

BrainStorm Cell Therapeutics

NASDAQ: BCLI



brainstorm
cell therapeutics

COMPANY UPDATE

Chaim Lebovits, CEO
February 2018

Forward Looking 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>.

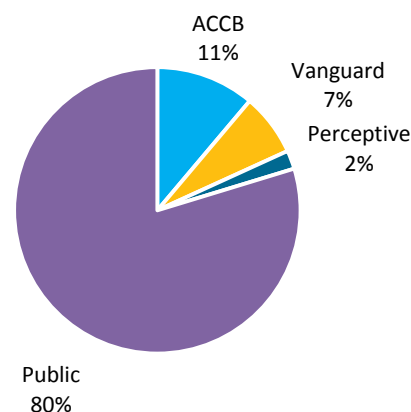
These factors should be considered carefully, and readers should not place undue reliance on BrainStorm's forward-looking statements. The forward-looking statements contained in this press release are based on the beliefs, expectations and opinions of management as of the date of this press release. 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.

Company Overview

Business Description

- BrainStorm Cell Therapeutics (NASDAQ: BCLI) is a biotechnology company, which develops innovative adult stem cell therapeutic products for neurodegenerative disease
- The company focuses on utilizing the patients' own bone marrow stem cells to generate neuron-like cells for treatment of amyotrophic lateral sclerosis (ALS), Parkinson's disease, multiple sclerosis and spinal cord injury
- BrainStorm's platform technology, NurOwn®, uses proprietary culture conditions to induce patient derived mesenchymal stem cells (MSCs) to secrete high levels of neurotrophic factors (NTFs) known to promote the survival of neurons and treat the degeneration associated with the above mentioned diseases
- Currently, the company's most progressed indication is treatment of ALS, for which it has recently (Oct 2017) commenced phase 3 studies

Ownership



Summary Financials

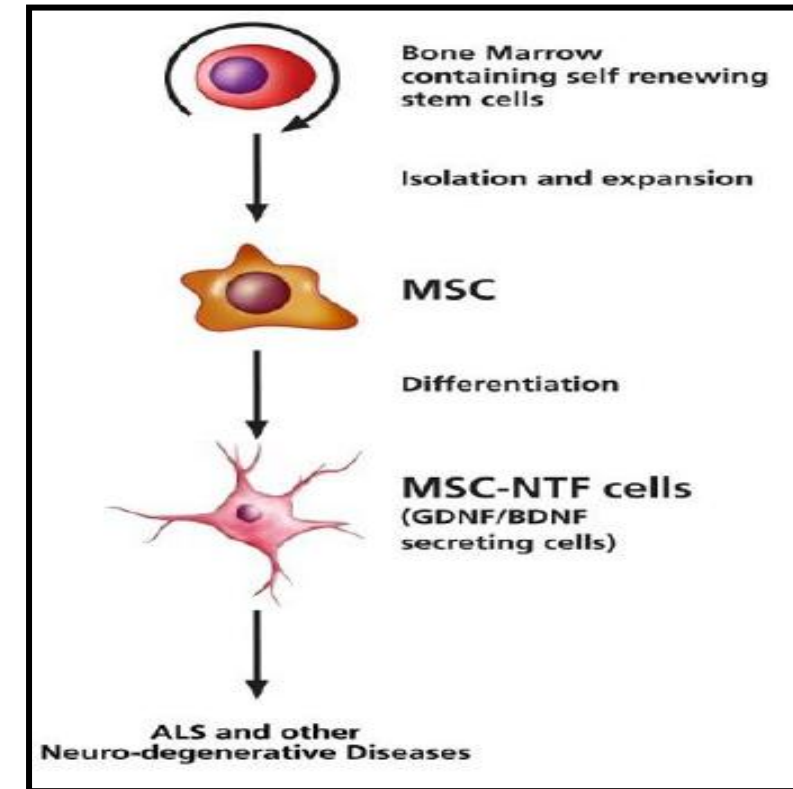
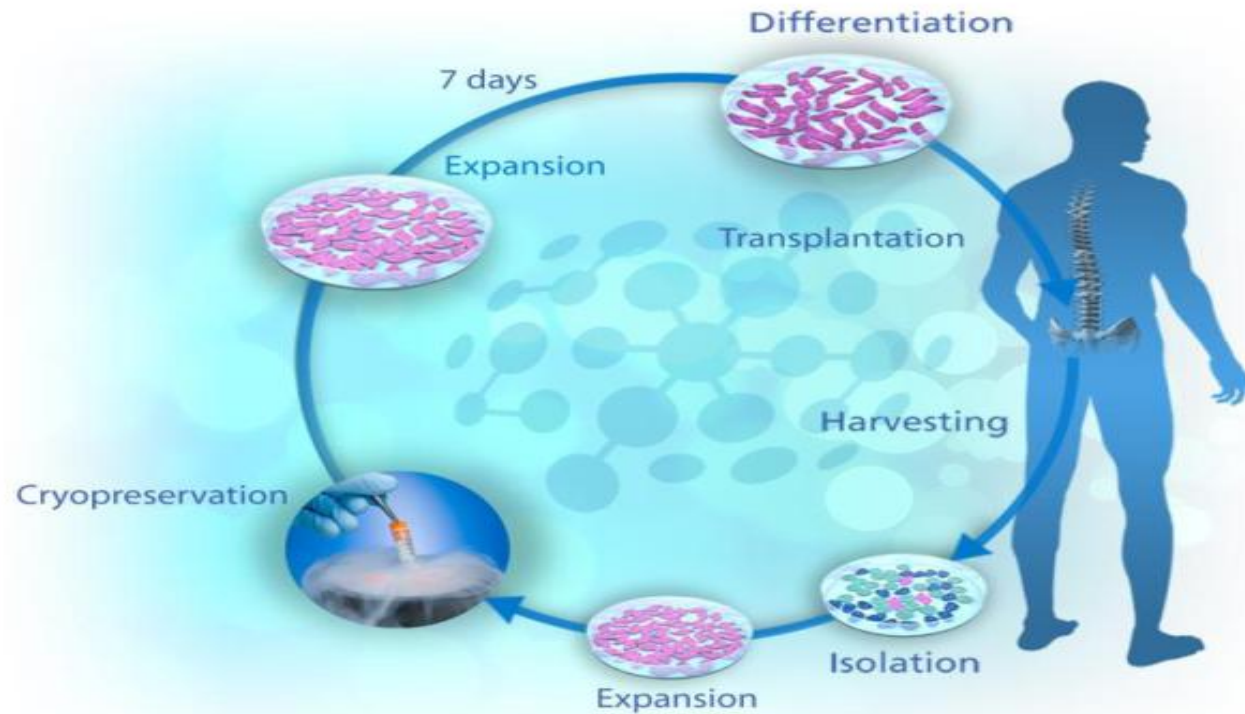
P&L (\$, 000')	2015	2016	Q3'17 LTM
Sales	-	-	-
R&D expenses	(4,949)	(2,250)	(2,867)
G&A expenses	(3,587)	(2,833)	(3,020)
Operating profit (loss)	(8,536)	(5,083)	(5,887)
Financial expenses (income), net	(48)	(101)	(35)
Taxes on income	-	-	-
Net profit (loss)	(8,584)	(5,184)	(5,922)

Management

- Chaim Lebovits, President and CEO** – Mr. Lebovits joined Brainstorm in July 2007 and since September 2015, he also serves as the CEO of the company. Prior to BrainStorm, he held various positions in companies in the mining, oil and energy industries
- Ralph Kern, MD, MHSc., EVP, COO and CMO** – joined BrainStorm in March 2017. Prior to BrainStorm, he served as Senior Vice President and Head of Worldwide Medical at Biogen and Head of Neuroscience Medical Unit at Novartis
- Eyal Rubin, EVP, CFO** – joined BrainStorm in November 2017 from Teva Pharmaceutical Industries where he served as Vice President and Head of Corporate Treasury since 2013
- Yael Gothelf, Ph.D., VP Scientific and Regulatory Affairs** – joined BrainStorm in January 2007. Prior to Brainstorm she served as the Scientific Manager of the Research and Process Development Division of InterPharm Laboratories, Israel a subsidiary of Ares-Serono.
- Yossef Levy, Ph.D., VP Cell Production** – As a member of the original Tel Aviv University research team that developed the NurOwn technology, Dr. Levy has been a core member of BrainStorm's R&D team since the inception of the company.
- Uri Yablonka, SVP, CBO** – joined BrainStorm in 2014 as COO and as a member of the Board of Directors. Prior to BrainStorm, he served as owner and General Manager of a business consulting firm

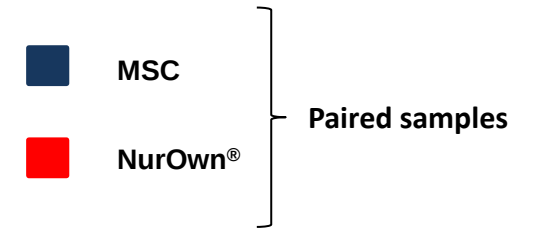
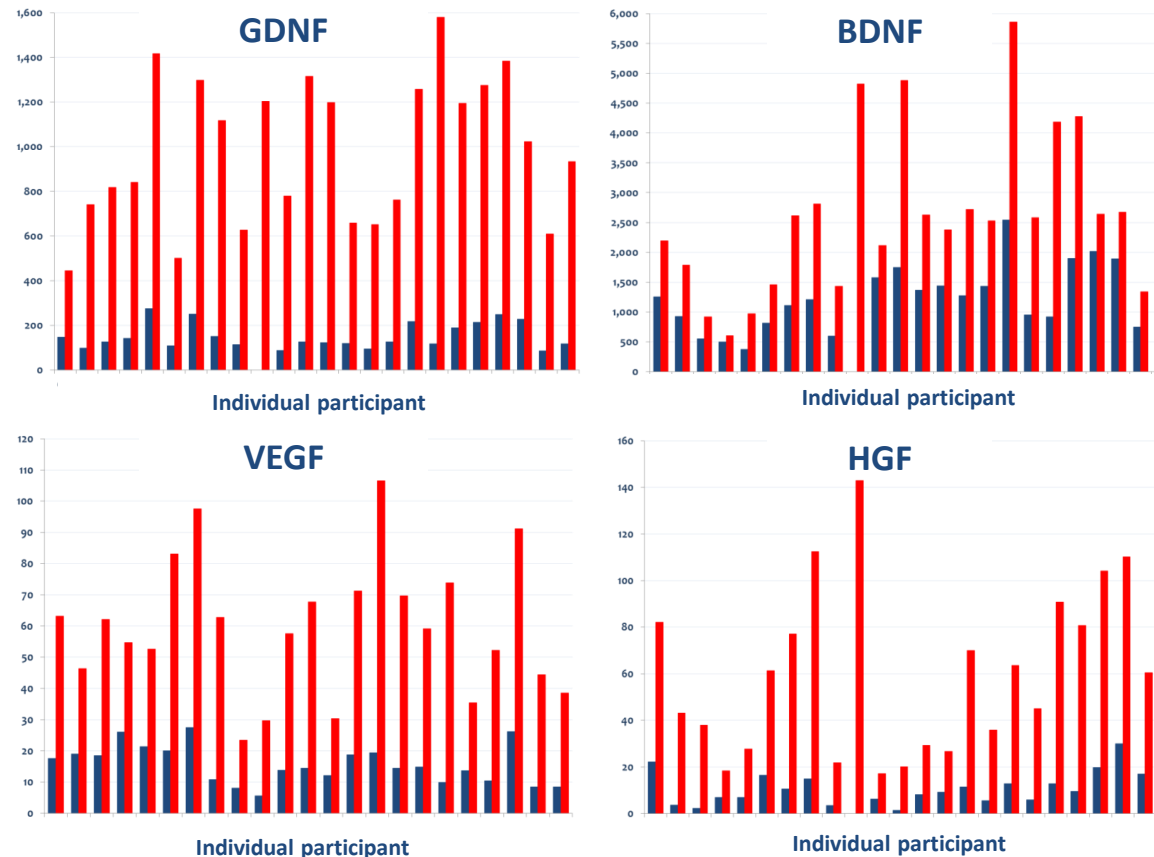
(1) ACCBT is a company that invested in the company during 2007-2010 and the CEO serves as a director.

NurOwn® Technology



NurOwn®: NTF and cytokine secretion compared to MSC cells of origin

Enhanced in-vitro neurotrophic-factor secretion differentiates NurOwn® from MSC cells of origin in ALS patients



NurOwn® successfully evaluated in preclinical models of neurodegenerative disease

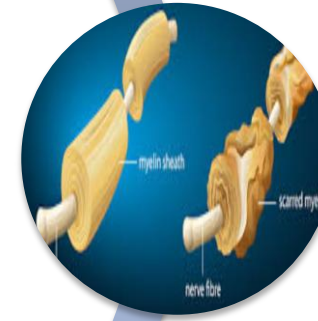
**Huntington's
Disease**



**Parkinson's
Disease**



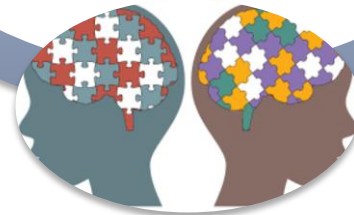
**Multiple
Sclerosis**



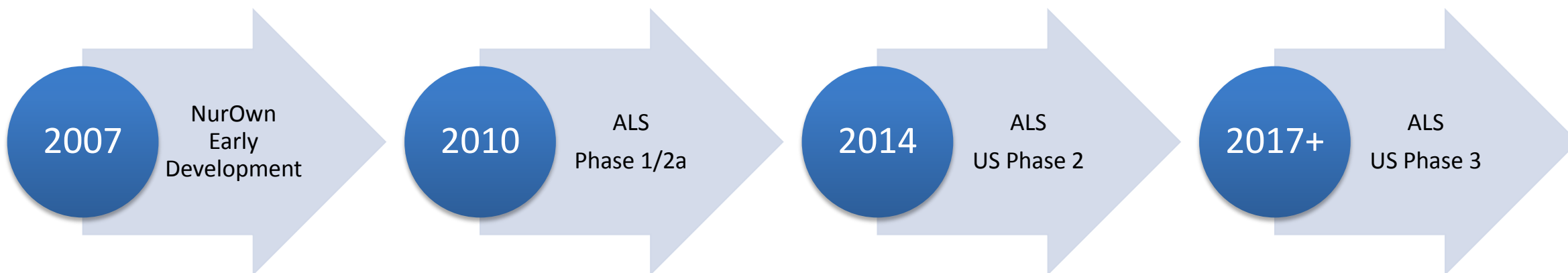
ALS



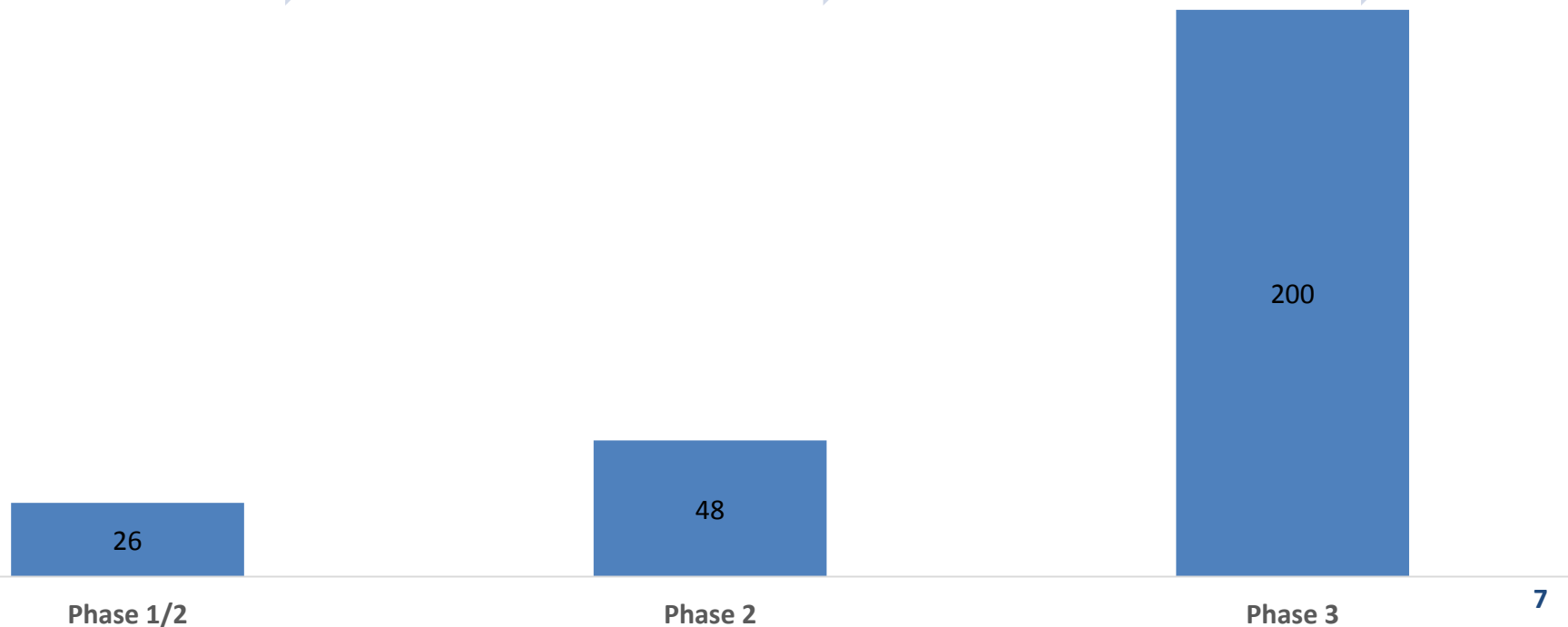
Autism



NurOwn® ALS Development

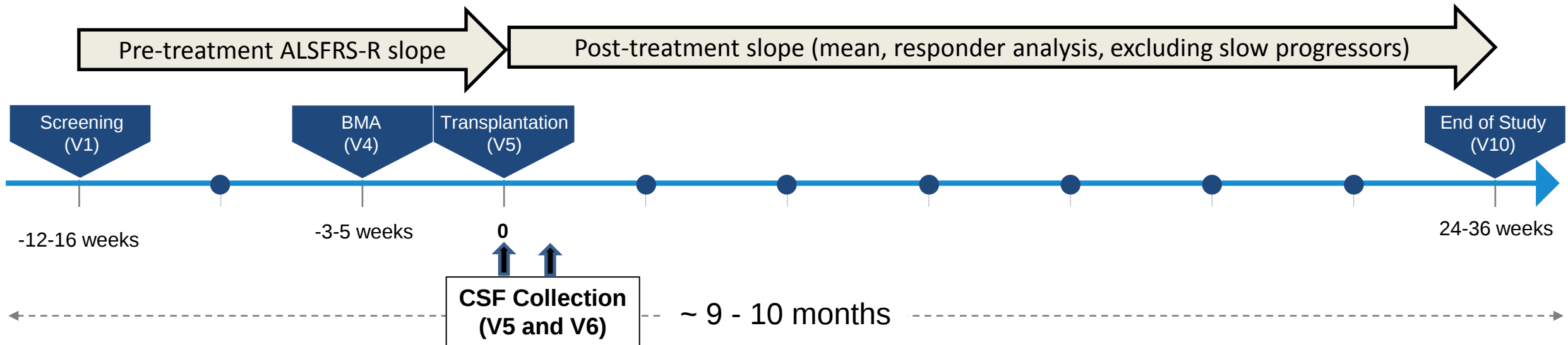


of Study Participants



NurOwn® BCT-001-US

Phase 2 Study Design



- 48 participants (16 per site)
- Randomized 3:1

- **IM:** 24 injections (12 into R biceps, 12 into R triceps); 2 million cells each
- **IT:** 125 million cells in 4mL

Phase 2 ALS participant disposition and demographics: baseline characteristics balanced

Disposition	MSC-NTF (N=36)	Placebo (N=12)	All Participants (N=48)
Analysis Populations	n (%)	n (%)	n (%)
Safety (ITT*)	36 (100.0)	12 (100.0)	48 (100.0)
Study Completion			
Completed	33 (91.7)	10 (83.3)	43 (89.6)
Discontinued	3 (8.3)	2 (16.7)	5 (10.4)

Demographics	MSC-NTF (N=36)	Placebo (N=12)	All Participants (N=48)
Sex	n (%)	n (%)	n (%)
Male	25 (69.4)	10 (83.3)	35 (72.9)
Female	11 (30.6)	2 (16.7)	13 (27.1)
Age (years)	Descriptive Statistics		
n	36	12	48
Mean (SD)	50.3 (11.9)	53.5 (9.11)	51.1 (11.27)

* ITT analyses included all participants

Ref. Tables 14.1.1.1, 14.1.2.2

NurOwn® BCT-001-US ALS Clinical Trial:



Key Endpoints

- **Primary:**
 - Safety and tolerability
- **Secondary:**
 - ALSFRS-R
 - Slow vital capacity (SVC)
- **Exploratory:**
 - Muscle strength (HHD)
 - CSF Biomarkers (added after the 1st 8 participants)

NurOwn® BCT-001-US ALS Clinical Trial:

Treatment was Safe and Well-Tolerated

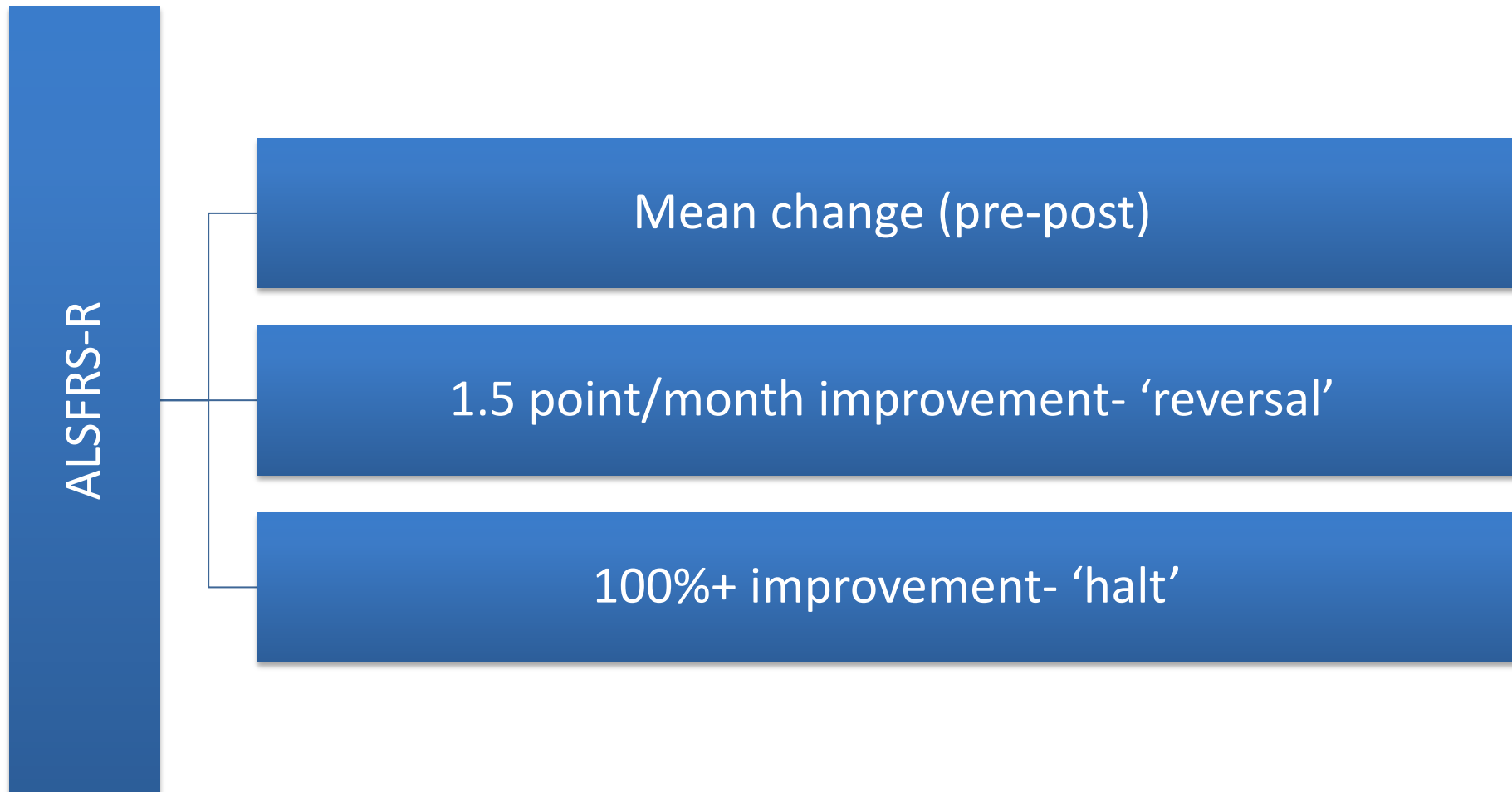
- No deaths
- No treatment-related SAEs observed
- No dropouts related to AEs
- Most common adverse events (>15%; most mild/mod severity):

Adverse Event	NurOwn® (%)	Placebo (%)
Headache and Procedural Headache	80.6	66.7
Back Pain	72.2	8.3
Pyrexia	33.3	0
Arthralgia	33.3	0
Injection Site Pain	27.8	8.3
Constipation	25	8.3
Pain in Extremity	22.2	0
Neck Pain	19.4	0
Myalgia	16.7	0
Cough	16.7	0
Nausea	16.7	0

- Post-therapy SAEs related to disease progression (e.g. G-tubes) were more frequent in the MSC-NTF cells group.

NurOwn® Phase 2 ALSFRS-R

Efficacy outcomes:

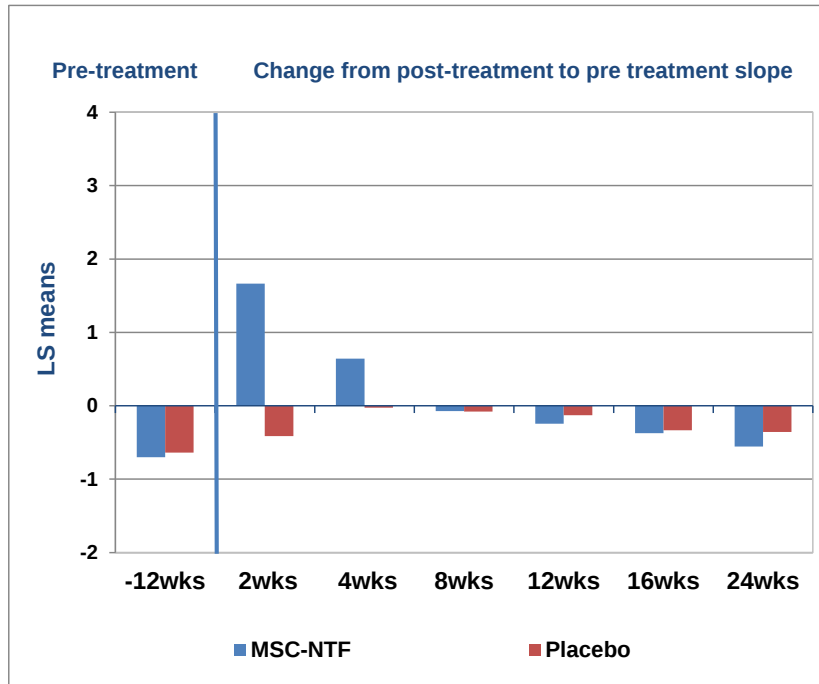


NurOwn® Phase 2 ALSFRS-R

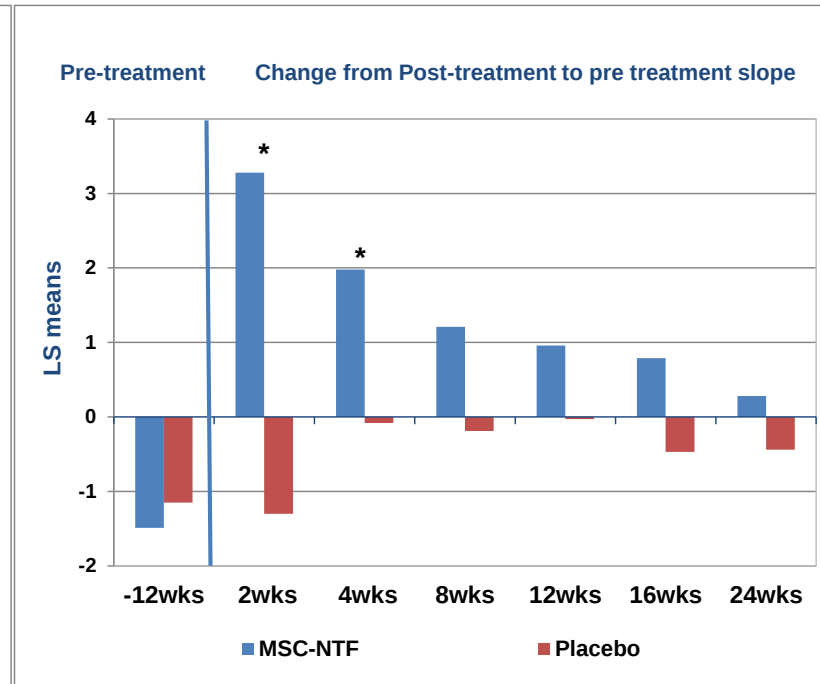
outcomes:

Mean ALSFRS-R slope improvement

All participants (n=46)



Excluding Slow progressors (n=21)

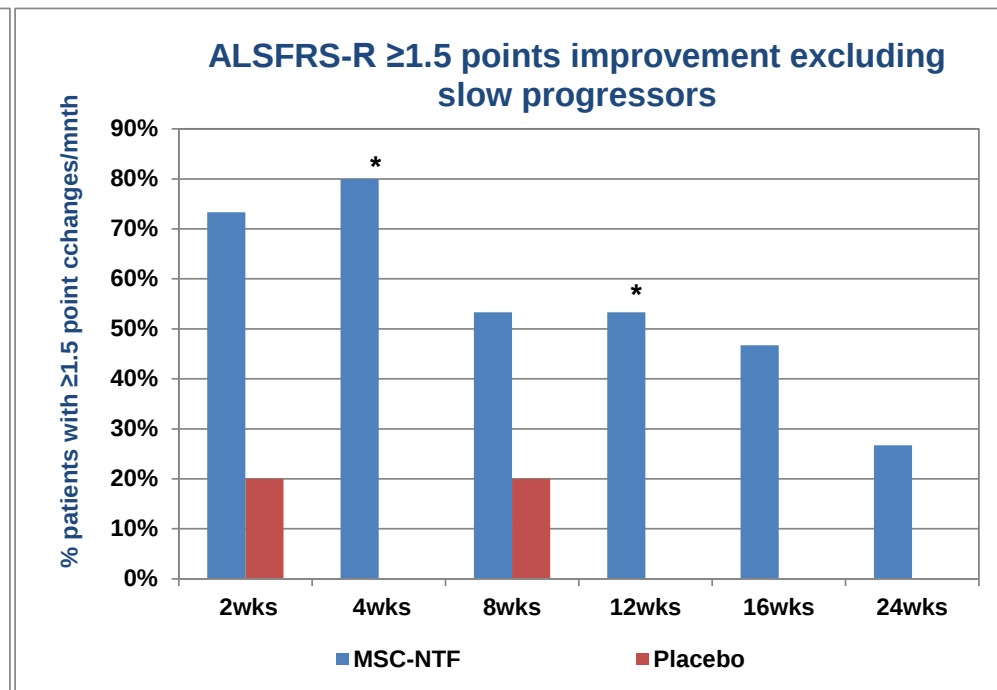
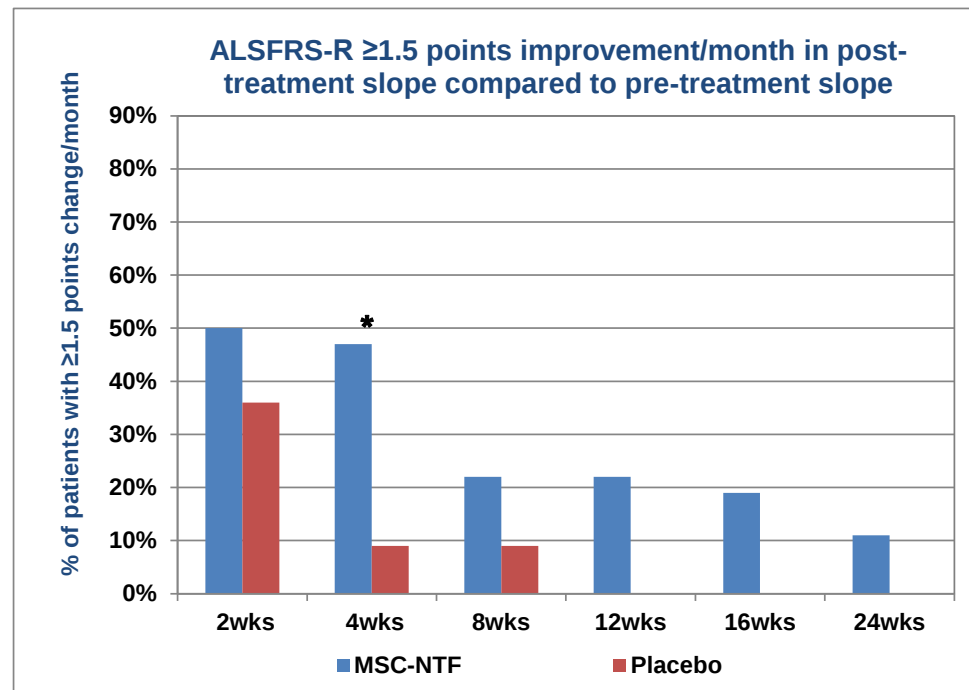


* p<0.05 (two-sided T test)

NurOwn® Phase 2 Responder Analysis: ≥1.5 points/month improvement

All participants (n=46)

Excluding slow progressors (n=21)



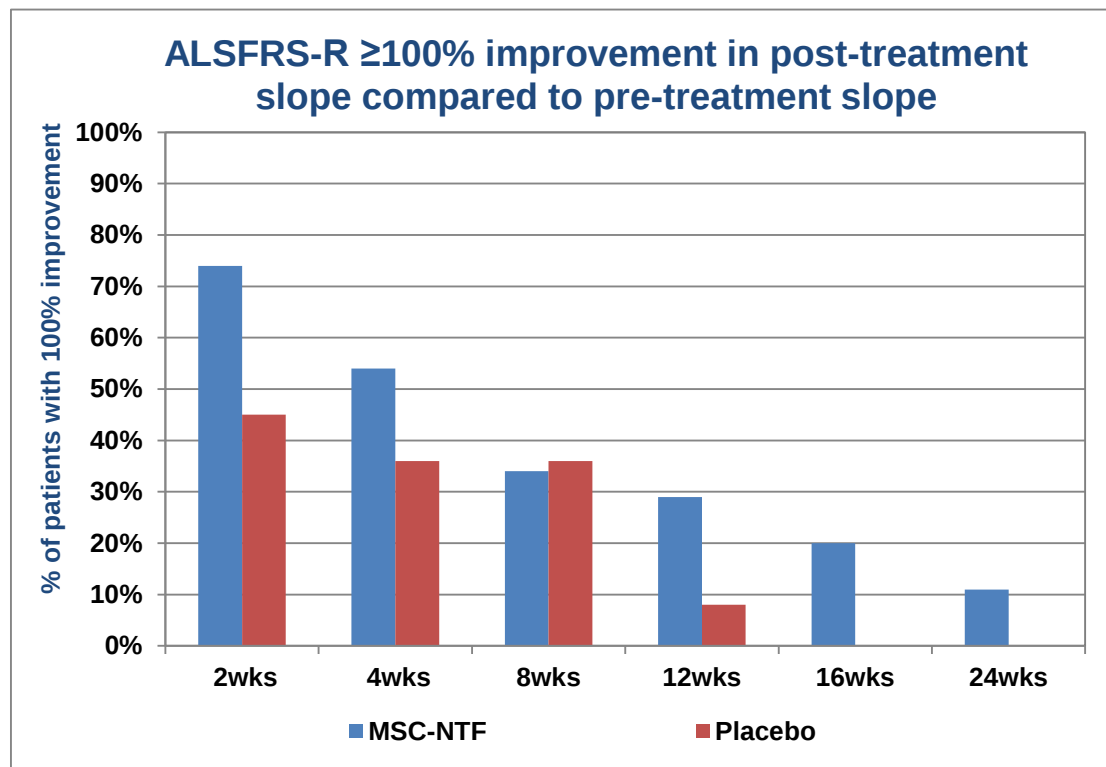
* p<0.05 (two-sided Fisher's exact test)

≥ 1.5 point/month improvement-responder analysis

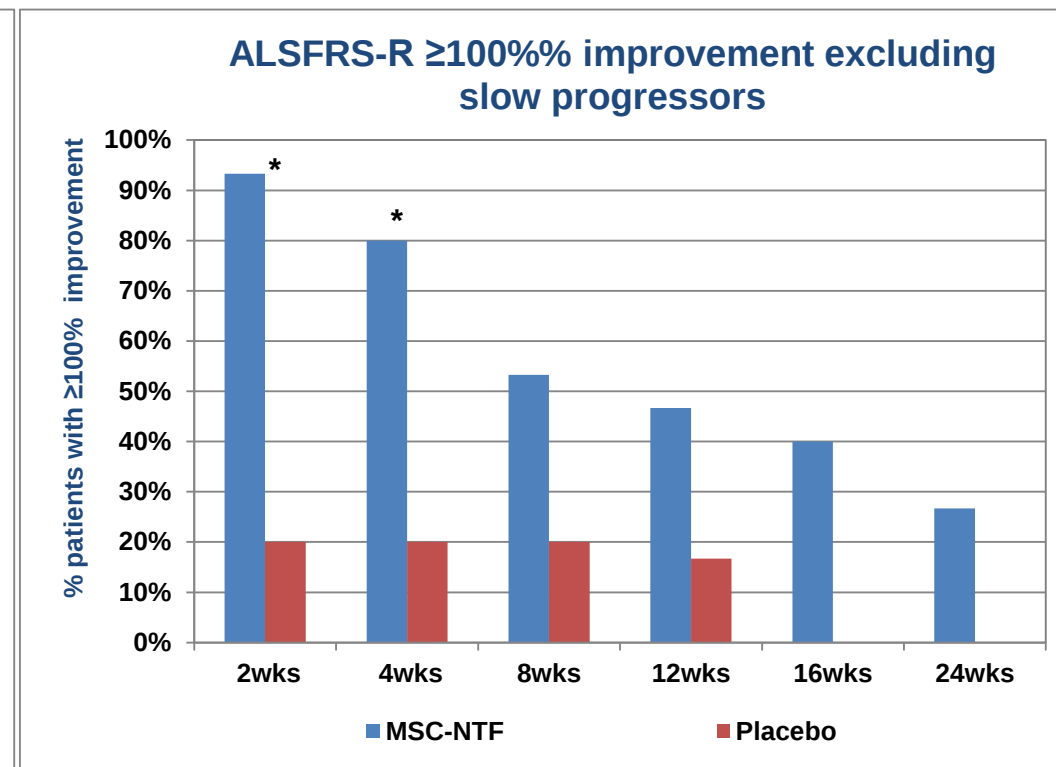
Group	12 weeks (n)	12 weeks (%)	16 weeks (n)	16 weeks (%)	24 weeks (n)	24 weeks (%)
MSC-NTF All Participants	7/35	20	7/35	20	4/34	12
MSC-NTF Fast Progressors	6/14	42	6/14	42	4/14	28
Placebo All Participants	0/12	0	0/11	0	0/11	0
Placebo Fast Progressors	0/6	0	0/5	0	0/6	0

NurOwn® Phase 2 Responder Analysis: *$\geq 100\%$ improvement*

All participants (n=46)



Excluding slow progressors (n=21)

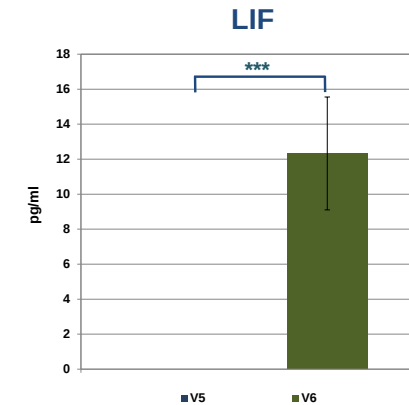
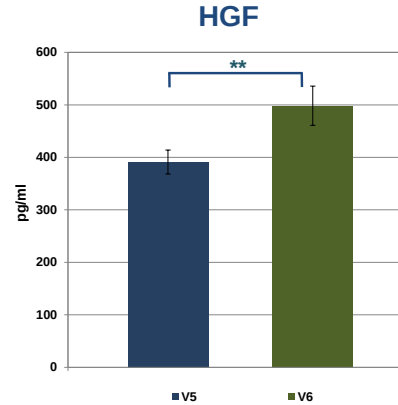
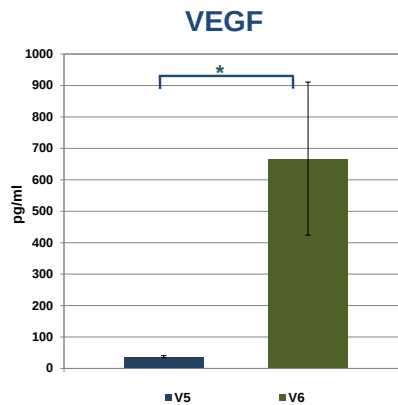


* $p < 0.05$ (two-sided Fisher's exact test)

NurOwn® Phase 2 ALS Study:

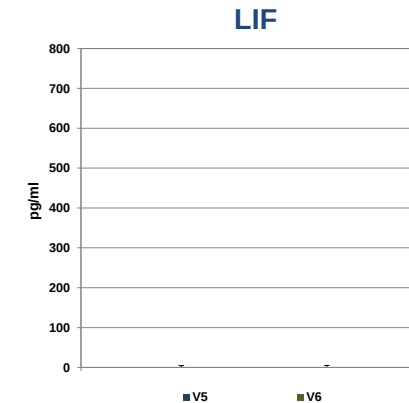
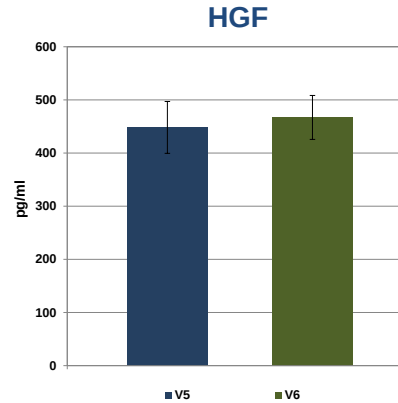
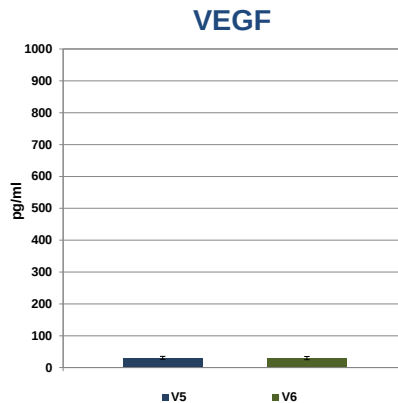
CSF NTFs Significantly Increased 2 Weeks Post-Treatment Compared to Baseline

NurOwn®
(n = 26)



■ Pre transplantation
■ Post transplantation

Placebo
(n = 9)



Mean ± SEM

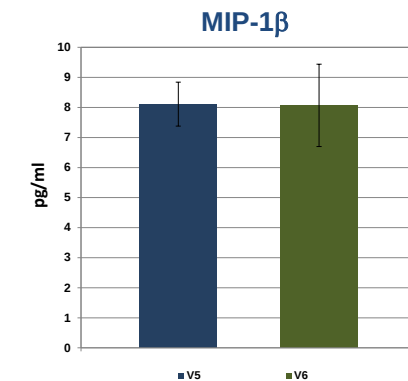
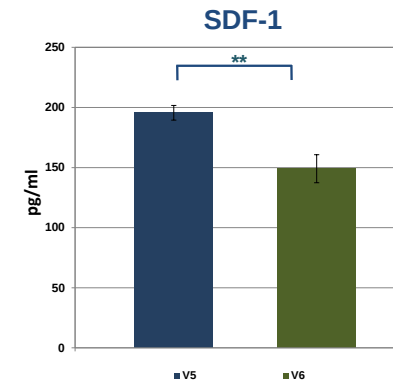
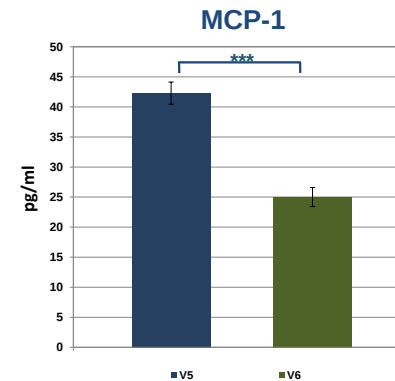
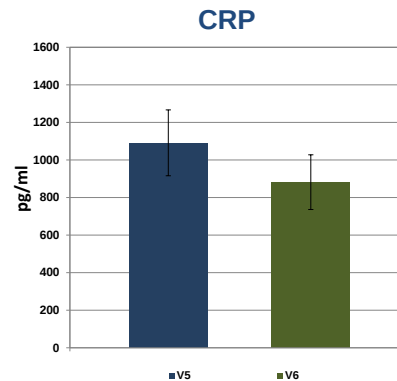
* p< 0.05 ** p<0.01 *** p< 0.001

NurOwn® Phase 2 ALS Study: CSF Inflammatory Markers Significantly Decreased Post-Treatment

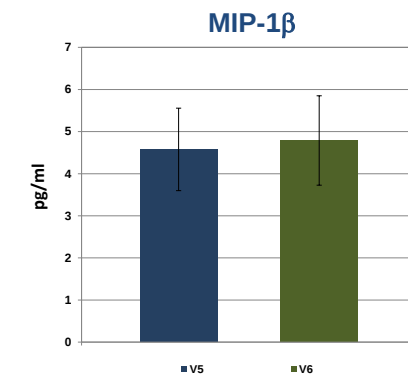
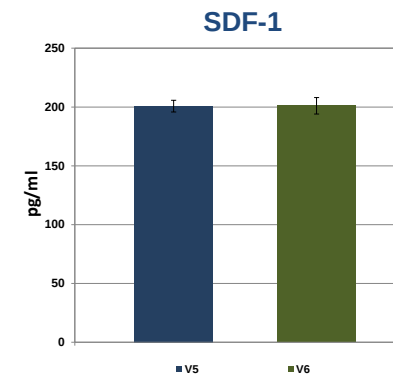
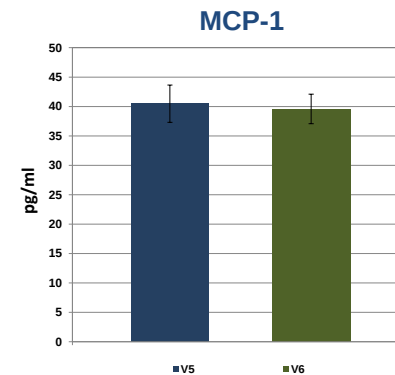
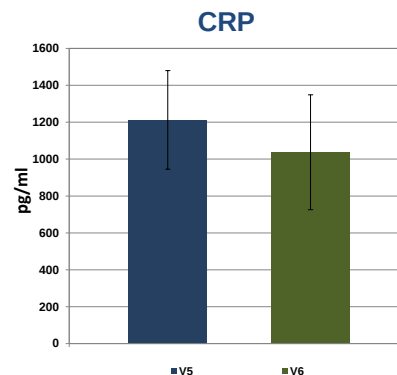
CSF MCP-1, SDF- markers
of neuroinflammation

■ Pre transplantation
■ Post transplantation

NurOwn®
(n = 26)



Placebo
(n = 9)



Mean ± SEM ** p<0.01 *** p< 0.001

NurOwn® Phase 3 ALS Study (BCT-002-US)

- Randomized, double-blind, placebo-controlled, multi-dose trial
- *200 patients; 1:1 randomization; 6 leading US ALS clinical sites*
- ***Actively recruiting and enrolling***
- Study design (**total study duration ~11.5 months**)
 - ***Pre-treatment:*** ~3 month baseline to determine ALSFRS-R slope- exclude slow progressors (<3 points decline ALSFRS-R; ~ 50% ALS patients)
 - ***Treatment:*** 3 doses over 4 months (q2 months)
 - ***Post-treatment:*** 28 week double-blind clinical follow-up after first dose
 - ***Primary outcome measure:*** ALSFRS responder analysis (≥ 1.25 points/month improvement)
- City of Hope Center for Biomedicine and Genetics is producing clinical supplies

Management Team

Chaim Lebovits
President and CEO

Ralph Kern, MD, MHSc.
COO and CMO

Eyal Rubin
EVP, CFO

Mary Kay Turner
VP, Patient Advocacy and
Government Affairs

Yael Gothelf PhD.
VP, Scientific and Regulatory Affairs

Uri Yablonka
SVP, Chief Business Officer

Yossef Levy PhD.
VP, Cell Production

Revital Aricha PhD.
VP, R&D



BrainStorm Cell Therapeutics

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Thank You