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

November 14, 2019

Conference Call and Webcast Today at 8:00 a.m. Eastern Time

Highlights Include: ALS Phase 3 Clinical Trial Fully Enrolled, Data Safety Monitoring Board Recommends ALS Phase 3 Clinical Trial Continue, Appointment of CFO, Phase 2 in Progressive MS Continues to Enroll Patients

NEW YORK, Nov. 14, 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 third quarter ended September 30, 2019 and recent corporate updates.

"On October 11, 2019 we reached a major corporate milestone by fully enrolling 200 patients in the Phase 3 clinical trial of NurOwn® in ALS (Amyotrophic Lateral Sclerosis). Additionally, on October 28, we announced that we received notification from the NurOwn Data Safety Monitoring Board (DSMB) that after reviewing all of the safety data as of September 30, the study should continue without any changes in the protocol. The DSMB indicated they did not identify any significant safety concerns," stated Chaim Lebovits, President and Chief Executive Officer of BrainStorm Cell Therapeutics. He added, "Our Phase 2 trial of NurOwn in Progressive MS (Multiple Sclerosis) continues to enroll patients in several of the leading U.S. medical centers and we anticipate announcing additional investigational centers of excellence in the near future. The first eight (8) participants have been enrolled in the study."

Third Quarter 2019 and Recent Corporate Highlights:

- October 28, DSMB Recommends ALS Phase 3 Clinical Trial Continue
- October 11, NurOwn Phase 3 Clinical Trial Fully Enrolled
- October 7, Notice of US Patent Allowance for NurOwn Cellular Therapeutics Technology Platform
- September 27, BrainStorm announced support for FDA Guidelines on ALS Drug Development
- September 25, Convened a Roundtable Discussion with ALS Advocacy Group Leaders and Members of The US Congress and their Staff
- September 9, Preetam Shah, Ph.D., M.B.A. Appointed Chief Financial Officer
- **Key Presentations:**
  -- November 12, Presentation at 7th Annual International Stem Cell Meeting
  -- October 25, Presentation at Dawson James Securities 5th Annual Conference
  -- October 24, Chaim Lebovits, Keynote Speaker at Cell Series UK 2019
  -- October 23-25, Neuromuscular Drug Development Drug Summit – Hosted workshop and presented on clinical trial design
  -- October 2, North East Amyotrophic Lateral Sclerosis Annual Meeting - Phase 2 Biomarker Data Poster Presentation
  -- September 13, ECTRIMS Late Breaking News ePoster

Financial Results for the Three Months Ended September 30, 2019

- Cash, cash equivalents, and short-term bank deposits were $2.1 million at September 30, 2019, compared to $2.7 million at June 30, 2019.
  -- Our total available funding which includes cash on hand as well as the remaining non-dilutive CIRM and IIA grants amounts to approximately $5.9 million
- Research and development expenses, net, for the three months ended September 30, 2019 were $4.01 million, compared to $1.98 million, net for the three months ended September 30, 2018.
- Excluding participation from IIA and CIRM under the grants and proceeds received under the Hospital Exemption regulatory pathway, research and development expenses increased by $1.59 million from $4.07 million in the third quarter of 2018 to $5.66 million in the third quarter of 2019
- General and administrative expenses for the three months ended September 30, 2019 were $1.54 million, compared to $1.26 million in the three months ended September 2018.
- Net loss for the three months ended September 2019 was $5.6 million, or ($0.25) per share, as compared to a net loss of $3.18 million, or ($0.15) per share for the three months ended September 30, 2018.

For further details on BrainStorm's financials, including financial results for the three months ended September 30, 2019, refer to Form 10-Q filed with the SEC on November 14th, 2019.

Conference Call and Webcast: Thursday, November 14, 2019 @ 8:00 a.m. Eastern Time

U.S. Toll Free:	**1-877-423-9813**
Toll/International:	**1-201-689-8573**
Webcast Link:	**https://bit.ly/2XaKWmm**

A webcast replay of the conference call will be available for 30 days on the "Investors & Media" page of BrainStorm's website:

Toll Free:	**1-844-512-2921**
Toll/International:	**1-412-317-6671**
Replay Pin Number:	**13696529**
Replay Start:	**Thursday, November 14, 2019, 11:00 AM ET**
Replay Expiry:	**Thursday, November 28, 2019, 11:59 PM ET**

About NurOwn®

NurOwn® (autologous MSC-NTF) cells represent a promising investigational therapeutic approach to targeting disease pathways important in neurodegenerative disorders. MSC-NTF cells are produced from autologous, bone marrow-derived mesenchymal stem cells (MSCs) that have been expanded and differentiated ex vivo. MSCs are converted into MSC-NTF cells by growing them under patented conditions that induce the cells to secrete high levels of neurotrophic factors. Autologous MSC-NTF cells can effectively deliver multiple NTFs and immunomodulatory cytokines directly to the site of damage to elicit a desired biological effect and ultimately slow or stabilize disease progression. BrainStorm has fully enrolled a Phase 3 pivotal trial of autologous MSC-NTF cells for the treatment of amyotrophic lateral sclerosis (ALS). BrainStorm also recently received U.S. FDA acceptance to initiate a Phase 2 open-label multicenter trial in progressive MS and enrollment began in March 2019.

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 has fully enrolled a Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of autologous MSC-NTF cells at six U.S. sites 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 Statement

Statements in this announcement other than historical data and information, including statements regarding future clinical trial enrollment and data, 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, BrainStorm's need to raise additional capital, BrainStorm's ability to continue as a going concern, regulatory approval of BrainStorm's NurOwn® treatment candidate, the success of BrainStorm's product development programs and research, regulatory and personnel issues, development of a global market for our services, the ability to secure and maintain research institutions to conduct our clinical trials, the ability to generate significant revenue, the ability of BrainStorm's NurOwn® treatment candidate to achieve broad acceptance as a treatment option for ALS or other neurodegenerative diseases, BrainStorm's ability to manufacture and commercialize the NurOwn® treatment candidate, obtaining patents that provide meaningful protection, competition and market developments, BrainStorm's ability to protect our intellectual property from infringement by third parties, heath reform legislation, demand for our services, currency exchange rates and product liability claims and litigation, 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)

	September 30, 2019	December 31, 2018
	U.S. $ in thousands	
	Unaudited	Audited
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 2,095	$ 942
Short-term deposit (Note 4)	34	6,122
Account receivable	1,924	2,009
Prepaid expenses and other current assets (Note 5)	619	1,197
Total current assets	4,672	10,270
Long-Term Assets:		
Prepaid expenses and other long-term assets	32	307
Operating lease right of use asset	2,443	-
Property and Equipment, Net	664	651
Total long-term assets	3,139	958
Total assets	$ 7,811	$ 11,228
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 9,144	$ 4,548
Accrued expenses	1,975	1,042
Other accounts payable	839	622
Total current liabilities	11,958	6,212
Long-Term Liabilities:		
Operating lease liability	2,630	-
Total long-term liabilities	2,630	-
Total liabilities	$ 14,588	$ 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 September 30, 2019 and December 31, 2018; Issued and outstanding: 22,606,492 and 20,757,816 shares at September 30, 2019 and December 31, 2018, respectively.		
Additional paid-in-capital	102,796	94,620
Receipts on account of shares	-	4,408
Accumulated deficit	(109,584)	(94,023)
Total stockholders' equity) deficit)	(6,777)	5,016
Total liabilities and stockholders' equity	$ 7,811	$ 11,228

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)
U.S. dollars in thousands
(Except share data)

	Nine months ended September 30,		Three months ended September 30,	
	2019	2018	2019	2018
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net	$ 11,018	$ 4,433	$ 4,008	$ 1,975
General and administrative	4,318	4,193	1,543	1,257

Operating loss	(15,336)	(8,626)	(5,551)	(3,232)
Financial expenses (income), net	225	(61)	83	(56)
Net loss	$ (15,561)	$ (8,565)	$ (5,634)	$ (3,176)
Basic and diluted net loss per share from continuing operations	$ (0.72)	$ (0.43)	$ (0.25)	$ (0.15)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	21,630,007	19,754,159	22,254,993	20,691,900

Source: BrainStorm Cell Therapeutics Inc.