BrainStorm Announces Operational Highlights and Financial Results for the Year Ended December 31, 2019

February 18, 2020

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

NEW YORK, Feb. 18, 2020 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, today announces financial results for fiscal year ended December 31, 2019.

"2019 was a tremendous year for BrainStorm, with significant progress and achievements across all clinical and operational fronts," stated Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "Most importantly, we fully enrolled our pivotal, double blind, placebo-controlled Phase 3 trial of NurOwn® for the treatment of ALS. We announced the trial conducted at six major U.S. medical centers of excellence for ALS, was fully enrolled on October 11, 2019, and on October 28, 2019 the Data and Safety Monitoring Board (DSMB), completed the second planned interim safety analysis for the first 106 patients who received repeat dosing of NurOwn in the Phase 3 trial. The DSMB concluded the trial should continue as planned without any clinical protocol changes." He added, "In addition, one of the most prestigious peer-reviewed journals, ***Neurology***, published 'NurOwn Phase 2 Randomized Clinical Trial in ALS: Safety, Clinical and BioMarker Results,' bringing news of our investigational therapy to the global scientific community. And, just last week, we were happy to announce that the Company recently held a high level meeting with the U.S. Food and Drug Administration (FDA) to discuss potential NurOwn regulatory pathways for approval in ALS."

Ralph Kern, MD, MHSc, Chief Operating Officer and Chief Medical Officer of BrainStorm added, "2019 was also a very significant year for those who suffer from progressive Multiple Sclerosis (MS). In February 2019, we announced Cleveland Clinic would serve as our first contracted site for a Phase 2 open-label, multicenter study of repeated intrathecal administration of NurOwn (autologous MSC-NTF cells) in participants with progressive MS (NCT03799718). We enrolled our first patient in March. We contracted with The Stanford University School of Medicine, The Keck School of Medicine of the University of Southern California, and the Mount Sinai Medical Center to further enroll patients." Dr. Kern added, "The importance of our research in progressive MS was acknowledged by a $495,000 grant award from the National Multiple Sclerosis Society through it's Fast Forward Program, and mid-December, the Data Safety Monitoring Board completed the first, pre-specified interim analysis, of safety outcomes for 9 participants and after careful review of all available clinical trial data, the DSMB unanimously concluded that the study should continue as planned without any protocol modification. As of December 31, 2019 we have enrolled 10 patients in the study (50% enrollment completed)."

Fourth Quarter Corporate Highlights:

- Received notice of US Patent Allowance for NurOwn Cellular Therapeutic Technology Platform
- Grant of New Japanese Patent for NurOwn
- Presentations at the 30th International Symposium on ALS/MND
- Phase 2 Biomarker Data Presentation at NEALS 18th Annual Meeting
- Chaim Lebovits as Keynote Speaker at Cell Series UK 2019
- Presentation at 7th Annual International Stem Cell Meeting
- Presentation at 35th ECTRIMS Congress
- Presentation at Neuromuscular Drug Development Summit
- Presentation at Dawson James Securities 5th Annual Small Cap Growth Conference

Financial Results for the Year Ended December 31, 2019 and Recent Updates

- Cash, cash equivalents, and short-term bank deposits were approximately $0.6 million as of December 31, 2019.
- As of February 14, 2020, we raised gross proceeds of approximately $18.6 million utilizing the ATM facility.
    - Cash, cash equivalents, and short-term bank deposits as of today were approximately $11.1 million.
- In addition, available funding from non-dilutive CIRM and IIA grants amounts to approximately $3.4 million.
- Research and development expenses, net, for the year ended December 31, 2019 were $17.2 million, compared to $8.3 million, net for year ended December 31, 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 $8.4 million from $16.3 million for the year ended December 31, 2018 to $24.7 million for the year ended December 31, 2019.
- General and administrative expenses for the year ended December 31, 2019 and 2018 were $5.79 million and $5.77 million respectively.

- Net loss for the year ended December 31, 2019 was $23.2 million, or ($1.06) per share, as compared to a net loss of $13.9 million or ($0.70) per share for the year ended December 31, 2018.

- As of February 14, 2019, the Company had 26,230,839 shares and 4,474,868 warrants issued and outstanding.

For further details on BrainStorm's financials, including financial results for the year ended December 31, 2019, refer to the Form 10-K filed with the SEC today.

Conference Call on Tuesday, February 18th @ 8:00 am Eastern Time

The investment community may participate in the conference call by dialing the following numbers:

Conference ID:	13698896
Toll Free:	1-877-423-9813
Toll/International:	1-201-689-8573
Audio Webcast:	Link to Webcast

Those interested in listening to the conference call live via the internet may do so by visiting the "Investors & Media" page of BrainStorm's website at www.ir.brainstorm-cell.com and clicking on the conference call link.

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:	13698896
Replay Start:	Tuesday February 18, 2020, 11:00 AM ET
Replay Expiry:	Tuesday March 3, 2020, 11:59 PM ET

About NurOwn®

NurOwn® (autologous MSC-NTF cells) represent a promising investigational 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. NurOwn® is currently being evaluated in a Phase 3 ALS randomized placebo-controlled trial and in a Phase 2 open-label multicenter trial in Progressive MS.

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® Cellular Therapeutic Technology Platform used to produce autologous MSC-NTF cells through an exclusive, worldwide licensing agreement as well as through its own patents, patent applications and proprietary know-how. 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 the 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 BLA filing for U.S. FDA approval of autologous MSC-NTF cells in ALS. Brainstorm received U.S. FDA clearance to initiate a Phase 2 open-label multi-center trial of repeat intrathecal dosing of MSC-NTF cells in Progressive Multiple Sclerosis (NCT03799718) in December 2018 and has been enrolling clinical trial participants since March 2019. For more information, visit the company's website.

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.

CONTACTS

Corporate:

Uri Yablonka
Chief Business Officer
BrainStorm Cell Therapeutics Inc.
Phone: 646-666-3188
uri@brainstorm-cell.com

Investor Relations:
Preetam Shah, MBA, PhD
Chief Financial Officer
BrainStorm Cell Therapeutics Inc.
Phone: 862-397-8160
pshah@brainstorm-cell.com

Media:
Sean Leous
Westwicke/ICR PR
Phone: +1.646.677.1839
sean.leous@icrinc.com

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands
(Except share data)

	December 31, 2019	2018
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 536	$ 942
Short-term deposit (Note 9)	33	6,122
Other accounts receivable (Note 4)	2,359	2,009
Prepaid expenses and other current assets (Note 5)	432	1,197
Total current assets	3,360	10,270
Long-Term Assets:		
Prepaid expenses and other long-term assets	32	307
Operating lease right of use asset (Note 6)	2,182	-
Property and Equipment, Net (Note 7)	960	651
Total Long-Term Assets	3,174	958
Total assets	$ 6,534	$ 11,228
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 14,677	$ 4,548
Accrued expenses	1,000	1,042
Operating lease liability (Note 6)	1,263	-
Other accounts payable	714	622
Total current liabilities	17,654	6,212
Long-Term Liabilities:		
Operating lease liability (Note 6)	1,103	-
Total long-term liabilities	1,103	-
Total liabilities	$ 18,757	$ 6,212
Stockholders' Equity (deficit):		

Stock capital: (Note 11)	11	11
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at December 31, 2019 and December 31, 2018 respectively; Issued and outstanding: 23,174,228 and 20,757,816 shares at December 31, 2019 and December 31, 2018 respectively.		
Additional paid-in-capital	105,042	94,620
Receipts on account of shares	-	4,408
Accumulated deficit	(117,276)	(94,023)
Total stockholders' equity (deficit)	(12,223)	5,016
Total liabilities and stockholders' equity	$ 6,534	$ 11,228

BRAINSTORM CELL THERAPEUTICS INC.

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

	Year ended December 31,	
	2019	**2018**
	U.S. $ in thousands	
Operating expenses:		
Research and development, net (Note 12)	$ 17,204	$ 8,293
General and administrative	5,797	5,770
Operating loss	(23,001)	(14,063)
Financial expenses (income), net	252	(115)
Net loss	$ (23,253)	$ (13,948)
Basic and diluted net loss per share	$ (1.06)	$ (0.70)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	21,906,257	19,997,710

Source: BrainStorm Cell Therapeutics Inc.