BrainStorm Issues 2019 Letter to Shareholders

NEW YORK, Dec. 18, 2019 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapeutics for neurodegenerative diseases, today issued a Letter to Shareholders.

Dear Valued Shareholders,

2019 was an extraordinary year for BrainStorm Cell Therapeutics! From a research and development, clinical, and corporate perspective, I appreciate the ongoing, dedicated support we have received from our patients and their families. I also want to acknowledge the many accomplishments of our employees, and the commitment we have received from our shareholders and our distinguished clinical partners, as we continue to execute on our goal of bringing much needed treatments to those suffering from neurodegenerative diseases.

In the second week of October, we announced full enrollment of the 200-patient Phase 3 clinical trial (NCT03280056) evaluating repeat intrathecal administration of NurOwn® cellular therapeutic (autologous MSC-NTF cells) in amyotrophic lateral sclerosis (ALS). This clinical milestone is a key inflection point in the development of NurOwn as an investigational therapeutic and confirming BrainStorm as the leading biotechnology company developing autologous stem cell therapy treating neurogenerative disease.

In late October 2019, the Data and Safety Monitoring Board (DSMB) completed the second planned interim safety analysis for the first 106 patients who received repeat dosing of NurOwn in the Phase 3 ALS trial. The DSMB concluded the trial should continue as planned without any protocol changes. Dr. Carlayne Jackson, M.D., chair of the Phase 3 DSMB stated, “After reviewing all of the safety data as of September 30th, the DSMB has recommended the study continue without any changes in the protocol. We did not identify any significant safety concerns.”

At the end of 2018, we announced the expansion of our pipeline by introducing a new indication for NurOwn in progressive Multiple Sclerosis (MS). Progressive MS has deeply affected the lives of many and dramatically impacted family members, caregivers and others. Today, there is no U.S. FDA approved therapy addressing more than one progressive form of MS. In March 2019, we enrolled the first patient in our Phase 2 open-label, multicenter study of repeated intrathecal administration of autologous MSC-NTF cells in participants with progressive MS. Throughout the year, due to our dedicated efforts, we successfully contracted with leading US clinical sites for our Phase 2 open-label, multicenter clinical trial of repeated intrathecal administration of autologous MSC-NFT cells in progressive MS. These clinical sites, which include the Cleveland Clinic, Stanford University School of Medicine, the University of Southern California and Mount Sinai Medical Center, are Centers of Excellence for MS research and treatment and are led by prominent and well-respected clinical investigators and KOLs in the field of progressive MS. In November, Our Phase 2 ALS clinical data was published in “Neurology”, the highly respected peer-reviewed journal and the official journal of the American Academy of Neurology. Concurrently, Brainstorm was also selected to be featured in an editorial by independent reviewers titled “Stem Cells in Amyotrophic Lateral Sclerosis - Hype or Hope”, which commented on Brainstorm’s ALS clinical study design and stated: “Berry and associates are to be commended for presenting the framework of a well-planned and designed study that should serve as a framework for other investigators to emulate.”

BrainStorm was recently awarded a grant of $495K from The National MS Society (NMSS) to support our Phase 2 biomarker study of NurOwn in progressive MS. This funding from the National MS Society will help us explore key neuroinflammation and neural repair biomarkers in progressive MS to confirm NurOwn’s unique mechanism of action and will guide the design of future clinical trials to address this important unmet patient need.

We also expanded our intellectual patent portfolio by obtaining additional United States and Japanese patents for BrainStorm's NurOwn cellular technology for the treatment of various neurogenerative diseases. These patents add another layer of protection around our cellular technology and are the result of our ongoing technical development and clinical progress.

Lastly, we strengthened our executive team by bringing on board Dr. Preetam Shah as our Executive Vice President and Chief Financial Officer to expand our Investor Relations program and future business development and capital strategy initiatives.

Our ongoing Phase 3 and Phase 2 clinical programs investigating NurOwn in ALS and progressive MS have received extensive and positive news coverage in the mainstream US media over the last year. I want to make sure that all our investors have an opportunity to read these articles and view these news items. The list of selected articles is listed below. The ABC Nightline segment was broadcast to more than 3 million households across the US and continues to be a major part of a full form documentary that will be broadcast by ABC Nightline and partners in 2020.

What is clear from these news items is that ALS and progressive MS represent significant unmet medical needs and that, despite the limited options currently available, patients are highly motivated to seek out new treatments and physicians recognize the potential of our autologous cellular therapy technology platform.

Approximately 6,000 people in the U.S. are diagnosed with ALS each year and more than 30,000 Americans are currently living with the disease. Worldwide it is estimated that 450,000 patients are living with ALS. Since 1995, only two new pharmaceuticals have been approved, but the medical need remains. NurOwn is the first autologous cellular investigational therapy to have advanced as far in a Phase 3 clinical trial. Progressive MS represents a US and worldwide addressable market opportunity of 500,000 and 1,250,000, individuals, respectively.

Looking ahead to 2020, we are highly focused on generating top-line results for our ALS phase 3 and progressive MS phase 2 trials in the fourth quarter, to initiating the regulatory submission and eventual commercialization of NurOwn in ALS, to further advancing our cellular technology and manufacturing capabilities. We will actively seek additional opportunities to expand our pipeline to address unmet need and to grow as a biotechnology company.

I want to personally thank you for your continued support.

Sincerely,

Chaim

Chaim Lebovits
President and CEO
BrainStorm Cell Therapeutics Inc.

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Selected Video Clips:

ABC Nightline

ALS patients share about their life 5 years after 'Ice Bucket Challenge': Part 1
https://abcnews.go.com/Nightline/video/als-patients-share-life-years-ice-bucket-challenge-64874152

Part 2
https://abcnews.go.com/Nightline/video/als-patient-rides-motorcycle-unable-years-part-64874209

KTLA Southern California

https://ktla.com/2019/11/21/l-a-firefighter-among-patients-undergoing-promising-treatment-for-als/

CBS Philadelphia

https://philadelphia.cbslocal.com/2019/03/11/als-patients-fighting-fda-for-experimental-drug-nurown/

Selected News Articles:

- ALS News Today – Phase 2 Trial Data on NurOwn Therapy, Supporting Safety And Early Efficacy, Published https://alsnewstoday.com/2019/11/25/phase-2-trial-nurown-cell-therapy-published-support-safety-and-early-efficacy-als/

- Multiple Sclerosis News Today – NMSS Awards $495K to Study Biomarkers in Phase 2 Trial of NurOwn in Progressive MS

https://multiplesclerosisnewstoday.com/news-posts/2019/11/15/brainstorm-cell-therapeutics-announces-research-grant-award-from-the-national-multiple-sclerosis-society/

- Seeking Alpha – Interview With Chaim Lebovits, CEO Of Brainstorm Cell Therapeutics https://seekingalpha.com/article/4301794-interview-chaim-lebovits-ceo-of-brainstorm-cell-therapeutics
- ALS News Today – Phase 3 Trial of NurOwn, Cell Therapy for ALS, Gets Thumbs Up in Safety Review by Independent Board https://alsnewstoday.com/2019/11/01/nurown-gets-good-safety-review-by-phase-3-trial-monitoring-board/
- ALS News Today – Phase 3 Trial of NurOwn Cell Therapy Fully Enrolls 200 Patients, BrainStorm Announces https://alsnewstoday.com/2019/10/14/phase-3-nurown-trial-fully-enrolls-200-als-patients-brainstorm-says/
- ALS News Today – Advancing Potential ALS Treatments Is Like Accelerating a Glacier https://alsnewstoday.com/2019/08/14/stem-cell-research-glacier-clinical-trials-progress/
- Money Week – How stem cells are changing the face of medicine https://moneyweek.com/511814/how-stem-cells-are-changing-the-face-of-medicine/
- MedPage Today – Baby Step Forward for ALS Cell Therapy https://www.medpagetoday.com/meetingcoverage/aan/79680
- Multiple Sclerosis News Today – Progressive MS Phase 2 Trial of NurOwn Stem Cell Therapy Enrolls 1st Patient https://multiplesclerosisnewstoday.com/2019/03/18/progressive-ms-phase-2-trial-of-nurown-stem-cell-therapy-enrolls-1st-patient/
- Bloomberg – Namesake of ‘Right to Try’ Law Gets ALS Therapy, Says It’s Working https://www.bloomberg.com/news/articles/2019-02-05/right-to-try-law-namesake-gets-als-therapy-says-it-s-working
- Multiple Sclerosis New Today – BrainStorm Expands Production of Autologous Stem Cell Therapy NurOwn for Phase 2 Trial in Multiple Sclerosis https://multiplesclerosisnewstoday.com/2019/01/09/brainstorm-expands-production-autologous-stem-cell-technology-nurown-phase-2-trial/

Safe-Harbor Statements

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.

Source: BrainStorm Cell Therapeutics Inc.

Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2019-12-18-BrainStorm-Issues-2019-Letter-to-Shareholders