BrainStorm Announces Financial Results for the First Quarter of 2019 and Provides a Corporate Update

Highlights Scientific Advances and Continued Progress in NurOwn® ALS Phase 3 Trial and Progressive MS Phase 2 Trial; Expansion of the proprietary cellular technology platform

NEW YORK, May 10, 2019 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today financial results for the first quarter ended March 31, 2019 and recent corporate updates.

“We are actively enrolling participants in our Phase 3 trial of NurOwn® in ALS (Amyotrophic lateral sclerosis) and in our Phase 2 trial of NurOwn® in Progressive MS (Multiple Sclerosis) in several of the preeminent U.S. medical institutions,” commented Chaim Lebovits, President and Chief Executive Officer of BrainStorm Cell Therapeutics. He added, “We anticipate approximately 150 patients will be enrolled in our investigational trials for the treatment of ALS by the end of this month and we are working diligently to finalize enrollment of all 200 patients during the Third Quarter of 2019. We are also moving forward with several clinical centers of excellence that will oversee our investigational studies for the treatment of Progressive MS and we will update the community as sites formally contract with BrainStorm and begin patient enrollment. Finally, I am pleased, not only with the success of patient enrollments, I am excited to announce that the team at BrainStorm expanded the Company’s proprietary cellular technology platform to include NurOwn®-derived exosomes for potential development across a broad range of Central Nervous System (CNS) disorders. We have a team of highly respected scientists advancing our understanding of stem cells and how they may one day offer breakthrough treatments for numerous unmet medical needs.”

First Quarter 2019 and Recent Corporate Highlights:

- By the end of May 2019 we expect to have enrolled ~150 patients in the company's phase 3 ALS randomized, double blind, placebo-controlled, repeat-dose clinical trial. In the coming months we expect to enroll 18-24 patients per month. By end of August we expect to finalize enrollment of all 200 patients.
- The Company announced first patient in its Phase 2 open-label, multicenter study of repeated intrathecal administration of autologous MSC-NTF cells in participants with progressive MS.
- On January 11, 2019, Dr. Ralph Kern, Chief Operating Officer and Chief Medical Officer, presented an update on the Phase 3 pivotal trial of the autologous MSC-NTF Cellular Therapy (NurOwn®) in ALS at the 9th Annual California ALS Research Summit in Irvine, CA.
- On March 28, 2019, the Company announced that two scientific abstracts were accepted for presentation at the 71st American Academy of Neurology (AAN) Annual Meeting in Philadelphia, PA, May 4-10, 2019. The scientific abstracts selected by the AAN for presentation provide a detailed molecular genetics characterization of neurotrophic factor production by NurOwn® and further correlate cerebrospinal fluid biomarkers with clinical improvement in the completed Phase 2 ALS study. These findings contribute to our overall understanding of the mechanism of action of NurOwn® and provide further evidence linking ALS clinical outcomes to highly relevant disease biomarkers.
- Strengthened intellectual property estate around NurOwn®:
  - In December 2018, the Israel Patent Office granted a patent titled “Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors.”
  - In March 2019, the European Patent Office ("EPO") granted a European-wide patent titled 'Mesenchymal Stem Cells for the treatment of CNS Diseases.' The European Patent Application published in the European Patent Bulletin 19/13 on 27 March 2019, under Patent No. 2620493.
- On April 30, 2019, the Company announced that it has expanded its proprietary cellular technology platform to include NurOwn®-derived exosomes for potential development across a broad range of CNS disorders.

Financial Results for the Three Months Ended March 31, 2019

- Cash, cash equivalents, and short-term bank deposits were $6.23 million at March 31, 2019, compared with $7.8 million at December 31, 2018.
  - Cash, cash equivalents (including short-term bank deposits) and cash commitments (including the remaining commitments of $3 million from the CIRM grant and approximately $1 million under the IIA 2018 grant) amounted to approximately $10.23 million.
- Research and development expenses, net, for the three months ended March 31, 2019 were $3.46 million, compared to $977,000, net for the three months ended March 31, 2018.
  - Excluding participation from IIA and CIRM under the grants, research and development expenses

increased by $2.03 million from $3.17 in the first quarter of 2018 to $5.2 million in the first quarter of 2019.
- General and administrative expenses for the three months ended March 31, 2019 were $1.5 million, in line with the $1.3 million reported in the three months ended March 31, 2018.
- Net loss for the three months ended March 31, 2019 was $5 million, or ($0.24) per share, as compared to a net loss of $2.3 million, or ($0.12) per share for the three months ended March 31, 2018.

For further details on BrainStorm's financials, including financial results for the three months ended March 31, 2019, refer to form 10Q filed with the SEC.

About BrainStorm Cell Therapeutics Inc.
BrainStorm Cell Therapeutics Inc. is a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases. The Company holds the rights to clinical development and commercialization of the NurOwn® technology platform used to produce autologous MSC-NTF cells through an exclusive, worldwide licensing agreement. Autologous MSC-NTF cells have received Orphan Drug status designation from the U.S. Food and Drug Administration (U.S. FDA) and the European Medicines Agency (EMA) in ALS. BrainStorm is currently enrolling a Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of autologous MSC-NTF cells at six sites in the U.S., supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The pivotal study is intended to support a filing for U.S. FDA approval of autologous MSC-NTF cells in ALS. BrainStorm also recently received U.S. FDA clearance to initiate a Phase 2 open-label multicenter trial in progressive Multiple Sclerosis. The Phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) started enrollment in March 2019. For more information, visit the company's website at www.brainstorm-cell.com

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.

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

(Except share data)

	March 31, 2019	December 31, 2018
	U.S. $ in thousands	
ASSETS	Unaudited	Audited
Current Assets:		
Cash and cash equivalents	$ 3,238	$ 942
Short-term deposit (Note 4)	2,987	6,122
Account receivable	795	2,009
Prepaid expenses and other current assets (Note 5)	1,237	1,197
Total current assets	8,257	10,270
Long-Term Assets:		
Prepaid expenses and other long-term assets (Note 5)	32	307
ROU assets	2,951	-
Property and Equipment, Net	611	651
Total long-term assets	3,594	958
Total assets	$ 11,851	$ 11,228
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 5,029	$ 4,548
Accrued expenses	2,246	1,042
Deferred grant income (Note 7)	511	-
Other accounts payable	694	622
Total current liabilities	8,480	6,212
Long-Term Liabilities:		
Lease liability	3,045	-
Total long-term liabilities	3,045	-
Total liabilities	$ 11,525	$ 6,212
Stockholders' Equity:		
Stock capital: (Note 8)	11	11
Common stock of $0.00005 par value - Authorized: 100,000,000 shares at each of March 31, 2019 and December 31, 2018; Issued and outstanding: 21,490,610 and 20,757,816 shares at March 31, 2019 and December 31, 2018, respectively.		
Additional paid-in-capital	98,325	94,620
Receipts on account of shares	1,040	4,408
Accumulated deficit	(99,050)	(94,023)

Total stockholders' equity	326	5,016
Total liabilities and stockholders' equity	$ 11,851	$ 11,228

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)
U.S. dollars in thousands
(Except share data)

	Three months ended March 31,	
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	U.S. $ in thousands	
Operating expenses:		
Research and development, net	$ 3,456	$ 977
General and administrative	1,472	1,330
Operating loss	(4,928)	(2,307)
Financial expenses (income), net	99	(9)
Net loss	$ (5,027)	$ (2,298)
Basic and diluted net loss per share from continuing operations	$ (0.24)	$ (0.12)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	20,917,329	19,047,350

The accompanying notes are an integral part of the consolidated financial statements.

Source: BrainStorm Cell Therapeutics Inc.

Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2019-05-10-BrainStorm-Announces-Financial-Results-for-the-First-Quarter-of-2019-and-Provides-a-Corporate-Update