

BrainStorm Announces Operational Highlights and Financial Results for the Year Ended December 31, 2017

March 8, 2018 6:31 AM ET

Conference Call and Webcast @ 8:30 a.m. Eastern Time Today

NEW YORK and PETACH TIKVAH, Israel, March 8, 2018 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, today announces financial results for the fourth quarter and fiscal year ended December 31, 2017.



"2017 was a very productive year for BrainStorm, with significant progress and achievements across clinical, operational and financial fronts," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "Most importantly, we began treating patients in our pivotal, double blind, placebo-controlled Phase 3 trial of NurOwn® for the treatment of ALS. The trial is being conducted at six leading ALS centers in the U.S., and is supported by a \$16 million non-dilutive grant from the California Institute of Regenerative Medicine (CIRM)."

"We met and exceeded expectations in 2017 on the manufacturing and product development fronts," continued Mr. Lebovits. "We contracted with the City of Hope's Center for Biomedicine and Genetics in California, to produce clinical supplies of NurOwn® for our US Phase 3 trial. Furthermore we have recently been granted Good Manufacturing Practice (GMP) certification by the Israel Ministry of Health (MoH) for our Israeli contract manufacturing facility. "

"We are building a world class team at BrainStorm and made a number of senior management appointments throughout 2017 including Ralph Z. Kern, MD, MHSc (Chief Operating Officer and Chief Medical Officer), Mary Kay Turner (VP of Patient Advocacy and Government Affairs), and Eyal Rubin (CFO). BrainStorm has also recently elected Senior Kite Pharma executive Anthony Polverino, Ph.D., to its Board of Directors," concluded Mr. Lebovits.

Fourth Quarter and Recent Corporate Highlights:

- Treated the first patients in the Phase 3 clinical trial investigating NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS).
 - The trial is expected to enroll 200 patients and is being conducted at six leading ALS clinical sites in the U.S.
 - The patient population is optimized to include the pre-specified subgroups who demonstrated superior outcomes in the NurOwn® Phase 2 ALS clinical trial.
 - Topline data are expected towards the end of 2019.
 - This trial is supported by a \$16 million non-dilutive grant from CIRM.
- Received Notice of Allowance from the U.S. Patent & Trademark Office (USPTO) for a US patent covering its NurOwn® technology to treat ALS and Parkinson's disease.
- Appointed Eyal Rubin as Chief Financial Officer.
 - Mr. Rubin previously served as VP and Head of Corporate Treasury, Teva Pharmaceutical Industries (2013-17)
- Published a study profiling NurOwn's unique miRNA signature in the peer-reviewed journal *Stem Cell Research & Therapy*.
- Presented two scientific posters describing innovative biomarker data from the NurOwn® Phase 2 study at the 28th International Symposium on ALS/MND in Boston, MA.
- The Israel Ministry of Health (MoH) granted "Good Manufacturing Practice" (GMP) approval to Brainstorm's

contract manufacturing facility in Israel.

- Senior Kite Pharma executive Anthony Polverino, Ph.D. joined the Company's Board of Directors.
 - Dr. Polverino is a highly accomplished senior biopharmaceutical executive with more than 25 years' industry experience in drug research and development.
- Two of the Company's scientific abstracts have been accepted for platform presentation at the American Academy of Neurology (AAN) annual meeting, to take place April 21-27, 2018 in Los Angeles. The posters describe ALSFRS-R subgroup analyses and innovative micro-RNA biomarker data from the NurOwn[®] Phase 2, placebo-controlled study.

Financial Results for the Year Ended December 31, 2017

- Cash equivalents and short-term bank deposits were \$7,756,000 at December 31, 2017, compared with \$9,990,000 at December 31, 2016.
- Research and development expenses, net of research and development grants for the years ended December 31, 2017 and 2016 were \$977,000 and \$2,250,000, respectively. The research and development grants that are recorded as an offset to expenses were from the Israel Innovation Authorities ("IIA") as well as the grant received from CIRM. IIA grants included as an offset were \$1,393,000 in 2017 and \$1,185,000 in 2016 while the CIRM grant included in research and development expenses was \$4,425,000 in 2017 only. Excluding the IIA and CIRM grants, research and development expenses were \$6,795,000 in 2017, compared with \$3,435,000 in 2016.
- General and administrative expenses for the year ended December 31, 2017 and 2016 were \$4,022,000 and \$2,833,000 respectively.
- Net loss for the year ended on December 31, 2017 was \$4,952,000 or (\$0.26) per share compared to a net loss of \$4,982,000 or (\$0.27) per share for the year ended December 31, 2016.

Conference Call on Thursday, March 8th @ 8:30am Eastern Time

Members of BrainStorm's senior management team, including Chaim Lebovits, CEO, and Ralph Kern, M.D., MHSc, COO and CMO, and Eyal Rubin, CFO will host a conference call and live webcast for the investment community on Thursday, March 8th @ 8:30am Eastern Time. The details are as follows:

Toll Free: 1-800-289-0438
International: 1-323-794-2423
Israel Toll Free: 1-809-212-883
Conference ID: 3071165
Webcast: <https://goo.gl/MnoNzL>

Replay: Dial-In – available through March 22, 2018 / Webcast – available through March 7, 2019:

Toll Free: 1-844-512-2921
Toll/international: 1-412-317-6671
Replay Pin Number: 3071165
Webcast: <https://goo.gl/MnoNzL>

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

Chief Business Officer

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)

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
	<u>U.S. \$ in thousands</u>	
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 2,483	\$ 547
Short-term deposit (Note 8)	5,273	9,443
Account receivable (Note 4)	672	306
Prepaid expenses and other current assets	1,195	148
Total current assets	<u>9,623</u>	<u>10,444</u>
Long-Term Assets:		
Prepaid expenses and other long-term assets (Note 5)	1,408	25
Property and Equipment, Net (Note 6)	<u>392</u>	<u>297</u>
Total Long-Term Assets	<u>1,800</u>	<u>322</u>
Total assets	<u>\$ 11,423</u>	<u>\$ 10,766</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:		
Accounts payables	\$ 1,424	\$ 345
Accrued expenses	817	152
Deferred grant income (Note 9)	2,625	-
Other accounts payable	677	367
Total current liabilities	<u>5,543</u>	<u>864</u>
Total liabilities	<u>\$ 5,543</u>	<u>\$ 864</u>
Stockholders' Equity:		
Stock capital: (Note 10)	11	11
Common Stock of \$0.00005 par value - Authorized: 100,000,000 shares at December 31, 2017 and December 31, 2016 respectively; Issued and outstanding: 18,976,169 and 18,687,987 shares at December 31, 2017 and December 31, 2016 respectively.		
Additional paid-in-capital	85,944	85,014
Accumulated deficit	(80,075)	(75,123)
Total stockholders' equity	<u>5,880</u>	<u>9,902</u>
Total liabilities and stockholders' equity	<u>\$ 11,423</u>	<u>\$ 10,766</u>

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESSTATEMENTS OF COMPREHENSIVE LOSS

U.S. dollars in thousands
(Except share data)

	Year ended	
	December 31,	
	2017	2016
	U.S. \$ in thousands	
Operating expenses:		
Research and development, net (Note 11)	\$ 977	\$ 2,250
General and administrative	<u>4,022</u>	<u>2,833</u>
Operating loss	(4,999)	(5,083)
Financial expenses (income), net	(47)	(101)
Taxes on income (Note 12)	<u>-</u>	<u>-</u>
Net loss	<u>\$ (4,952)</u>	<u>\$ (4,982)</u>
Basic and diluted net loss per share from continuing operations	<u>\$ (0.26)</u>	<u>\$ (0.27)</u>
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	<u>18,777,348</u>	<u>18,663,162</u>

[highlights-and-financial-results-for-the-year-ended-december-31-2017-300610591.html](https://www.brainstormcell.com/financial-reports/highlights-and-financial-results-for-the-year-ended-december-31-2017-300610591.html)

SOURCE BrainStorm Cell Therapeutics Inc.