

BrainStorm Cell Therapeutics

NASDAQ: BCLI



brainstorm
cell therapeutics

December 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.

Brainstorm at a Glance

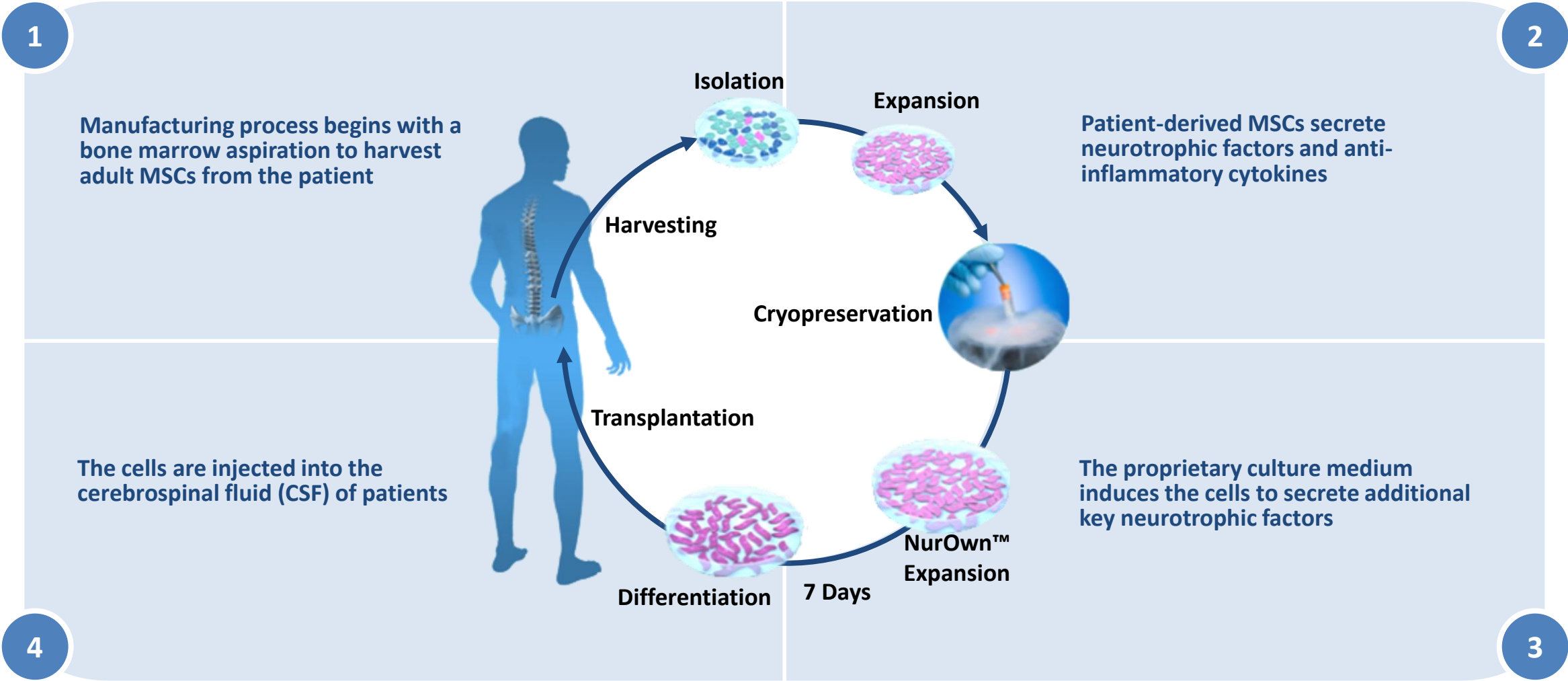
Targeted, innovative, proprietary and validated autologous cellular technology platform for the treatment of neurodegenerative disease

Actively recruiting ALS phase 3 Clinical Trial, an orphan disease with no existing cure and limited treatment options

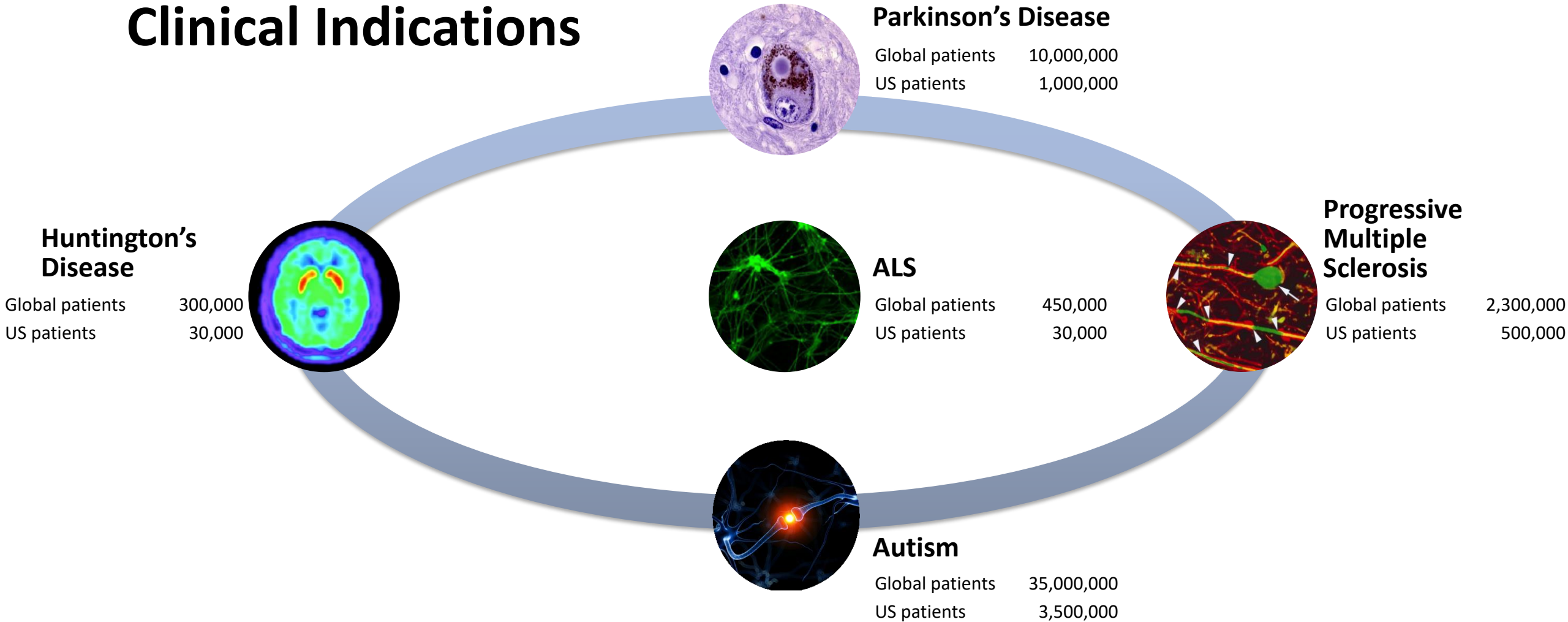
Large addressable market – progressive MS (500K US population) and over 45 million total global patients in main therapeutic targets (ALS, MS, Parkinson's, Huntington's and Autism)

Strong financial position - \$19million of cash and cash commitments

Robust IP portfolio



NurOwn® - Potential Clinical Indications



NurOwn® successfully evaluated in preclinical models of neurodegenerative disease

What is ALS?

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, is a progressive neurodegenerative disease that affects the function of nerves and muscles. This debilitating condition usually affects people aged 40 to 70, however, individuals in their 20s and 30s have also been known to develop ALS.*



Future Predictions

Researchers have predicted that the number of worldwide ALS cases will increase by 69% in 2040, compared to 2015. The main cause of this projected increase is due to an ageing population, particularly in developing nations.

ALS Incidence

It is estimated that 450,000 people worldwide are living with ALS, with over 30,000 people in the U.S. suffering from this neurodegenerative condition at any given time.

Someone is diagnosed
with ALS every

90

minutes

New cases per year

6,000

Men

are more likely to be diagnosed
with ALS than women

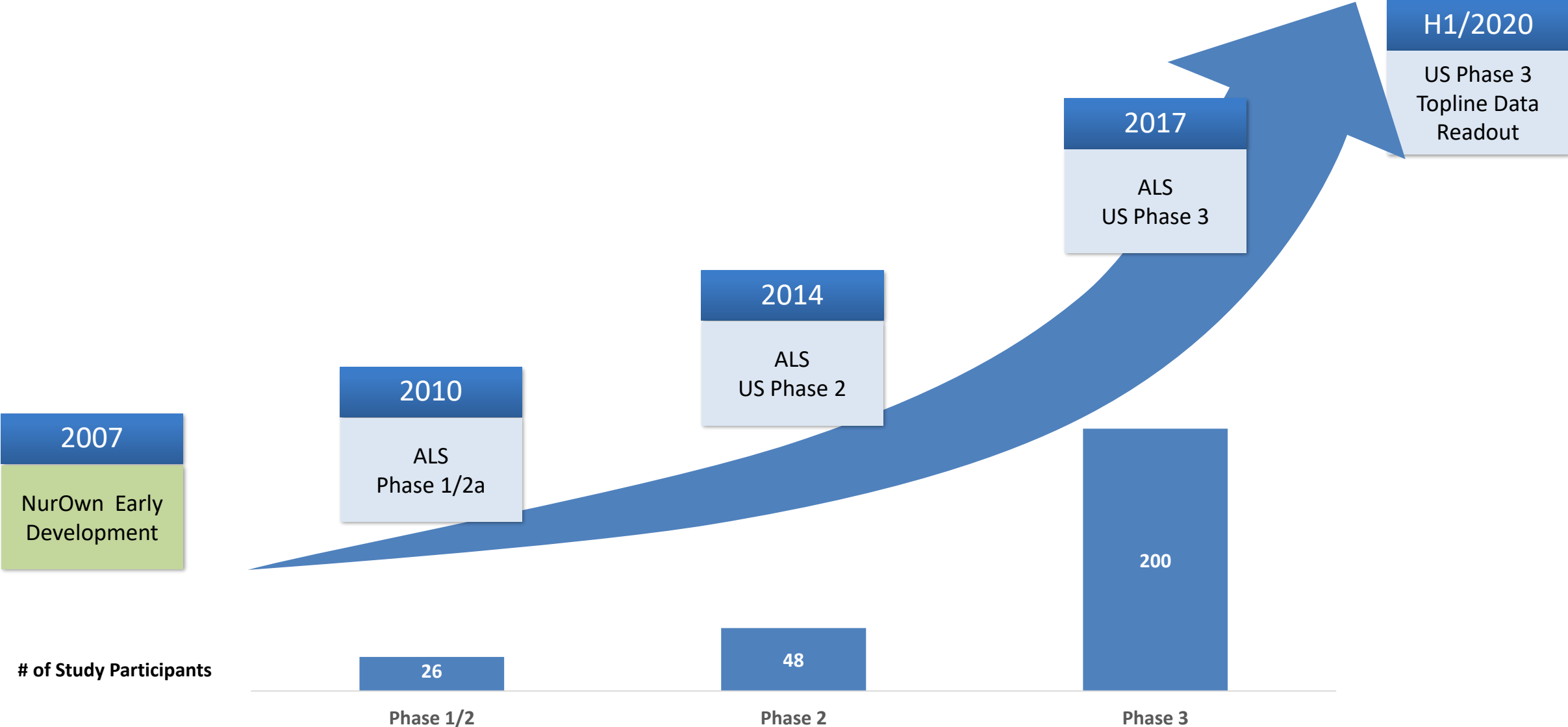
Worldwide, ALS affects males
aged

50+

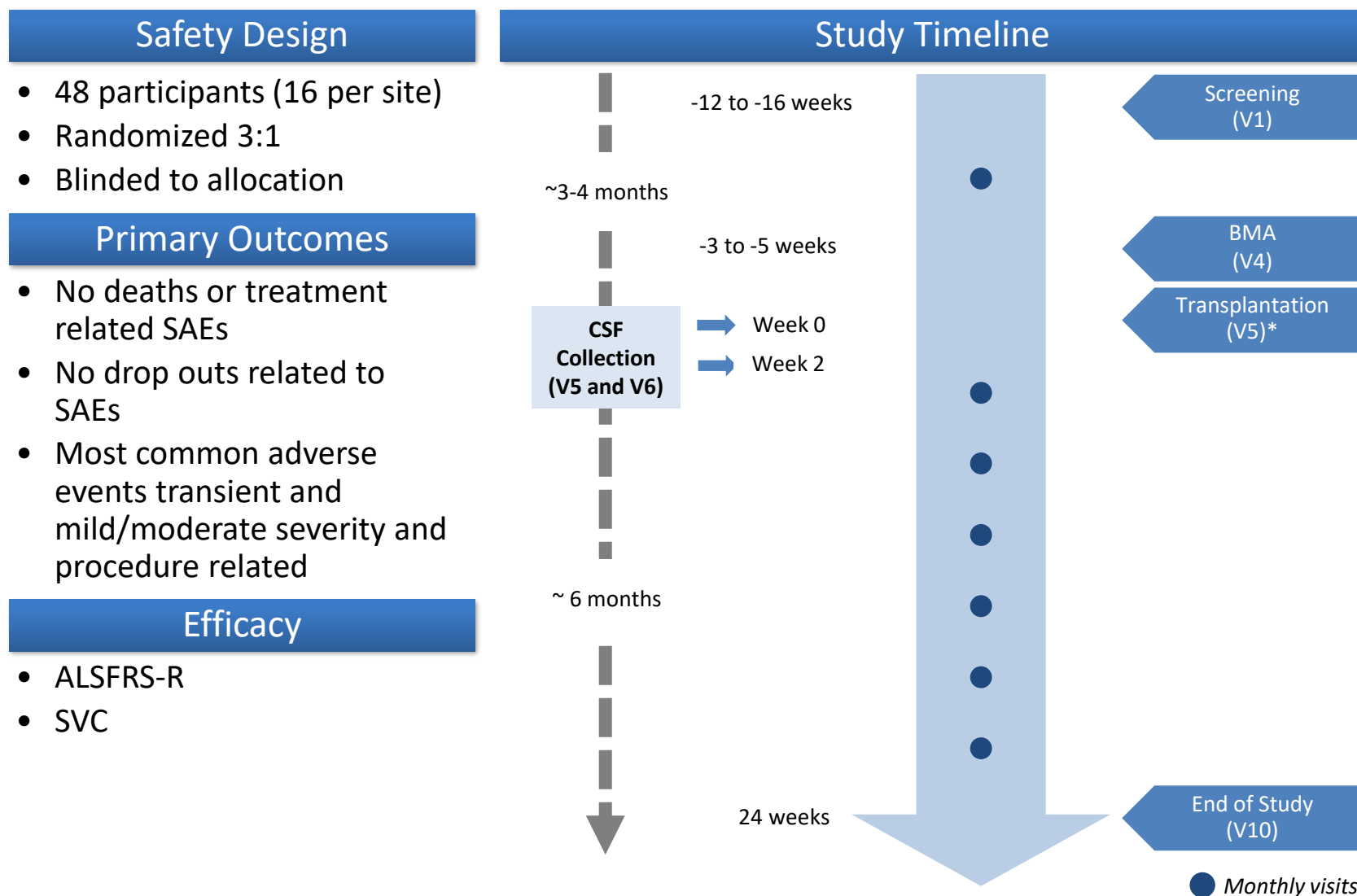
more than any other group

*Lou Gehrig was a famous American baseball player diagnosed with ALS in 1939.

NurOwn® ALS Development

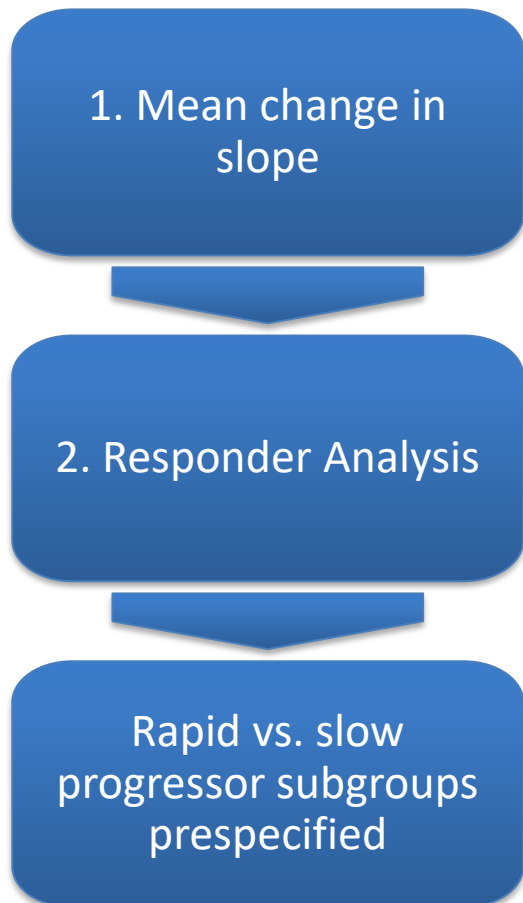


ALS Phase 2 Trial Design and Safety Outcomes



Phase 2 Trial – Approach to Data Analysis

Phase 2 Trial: 3 Types of Efficacy Analysis



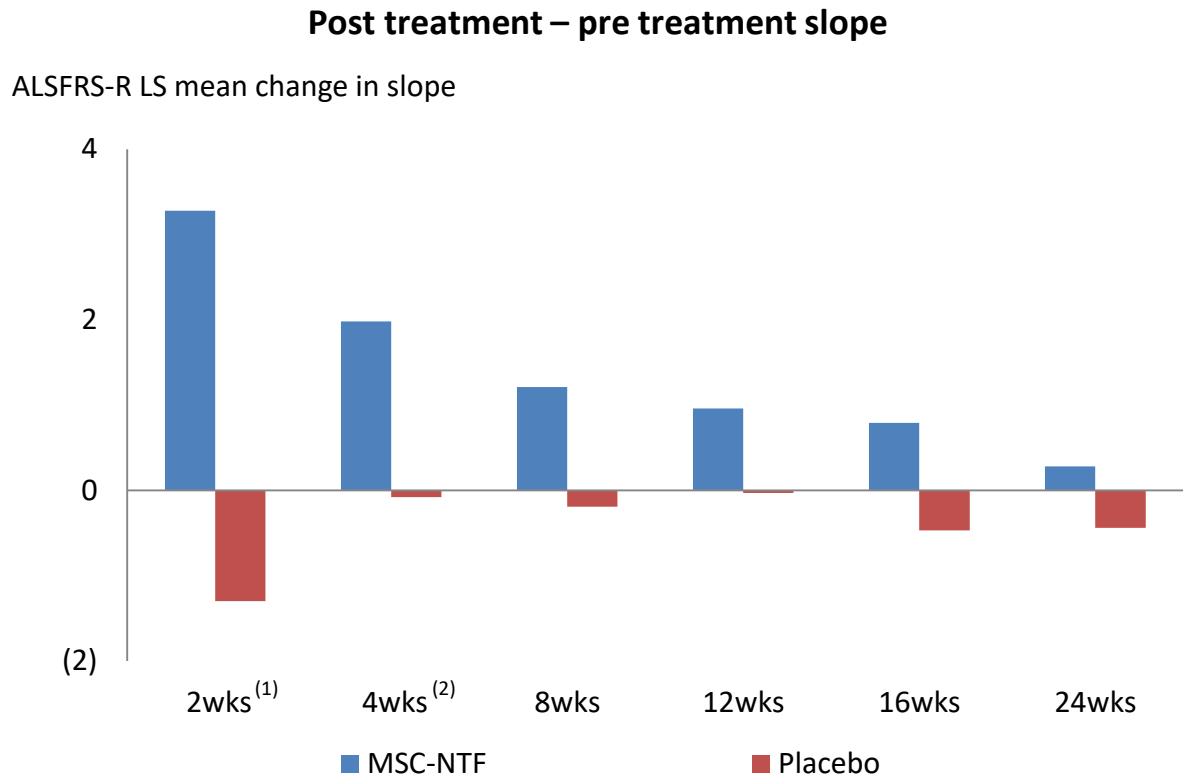
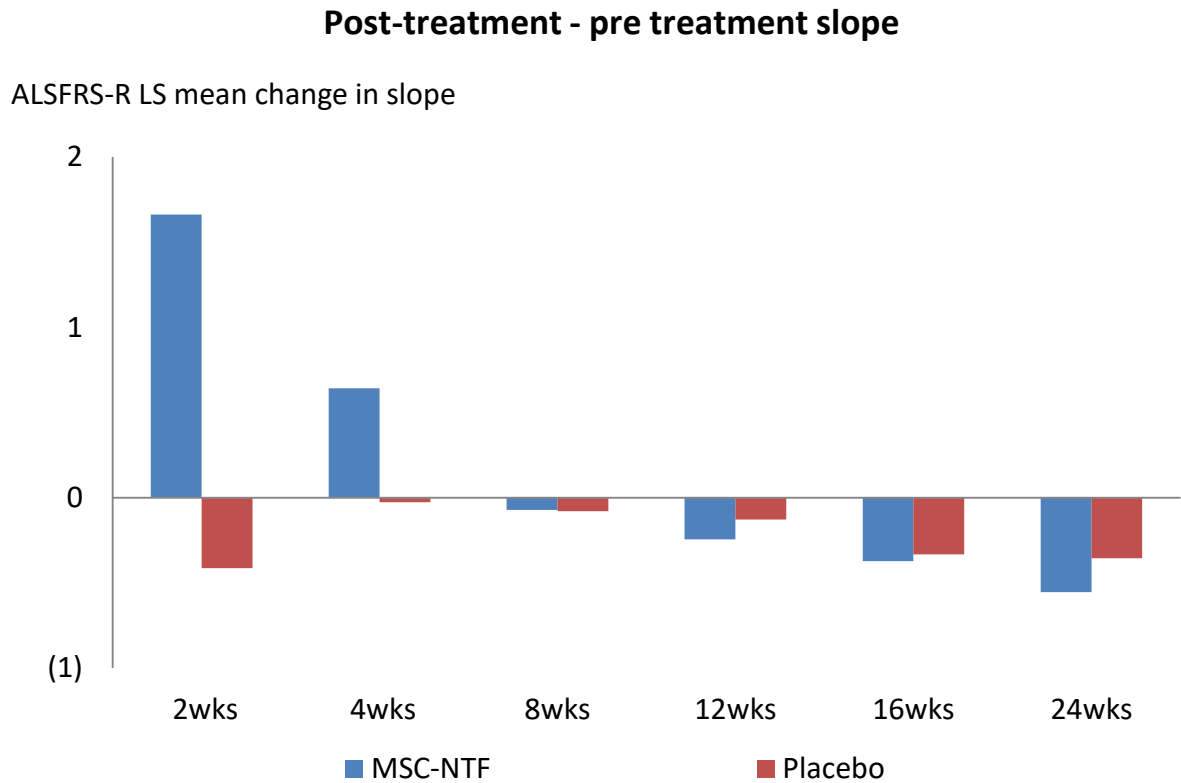
ALS Rapid Progressor Subgroup Has Different Characteristics

- ✓ Change in ALS function in rapid progressors more closely predicts survival and quality of life
- ✓ Higher response rate in rapid progressors enables smaller study
- ✓ Rapid progressors show more inflammation in relevant disease biomarkers

1. NurOwn® Phase 2: ALSFRS-R slope improvement (mean slope change/month)

All participants (n=46)

Rapid progressors (n=21)



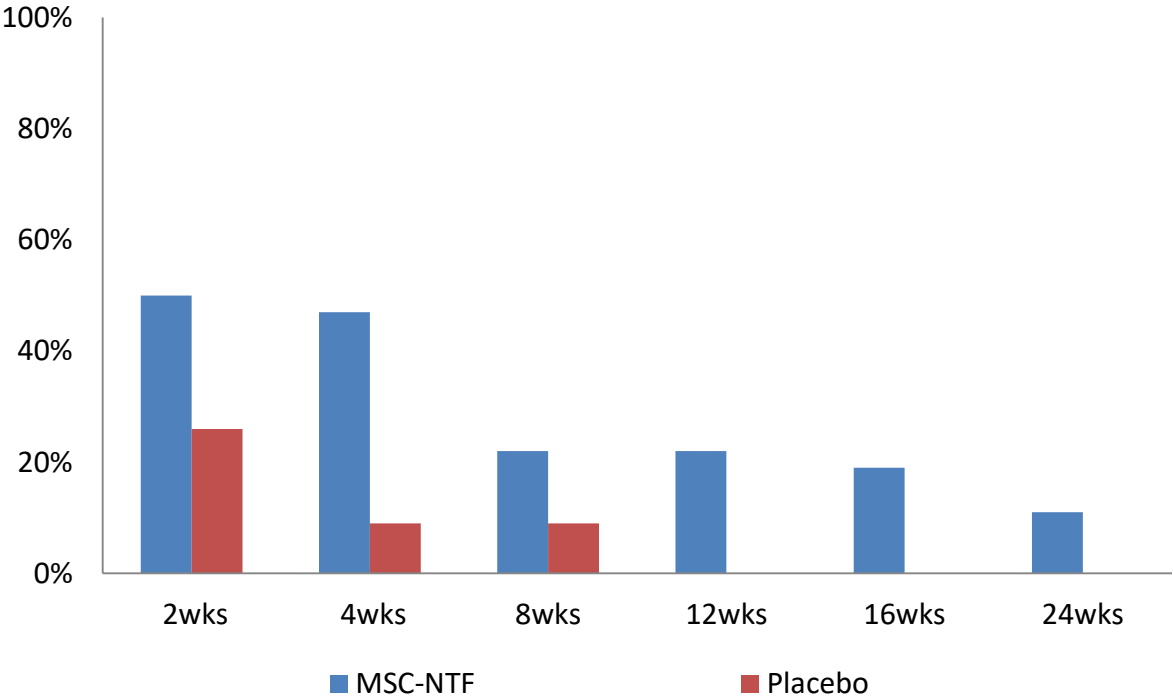
1. $p=0.021$
2. $P=0.033$

2. NurOwn® Phase 2: Responder Analysis: (≥1.5 points/month ALSFRS-R slope improvement)

All participants (n=46)

ALSFRS-R ≥ 1.5 points improvement/month in
post-treatment slope compared to pre-treatment slope

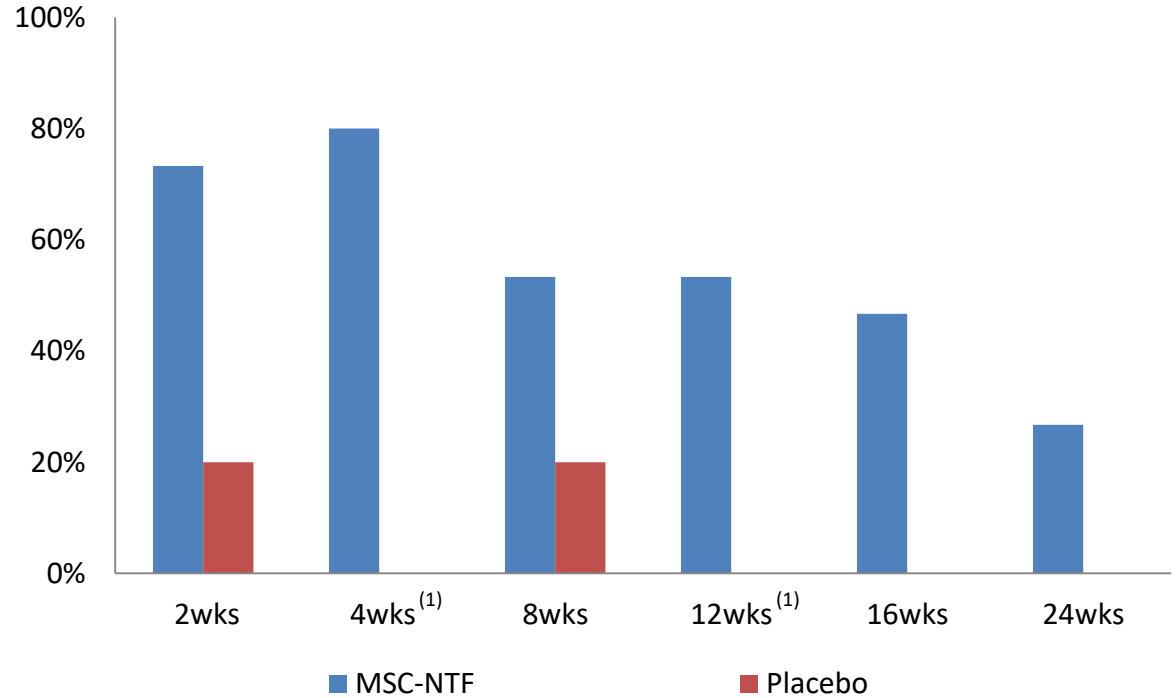
% patients with ≥ 1.5 point improvement/month



Rapid progressors (n=21)

ALSFRS-R ≥ 1.5 points improvement in post-treatment slope
compared to pre-treatment slope

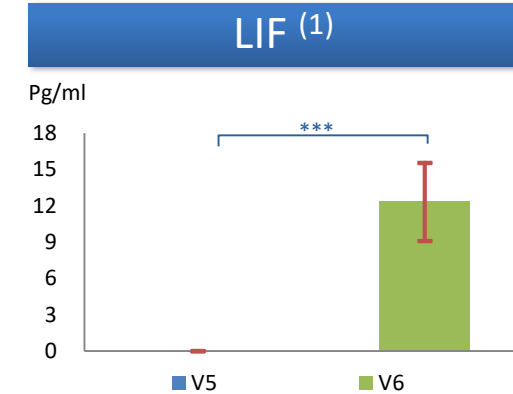
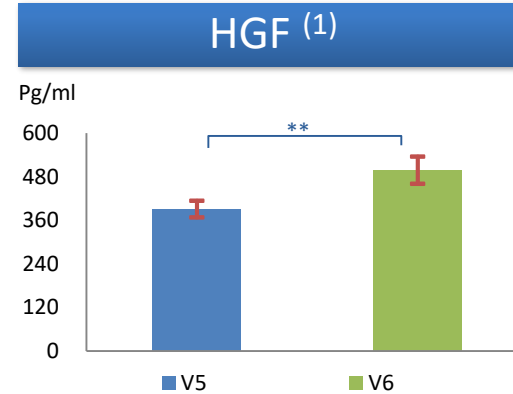
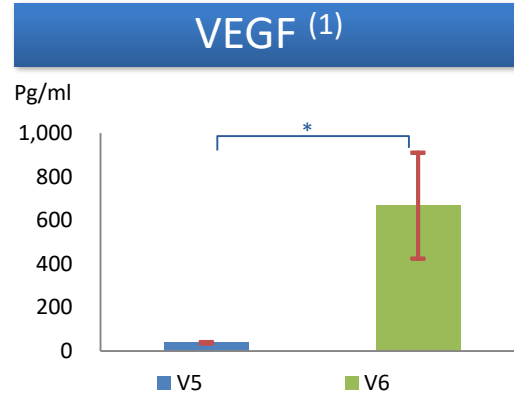
% patients with ≥ 1.5 point improvement/month



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

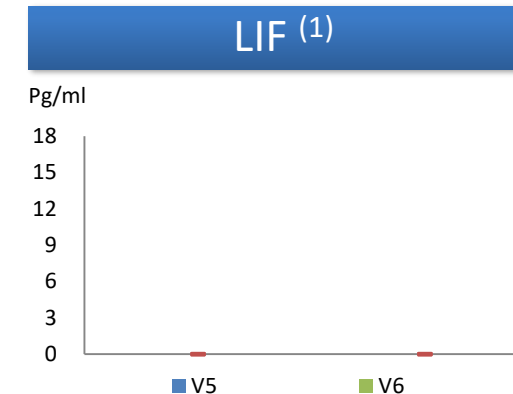
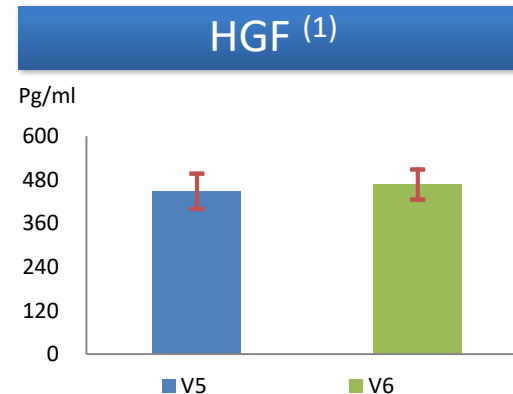
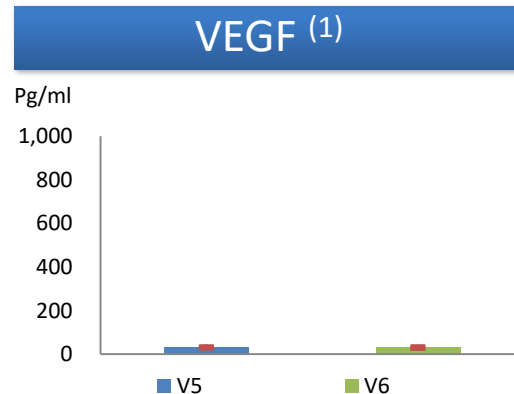
NurOwn® Phase 2 ALS Trial: CSF NTFs Significantly Increased 2 Weeks Post- Treatment Compared to Baseline

NurOwn®
(n = 26)



■ Pre transplantation
■ Post transplantation

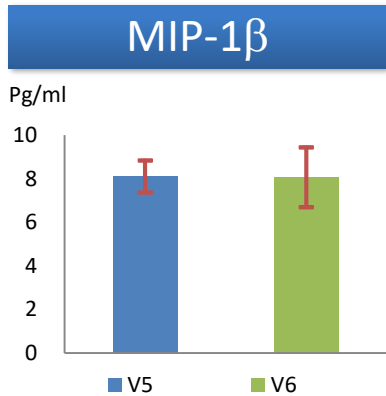
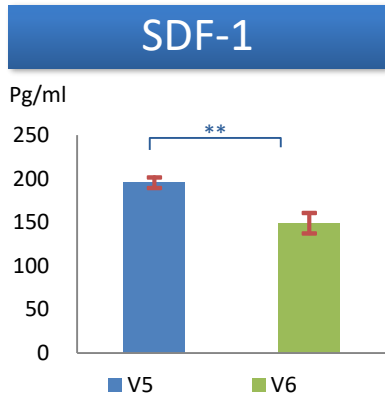
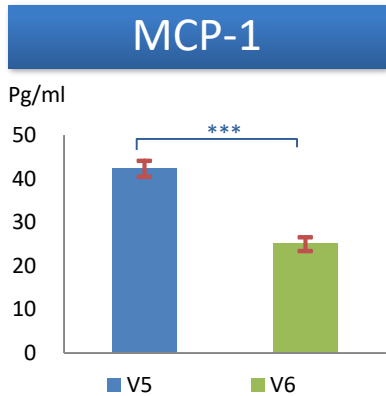
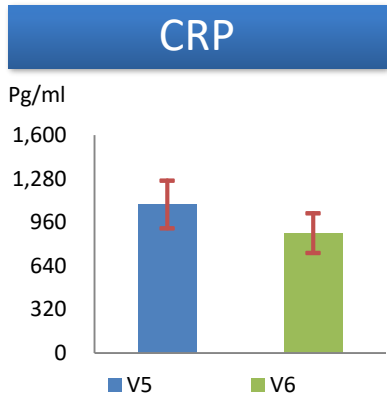
Placebo
(n = 9)



NurOwn® Phase 2 ALS Trial: CSF Inflammatory Markers Significantly Decreased 2 weeks Post-Treatment Compared to Baseline

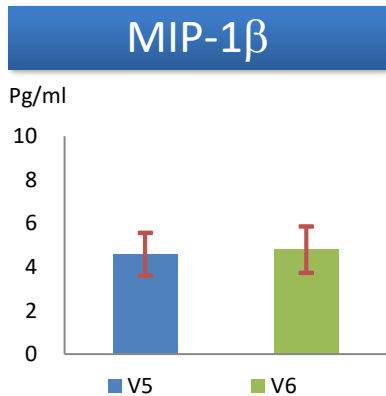
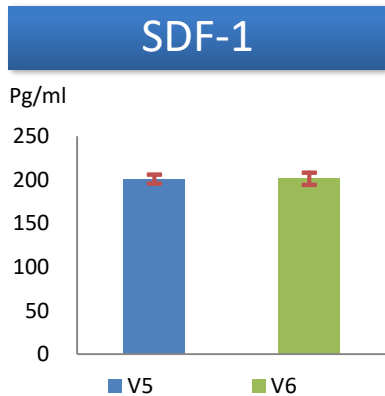
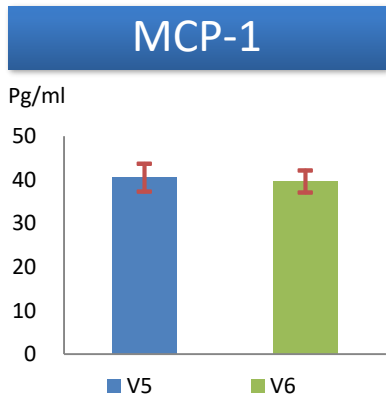
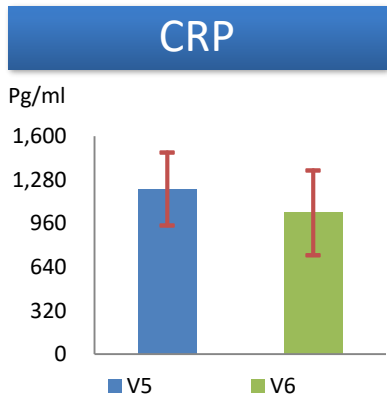


NurOwn®
(n = 26)



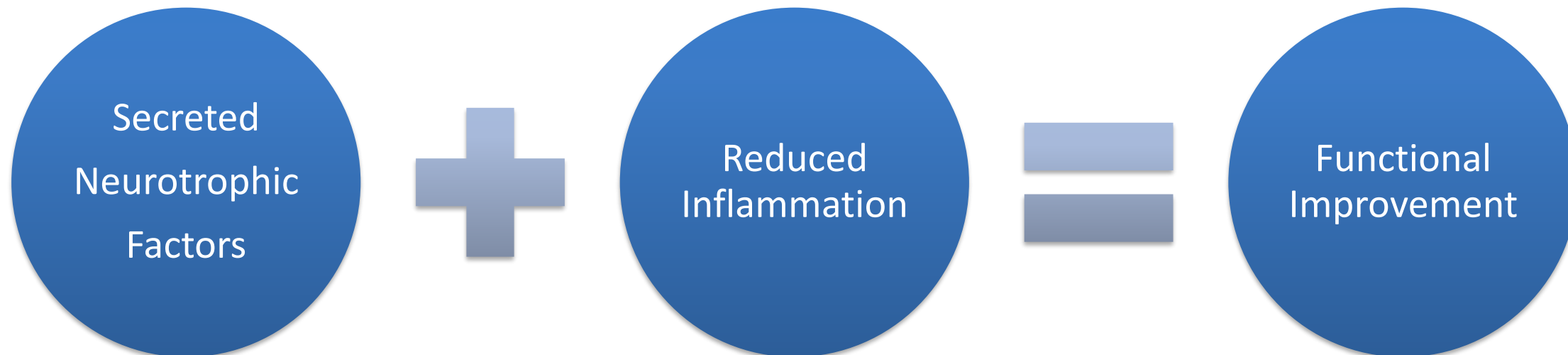
Pre transplantation
Post transplantation

Placebo
(n = 9)

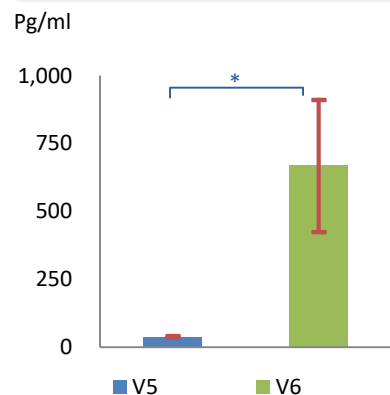


1. Mean ± SEM. $p < 0.01$, $p < 0.001$ for [], respectively.

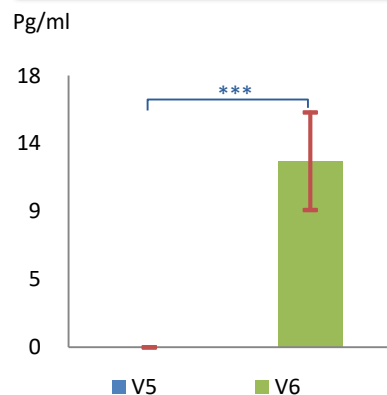
Phase 2 ALS Trial Summary



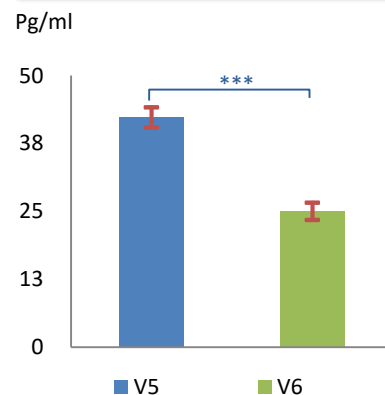
VEGF



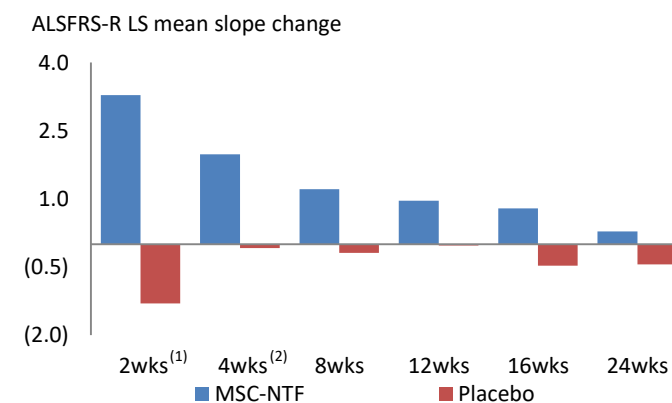
LIF



MCP-1



Change from Post-treatment to pre-treatment slope



1. $p=0.021$
2. $P=0.033$

NurOwn® ALS Phase 3 Clinical Trial

Pre-Treatment

- Inclusion criteria
 - Less than 60 years of age
 - SVC > 65%
 - ALS ≤ 2 years
 - Rapid progressors
- Exclusion criteria
 - Edaravone
 - Ventilation
 - Feeding tube
- Randomization
- Bone Marrow Aspiration

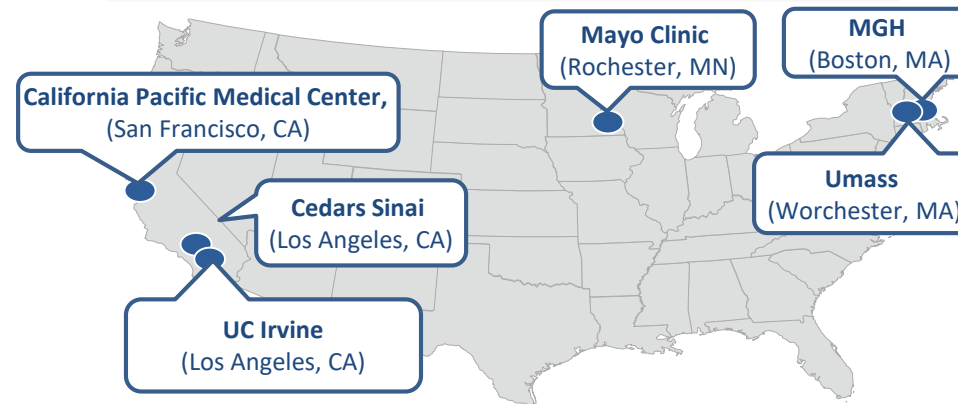
Treatment

- N=200 patients
 - Enrollment completed by mid-2019
- 1:1 randomization
- Study duration: 11.5 months
 - Seven months post-first transplantation
- Top-line data expected mid 2020

Outcomes

- ALSFRS-R responder analysis (post-treatment slope change)
- Safety
- ALSFRS-R change from baseline
- SVC
- Tracheostomy-free survival
- CSF/biomarkers (seven samples over six months)

Site Location



What is MS?

MS is a chronic inflammatory, demyelinating and neurodegenerative disease of the central nervous system. It usually begins in young adults, affects women more frequently than men, and initially responds to disease modifying therapies aimed at reducing immune mediated attacks.

What is Progressive MS?

In about half of affected individuals the disease enters a progressive phase with increasing disability and cognitive impairments. In progressive MS ongoing inflammation and neurodegeneration are prominent features.

Nature Review Disease Primers. November 2018

MS Incidence



It is estimated that 2.3 million people worldwide are living with MS, with 1,000,000 people in the U.S. suffering from this neurodegenerative condition at any given time. Eventually half will develop progressive disease.*

US MS prevalence

1M

Progressive MS

50%

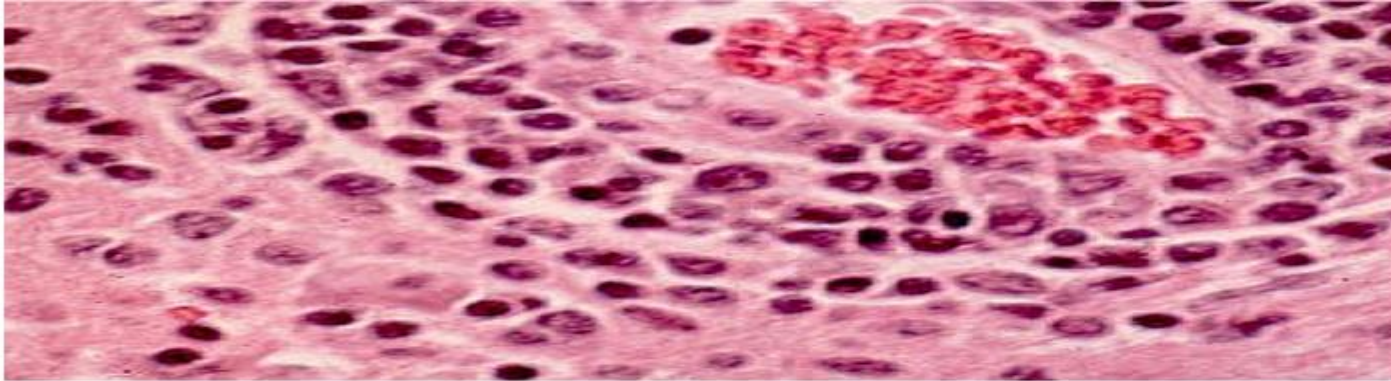
Women

are more likely to be diagnosed
with MS than men

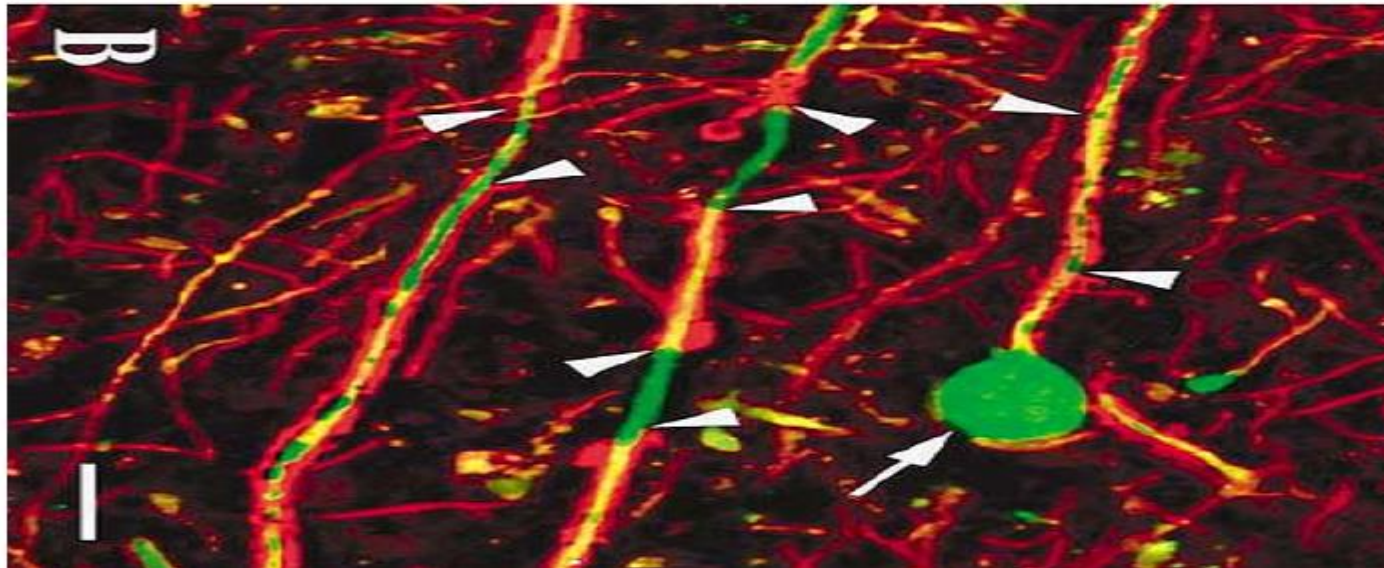
\$4.3B

US annual economic burden

Progressive MS: MSC-NTF Disease Targets: Inflammation and Neurodegeneration



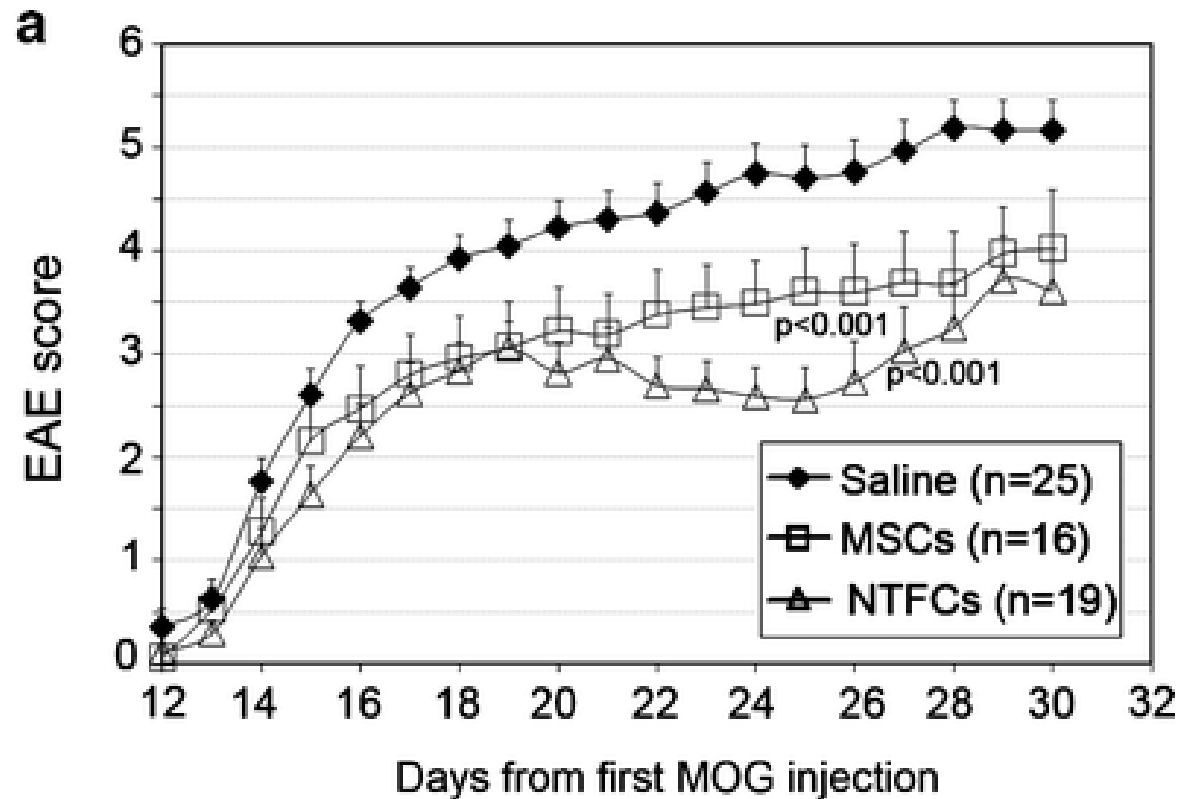
inflammation



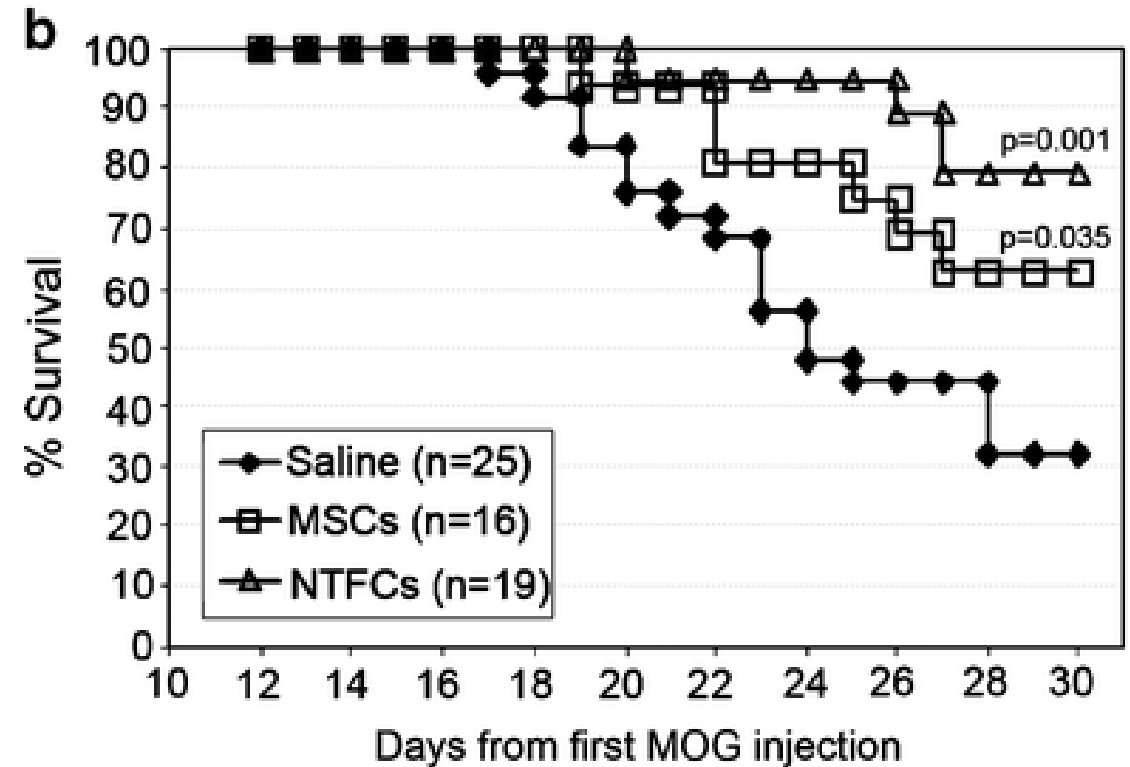
Protect from demyelination
and axonal transection

Images Courtesy J Cohen

Intracerebroventricular NTF cells improves motor function and survival in rodent MS model (EAE)



Intracerebroventricular injection of 2.5×10^5 cells



Progressive MS Trial Population

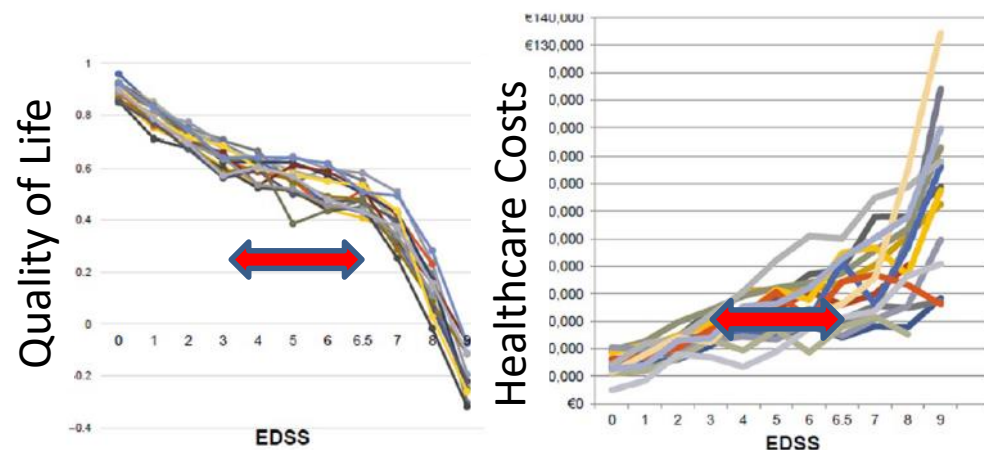
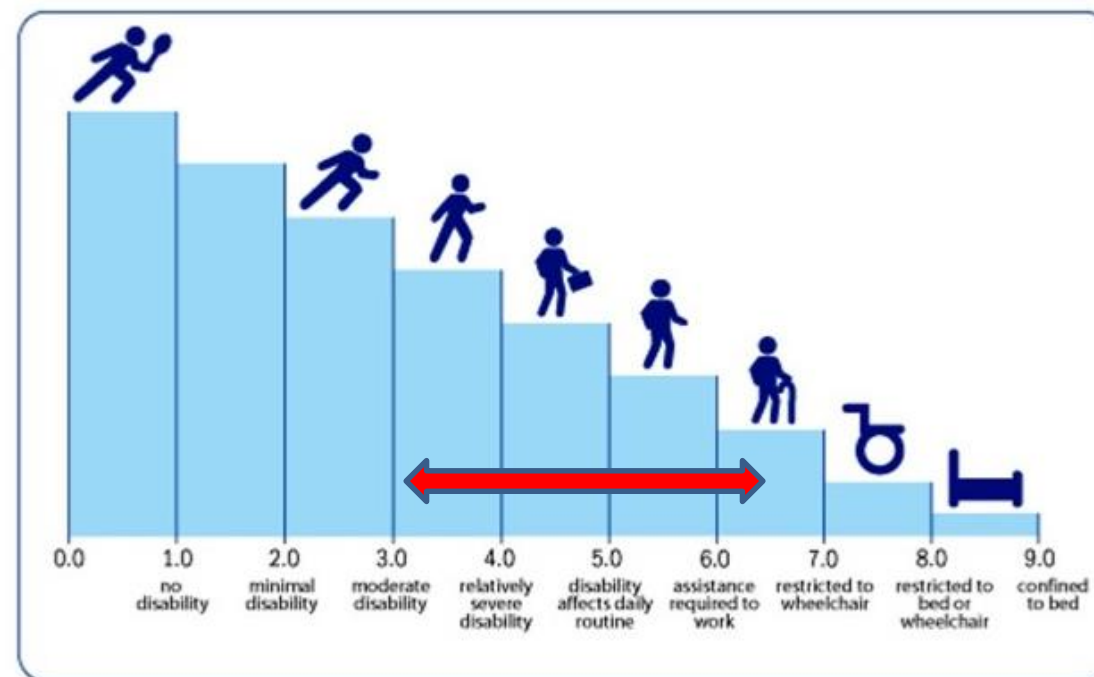


Figure 1. Effect of disease progression in multiple sclerosis patients on quality of life (left) and financial burden (right) in 16 European countries.

Source: Kobelt *et al.*¹

EDSS, Expanded Disability Status Scale.



Financial Highlights

\$US in Thousands <small>(except for Shares, Warrants and Options data)</small>	September 30, 2018
Cash and cash equivalents	697
Short-term deposit	10,194
Non-Dilutive Grants	8,000
Total Liquidity	18,891
Cap Structure	
Debt	-
Shares Outstanding <small>(including outstanding Warrants and Options)</small>	20,700,713
Options / Warrants outstanding	1,457,620 / 4,578,867
Net Operating Loss	88,640

BrainStorm 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

Joe Petroziello BS MS
VP, Scientific and Corporate
Communications

Yael Gothelf PhD.
VP, Scientific and Regulatory Affairs

Uri Yablonka
EVP, Chief Business Officer

Yossef Levy PhD.
VP, Cell Production

Revital Aricha PhD.
VP, R&D

Susan Ward PhD
Head Clinical Research Operations

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Thank You

Appendix

Additional Professional Board Members

June S. Almenoff MD PhD

- Chief Operating Officer & Chief Medical Officer of Innovate Biopharmaceutical
- Formerly President and CMO of Furiex Pharmaceuticals and Board member of Tigenix NV (TIG)

Tony Polverino PhD

- CSO - Kite Pharmaceuticals

Scientific Advisory Board

Jerold Chun, M.D., PhD -Chair

- Neuroscientist, Professor and Senior Vice President of Neuroscience Drug Discovery, Sanford Burnham Prebys Medical Discovery Institute, San Diego CA.

Stanley H. Appel, M.D

- Peggy and Gary Edwards Distinguished Endowed Chair for the Treatment and Research of ALS, Department of Neurology, Neurological Institute, Houston Methodist Hospital, Houston TX.

Amit Bar-Or, M.D.

- Presidential Endowed Chair at the University of Pennsylvania (UPenn/CHOP), Director of the Centre for Neuroinflammation and Experimental Neurotherapeutics and Chief, MS Division, Philadelphia PA.

IP Portfolio

Patent Name/ Int. App. No.	Pending Jurisdictions	Allowed Jurisdictions	Granted Jurisdictions	Expiry Date
ISOLATED CELLS AND POPULATIONS COMPRISING SAME FOR THE TREATMENT OF CNS DISEASES/PCT/IL2006/000699	US		Europe, US	2030
MESENCHYMAL STEM CELLS FOR THE TREATMENT OF CNS DISEASES PCT/ IL2009/000525		Hong Kong	US, Europe, Israel	2032
METHODS OF GENERATING MESENCHYMAL STEM CELLS WHICH SECRETE NEUROTROPHIC FACTORS / PCT/IL2013/050660	Europe, Hong Kong, Israel, Canada, Brazil, Japan	Israel	US, Japan	2038
METHOD OF QUALIFYING CELLS /PCT IL2015/050159	US, Europe, Hong Kong, Israel, Canada, Brazil, Japan			2040
Methods of treating ALS PCT/IL2017/050801	PCT			2042