BrainStorm Announces Financial Results for the First Quarter of 2020 and Provides a Corporate Update

May 7, 2020

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

ALS Phase 3 Clinical Trial Remains on Track for Q4'20 Top-line Data Readout

NEW YORK, May 07, 2020 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, announced today financial results for the first quarter ended March 31, 2020 and recent corporate updates.

"While many companies have been greatly hindered by the COVID-19 pandemic, Brainstorm, due to the incredible strength of our clinical trial participants, the amazing teams at our U.S. investigational sites and the talent and commitment of each and every team member at BrainStorm, the Phase 3 ALS trial remains on track for a Q4'20 topline data readout. Participants in the fully enrolled clinical trial in our 6 United States medical centers of excellence continue to receive their scheduled treatments with the necessary safety protocols in place," stated Chaim Lebovits, Chief Executive Officer of BrainStorm Cell Therapeutics. He added, "We were able to advance our global footprint by signing an agreement with a senior, leading EMEA (European Medicines Agency) regulatory consultant who will advise us as we approach EMEA Regulatory Institutions to present data for NurOwn in ALS, and the advancement of NurOwn in other disease indications. Additionally, we entered into a lease agreement with the Tel Aviv Sourasky Medical Center (Ichilov Hospital) in Tel Aviv, Israel, to produce NurOwn in three state-of-the-art cleanrooms. The new facility will significantly increase the Company's manufacturing capacity, allowing us to strategically enter the European and Israeli markets."

Dr. Ralph Kern, President and Chief Medical Officer of Brainstorm Cell Therapeutics said, "The COVID-19 pandemic has resulted in delays in the pace of enrollment for our Phase 2 Progressive MS clinical trial. Scheduled March and April 2020 new participant enrollments were deferred to May 2020 when the affected healthcare sites anticipate their access restrictions may be mitigated. We anticipate that enrollment will continue in 2020 subject to any site access restrictions related to COVID-19. Additionally, we are collecting clinical and biomarker data from the treated progressive MS participants and plan to perform an interim analysis after 50% of participants in the trial have been treated. Our clinical team has maximized this disruptive time to re-examine our data and make sure our data is pristine for future regulatory submissions." Dr. Kern concluded, "In terms of the Hospital Exemption Program, the Company has not completed treatment of all the first 13 patients as non-Israeli patients are unable to travel to Israel at the present time due to COVID-19 travel restrictions. The Company is currently collecting HE clinical data for the patients who already received treatment at the Tel Aviv Sourasky Medical Center. Once the complete data set for the first 13 treated patients is available, we will perform a detailed analysis."

First Quarter 2020 and Recent Corporate Highlights:

- April 3: Awarded $1.5 Million Non-Dilutive Grant for 2020 by the Israel Innovation Authority
- April 1: Appoints David Setboun as COO; Dr. Ralph Kern promoted to President
- March 31: Appoints distinguished economist Dr. Jacob Frenkel as chairman of the board; appoints Mr. Sankesh Abbhi, a seasoned executive and entrepreneur in life sciences as new board member
- March 16: Announced receipt of $2.2 million from CIRM for meeting prespecified milestones
- March 6: Raised gross proceeds of $10 million financing from Abbhi Investments, LLC in a registered direct offering
- March 6: Enters common stock ATM distribution agreement for up to $50 million with Raymond James
- February 11: Announced that the Company and FDA agreed to potential NurOwn® regulatory pathway for approval in ALS and committed to work collaboratively, including opportunities to expedite statistical review of data from the Phase 3 trial.

Scientific and Company Presentations:

- February 17 - Presentation at Noble Capital Markets' Sixteenth Annual Investor Conference
- February 11 - Presentation at BIO CEO & Investor Conference
- January 24 - Podium presentation at the 10th Annual California ALS Research Summit
- January 12 - Presentation and participation at the Rare & Orphan Diseases Panel at the 3rd Annual Neuroscience Innovation Forum

Financial Results for the Three Months Ended March 31, 2020

- Cash, cash equivalents, and short-term bank deposits were approximately $14.5 million at March 31, 2020, compared to $6.2 million at March 31, 2019.
- Research and development expenses, net, for the three months ended March 31, 2020 were $5.95 million, compared to $3.46 million, net for the three months ended March 31, 2019.
  - Excluding participation from IIA and CIRM under the grants and proceeds received under the Hospital Exemption

regulatory pathway, research and development expenses increased by $1.94 million from $5.20 million in the first quarter of 2019 to $7.14 million in the first quarter of 2020

- General and administrative expenses for the three months ended March 31, 2020 were $2.36 million, compared to $1.47 million in the three months ended March 31, 2019.
- Net loss for the three months ended March 31, 2020 was $8.1 million, or ($0.32) per share, as compared to a net loss of $5.03 million, or ($0.24) per share for the three months ended March 31, 2019.

For further details on BrainStorm's financials, including financial results for the three months ended March 31, 2020, refer to Form 10-Q filed with the SEC on May 7th, 2020

Conference Call and Webcast: Thursday, May 7, 2020 @ 8:30 a.m. Eastern Time

U.S. Toll Free:	**877-407-9205**
Toll/International:	**201-689-8054**
Webcast Link:	**https://www.webcaster4.com/Webcast/Page/2354/34588**

A teleconference replay of the conference call will be available for 14 days on the "Investors & Media" page of BrainStorm's website:

Toll Free:	**877-481-4010**
Toll/International:	**919-882-2331**
Replay Passcode:	**34588**

Teleconference Replay Expiration: Thursday, May 21, 2020

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)

	March 31, 2020 U.S. $ in thousands Unaudited	December 31, 2019 Audited
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 12,471	$ 536
Short-term deposit (Note 4)	2,020	33
Other accounts receivable	435	2,359
Prepaid expenses and other current assets (Note 5)	279	432
Total current assets	15,205	3,360
Long-Term Assets:		
Prepaid expenses and other long-term assets	31	32
Operating lease right of use asset (Note 6)	1,917	2,182
Property and Equipment, Net	918	960
Total Long-Term Assets	2,866	3,174
Total assets	$ 18,071	$ 6,534
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 4,571	$ 14,677
Accrued expenses	1,303	1,000
Operating lease liability (Note 6)	1,208	1,263
Other accounts payable	1,170	714
Total current liabilities	8,252	17,654
Long-Term Liabilities:		
Operating lease liability (Note 6)	808	1,103
Total long-term liabilities	808	1,103
Total liabilities	$ 9,060	$ 18,757
Stockholders' Equity (deficit):		

Stock capital: (Note 7)	12	11
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at March 31, 2020 and December 31, 2019 respectively; Issued and outstanding: 28,423,837 and 23,174,228 shares at March 31, 2020 and December 31, 2019 respectively.		
Additional paid-in-capital	134,389	105,042
Receipts on account of shares	-	-
Accumulated deficit	(125,390)	(117,276)
Total stockholders' equity (deficit)	9,011	(12,223)
Total liabilities and stockholders' equity	$ 18,071	$ 6,534

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,	
	2020	**2019**
	U.S. $ in thousands	
Operating expenses:		
Research and development, net	$ 5,948	$ 3,456
General and administrative	2,360	1,472
Operating loss	(8,308)	(4,928)
Financial expenses (income), net	(194)	99
Net loss	$ (8,114)	$ (5,027)
Basic and diluted net loss per share from continuing operations	$ (0.32)	$ (0.24)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	28,423,837	20,917,329

Source: BrainStorm Cell Therapeutics Inc.