BrainStorm Announces Financial Results for 2016 and Provides Business Update

HACKENSACK, N.J. and PETACH TIKVAH, Israel, March 30, 2017 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, announced financial results for the year ended December 31, 2016.

"2016 was a highly successful and pivotal year for Brainstorm, with a number of important achievements and significant progress made on clinical, regulatory and operational fronts," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm Cell Therapeutics. "We announced positive top-line Phase 2 data of NurOwn® in the treatment of amyotrophic lateral sclerosis (ALS), demonstrating the potential of this therapy to halt or reverse ALS disease progression. Following our End of Phase 2 meeting with the FDA, we are making final preparations to begin a Phase 3 clinical trial, which when successful will position us to bring to ALS patients and their families a much needed and innovative ALS disease modifying therapy."

2016 and Recent Clinical Highlights:

- Announced in July positive topline results from the U.S. Phase 2 randomized, placebo controlled study of NurOwn in patients with ALS.
    - Study achieved its primary objective, demonstrating that NurOwn was safe and well tolerated.
    - NurOwn also achieved multiple efficacy endpoints, showing clear evidence of a clinically meaningful benefit.
    - Response rates (based on ALSFRS-R responder analysis of halt or reverse of disease progression) were higher in NurOwn-treated subjects compared to placebo at all time points in the study out to 24 weeks.
    - In depth analysis of the Phase 2 data presented by Dr.James Berry of Mass. General Hospital at the 27th International Symposium on ALS/MND in Dublin, Ireland, demonstrating evidence that NurOwn has the potential to halt or reverse disease progression.
- Completed a successful End-of-Phase 2 Meeting with the United States Food and Drug Administration (FDA).
    - Reached a general agreement with the FDA to proceed to a Phase 3 trial. Importantly, the FDA has accepted the key elements of the Phase 3 program to support a Biologic License Application (BLA) for NurOwn.
    - The planned Phase 3 clinical trial will be a randomized, double-blind, placebo-controlled multi-dose trial to be conducted at multiple sites in the U.S. and in Israel.
    - The trial is expected to begin enrolling patients in the second quarter of 2017.
- Announced plans to contract with City of Hope's Center for Biomedicine and Genetics to produce clinical supplies of NurOwn adult stem cells for the company's planned Phase 3 clinical study in ALS.
    - City of Hope is expected to manufacture and provide NurOwn to all U.S. medical centers that will be participating in the Phase 3 trial.
- Signed a Memorandum of Understanding (MOU) with the Medical Research, Infrastructure, and Health Services Fund of the Tel Aviv Sourasky Medical Center (Ichilov Hospital) to explore the possibility of making NurOwn available to ALS patients under the provisions of Hospital Exemption regulation.
    - The MOU also covers the participation of Tel Aviv Sourasky Medical Center in the planned Phase 3 trial that will investigate NurOwn in ALS.
    - The agreement is expected to be formalized in the first half of 2017.
- Validated cryopreservation process for NurOwn in preparation for the planned Phase 3 clinical study in ALS.
    - Cryopreservation will allow the Company to provide in Phase 3 repeated doses of autologous NurOwn from a single bone marrow aspirate. This will avoid the need for patients to undergo repeated bone marrow aspirations.

2016 and Recent Corporate Highlights:

- Appointed Ralph Z. Kern, MD, MHSc to the positions of Chief Operating Officer and Chief Medical Officer.
    - Dr. Kern joined BrainStorm from Biogen, where he was Senior VP and Head of Worldwide Medical. Previous industry appointments include Head of Neuroscience Medical Unit at Novartis and Global Medical Director of Personalized Genetic Health at Genzyme Corp.

- Appointed June S. Almenoff, M.D., Ph.D., FACP, and Arturo O. Araya, M.A., M.B.A. to the Board of Directors.
- Awarded a non-dilutive grant of approximately $1,470,000 from Israel's Office of the Chief Scientist (OCS).
- Granted United States Patent No. 9,474,787 titled "*Mesenchymal Stem Cells for the Treatment of CNS Diseases*."

Financial Results for the Fourth Quarter Ended December 31, 2016
Net R&D expenses for the fourth quarter of 2016 were $323,000, compared with $826,000 for the fourth quarter of 2015. The decrease was primarily the result of decreased U.S. clinical trial expenses. In the fourth quarter of 2016, general and administrative expenses were $327,000, compared with $571,000 in the same period of 2015. This was driven by decreased consultants expenses and decrease in Delaware Franchise Tax. Net loss for the fourth quarter was $624,000 or ($0.03) per share, versus $1.4 million or ($0.07) per share in the same period of 2015.

Financial Results for the Year Ended December 31, 2016
Research and Development expenses for the year ended December 31, 2016 were $2.3 million, compared to $4.9 million in the same period of 2015, primarily as a result of decreased U.S. clinical trial costs and partially offset by in the costs of activities related to the Israeli clinical trials and costs of materials. General and administrative expenses for the year were $2.8 million, compared to $3.6 million in the same period of 2015, primarily due to a decrease in the cost of our investor relations and public relations activities, our Delaware Franchise tax and rent. This decrease was partially offset by an increase in payroll expenses and consultants. Net loss for the year ended December 31, 2016, was $5.0 million, or ($0.27) per share, compared with a net loss of $8.5 million, or ($0.46) per share, for the year ended December 31, 2015.

As of December 31, 2016, BrainStorm had approximately $10.0 million in cash, cash equivalents and short-term deposits, compared with approximately $16.0 million at December 31, 2015.

About BrainStorm Cell Therapeutics Inc.
BrainStorm Cell Therapeutics Inc. is a biotechnology company engaged in the development of first-of-its-kind adult stem cell therapies derived from autologous bone marrow cells for the treatment of neurodegenerative diseases. The Company holds the rights to develop and commercialize its NurOwn technology through an exclusive, worldwide licensing agreement with Ramot, the technology transfer company of Tel Aviv University. NurOwn has been administered to approximately 75 patients with ALS in clinical trials conducted in the United States and Israel. In a randomized, double-blind, placebo-controlled clinical trial conducted in the U. S., a clinically meaningful benefit was demonstrated by higher response to NurOwn compared with placebo. For more information, visit the company's website at www.brainstorm-cell.com.

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.

CONTACTS

Media:
Uri Yablonka
Brainstorm Cell Therapeutics Inc.
Phone: (646) 666-3188
uri@brainstorm-cell.com

Investors:
Michael Rice
LifeSci Advisors, LLC
Phone: 646-597-6979
mrice@lifesciadvisors.com

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands
(Except share data)

	December 31,	
	2016	**2015**
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 547	$ 428
Short-term deposit	9,443	15,527
Account receivable (Note 4)	306	759
Prepaid expenses and other current assets	148	74
Total current assets	10,444	16,788
Long-Term Assets:		
Prepaid expenses and other long-term assets	25	21
Property and Equipment, Net (Note 5)	297	271
Total Long-Term Assets	322	292
Total assets	$ 10,766	$ 17,080
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payables	$ 345	$ 1,169
Accrued expenses	152	1,500
Other accounts payable	367	283
Total current liabilities	864	2,952
Total liabilities	$ 864	$ 2,952
Stockholders' Equity:		
Stock capital:	11	11
Common stock of $0.00005 par value - Authorized: 100,000,000 shares at December 31, 2016 and December 31, 2015 respectively; Issued and outstanding: 18,687,987 and 18,643,288 shares at December 31, 2016 and December 31, 2015 respectively.		
Additional paid-in-capital	85,014	84,258
Accumulated deficit	(75,123)	(70,141)
Total stockholders' equity	9,902	14,128
Total liabilities and stockholders' equity	$ 10,766	$ 17,080

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
U.S. dollars in thousands
(Except share data)

	Year ended December 31,	
	2016	**2015**
	U.S. $ in thousands	

Operating expenses:		
Research and development, net	$ 2,250	$ 4,949
General and administrative	2,833	3,587
Operating loss	(5,083)	(8,536)
Financial expenses (income), net	(101)	(48)
Taxes on income (Note 10)	-	-
Net loss	$ (4,982)	$ (8,488)
Basic and diluted net loss per share from continuing operations	$ (0.27)	$ (0.46)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	18,663,162	18,405,610

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