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): September 25, 2023

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)

(801) 676-9695

(Registrant's telephone number, including area code)

N/A

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	CLNN	The Nasdaq Capital Market
Warrants, to acquire one-half of one share of Common Stock for $11.50 per share	CLNNW	The Nasdaq Capital Market

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

Emerging growth company ☒

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

Item 7.01 Regulation FD Disclosure.

In connection with the press release discussed under Item 8.01 in this Current Report on Form 8-K, on September 25, 2023, Clene Inc. (the "Company") released an updated corporate presentation (the "Corporate Presentation") on its website, invest.clene.com. A copy of the Corporate Presentation is furnished as Exhibit 99.1 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 99.1, 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, 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 8.01 Other Events.

On September 25, 2023, the Company issued a press release announcing significant long-term survival improvement from CNM-Au8® treatment in the HEALEY ALS Platform Trial compared to PRO-ACT historical controls. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Corporate Presentation.
99.2	Press Release, dated September 25, 2023, announcing significant long-term survival improvement from CNM-Au8 treatment in HEALEY ALS Platform Trial compared to PRO-ACT historical controls.
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: September 25, 2023

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

Exhibit 99.1

Forward Looking Statements

This presentation contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, which are intended to be covered by the "safe harbor" provisions created by those laws. Clene's forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements represent our views as of the date of this presentation and involve a number of judgments, risks and uncertainties. We anticipate that subsequent events and developments will cause our views to change. We undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include our substantial dependence on the successful commercialization of our drug candidates, if approved, in the future; our inability to maintain the listing of our common stock on Nasdaq; our significant net losses and net operating cash outflows; our ability to demonstrate the efficacy and safety of our drug candidates; the clinical results for our drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; our ability to achieve commercial success for our drug candidates, if approved; our ability to obtain and maintain protection of intellectual property for our technology and drugs; our reliance on third parties to conduct drug development, manufacturing and other services; our limited operating history and our ability to obtain additional funding for operations and to complete the licensing or development and commercialization of our drug candidates; the impact of the COVID-19 pandemic on our clinical development, commercial and other operations; changes in applicable laws or regulations; the effects of inflation; the effects of staffing and materials shortages; the possibility that we may be adversely affected by other economic, business, and/or competitive factors; and other risks and uncertainties set forth in "Risk Factors" in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements. All information in this presentation is as of the date of this presentation. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this presentation.

Building the Clinical Case for Neuroprotection & Remyelination

RepairPD
RepairMS

RESCUEALS

HEALEY ALS Platform Trial

VISIONARY-MS STUDY

Demonstrated brain target engagement in early PD and stable relapsing MS patients

CNM-Au8 treatment resulted in statistically significant survival benefit of 75% decreased risk of death through 3.5 years

CNM-Au8 demonstrated a >90% reduction in risk of death or permanently assisted ventilation for the 30 mg dose at 24 weeks

CNM-Au8 demonstrated global neurological improvement in stable relapsing MS **as an adjunct** to immunomodulatory DMTs

Growing Body of Clinical Evidence Across ALS and MS Supports CNM-Au8 Therapeutic Potential to Treat Neurodegenerative Diseases

Proprietary Nanotherapeutic Manufacturing
Strong IP: 150+ granted patents PLUS Trade Secrets

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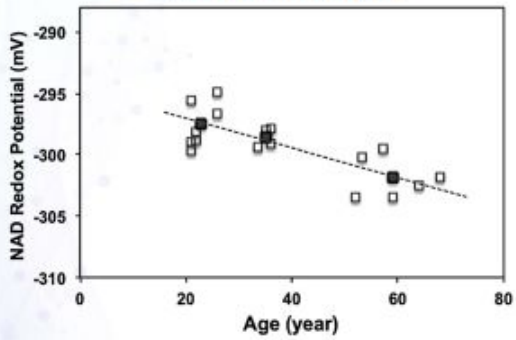
Neurodegenerative Diseases Share A Common Mechanism: A Decline In The Brain's Ability To Produce Energy

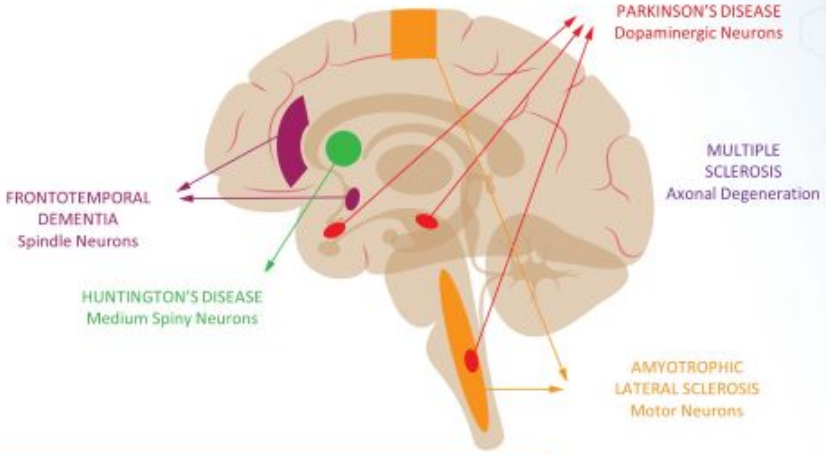
Brain Energy Potential
Declines With Normal Aging



~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



Energetic impairments in the CNS both pre-dispose and drive progression in neurodegenerative diseases

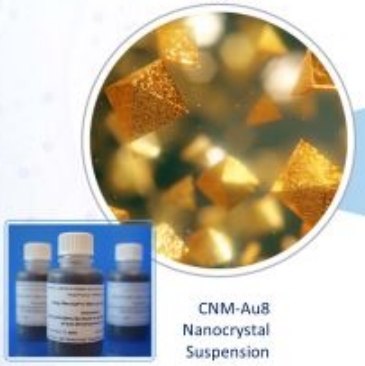
Fu, H., et al; Nature Neuroscience (2018) 21: 1350-1358. Zhu et al. Proc Natl Acad Sci USA 2015 Mar 3;112(9):2876-81. Ilone et al. J Neurosci. 2016 Apr 27;36(17):4698-707.

CLene NANOMEDICINE

CNM-Au8® | **Pioneering A New Drug Class To Improve Cellular Energy Production And Utilization**

CNM-Au8 Nanocrystals

Clean Surfaced, Highly Faceted Shapes



CNM-Au8 Nanocrystal Suspension

Mechanistic Effects

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

=

Improved Energy Production and Utilization

By targeting energy metabolism, CNM-Au8 may protect neuronal health

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

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Significant Global Opportunity for Treatment in Combination with Standard of Care

Motor Neuron Disease (ALS, Other Orphan Disorders)

ALS PATIENTS IN US & EU ~40K[1] $1B GLOBAL SALES BY 2029[3]

Current drugs are largely ineffective, mostly generic.

2-5 YEARS[2] LIFE EXPECTANCY 100% FATAL

Multiple Sclerosis (MS)

MS PATIENTS GLOBALLY 2.2M $23B MARKET[2]

Existing treatments only target immunomodulation

EMERGING EVIDENCE THAT EARLY MS IS NEURODEGENERATIVE

Parkinson's Disease (PD)

2ND MOST COMMON DISORDER $6B PROJECTED BY 2026[4]

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

30% OF DOPAMINERGIC NEURONS ARE LOST AT DIAGNOSIS[5]

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

1. Clarkson, DRG, ALS 2020. 2. https://pubmed.ncbi.nlm.nih.gov/27697351/ 3. Wenzel et al. 2017, doi:10.3390/ijms18071591. 4. Parkinson's Market Data Forecast, April 2021. 5. Cheng HC, Ulane CM, Burke RE. Clinical progression in Parkinson disease and the neurobiology of axons. Ann Neurol 2010;67:715-725.

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Two REPAIR Trials Demonstrated Target Brain Engagement and Improved Energy Metabolism in Early Parkinson's and Stable Relapsing MS

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

RepairPD
Early Parkinson's Disease

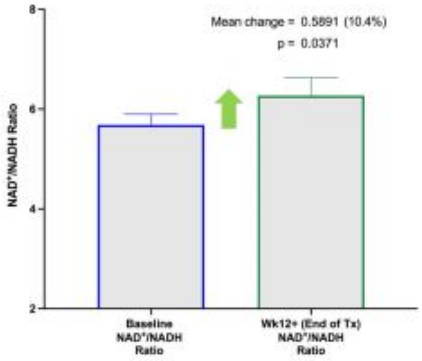
RepairMS
Stable Relapsing MS

RepairMS
Non-Active Progressive MS
(Ongoing)

Results demonstrated a potentially meaningful 10% improvement in NAD+/NADH ratio, an essential molecule for energy production[1]

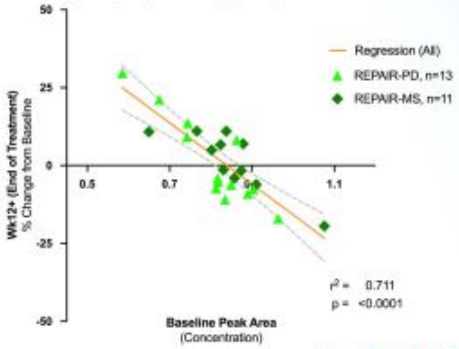
1° Endpoint (integrated PD & MS)[2]

^{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)



Exploratory
(ATP Normalization)

REPAIR Integrated Analysis
^{31}P-MRS Change in β-ATP at End of Treatment
Full Volume Coil ^{31}P Signal Area (Integral)
Exploratory Endpoint, Percent (%) Change vs. Baseline Value



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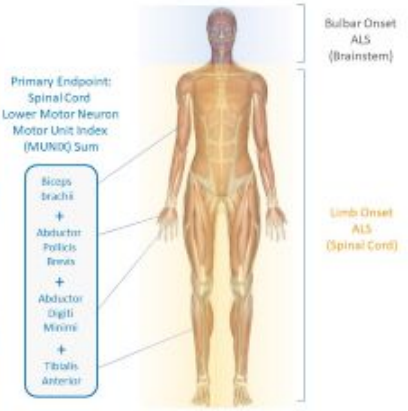
[1]Zhu et al. Proc Natl Acad Sci USA 2015 Mar 3;112(9):2876-81.; 2. Glanzman et al Improvement of Brain Energy Metabolism in Relapsing Multiple Sclerosis Patients - Results from Phase 2 REPAIR-MS Clinical Trial With CNM-Au8, ACTRIMS February 2022

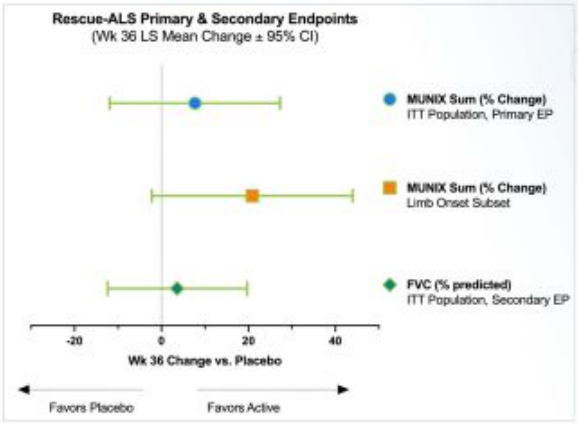
RESCUEALS Encouraging Efficacy Signals in Phase 2 Trial

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

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



1° & 2° Endpoints



Results favor CNM-Au8 treatment

Vucic et al. EClinicalMedicine. 2023 Jun 8;60:102036.
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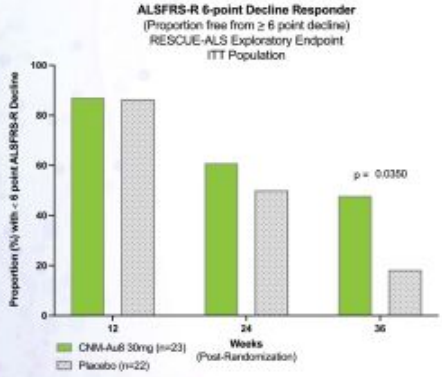
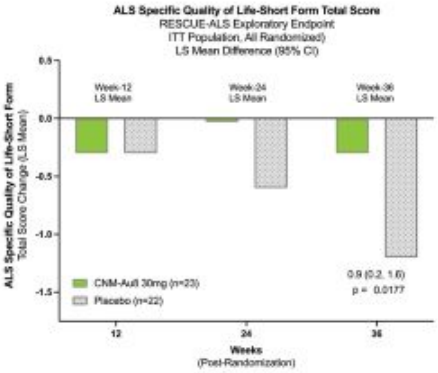
CNM-Au8 Improved Patient Function, QOL, and Slowed Time to ALS Clinical Worsening

Phase 2 Study: 36-Week Placebo-Control Treatment Period 1:1 Randomization (Active 30 mg: Placebo); N=45 enrolled with early ALS

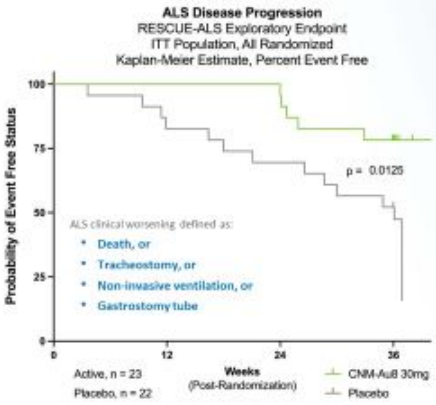
Proportion with <6 point decline



ALS Specific QOL



ALS Clinical Worsening

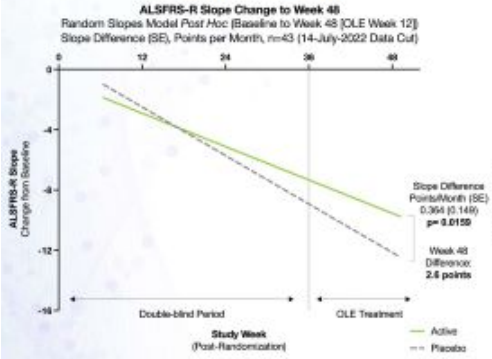


Vucic et al. EClinicalMedicine. 2023 Jun 8;60:102036.

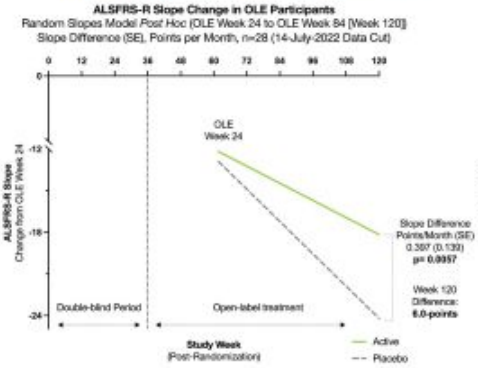
RESCUEALS OLE | Preserved ALSFRS-R Functional Decline

Early CNM-Au8 Treatment Impacts Long-Term Function Compared to Original Placebo

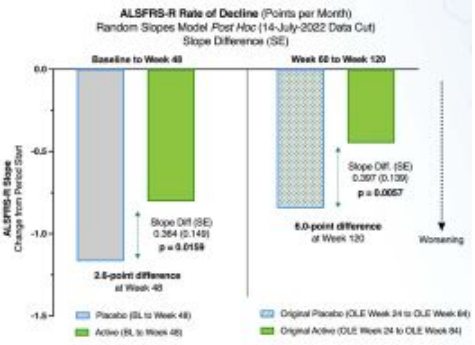
ALSFRS-R Slope Baseline to Week 48



ALSFRS-R Slope Week 60 [OLE Week 24] to Week 120



ALSFRS-R Slope Summary



- CNM-Au8 preserved functional decline: ALSFRS-R of 2.6 points at 48 weeks compared to placebo
- Early CNM-Au8 treatment preserved long-term ALSFRS-R score by 6.0 points vs. OLE original placebo

OLE 12-month LPLV data cut of July 14, 2022.

Vucic et al. EClinicalMedicine. 2023 Jun 8;60:102036.

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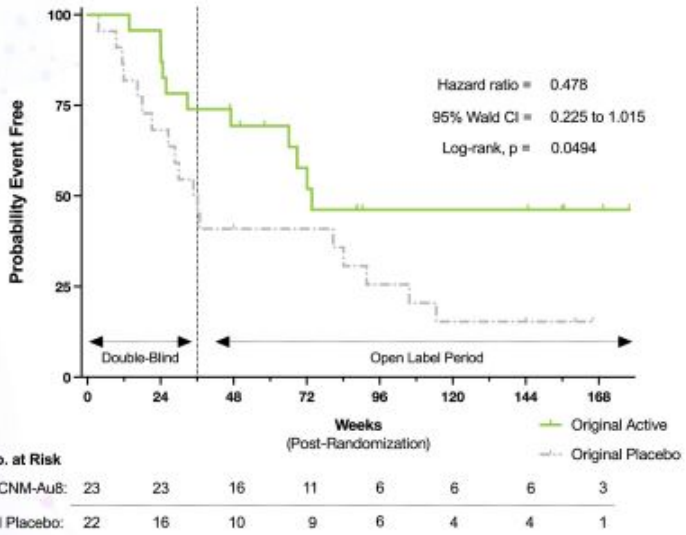
RESCUEALS OLE | Reduced Risk of ALS Clinical Worsening

ALS Clinical Worsening Events
Time to Death, Tracheostomy, Assisted Ventilation, or Feeding Tube
RESCUE-ALS Double-Blind & OLE Periods (24-month LPLV data cut)
Proportion Event Free, Kaplan-Meier Analyses



No. at Risk								
Original CNM-Au8:	23	23	16	11	6	6	6	3
Original Placebo:	22	16	10	9	6	4	4	1

The risk of ALS clinical worsening was decreased 52% for CNM-Au8 compared to placebo in OLE up to 168 weeks

Clinical worsening events included:

- Death,
- Tracheostomy,
- Need for non-invasive ventilatory support, or
- Gastrostomy (feeding) tube placement.

Participants were right-censored at loss of follow-up with OLE withdrawal, as applicable

Data on File, Clene Nanomedicine, Inc.

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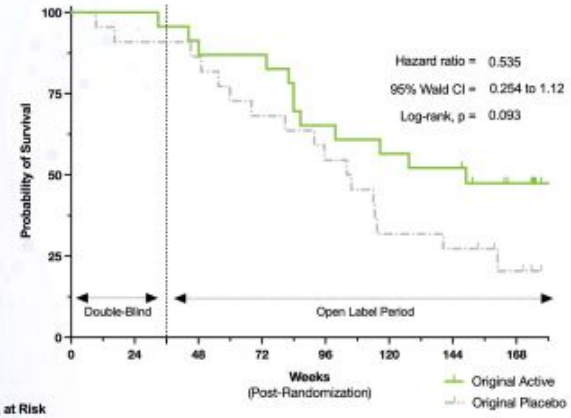
RESCUEALS Survival Benefit vs. Original Placebo up to 3.5 years

Unadjusted Survival Difference: 10.1 Month

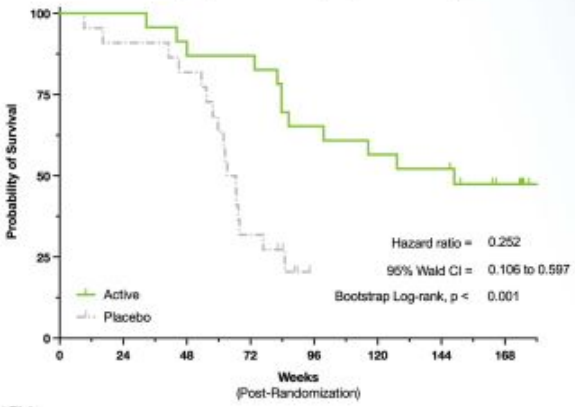
Overall Survival (All-Cause Mortality)
RESCUE-ALS (24-month LPLV data cut), ITT Population (n=45)
Proportion Event Free, Kaplan-Meier Analyses



No. at Risk								
Original CNM-Au8:	23	23	21	21	16	14	13	8
Original Placebo:	22	21	20	16	13	8	7	7

Cross-Over Adjusted Survival Difference: 19.3 Month

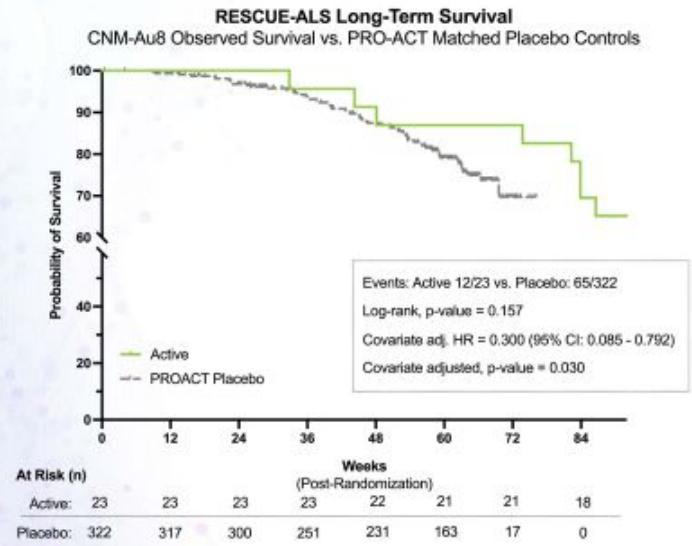
Cross-Over Adjusted Analysis of Survival
RESCUE-ALS (24-month LPLV data cut), ITT Population (n=45)
RPSTFM, Proportion Event Free, Kaplan-Meier Analyses



No. at Risk								
Original CNM-Au8:	23	23	21	21	16	14	13	8
Original Placebo:	22	21	19	8	1	0	0	0

Data on File, Clene Nanomedicine, Inc.

Consistent Long-Term Survival Benefit Compared to Historical Matched PRO-ACT Placebo Controls



At Risk (n)								
Active:	23	23	23	23	22	21	21	18
Placebo:	322	317	300	251	231	163	17	0

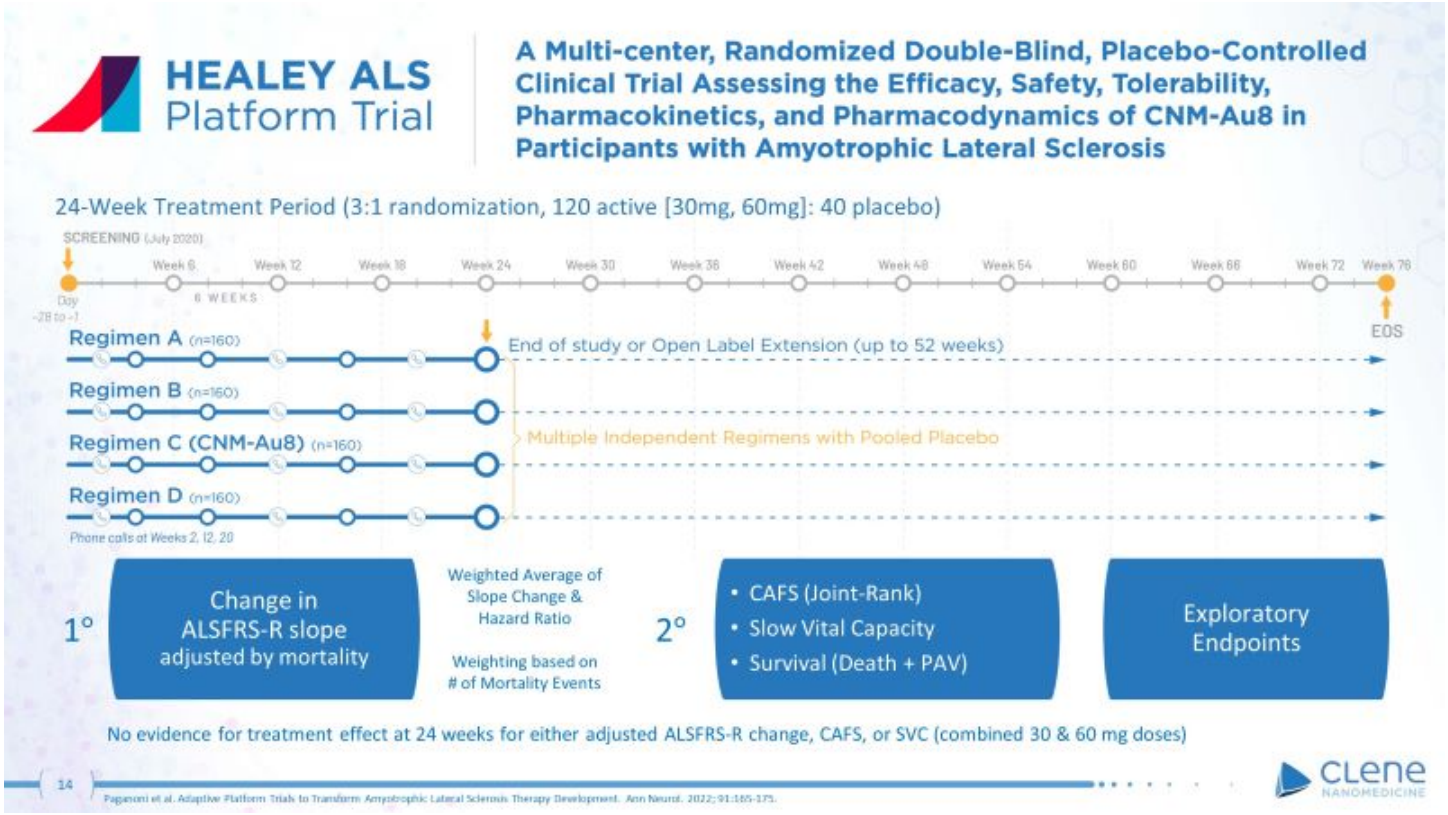
CNM-Au8 treatment demonstrated a significant survival benefit:

- Follow-up of active compared to matched placebo from PRO-ACT
- 70% decreased risk of death

PRO-ACT contains approximately 12,000 patient records from multiple completed clinical trials.

Time to all-cause mortality amongst participants originally randomized to CNM-Au8 compared to propensity matched placebo controls derived from the PRO-ACT database (n=322). Covariates included: Onset Age, Sex, BMI, Pre-Treatment ALSFRS-R Slope (Delta-FS), ALSFRS-R Total Score, Vital Capacity (% predicted), and Diagnostic Delay (Covariates selected by minimizing AICc).

Data on File, Clene Nanomedicine, Inc.


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
24-Week Treatment Period (3:1 randomization, 120 active [30mg, 60mg]: 40 placebo)
SCREENING (July 2020)
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
Day -28 to -1
6 WEEKS
EOS
Regimen A (n=160)
Regimen B (n=160)
Regimen C (CNM-Au8) (n=160)
Regimen D (n=160)
End of study or Open Label Extension (up to 52 weeks)
Multiple Independent Regimens with Pooled Placebo
Phone calls at Weeks 2, 12, 20
1°
Change in ALSFRS-R slope adjusted by mortality
Weighted Average of Slope Change & Hazard Ratio
Weighting based on # of Mortality Events
2°
• CAFS (Joint-Rank)
• Slow Vital Capacity
• Survival (Death + PAV)
Exploratory Endpoints
No evidence for treatment effect at 24 weeks for either adjusted ALSFRS-R change, CAFS, or SVC (combined 30 & 60 mg doses)
14
Paganoni et al. Adaptive Platform Trials to Transform Amyotrophic Lateral Sclerosis Therapy Development. Ann Neurol. 2022;91:165-175.
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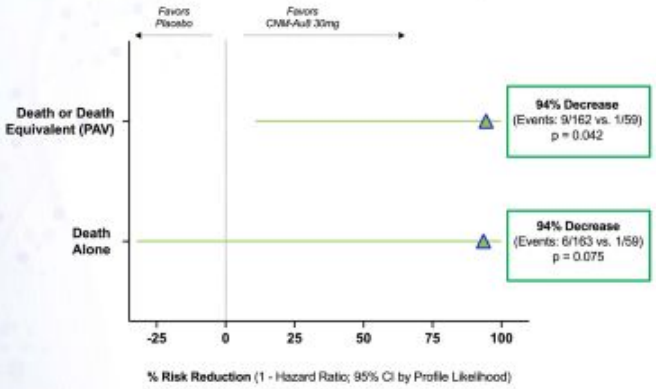
Survival Signal | >90% Reduced Risk of Death with CNM-Au8 30mg

HEALEY ALS Platform Trial

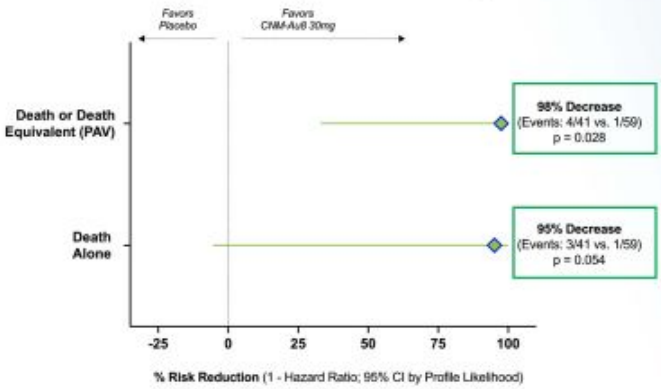
Shared Placebo Across Regimens

CNM-Au8 30mg Survival | Adjusted Cox Proportional Hazard
Full Analysis Set (All Shared Placebo, Regimens A, B, C, D)
% Hazard Reduction at Week 24
(1 - Hazard Ratio, 95% Confidence Interval)



CNM-Au8 Regimen Only (Regimen C)

CNM-Au8 30mg Survival | Adjusted Cox Proportional Hazard
Efficay Regimen Only Set (Within Regimen Analysis)
% Hazard Reduction at Week 24
(1 - Hazard Ratio, 95% Confidence Interval)



PAV = Permanently Assisted Ventilation; Prespecified covariate adjustments include: (i) time from symptom onset, (ii) pre-baseline ALSFRS-R slope, (iii) riluzole use, (iv) edaravone use, (v) age. Events (placebo vs. active). p-values are not adjusted for multiple comparisons; exploratory analyses by dose.

Data on File, Clene Nanomedicine, Inc.

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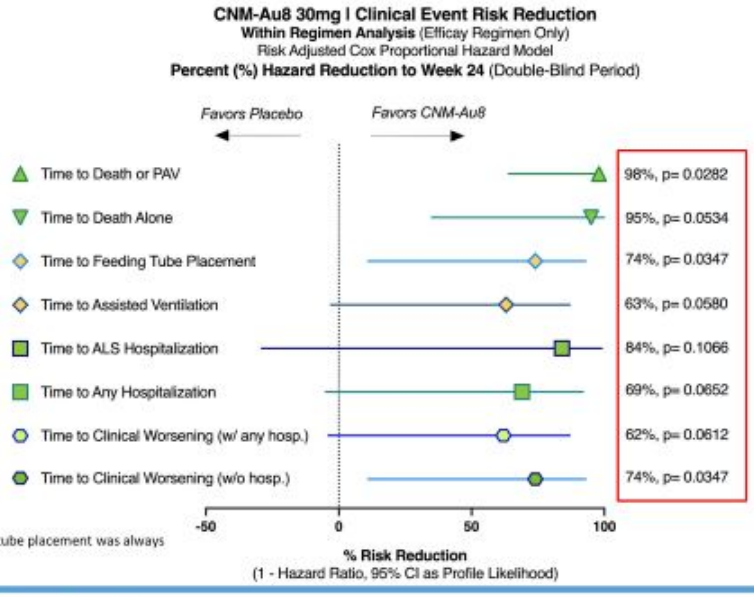
Delayed Time to Clinical Event Summary

CNM-Au8 30mg | Within Regimen Analysis (Primary Model)

HEALEY ALS Platform Trial

CNM-Au8 30mg delayed time to clinical worsening at 6 months

- Death
- Tracheostomy
- Permanent Assisted Ventilation (NIV >22 hours per day)
- Feeding Tube Placement



Supportive sensitivity analyses incorporating baseline neurofilament light chain (NfL) levels were similarly robust and resulted in increased effect sizes and smaller nominal p-values.

Prespecified covariate risk adjustments included: (i) time from symptom onset, (ii) pre-baseline ALSFRS-R slope, (iii) riluzole use, (iv) edaravone use, and (v) age.

For the within regimen (ERO) analysis, feeding tube placement was always the first initiating event for the composite.

Data on File, Clene Nanomedicine, Inc.

CLene NANOMEDICINE

Plasma NfL Difference | CNM-Au8 vs. Placebo

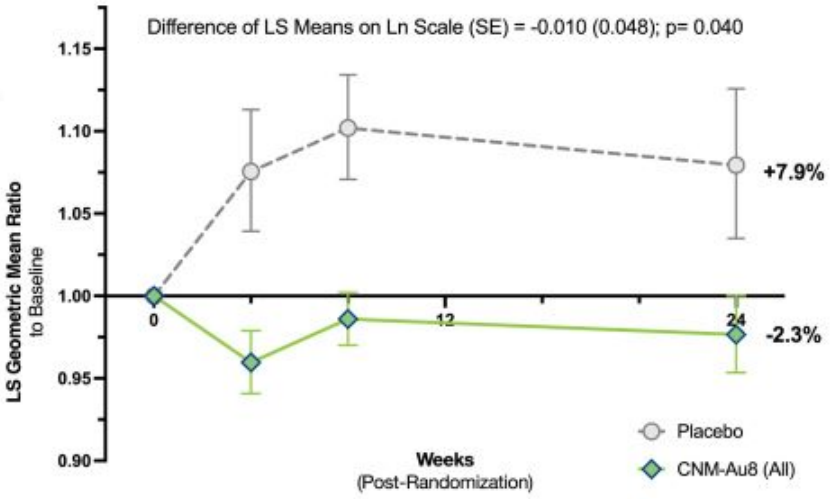
All RGC Participants

HEALEY ALS Platform Trial

Plasma NfL

RGC Within Regimen Analyis | Quanterix 4NPA

All RCG (n=161); Difference of LS Means on Ln Scale (SE)



MMRM log NfL by group, contrast model; prespecified covariates included: (i) pre-treatment ALSFRS-R slope (delta-FS), (ii) months from symptom onset, (iii) use of riluzole, (iv) use of edaravone; (v) covariate by visit interaction, (vi) treatment by visit interaction

Data on File, Clene Nanomedicine, Inc.

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Long-Term Survival | Propensity Matched Placebo

PRO-ACT Placebo Matching vs. Regimen C CNM-Au8 30mg

HEALEY ALS Platform Trial

Baseline Values Mean (SD) or Percent (%)	HEALEY Regimen C		Integrated Meta-Analysis	
	CNM-Au8 30mg (n=59)	PRO-ACT Placebo Matches (i) (n=322)	CNM-Au8 30mg (n=82)	PRO-ACT Placebo Matches (ii) (n=322)
Onset Age	55.4 (10.4)	55.5 (11.0)	55.4 (11.1)	55.0 (11.4)
Sex (Male, %)	56%	62%	56%	65%
BMI (kg/m²)	27.4 (5.3)	26.5 (4.9)	27.2 (5.2)	26.6 (5.0)
ALSFRS-R (Total Score)	34.5 (5.8)	37.7 (5.5)	35.7 (6.3)	37.9 (5.5)
Delta-FS (Pre-treatment slope)	0.77 (0.58)	0.75 (0.50)	0.76 (0.57)	0.74 (0.51)
Vital Capacity (% predicted)	74.4 (16.0)	89.2 (17.0)	77.3 (17.1)	89.3 (16.9)
Diagnostic Delay (months)	9.8 (5.2)	8.8 (5.2)	10.6 (6.1)	8.9 (5.4)
Site of Onset (Bulbar, %)	17%	20%	21%	20%
Riluzole Treatment (%)	76%	98%	82%	98%

Source(s): Data on File, Cene Nanomedicine, Inc. (Table 14.1.4.1.1 Pooled vs. PROACT; Table 14.1.4.1.2 Healey vs. PROACT)
Notes: Vital capacity reported as SVC or FVC based on individual study characteristics.

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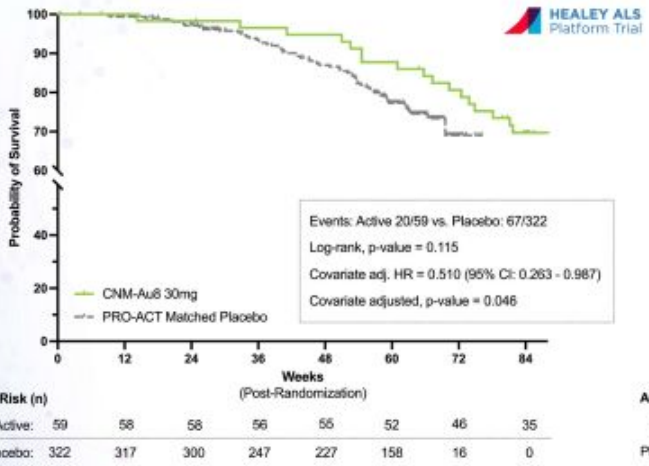
Long-Term Survival | Propensity Matched Placebo

PRO-ACT Placebo vs. CNM-Au8 30mg

CNM-Au8 30mg HEALEY

HEALEY-ALS Platform Long-Term Survival

CNM-Au8 30mg Observed Survival vs. PRO-ACT Matched Placebo Controls

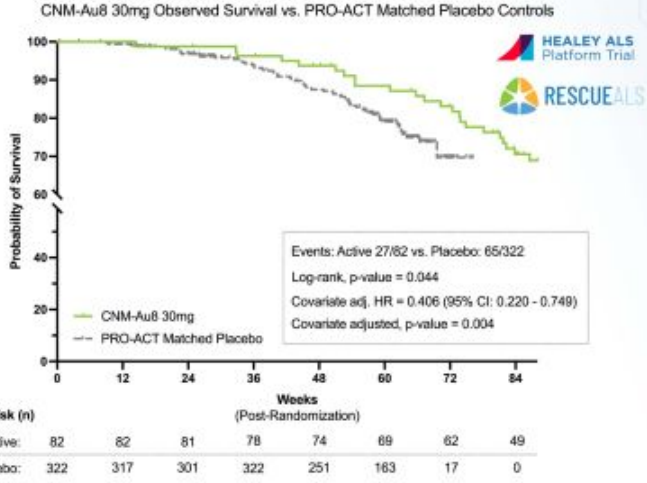


At Risk (n)								
Active:	59	58	58	56	55	52	46	35
Placebo:	322	317	300	247	227	158	16	0

CNM-Au8 30mg Integrated Meta-Analysis

Integrated Meta-Analysis of CNM-Au8 30mg Long-Term Survival
RESCUE-ALS + HEALEY ALS Platform Trial

CNM-Au8 30mg Observed Survival vs. PRO-ACT Matched Placebo Controls



At Risk (n)								
Active:	82	82	81	78	74	69	62	49
Placebo:	322	317	301	322	251	163	17	0

Covariates: Onset Age, Sex, BMI, Pretreatment ALSFRS-R Slope, ALSFRS-R Total at Baseline, Vital Capacity % at Baseline, Diagnostic Delay

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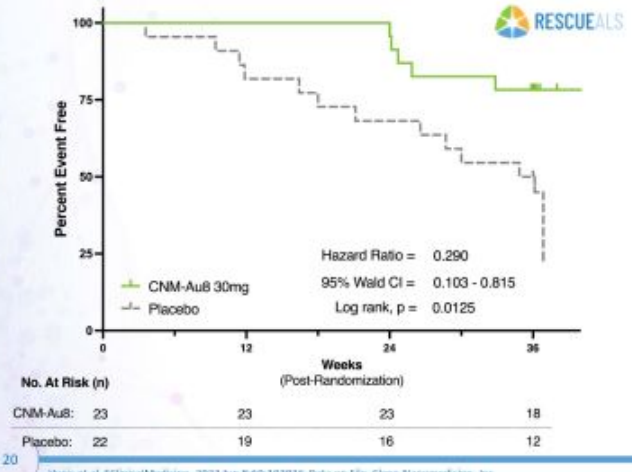
CNM-Au8 | ALS Clinical Worsening Summary

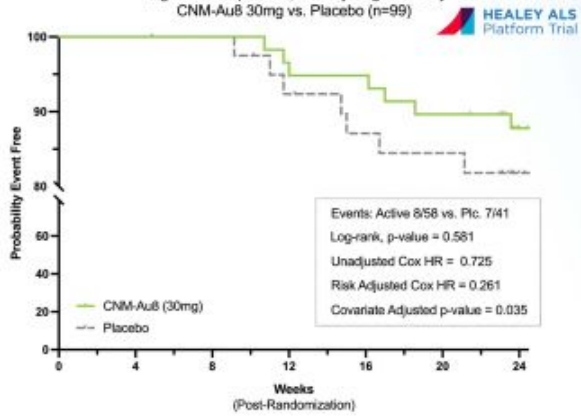
Evidence for Decreased Clinical Worsening Events Across Two Phase 2 Studies

Phase 2 RESCUE-ALS CNM-Au8 30mg
Decreased Time to Clinical Worsening



No. At Risk (n)				
CNM-Au8:	23	23	23	18
Placebo:	22	19	16	12

Phase 2 HEALEY ALS Platform CNM-Au8 30mg
Decreased Time to Clinical Worsening



Vucic et al. EClinicalMedicine. 2023 Jun 8;60:102036. Data on File, Clene Nanomedicine, Inc.

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CNM-Au8 Has Demonstrated ALS Survival Benefit at 30mg Dose in Two Phase 2 Studies

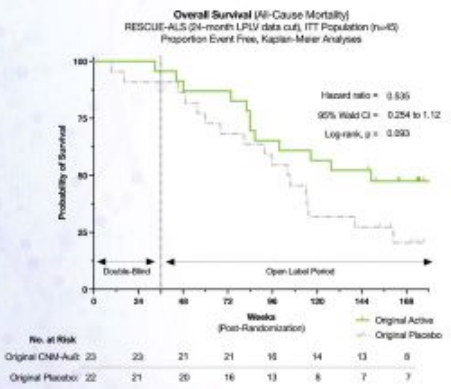
RESCUEALS

Up to 75% decreased risk of death through 168 weeks

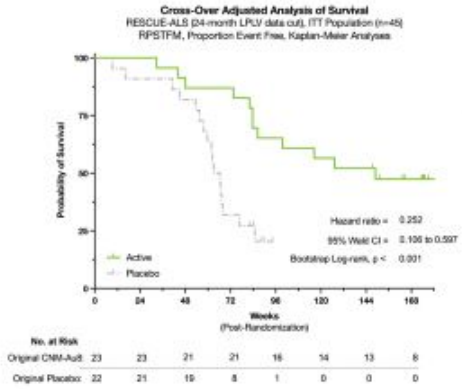
HEALEY ALS Platform Trial

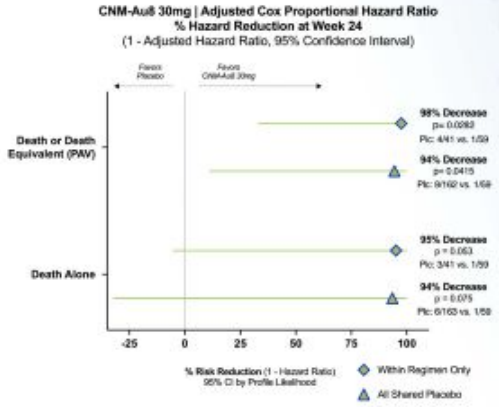
>90% risk reduction of death at 30mg at 24 weeks

Unadjusted Survival



Cross-Over Adjusted Survival





Data on File, Clene Nanomedicine, Inc.

CLene NANOMEDICINE

Promising Evidence from Two Phase 2 Trials and Long-Term Data

CNM-Au8 Demonstrated Survival, Delayed Clinical Worsening, and Preserved Function

	RESCUE-ALS	RESCUE-OLE	HEALEY ALS Platform	HEALEY OLE	EAP
ALS Patient Demographics	Early-to-Mid-Stage	Early-to-Mid-Stage	Mid-to-Late-Stage	Mid-to-Late-Stage	Real-World Experience
Duration	36-weeks	Up to 173 weeks	24-weeks	Through April '23	Up to 3.8 years
Survival	--	✓	✓	✓ PRO-ACT	✓
Delayed Time to Clinical Worsening	✓	✓	✓	Pending data 2H 2023	Not routinely collected
Preserved Function (ALSFRS-R)	--	✓	--		
Progression Biomarkers	p75 trend	UCHL1 ↓*	✓		

Consistent Evidence for CNM-Au8 30mg Dose Across Broad ALS Patient Population

Data on File, Clene Nanomedicine, Inc. *Small sample available for analyses in RESCUE OLE

HEALEY ALS Platform Safety Summary

- Occurrence of TEAEs were balanced between CNM-Au8 and placebo
- No SAEs were assessed as related to CNM-Au8

Treatment Emergent Adverse Events (TEAEs)	All Shared Placebo (%)	Regimen Placebo (%)	CNM-Au8 30 mg (%)	CNM-Au8 60 mg (%)
Participants with Any TEAE	90%	93%	92%	93%
Participants with Related TEAEs	39%	34%	29%	43%
Participants with SAE	9%	17%	10%	16%
Participants with Related SAEs	1%	2%	0%	0%
Participants Withdrawn due to TEAE	7%	7%	7%	7%

All Shared Placebo (n=164 placebo from Regimens A, B, C, D); Regimen placebo (n=41) includes only concurrent randomization within Regimen C (CNM-Au8)

Data on File, Clene Nanomedicine, Inc.

VISIONARY-MS STUDY Core Design Elements

Phase 2 Study: 48-Week Placebo-Control Treatment Period 2:1 Randomization (Active [15mg, 30 mg]: Placebo)

- Enrolled stable relapsing remitting MS participants with chronic optic neuropathy on background DMTs
- 92% treated with background DMTs (inc 53% monoclonal antibodies, 32% oral)
- n=73 of 150 planned (~50%) study ended prematurely due to COVID-19 pandemic enrollment challenges
- Modified ITT (mITT) Analysis Population; Pre-specified statistical threshold set at p=0.10
- CNM-Au8 Open Label Extension (OLE) for original active and placebo continues for up-to-96 weeks

1° Change in Low Contrast Letter Acuity (LCLA)

2° Change in modified MS Functional Composite (mMSFC)

9HPT SDMT T25FWT LCLA

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

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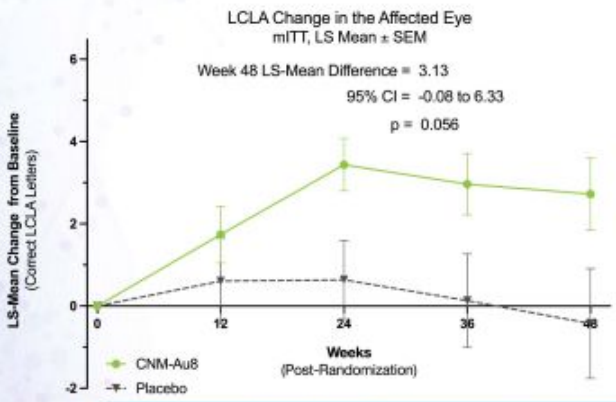
CNM-Au8 Demonstrated Vision and Global Neurological Improvement in Stable MS patients on DMTs

VISIONARY-MS STUDY

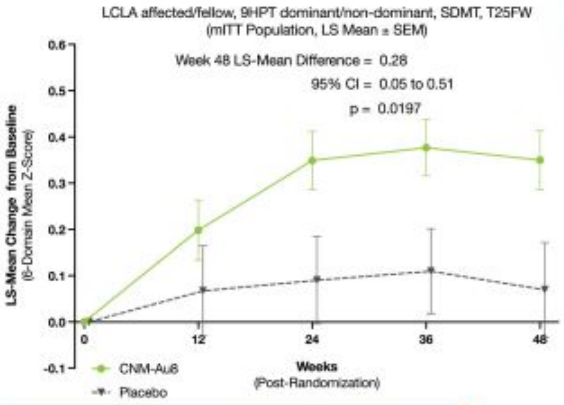
Significantly Improved Vision

Change in Low Contrast Letter Acuity (LCLA)



Global Neurological Improvement

Change in modified MS Functional Composite (mMSFC)



Global neurological clinical improvement was driven by cognition, manual dexterity, and low contrast letter acuity

Data on File, Clene Nanomedicine, Inc.

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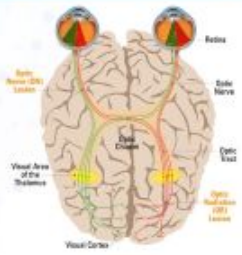
CNM-Au8 Improved Information Signal in the Visual Pathway

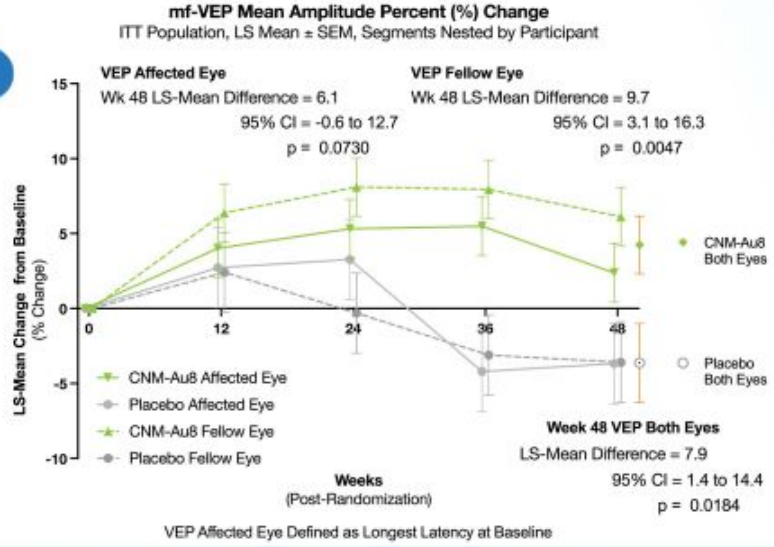
VISIONARY-MS STUDY

Visual Evoked Potentials (VEP)



Increased Amplitude (Signal Strength)

From the Eye to the Brain's Visual Cortex



Increased VEP amplitude is associated with improved axonal integrity; provides evidence that previously impaired neurons can contribute to information signaling after treatment

Data on File, Clene Nanomedicine, Inc.

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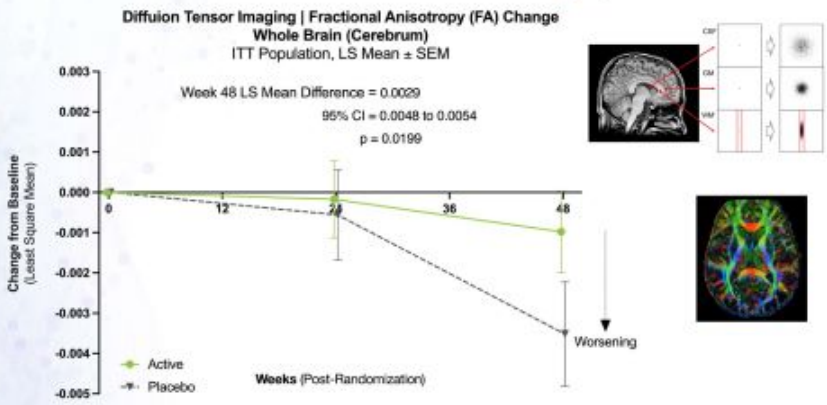
CNM-Au8 Preserved White Matter Integrity Throughout the Brain

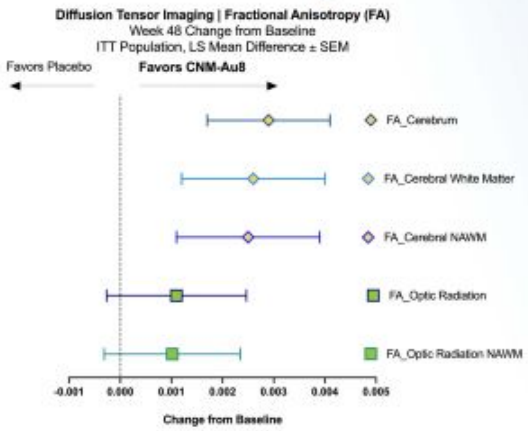
VISIONARY-MS STUDY

Advanced MRI Techniques

Preserved Whole Brain White Matter Integrity



Consistent Effect Across All Brain Regions



Preservation of white matter integrity associated with decreased cognitive and functional decline in MS patients

Data on File, Clene Nanomedicine, Inc.

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Over 500 Years of Subject Exposure Without Identified Safety Signals Across ALS, MS, and PD

Clean Toxicology Findings

All Animal Toxicology Studies Resulted in No-Adverse Effect Level (NOAEL) Findings

- Multiple species up to 9-months treatment
- Up to maximum feasible dosing without any toxicology findings related to CNM-Au8

Well Tolerated Adverse Event (AE) Profile

Assessed as Predominantly Mild-to-Moderate Severity and Transient

- No SAEs related to CNM-Au8 considered severe, life-threatening, or resulting in death
- AEs transient and predominantly mild-to-moderate severity

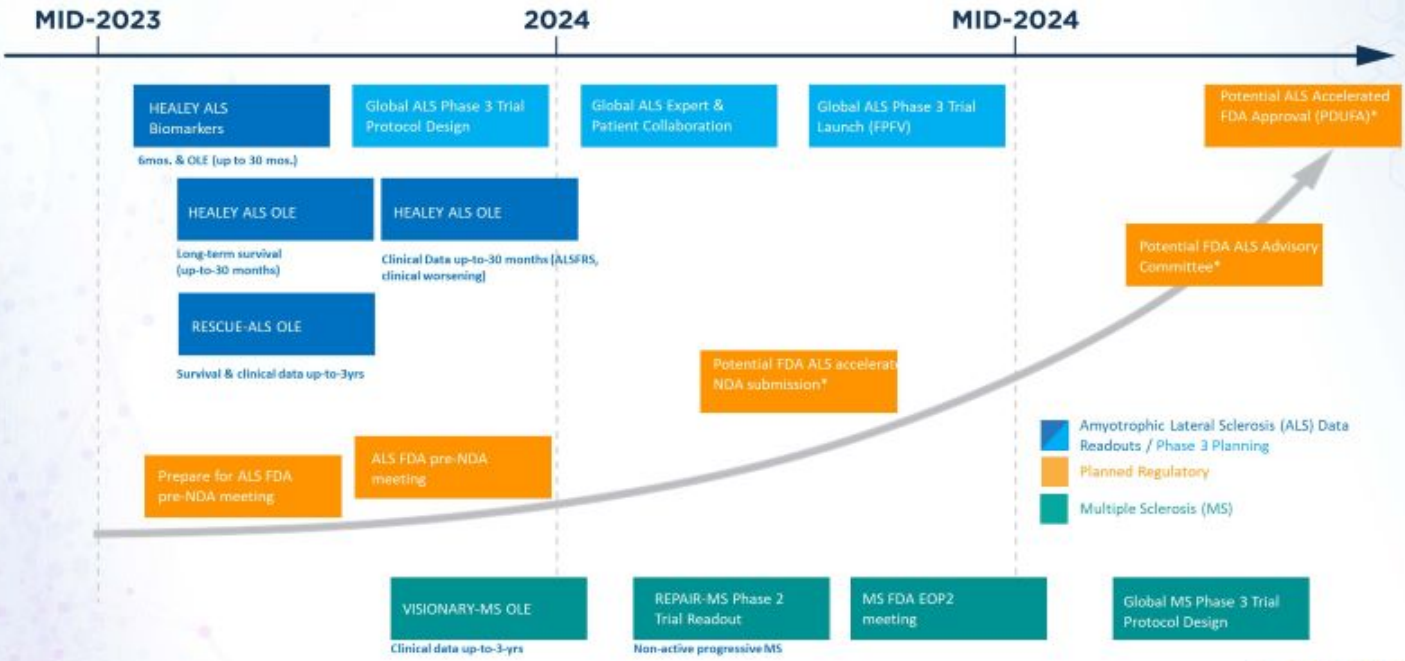
Patient Exposure Across ALS, MS & PD

Over 500 Years of Subject Exposure Without Identified Safety Signals

- Long-term dosing experience up to 4 years

Data on File, Clene Nanomedicine, Inc. MS: Multiple Sclerosis, ALS: Amyotrophic lateral sclerosis, and PD: Parkinson's Disease.

Clene | CNM-Au8 Path to Regulatory Approval



Evidence Supports CNM-Au8 Therapeutic Potential to Treat Neurodegenerative Diseases

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

RESCUEALS

75% decreased risk of death in ALS through 168 weeks

HEALEY ALS Platform Trial

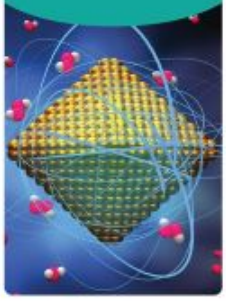
>90% decreased risk of death with 30 mg in ALS

VISIONARY-MS

Demonstrated global neurological improvement in MS patients on adjunctive DMT standard of care

>475
patient years of CNM-Au8 clinical exposure

Strong IP:
150+
patents on nanotherapeutic platform



As of June 30, 2023, cash and equivalents on hand (unaudited):

$49.2M

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

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Version: 25-September-2023

Exhibit 99.2

CLENE REPORTS SIGNIFICANT LONG-TERM SURVIVAL IMPROVEMENT FROM CNM-Au8 TREATMENT IN HEALEY ALS PLATFORM TRIAL COMPARED TO PRO-ACT HISTORICAL CONTROLS

- *Prolonged life with 49% decreased risk of death for participants in the HEALEY ALS Platform Trial treated with CNM-Au8® 30mg compared to PRO-ACT matched placebo over long-term follow-up, p=0.046*
- *Prolonged life with 59% decreased risk of death for participants in an integrated meta-analysis across HEALEY ALS Platform Trial and RESCUE-ALS Trial with CNM-Au8® 30mg compared to PRO-ACT matched placebo over long-term follow-up, p=0.004*
- *More than 500 patient years of CNM-Au8 treatment exposure without any identified safety signals*

SALT LAKE CITY, Sept. 25, 2023 -- Clene Inc. (Nasdaq: CLNN) through its wholly owned subsidiary Clene Nanomedicine, Inc. (collectively "Clene"), today announced long-term follow-up data for patients treated with CNM-Au8® 30mg for up to 133 weeks in the HEALEY ALS Platform Trial. These *post hoc* results show significantly improved survival with a 49% decreased risk of death for the covariate risk-adjusted analyses compared to the largest U.S. clinical database of previous amyotrophic lateral sclerosis (ALS) trials (PRO-ACT) (hazard ratio: 0.510, 95% CI: 0.263 - 0.987, p=0.046).

The HEALEY ALS Platform Trial is a perpetual multi-center, randomized, double-blind, placebo-controlled clinical trial program designed to evaluate the efficacy and safety of multiple investigational products in people living with ALS. Enrollment in the CNM-Au8 Regimen was initiated in the summer of 2020. Participants received CNM-Au8 in addition to ALS standard-of-care and were randomized to the drug or placebo during the 24-week double-blind period. CNM-Au8 was then offered to all participants who were eligible, and 92% elected to continue into the Open Label Extension (OLE). CNM-Au8 30mg was selected as the dosage going forward after the double-blind period.

In ALS, clinical studies with shorter double-blind treatment duration such as 24 weeks have used historical placebo controls from prior trials to determine the relative survival benefit of investigational treatment over longer-term follow-up (open label data). The PRO-ACT dataset is derived from pooled ALS clinical trial data from 29 completed Phase 2 and Phase 3 ALS clinical trials. Millions of de-identified longitudinally collected records from more than 11,600 individuals with ALS were standardized across trials and merged to create the Pooled Resource Open-Access ALS Clinical Trials (PRO-ACT) database. This database provides a useful and validated surrogate for survival status of past participants in ALS clinical trials with long-term follow-up.

In this analysis, 59 participants who were originally randomized to CNM-Au8 30mg were compared to matched placebo participants derived from the PRO-ACT dataset:

Survival Improvement

- Originally randomized CNM-Au8 30mg treated participants (n=59) demonstrated a statistically significant 49% decreased risk of death compared to PRO-ACT matched placebo patients through long-term follow-up (covariate adjusted HR=0.510; 95% CI 0.263-0.987, p=0.046).
- In a pooled analysis of the HEALEY ALS Platform Trial and the RESCUE-ALS Trial, participants originally randomized to CNM-Au8 30mg (n=82) demonstrated a statistically significant 59% decreased risk of death compared to PRO-ACT matched placebo patients through long-term follow-up (covariate adjusted HR=0.406, 95% CI: 0.220-0.749, p=0.004).

Safety

- More than 500 estimated years of collective exposure across ALS, multiple sclerosis (MS), and Parkinson's disease participants in CNM-Au8 clinical trials and Expanded Access Protocol (compassionate use) programs without any observed safety signals.
- No serious adverse events have been assessed as related to CNM-Au8 treatment; adverse events observed with CNM-Au8 have been characterized as transient and predominantly mild-to-moderate in severity.

Benjamin Greenberg, M.D., Head of Medical at Clene, added, "To show such profound survival improvement using the HEALEY ALS Platform Trial data set alone and a pooled HEALEY and RESCUE data set is remarkable, and helps confirm the survival benefit seen in the prespecified secondary endpoint. Clene is extremely gratified to see this consistent long-term survival data from the HEALEY ALS Platform Trial OLE, with a continued clean safety profile, adding to the totality of the survival evidence."

Merit Cudkowicz, M.D., Chair, Neurology Department, Massachusetts General Hospital, Director, Sean M Healey & AMG Center for ALS, and the Principal Investigator of the HEALEY ALS Platform Trial, said, "Improved survival status is an important measure of drug effect. We previously reported a benefit for decreased risk of death or permanent assisted ventilation and delayed time-to-clinical-worsening events associated with CNM-Au8 30mg from the double-blind period, and we are pleased to see these data from our long-term follow-up as further support of a survival signal in our HEALEY ALS Platform Trial." She concluded, "I am also happy to see how helpful a shared open-source dataset such as PRO-ACT is to the field to analyze data from the OLE portions of clinical trials. We encourage all companies working in ALS to contribute their data to PRO-ACT once their trial is complete. I want to also thank all the people with ALS who are part of clinical trials and are helping the community find new treatments."

About Clene

Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene"), and its wholly owned subsidiary Clene Nanomedicine Inc., is a late clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis, Parkinson's disease, and multiple sclerosis. CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc. 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" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, which are intended to be covered by the "safe harbor" provisions created by those laws. Clene's forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements represent our views as of the date of this press release and involve a number of judgments, risks and uncertainties. We anticipate that subsequent events and developments will cause our views to change. We undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include our ability to demonstrate the efficacy and safety of our drug candidates; the clinical results for our drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; our ability to achieve commercial success for our drug candidates, if approved; our limited operating history and our ability to obtain additional funding for operations and to complete the development and commercialization of our drug candidates; and other risks and uncertainties set forth in "Risk Factors" in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements. All information in this press release is as of the date of this press release. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this press release.

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