BrainStorm Issues 2018 Letter to Shareholders

December 27, 2018 7:35 AM ET

NEW YORK, Dec. 27, 2018 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today issued a Letter to shareholders.

Dear Valued Shareholder,

This past year was an extraordinary success for BrainStorm Cell Therapeutics from a research and development, clinical, financial and corporate perspective. I appreciate the many accomplishments of our employees and the dedicated support we have received from investors, as we execute on our goal of bringing critical treatments to those suffering from neurodegenerative diseases.

I want to acknowledge the efforts of the six key centers enrolling patients in the Company's NurOwn® Phase 3 clinical trial for the treatment of amyotrophic lateral sclerosis (ALS): Mass General Hospital, UMass, Mayo Clinic, CPMC, Cedars Sinai and UC Irvine, and to the ALS patients and their families for helping us advance the pivotal study. We are targeting to enroll 200 ALS patients in this trial, and we remain on track to achieve this key milestone by mid-2019.

In August 2018, the Data and Safety Monitoring Board (DSMB) completed the first planned interim safety analysis for the ALS Phase 3 study and concluded that there were no safety concerns and the study should continue as planned. Dr. Carlayne Jackson, M.D., who is the chair of the DSMB reviewing NurOwn commented, "We appreciate the continued commitment of BrainStorm Cell Therapeutics for conducting this trial in such an exemplary manner." The DSMB will conduct an additional planned interim safety analysis by July 2019, for which we will report the outcome when it becomes available.

On the research and development front, the U.S. Food and Drug Administration recently approved the Company's NurOwn investigational new drug application for a Phase 2 study in progressive Multiple Sclerosis (MS). We plan to initiate a study in this patient population in the first quarter of 2019 and will provide additional details regarding the trial design and participating centers. Expanding our clinical trial program into progressive MS is an important achievement in establishing NurOwn as a platform technology, and furthermore, we are conducting pre-clinical research in other neurodegenerative diseases, and plan to announce additional potential indications in 2019.

This year we also expanded our NurOwn manufacturing capabilities by transferring operations to the Dana Farber Cancer Institution, in addition to the on-going production at the City of Hope for Biomedicine and Genetics.

In 2018, we focused on strengthening our financial position; we received $12.3 million from warrant activation and additional milestone payments as part of the previously awarded $16 million non-dilutive grant from the California Institute for Regenerative Medicine. In addition, for the 11th consecutive year, we received non-dilutive grants from the Israel Innovation Authority to further support the development of NurOwn®, including a research and development grant of $1 million. BrainStorm is entering 2019 in a position of financial strength, which will enable us to remain laser focused on executing our clinical trials and operational initiatives.

We expanded our patent portfolio by obtaining additional United States, European and Japanese patents for BrainStorm's NurOwn® technology for the treatment of ALS and Parkinson's disease. These additional patents further protect our technology, and are the result of our ongoing technology development and clinical progress.

Lastly, we strengthened our executive team and board of directors. We added three senior members to our executive team: Arturo Araya as Chief Commercial Officer, Susan Ward as Head of Clinical Operations, and Joseph Petroziello as Vice President, Scientific & Corporate Communications. These individuals were sought after for their deep neuroscience experience, significant industry expertise and long track record of industry achievements. Our Board of Directors was strengthened with the appointment of Anthony Polverino, Ph.D., Executive Vice President of Early Development & Chief

Scientific Officer at Zymeworks Inc. and formerly interim Chief Scientific Officer of Kite Pharma. Dr. Polverino is a highly accomplished senior biopharmaceutical executive with more than 25 years' industry experience in drug research and development.

Looking ahead to 2019, we remain focused on completing enrolment in the ALS phase 3 study and initiating the progressive MS phase 2 studies are our highest priorities. We will continue to lead the development of cellular therapeutics in neurodegenerative disease, seek additional opportunities to expand our pipeline to address unmet need and continue to enhance our manufacturing capabilities and infrastructure.

I want to personally thank you for your continued support.

Sincerely,
Chaim Lebovits, CEO

CONTACTS

Media:
Joseph Petroziello
BrainStorm Cell Therapeutics
Phone: +1.215.485.6797
Email: JP@brainstorm-cell.com

Investors:
Marcy Beth Nanus
Solebury Trout
Phone: +1.646.378.2927
Email: MNanus@troutgroup.com

download.jpg

BrainStorm Cell Therapeutics Inc.