

BrainStorm Announces Financial Results for 2015 and Provides Business Update

HACKENSACK, N.J. and PETACH TIKVAH, Israel, March 10, 2016 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, today announced financial results for the three months and year ended December 31, 2015. Brainstorm filed its annual report on Form 10-K reporting the results on March 9, 2016.

"2015 was a year of continued progress and momentum for Brainstorm," stated Chaim Lebovits, Chief Executive Officer of BrainStorm. "We achieved a number of important milestones including completion of enrollment and treatment of all patients in our ongoing Phase 2 trial investigating NurOwn® in Amyotrophic Lateral Sclerosis (ALS). We look forward to completing the final follow-up patient visits and learning the results of this study within the next few months. As there are limited treatment options for patients with ALS, we are hopeful that this study will move NurOwn® another step closer to becoming a commercial treatment for ALS."

"Recently, in early 2016, we announced an agreement with Hadassah Medical Center in Jerusalem, to conduct the planned Phase 2 trial with NurOwn® in ALS in Israel. This trial will explore the safety and efficacy of a multidose treatment with NurOwn, which is an important next step in understanding the treatment effect. We were also very pleased to have the peer review publication of the results from our prior Phase 1/2 and Phase 2a studies with NurOwn® in *JAMA Neurology*. The data provide indication of clinically meaningful benefit as reflected by a slower rate of disease progression in the period post treatment. Importantly, these were the first published clinical data with stem cells that have been induced under culture conditions to produce neurotrophic factors (NTFs), with the potential to achieve a neuroprotective effect in ALS and modify the course of disease."

Major Clinical Highlights for 2015 and early 2016:

- In January 2016, a peer-review paper was published in the January 2016 online edition of *JAMA Neurology*, summarizing the results of the Phase 1/2 and Phase 2a clinical studies with NurOwn® in ALS patients. The data provides indication of clinically meaningful benefit as reflected by a slower rate of disease progression in the 6 months post treatment follow-up period, as compared to the pretreatment run-up period. To access this article, refer to <http://archneur.jamanetwork.com/article.aspx?articleid=2480881&resultClick=3>.
- U.S. Phase 2 double blind, placebo controlled, ALS clinical trial:
 - In August 2015, we completed enrollment of all 48 patients in our multicenter randomized, double-blind placebo-controlled Phase 2 U.S. clinical trial of NurOwn® in ALS.
 - In October 2015, the last patient in this trial was treated.
 - In November 2015, we announced positive DSMB (Data and Safety Monitoring Board) review. The DSMB reviewed safety data collected through a cutoff date in October 2015, which included 47 of the 48 patients enrolled in the study and, importantly, no treatment-related serious adverse events (SAEs) were reported. Beyond this, the DSMB did not identify any adverse events, lab abnormalities or significant protocol deviations that would be cause for concern.
- Israeli Phase 2 ALS multi-dose clinical trial:
 - In January 2016, we announced that we entered into a collaborative agreement with the Hadassah Medical Center in Jerusalem, Israel, to conduct the planned multi dose Phase 2 trial with NurOwn® in ALS. The Hadassah Medical Center Internal Review Board ("Helsinki committee") has already approved the application, which is now pending Ministry of Health (MoH) approval
- Israeli Phase 2a ALS clinical trial:
 - In January 2015, we announced the final analysis of our Phase 2a ALS study, showing nearly all subjects experienced clinical benefit from NurOwn® (see above)

Major Corporate Highlights for 2015 and early 2016:

- In December 2015, we announced that, together with Octane Biotech Inc., a Canadian company that focuses on clinical systems for cell and tissue therapy, we have made significant progress toward the development of a novel bioreactor for industrial-scale manufacture of BrainStorm's NurOwn® neurotrophic-factor secreting mesenchymal stem cells. The companies have completed key development activities related to the customization of specific features of Octane's Cocoon™ instrumentation platform to enable efficient delivery of BrainStorm's NurOwn® stem cell therapy.
- In December 2015, we announced the appointment of Dr. Revital Geffen-Aricha as VP of R&D.
- In November 2015, we announced that we were awarded an additional \$735,000 non-dilutive grant from Israel's Office of the Chief Scientist.
- In October 2015, we announced that we have strengthened our intellectual property position, by being granted a patent for our NurOwn® technology platform – titled "Isolated Population of Cells, Methods of Generating Same, and Uses Thereof in the Treatment of CNS Diseases".
- In September 2015, we announced the appointment of Chaim Lebovits as Chief Executive Officer.
- In July 2015, we announced the appointment of Yoram Bibring as Chief Financial Officer.
- In January 2015, we announced entering into a Warrant Exercise Agreement for approximately \$13 million; also, we announced approximately \$3.1 million, gross received from Warrant Exercises.

Financial Results for the Quarter Ended December 31, 2015

Net R&D expenses for the fourth quarter of 2015 were \$0.8 million, compared with \$1.6 million for the fourth quarter of 2014. The decrease was primarily the result of decreased U.S. clinical trial expenses. In the fourth quarter, general and administrative expenses for 2015 totaled \$0.6 million, compared with \$1.0 million in 2014. This was driven by decreased stock-based compensation expenses related to cancellation of employee stock options of the previous CEO of the Company. Net loss was \$1.4 million or \$0.07 loss per share, versus \$2.7 million or

\$0.18 loss per share in 2014.

Financial Results for the Year Ended December 31, 2015

Gross R&D expenses for the year totaled \$6.3 million compared with \$6.1 million for 2014, primarily the result of increased U.S. clinical trial costs partially offset by reduced costs in Israel. Net of support from the Office of the Chief Scientist, R&D expenses for the year were \$4.9 million in 2015 and \$4.8 million in 2014. General and administrative expenses for 2015 totaled \$3.6 million, compared with \$2.6 million in 2014. This was driven by increased payroll expenses due to the hiring of a new CEO in June 2014, his replacement in September 2015 as well as a new CFO in July 2015. In addition, the Company's investor relations costs increased as well as its Franchise Tax expenses. Financial income in 2015 was negligible compared to financial expense of \$1.8 million in 2014 as a result of the re-valuation of certain warrants issued to investors in the August 2013 public offering.

Net loss for the year ended December 31, 2015, was \$8.5 million, or \$0.46 per share, compared with a net loss of \$9.2 million, or \$0.68 per share, for the year ended December 31, 2014. The number of shares outstanding as of December 31, 2015 was 18,643,288. As of December 31, 2015, BrainStorm had \$15.96 million dollars in cash, cash equivalents and short-term deposits, compared with \$8.5 million dollars at year-end 2014.

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. 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.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES **CONSOLIDATED BALANCE SHEETS** **U.S. dollars in thousands**

	Year Ended December 31,	
	2015	2014
ASSETS		
Current Assets:		
Cash and cash equivalents	428	4,251
Short-term deposit	15,527	4,290
Account receivable	759	1,005
Prepaid expenses and other current assets	74	32
Total current assets	16,788	9,578
Long-Term Assets:		
Prepaid expenses and other long-term assets	21	20
Property and Equipment	271	313
Total assets	17,080	9,911
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payables	1,169	1,542
Accrued expenses	1,500	1,347
Other accounts payable	283	224
Total current liabilities	2,952	3,113
Warrants issued to investors	-	123
Total liabilities	2,952	3,236
Stockholders' Equity:		
Stock capital	11	11
Additional paid-in-capital	84,258	68,317
Accumulated deficit	(70,141)	(61,653)
Total stockholders' equity	14,128	6,675
Total liabilities and stockholders' equity	17,080	9,911

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

	Year Ended, December 31,		Three Months Ended December 31,	
	2015	2014	2015	2014
Operating costs and expenses:			Unaudited	Unaudited
Research and development, net	\$ 4,949	\$ 4,772	\$ 826	\$ 1,643
General and administrative	3,587	2,649	571	1,023
Total operating costs and expenses	8,536	7,421	1,397	2,666
Operating loss	(8,536)	(7,421)	(1,397)	(2,666)
Financial (expenses) income, net	48	(1,825)	13	(64)
Pre-Tax Loss	(8,488)	(9,246)	(1,384)	(2,730)
Taxes on income	-	-	-	-
Net loss	\$ (8,488)	(9,246)	\$ (1,384)	(2,730)
Basic and diluted net loss per share from continuing operations	(0.46)	(0.68)	(0.07)	(0.18)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	18,405,610	13,662,758	18,550,438	15,267,005

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Additional assets available online:  [Photos \(1\)](#)

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