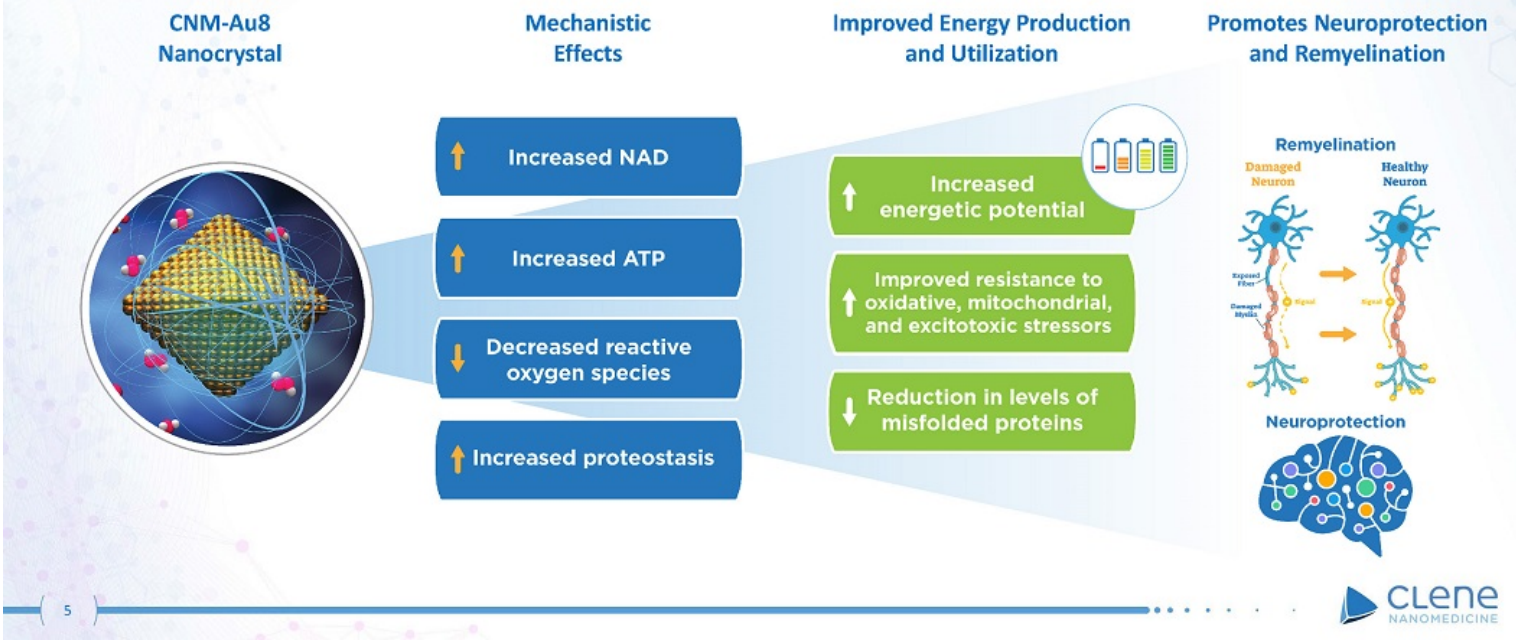
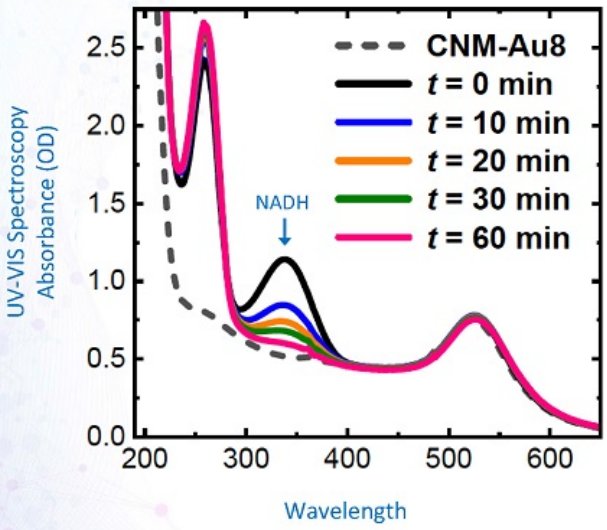
CNM-Au8 | Improves Energy Production to Promote Neuroprotection and Remyelination



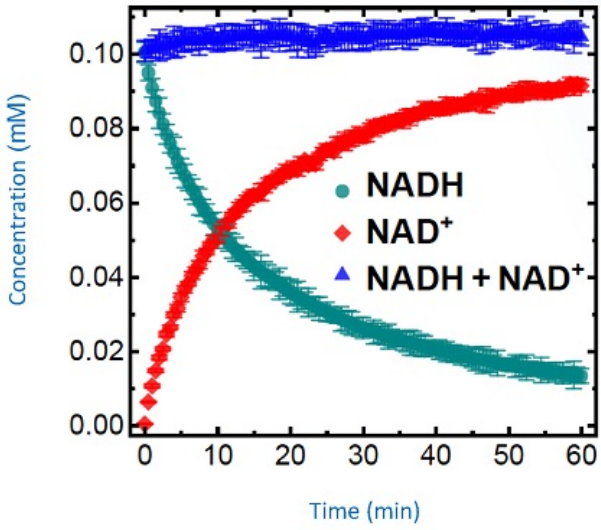
CLene NANOMEDICINE

CNM-Au8 | Catalysis of NADH to NAD⁺

Catalysis of NADH to NAD⁺



NAD⁺ & NADH Concentration vs. Time



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

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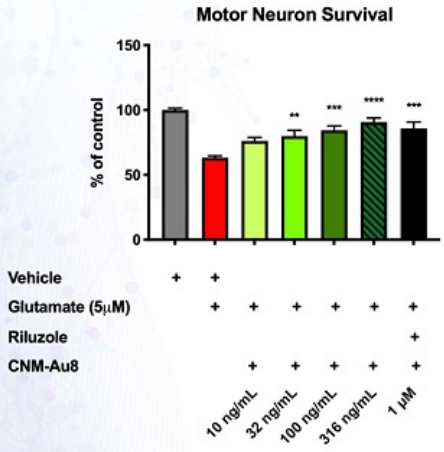
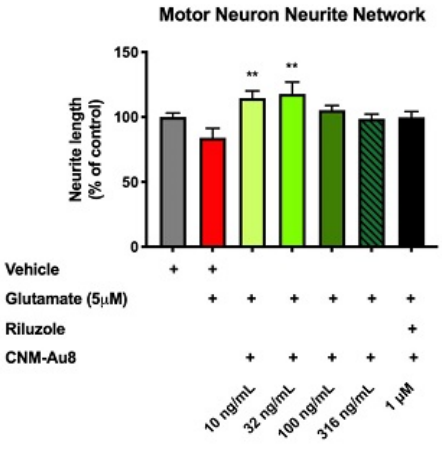
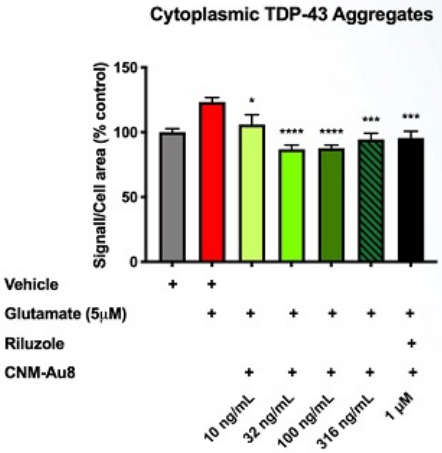
CNM-Au8 | Neuroprotection from Excitotoxic Glutamate

Rat Primary Motor Neurons *In Vitro* Results







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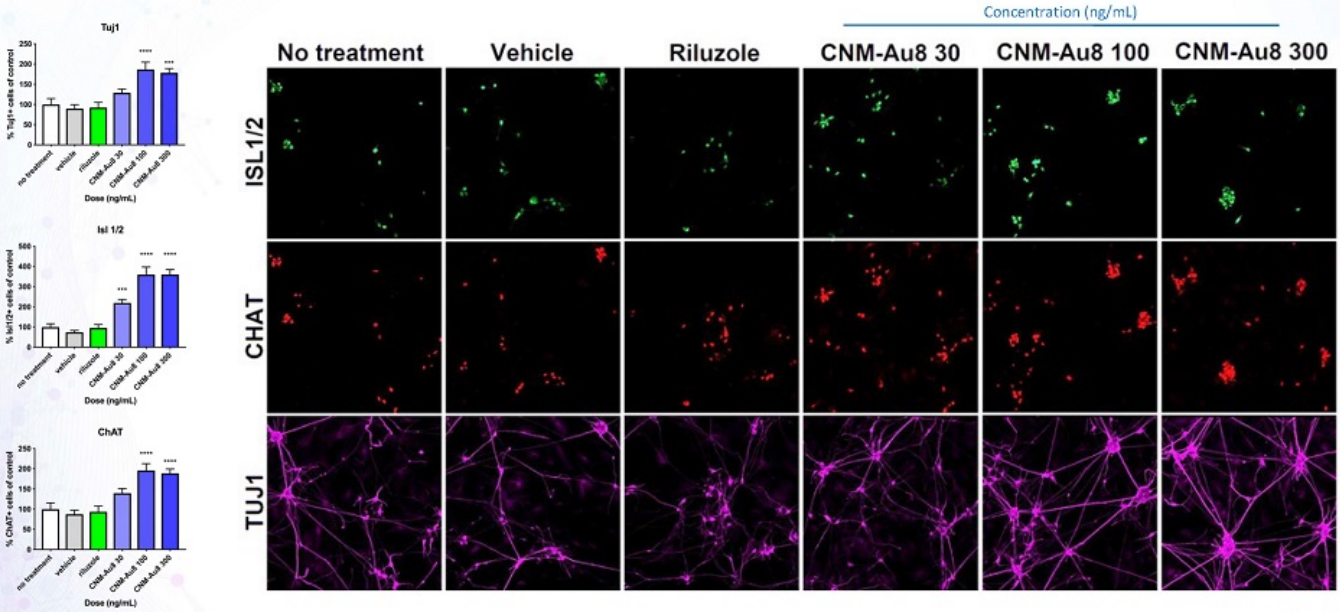
CNM-Au8 | ALS Neuroprotection in Human iPSCs

iPSC *In Vitro* Survival Results – SOD1^{A4V} Astrocytes with Human Motor Neuron



Ho et al.

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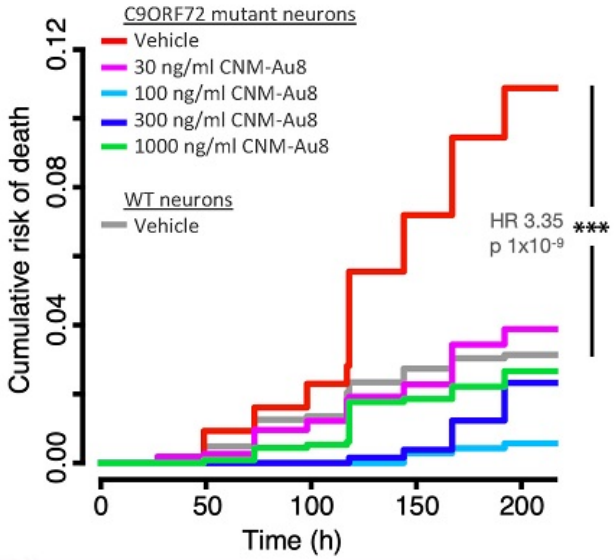
CNM-Au8 | Survival in Human C9ORF72 iPSC Neurons

iPSC Derived Neurons *In Vitro* Results – Cortical Neurons (Forebrain)



Significant Survival Benefit

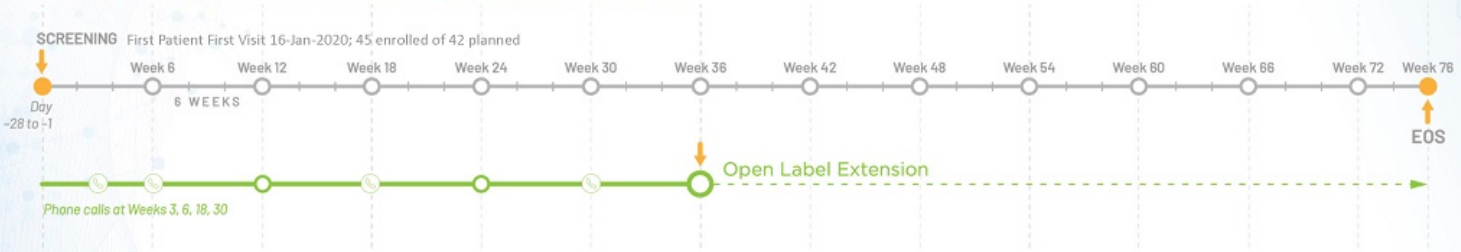
Reference	Treatment	HR (vs. vehicle)	p
C9ORF72 + vehicle	CNM-Au8 30ng/ml	0.36	$1x10^{-8}$
C9ORF72 + vehicle	CNM-Au8 100ng/ml	0.07	$1x10^{-7}$
C9ORF72 + vehicle	CNM-Au8 300ng/ml	0.21	$4x10^{-14}$
C9ORF72 + vehicle	CNM-Au8 1000ng/ml	0.26	$4x10^{-11}$

Data on File, Clene Nanomedicine, Inc.

Phase 2
RESCUEALS

Design Overview

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



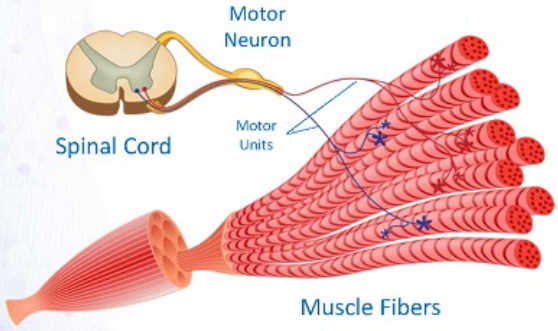
Neurophysiology	Pulmonary Function	Function & QoL	Disease Progression & Survival
MUNIX[1]	Forced Vital Capacity	ALSFRS-R, ALSSQOL-SF	

[1] Study was powered for MUNIX primary endpoint based on 50% relative decrease in rate of MUNIX decline

RESCUEALS | Pioneered Use of MUNIX Biomarker

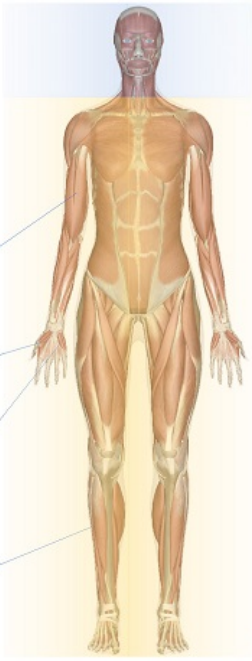
Primary Endpoint: Spinal Cord Lower Motor Neuron Protection

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



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

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



Bulbar Onset
ALS
(Brainstem)

Limb Onset
ALS
(Spinal Cord)

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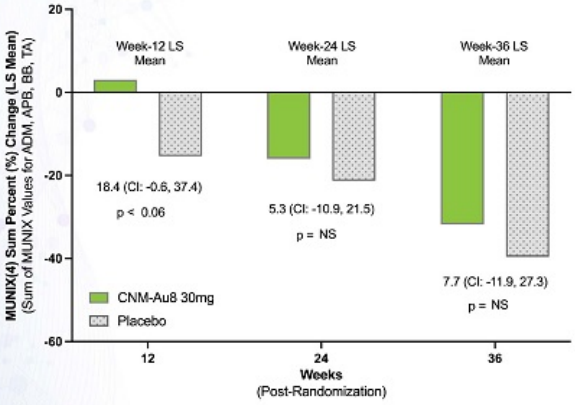
RESCUEALS | Evidence for Motor Neuron Protection

Primary Endpoint (MUNIX %, LS Mean Change)

All Randomized

MUNIX(4) Sum Percent Change from Baseline
RESCUE-ALS Primary Endpoint
Mixed Model Repeat Measure (ITT Population, All Randomized)
LS Mean Difference



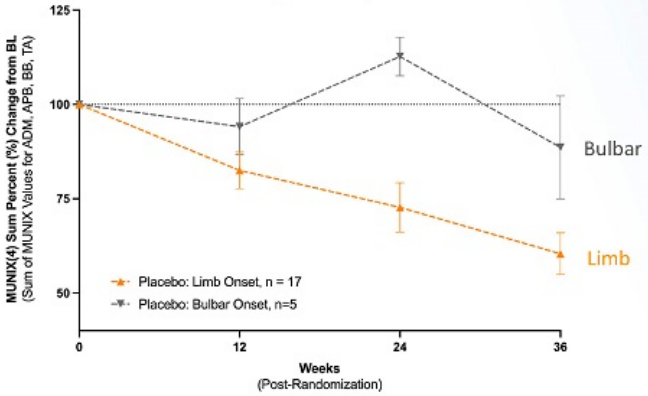
Active, n =	21	21	20
Placebo, n =	21	19	16

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

All Placebo

Limited Rate of MUNIX Decline in Bulbar Onset

MUNIX(4) Sum Percent Change from Baseline
RESCUE-ALS: Placebo Rate of Progression
Observed Values (Limb Onset vs. Bulbar Onset)
(Mean ± SEM)



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

Data on File, Clene Nanomedicine, Inc.

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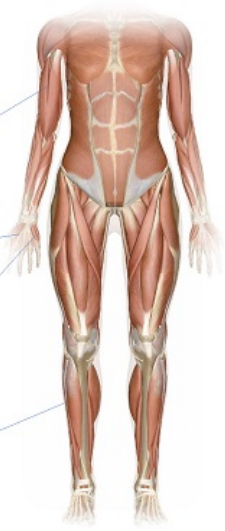
RESCUEALS | MUNIX Biomarker Efficacy in Limb Onset

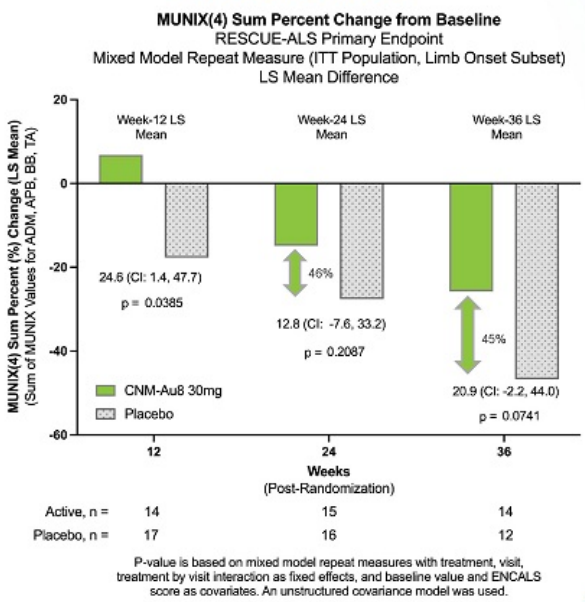
Primary Endpoint (MUNIX %, LS Mean Change, Limb Onset Subset)

Spinal Cord
Lower Motor Neuron
Motor Unit Index
(MUNIX) Sum

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



Pre-specified: Limb Onset



Active, n =	14	15	14
Placebo, n =	17	16	12

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

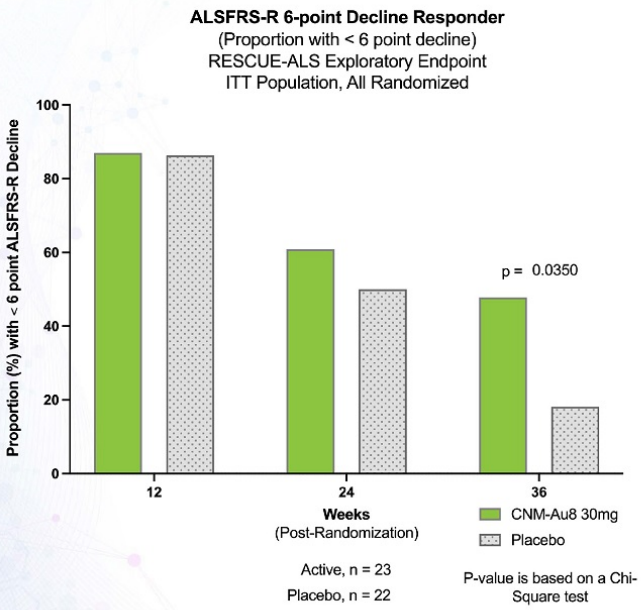
Data on File, Clene Nanomedicine, Inc.

clene NANOMEDICINE

RESCUEALS | Significant Impact on ALSFRS-R Decline

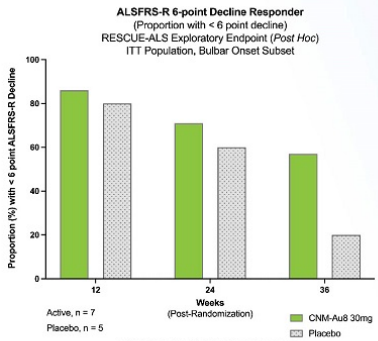
Exploratory (ALSFRS-R Responder Analysis, < 6-point decline)

All Randomized

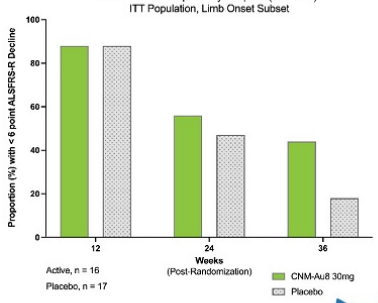


Sensitivity

All Bulbar



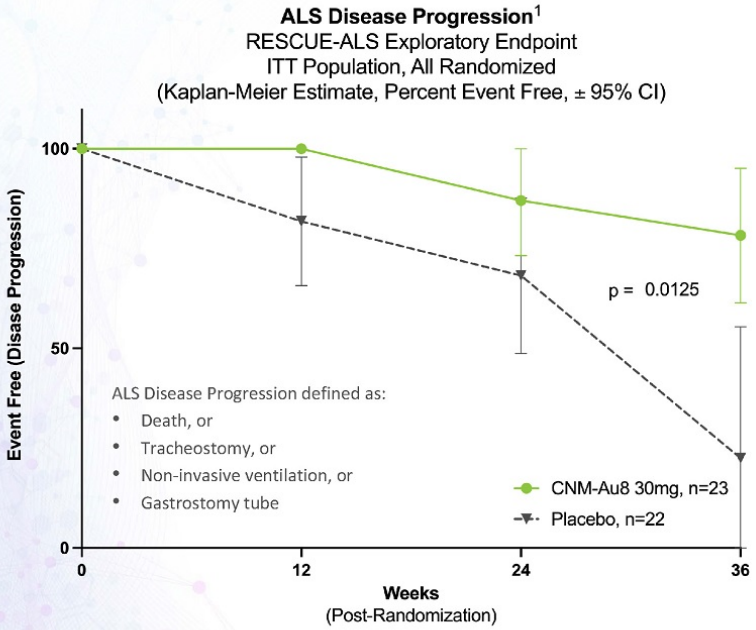
All Limb



Data on File, Clene Nanomedicine, Inc.

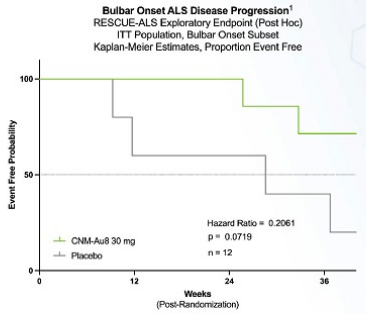
RESCUEALS | Significantly Reduced Disease Progression Risk

Exploratory Endpoint (Disease Progression)



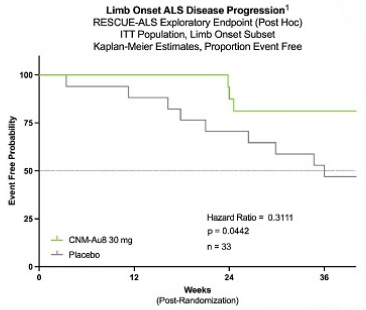
Sensitivity

All Bulbar



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

All Limb



Data on File, Clene Nanomedicine, Inc.

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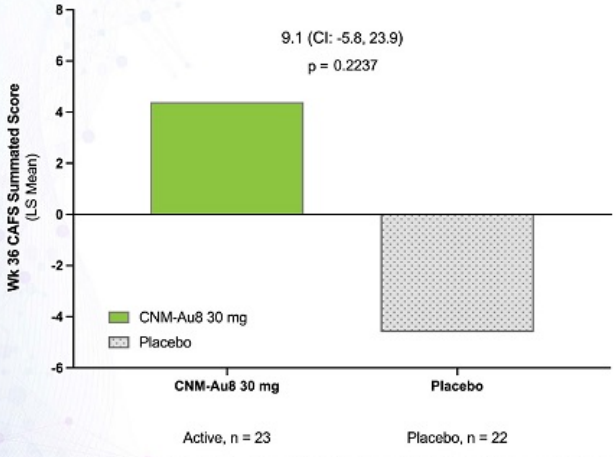
RESCUEALS | Impact on CAFS Progression to Wk36

Exploratory (Combined Assessment of Function & Survival)

By Average of Summated Scores

Combined Assessment of Function (ALSFRS-R) and Survival
RESCUE-ALS Exploratory Endpoint
ANCOVA Model (ITT Population, All Randomized)
Week 36 LS Mean Difference

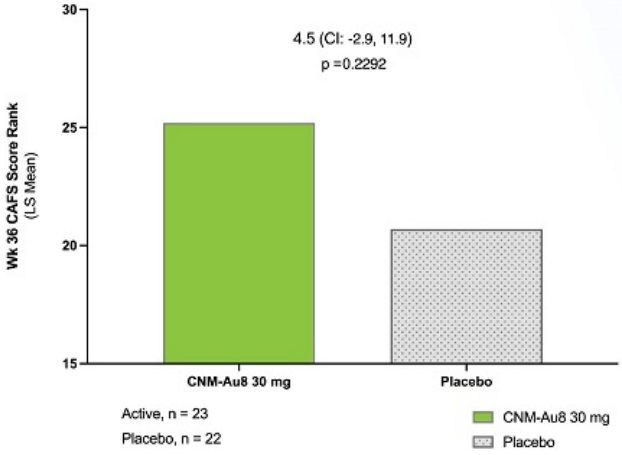


Active, n = 23 Placebo, n = 22

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

By Average of Ranks

Combined Assessment of Functional (ALSFRS-R) and Survival
RESCUE-ALS *Post Hoc* Endpoint
Ranked Analysis (ITT Population, All Randomized)
Week 36 LS Mean Difference



Active, n = 23
Placebo, n = 22

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

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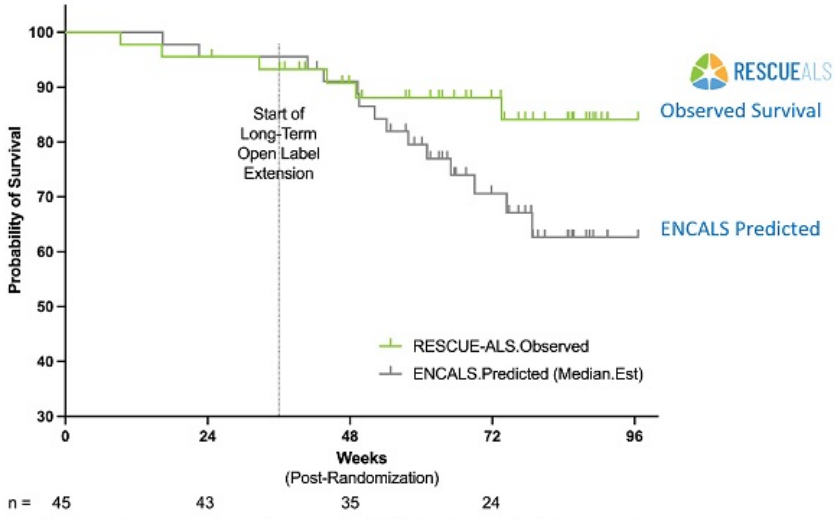
RESCUEALS | Potential Survival Signal

Exploratory Endpoint (Observed Survival vs. Predicted)

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



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

Data on File, Clene Nanomedicine, Inc.

RESCUEALS | Well Tolerated & No Safety Signals

Safety Summary

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

Data on File, Clene Nanomedicine, Inc.

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