Brainstorm Cell Therapeutics

Nasdaq: BCLI

Safe Harbor Statement

Statements in this announcement other than historical data and information constitute "forward-looking statements" and involve risks and uncertainties that could cause Brainstorm Cell Therapeutics Inc.'s actual results to differ materially from those stated or implied by such forward-looking statements. Terms and phrases such as "may", "should", "would", "could", "will", "expect", "likely", "believe", "plan", "estimate", "predict", "potential", and similar terms and phrases are intended to identify these forward-looking statements. The potential risks and uncertainties include, without limitation, risks associated with Brainstorm's limited operating history, history of losses; minimal working capital, dependence on its license to Ramot's technology; ability to adequately protect the technology; dependence on key executives and on its scientific consultants; ability to obtain required regulatory approvals; and other factors detailed in Brainstorm's annual report on Form 10-K and quarterly reports on Form 10-Q available at http://www.sec.gov. These factors should be considered carefully, and readers should not place undue reliance on Brainstorm's forward-looking statements. The forward-looking statements contained in this press release are based on the beliefs, expectations and opinions of management as of the date of this press release. We do not assume any obligation to update forward-looking statements to reflect actual results or assumptions if circumstances or management's beliefs, expectations or opinions should change, unless otherwise required by law. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Brainstorm Cell Therapeutics: A Clinical Stage Biotechnology Company

Our Mission	Brainstorm pioneers autologous cell therapies for neurological disorders, focusing on ALS and MS
Flagship Product	NurOwn® - a cutting-edge autologous cell therapy platform
Strong Pipeline	NurOwn® innovative therapy serves as a platform for treating neurodegenerative diseases
Experienced Leadership	Decades of expertise in cell therapy and biopharma commercialization

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Pioneering Breakthrough: First-In-Class Therapy to Transform ALS Treatment

Promising data from our previous trials continues to support the therapeutic potential of NurOwn®, demonstrating meaningful improvements in key areas.

Robust biomarker data strongly supports NurOwn®'s mechanism of action.

Aligned with FDA on new clinical trial design through the Special Protocol Assessment (SPA), ensuring regulatory confidence and trial integrity.

Phase 3b plans: Comprehensive plan for Phase 3b trial, optimizing patient selection and dosing strategies.

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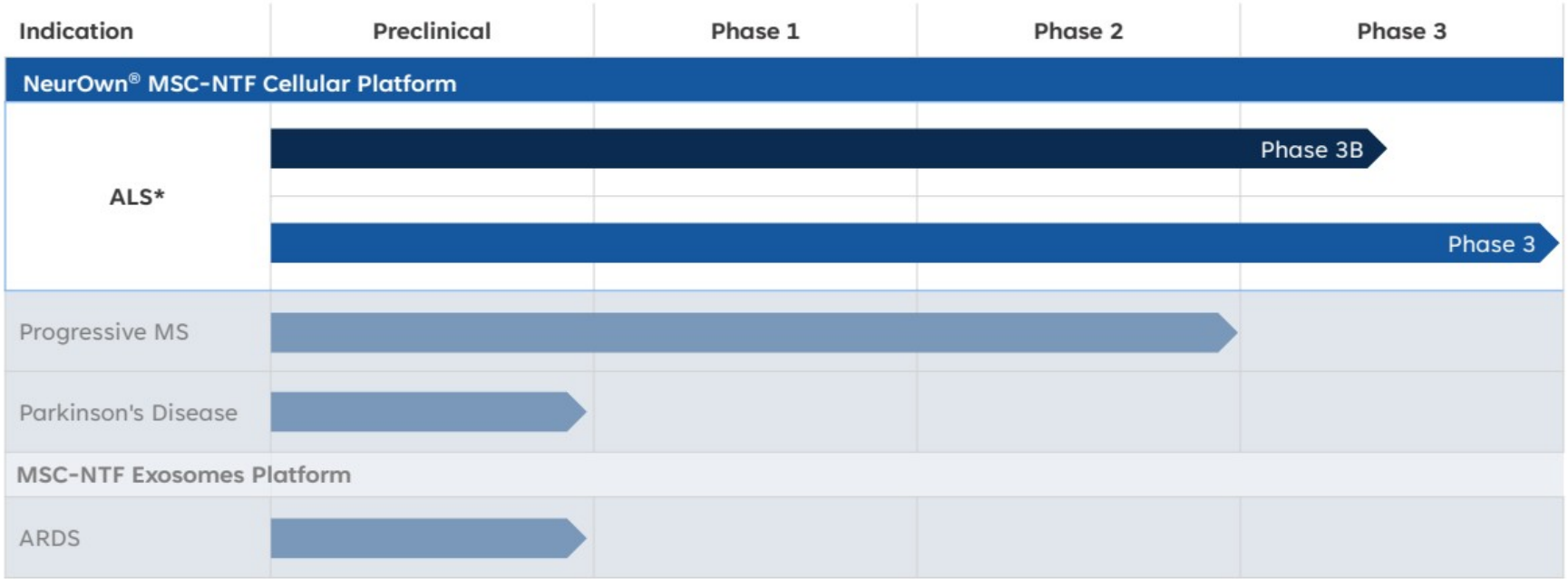
Innovating Cell Therapies for Neurodegenerative Diseases



*dependent on future funding

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Experienced Team in Cell Therapy Development

Proven Expertise	Decades of experience in developing innovative cell therapies across multiple therapeutic areas.
Successful Track Record	Led the development of NurOwn®, producing over 470 GMP clinical batches for 190+ ALS trial. Extensive experience across all phases of clinical development, from preclinical to commercialization.
Manufacturing Excellence	Expertise in scaling up complex cell therapy manufacturing processes to meet clinical and regulatory standards.
Regulatory and Quality Leadership	Strong regulatory affairs team with a proven history of engaging with global health authorities, including the FDA and EMA.
Innovation-Driven Approach	Focus on cutting-edge science and advancing new cell therapy technologies to improve patient outcomes.

Proven Leadership with Deep Expertise in Biotechnology

Chaim Lebovits President and CEO	Haro Hartounian, PhD COO	Bob Dagher, MD CMO	Uri Yablonka CBO
Mary Kay Turner SVP, Advocacy and Government Affairs	Netta Blondheim-Sharga SVP, Research and Development	Yossef Levy, PhD VP. Cell Production	Leticia Tarilonte VP, Global Clinical Operations

Looking Ahead: Key Upcoming Expected Milestones

Clinical Trial Agreements (CTA) Signed	Finalize agreements with leading clinical sites, setting the stage for a successful Phase 3b trial.
15 Clinical Sites Announced	Officially unveil our partnership with 15 premier clinical sites, ensuring broad geographic coverage and access to top-tier patient care.
GMP Manufacturing in Full Swing	GMP manufacturing of clinical-grade products is ready to support upcoming trials, ensuring timely execution and quality.
Engaging Top-Tier CRO	Signed an agreement with a leading CRO to manage patient recruitment, trial execution, and regulatory compliance, maximizing trial success.
First Patient Enrollment by December	On track to enroll the first patient in December 2024, marking a significant milestone in advancing NurOwn®.

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Our Technology

Cutting-Edge Innovation: Advancing the Future of Cell Therapy

Developing NurOwn® as a Groundbreaking Platform to Treat ALS

ALS is a progressive neurodegenerative disease that impairs walking, talking, eating, and breathing, and is currently 100% fatal

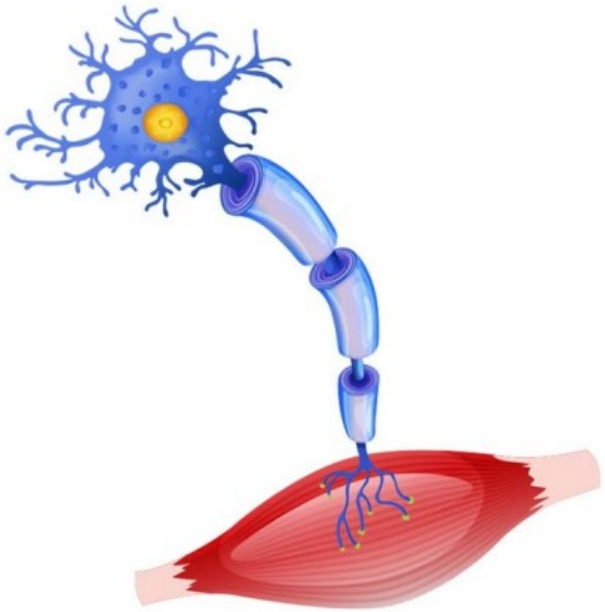
- Survival is 2 to 5 years from onset, with a lifetime risk of 1 in 300 people.
- ALS affects 1.6 per 100,000 people annually worldwide.
- 90% to 95% of ALS cases are sporadic, with no known family history.
- Projected to grow significantly, driven by factors such as advancements in research, rising prevalence due to aging populations, and emerging therapeutic modalities like cell and gene therapy.
- Valued at approximately $669 million in 2023, is expected to surpass $1.2 billion by 2034, growing at a compound annual growth rate (CAGR) of around 6.4% (Datam Intelligence (IMARC).

1. Brotman RD, et al. StatPearls. 2020
2. Masrori P, et al. Eur J Neurol. 2020; 27:1918-1929
3. Brown RH, et al. N Engl J Med. 2017; 377:162-172

Amyotrophic Lateral Sclerosis- ALS

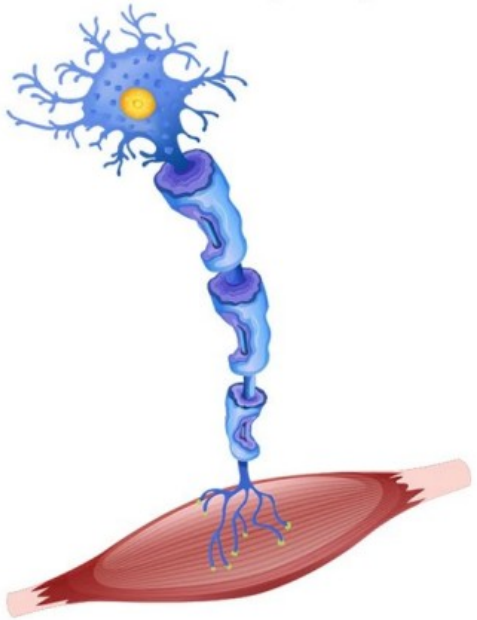
Devastating Disease with Hope on the Horizon through Our Groundbreaking Treatment

normal motor neuron



muscle contracts

motor neuron damaged by ALS



muscle unable to contract

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NurOwn®: Harnessing MSC Characteristics and NTF Production

MSCs

Intrinsic immunomodulation properties

Tropism to sites of damage

In ALS murine models

- Delay motor neuron degeneration
- Improve motor performance
- Prolong survival

+

NTFs

Multiple evidence for neuroprotection

Deficient in several neurodegenerative diseases, including ALS

Single NTFs tested as potential treatment in humans (e.g. BDNF & GDNF), with limited success

MSC-NTFs (NurOwn®)

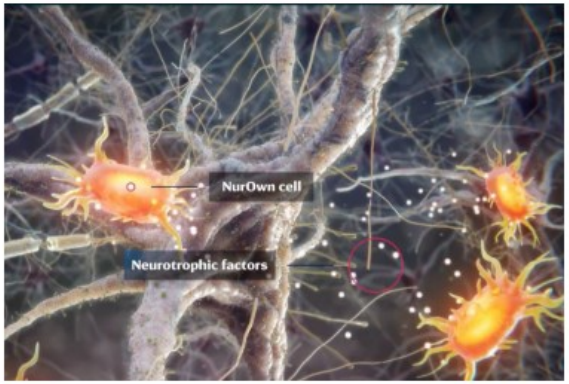
Enhanced secretion of multiple NTF (e.g. VEGF, HGF, GDNF, BDNF & Gal-1)

Enhanced immunomodulatory effects

Enhanced effects in ALS and other neurodegenerative diseases

Our Technology: Transforming ALS Treatment with Advanced Cell Therapy

- NurOwn®: Uses the patient's own cells, reducing immune rejection risks, contributes to the high tolerance and good safety profile, and enhancing natural neurorepair.
- Introduced to the spinal cord CSF, MSC-NTF cells secrete bioactive molecules like NTFs, microRNA, and cytokines, activating neuroprotective and immunomodulatory pathways after intrathecal administration.
- FDA-Approved Therapies: Riluzole and Edaravone offer limited benefits, targeting glutamate toxicity and oxidative stress, respectively.
- NurOwn® Platform: Explored for use in other neurodegenerative diseases like MS and Parkinson's, showing broad potential.



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Robust biomarker data strongly supports NurOwn®'s mechanism of action

Changes in biomarkers across main-pathways following NurOwn treatment

Inflammatory pathway ↓

MCP-1
OPG
S100B
SDF-1a
CHI3L1/YKL-40
Chitotriosidase-1
GFAP
ICAM-1
IP-10*
TREM-2

Anti-Inflammatory pathway ↑

Fetuin-A
IL-37
LAP (TGF-β1)
MSR1
hsa-miR-146a-5p
hsa-miR-146b-5p

Neurodegeneration pathway ↓

pNfH
DR6
NfL
TWEAK
Tau
UCH-L1
hsa-miR-142-5p*
Caspase-3

Neuroprotection pathway ↑

VEGF-A
BDNF
G-CSF
GDF-15
Galectin-1
HGF
NMNAT1
Clusterin/ ApoJ
LIF

Bold = significant change from baseline detected during the study; $p<0.05$

*= non-significant trend in other direction

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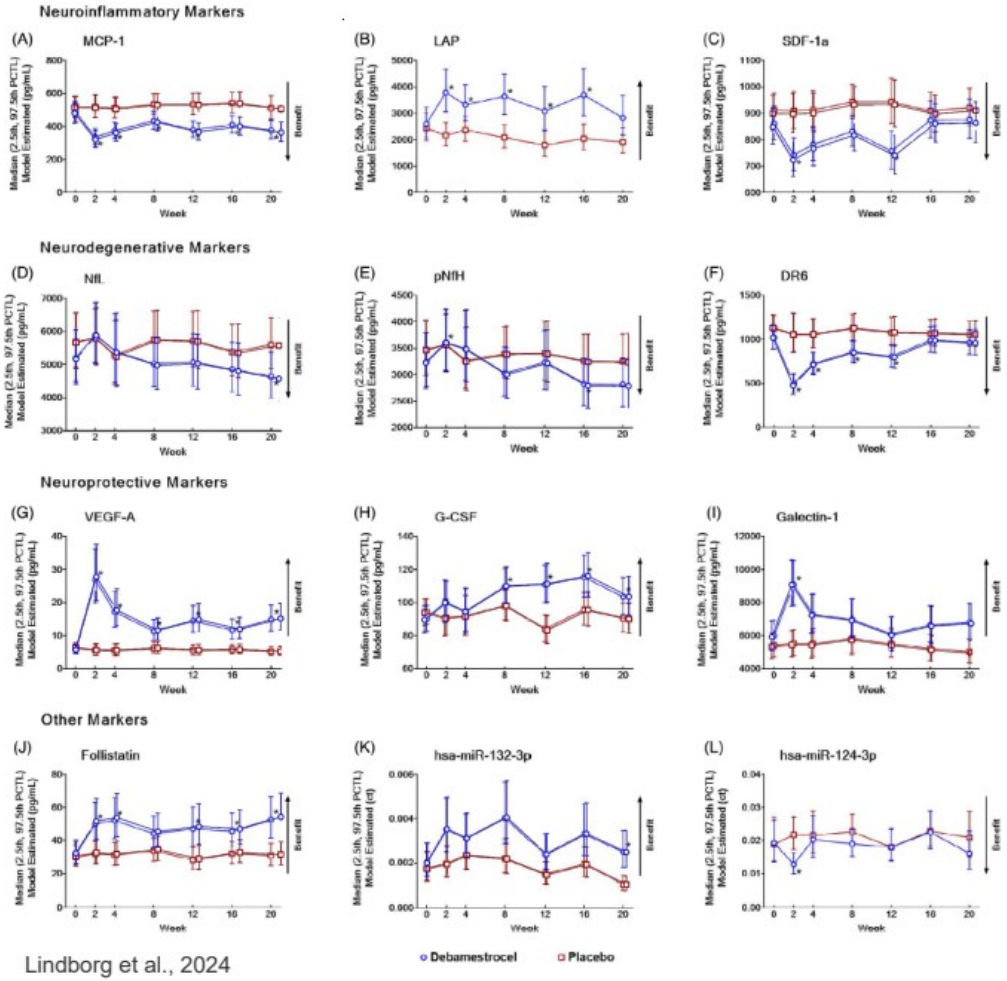
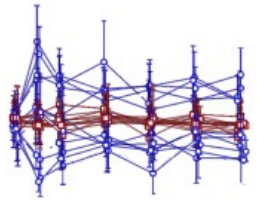
Biomarkers Change Following NurOwn Treatment



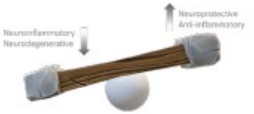
Lindborg et al., 2024

Illustrative approach to demonstrate the cumulative biomarker changes over time following NurOwn treatment, compared to placebo:



Change from placebo, neuroprotective markers

Change from placebo, neurodegenerative and neuroinflammatory markers



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NurOwn®: Tipping the Balance to Favor Neuroprotection

Biomarkers in CSF from ALS patients demonstrate pathological hallmarks of active neurodegenerative and neuroinflammatory processes

CSF biomarker changes following NurOwn treatment suggest a favorable disruption of pathological processes:

- Reduction in CSF neuroinflammatory and neurodegenerative biomarkers
- Increase observed in CSF anti-inflammatory and neuroprotective biomarkers

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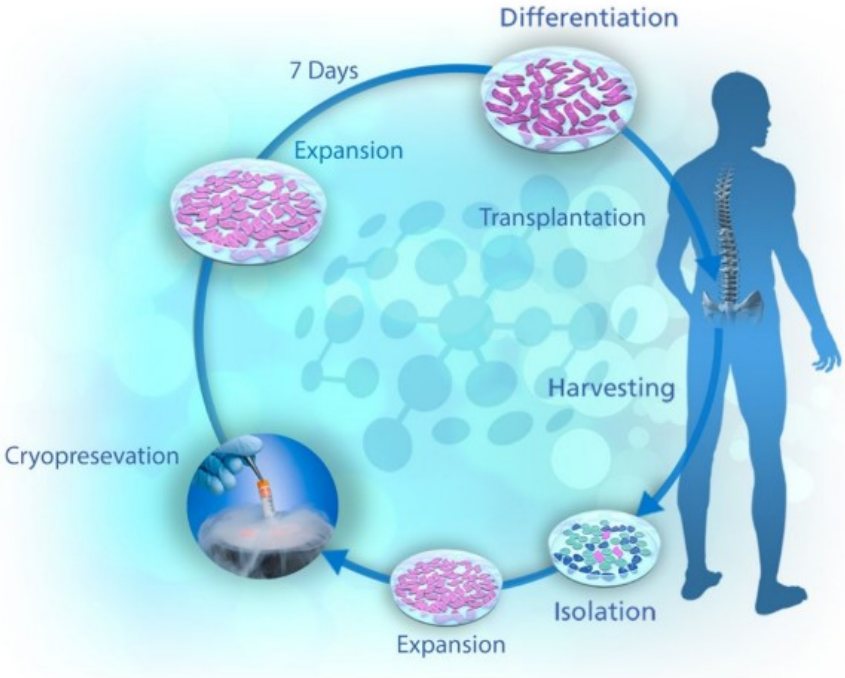
The NurOwn® Process: Step by Step

- The patient's bone marrow is harvested and Mesenchymal Stromal Cells (MSCs) are isolated from the total bone marrow population.
- The MSCs are expanded ex-vivo and cryopreserved.
- Cryopreserved MSCs are thawed, expanded and induced to differentiate into MSC-NTF cells (MSC cells that secrete Neurotrophic Factors).
- The MSC-NTF cells are then injected back into the patient at or near the site of damage (the spinal cord).



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Manufacturing Expertise: Delivering Quality and Scale for NurOwn®

- 470+ GMP Batches Produced: Proven ability to deliver clinical-grade materials at scale, dosing over 190 patients in multiple trials.
- Successfully executed technology transfer across multiple clinical sites for the production of NurOwn®, ensuring consistency and quality in manufacturing.
- State-of-the-Art Facilities: Advanced manufacturing in the US and Israel with cutting-edge technology for precision and efficiency.
- cGMP Compliance: Fully compliant with cGMP, ensuring consistent product quality and safety through rigorous quality controls.
- Global Manufacturing Footprint: Supporting global clinical and commercial needs with best-in-class facilities.

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NurOwn®

A Breakthrough in ALS Treatment with Promising Clinical Data

Our Milestones: NurOwn® Development Program in ALS

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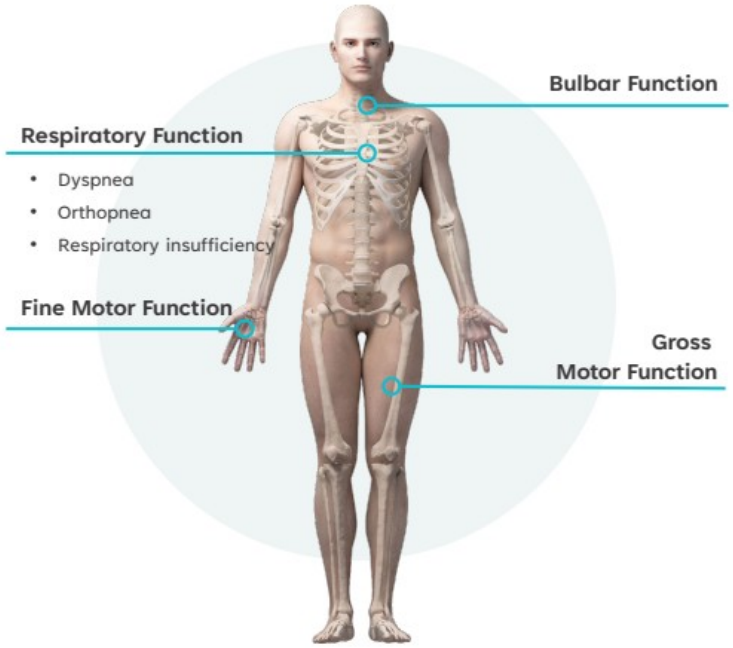
Primary Endpoint ALS Functional Rating Scale- Revised (ALSFRS-R)

Change in ALSFRS-R slope (rate of disease progression) >20-25% is clinically meaningful[2]

Validated approvable questionnaire-based tool

Used as basis for approval of Radicava in 2017 with mean score change at 24 weeks as primary endpoint

Data from the PRO-ACT database shows the average rate of ALSFRS-R decline is 1.02 points/month



48-point scale with 4 domains

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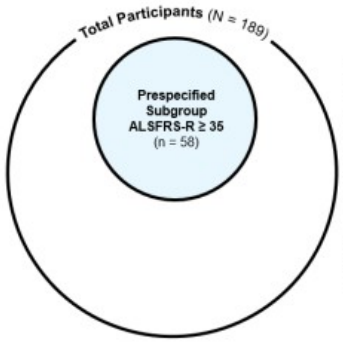
NurOwn®: Phase 3 Clinical Trial in ALS (BCT-002-US)

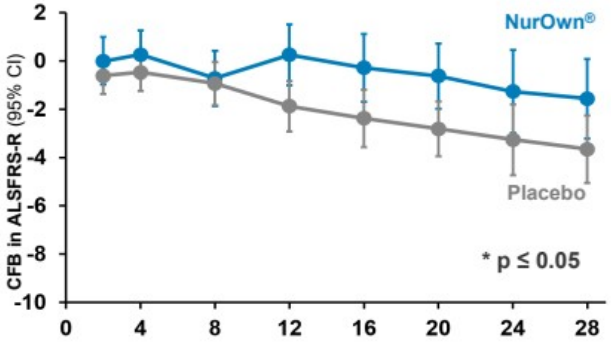
Subgroup analysis: positive results in early disease population (N=58)

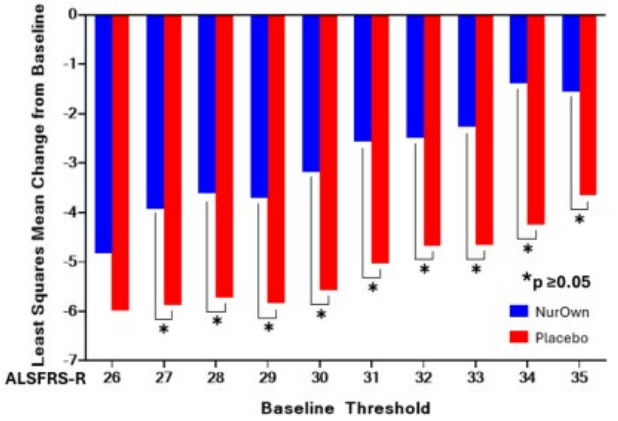
- Consistent treatment effects across multiple endpoints and over time
- Over ~2 points benefit in function at Week 28

Pre-specified subgroup with baseline ALSFRS-R ≥35

- ALSFRS-R treatment difference nominally significant starting at week-12, through the end of trial







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Clinical Data Summary

NurOwn® demonstrated a significant treatment effect in subgroup of patient with less advanced disease.

More advanced ALS patients did not show a treatment benefit, likely due to a floor effect.

Data reinforces the safety of repeat intrathecal administration.

The next trial will focus on enrolling less advanced patients and measuring the delta between the baseline and week 24 to maximize the statistical power.

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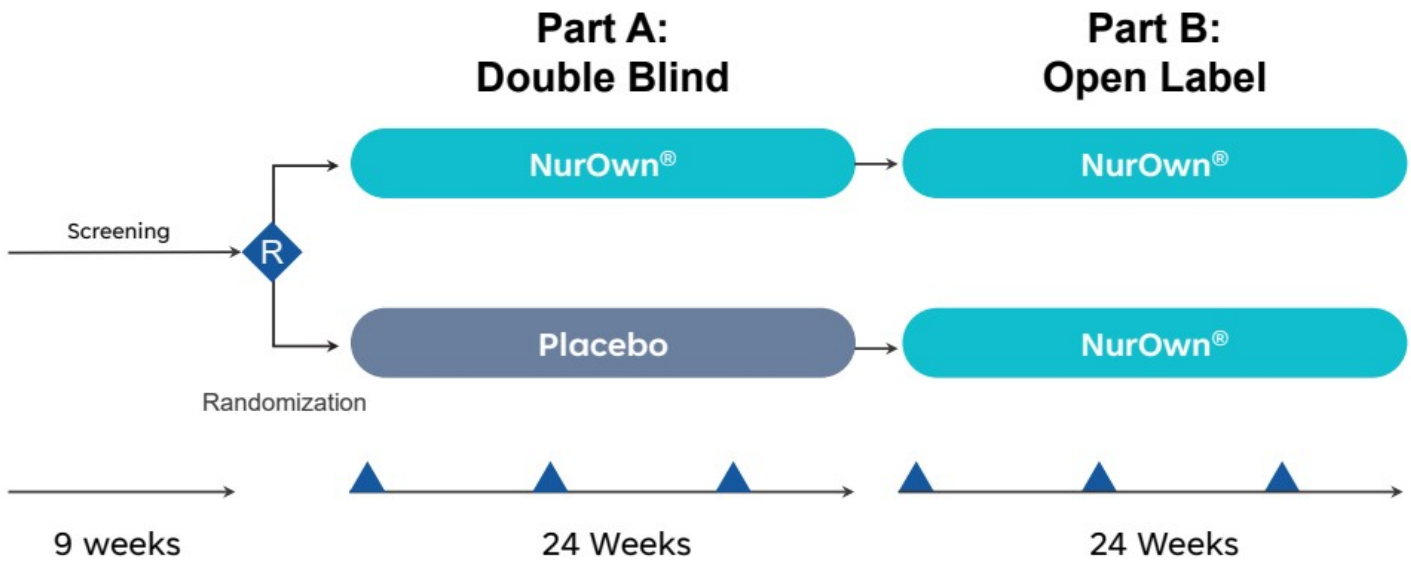
NurOwn®:
Optimized Phase 3b Trial in Early ALS Disease

NurOwn®: Phase 3 Clinical Trial in ALS (BCT-006-US)



Upon successful completion of our double-blind Phase 3b study, we will be positioned to submit our Biologics License Application (BLA) for regulatory approval, potentially accelerating our path to market.

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NurOwn® Phase 3b (BCT-006): Key Design Criteria

Significant Changes Made to Upcoming Phase 3b Clinical Trial

	Phase 3 (BCT-002-US)	Phase 3b (BCT-006)
Patient population	≥25, followed by 20-week "run-in" period, allowing the possibility to enroll advanced-disease participants	Early-disease participants: ALSFRS-R criteria targeting less advanced levels of functional decline (≥ 2 points on each item of the ALSFRS- R ...)
Primary endpoint	Responder: proportion with ≥1.25 points/month improvement in the post-treatment slope vs. pre-treatment slope in ALSFRS-R at week 28	Use of "gold standard" in recent registrational trials (change from baseline to Week 24 in ALSFRS-R total score) • p-value derived from inference model of Combined Assessment of Function and Survival (CAFS)
Study duration	28-week double blind period	24-week double blind (Part-A) to be followed by 24-week open label extension (Part B) • Extended to evaluate long-term effects on survival and neurodegenerative biomarkers
Screening period	20 weeks screening, including 3-months "run-in" period to evaluate pre-treatment disease progression via ALSFRS-R	Elimination of "run-in" and shortening of screening period to minimize changes between screening and baseline
Regulatory	Filing at week-28: Responder analysis in overall population, including advanced disease	Filing at week-24: Special Protocol Assessment (SPA) agreement with FDA

NurOwn®: Positioned for Success

Proven Expertise	Our team has extensive experience in conducting clinical trials, including Phase 1, 2, and 3 studies.
Regulatory Alignment	Strong alignment from the FDA with Special Protocol Assessment (SPA) approval, ensuring trial design meets regulatory standards and de-risking regulatory aspects of the program.
Data-Driven Approach	Lessons from prior Phase 3 trials have refined patient selection, endpoints, and trial protocols, increasing the probability of success.
Robust Manufacturing Process	Securing partnerships with leading CDMOs for reliable production of clinical-grade materials, ensuring smooth execution.
Operational Excellence	A dedicated team, resources, and a clear execution plan are in place to manage and monitor the trial effectively.

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Thank you

Chaim Lebovits
President & CEO

BrainStorm Cell Therapeutics

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