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

Conference Call and Webcast Today at 8:00 a.m. Eastern Time
Highlights Include: Special High-level FDA Meeting,Continued Progress in NurOwn® ALS Phase 3 Trial and Progressive MS Phase 2 Trial, ALS Phase 3 Trial Enrollment Update

NEW YORK, Aug. 13, 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 second quarter ended June 30, 2019 and recent corporate updates.

“We continue to actively enroll patients 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. “We anticipate completing enrollment in our Phase 3 ALS study during the second week of October 2019 and expect top-line results by eleven months after completion of enrollment. Over the past few months, we were excited to add the support of Stanford University School of Medicine and the Keck School of Medicine of the University of Southern California as additional sites currently enrolling patients in our Phase 2 Progressive MS study. We continue to appreciate the support of our shareholders and patient advocacy groups as we advance the development of NurOwn® to fill the unmet medical need for patients with ALS and Progressive MS.”

Second Quarter 2019 and Recent Corporate Highlights:

- By the end of July 2019, 170 patients enrolled in the Company's phase 3 ALS randomized, double blind, placebo-controlled, repeat-dose clinical trial. By the second week of October we expect to finalize enrollment of all 200 patients.
- In July 2019, the BrainStorm management team was invited to a special high-level meeting with FDA senior management and I AM ALS, a grass roots ALS advocacy group advocating for an ALS cure.
- The Company added two additional clinical sites to enroll patients in its Phase 2 open-label, multicenter study of repeated intrathecal administration of autologous MSC-NTF (NurOwn) cells in participants with progressive MS.
- On May 31, 2019, Dr. Ralph Kern, Chief Operating Officer and Chief Medical Officer, presented a poster of the Company’s “Phase 2 Open-Label, Multicenter Study of Repeated Intrathecal Administration of Autologous MSC-NTF cells in Progressive Multiple Sclerosis (MS)” at the Annual Meeting of the Consortium of Multiple Sclerosis Centers, in Seattle, WA.
- On May 16, 2019, Chaim Lebovits, President and Chief Executive Officer, lead a roundtable discussion titled “Stem Cells for Neurological Applications” at the World Advanced Therapy and Regenerative Medicine Congress in London, England.

Financial Results for the Three Months Ended June 30, 2019

- Cash, cash equivalents, and short-term bank deposits were $2.7 million at June 30, 2019, compared to $6.23 million at March 31, 2019.
    - Cash, cash equivalents (including short-term bank deposits) and cash commitments (including the remaining commitments from the CIRM and IIA grants) amounted to approximately $6.5 million.
    - As of August 6, 2019, Cash, cash equivalents, and short-term bank deposits were $4.5 million.
- Research and development expenses, net, for the three months ended June 30, 2019 were $3.55 million, compared to $1.5 million, net for the three months ended June 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 $3.23 million from $3.3 million in the second quarter of 2018 to $6.53 million in the second quarter of 2019
- Additional proceeds from Hospital Exemption is expected it the upcoming quarter.
- General and administrative expenses for the three months ended June 30, 2019 were $1.3 million, compared to $1.6 million in the three months ended June 30, 2018.
- Net loss for the three months ended June 30, 2019 was $4.9 million, or ($0.23) per share, as compared to a net loss of $3.1 million, or ($0.16) per share for the three months ended June 30, 2018.

For further details on BrainStorm’s financials, including financial results for the three months ended June 30,

2019, refer to Form 10-Q filed with the SEC on August 13, 2019.

Conference Call and Webcast: Tuesday, August 13, 2019 @ 8:00 a.m. Eastern Time

U.S. Toll Free	1-877-423-9813
Toll/International:	1-201-689-8573
Conference Call ID:	13693394
Webcast Link:	http://public.viavid.com/player/index.php?id=135728

Replays, Available through August 27, 2019:
U.S. Toll Free: 1-844-512-2921

Toll/International: 1-412-317-6671

Replay Pin Number: 13693394

Replay Start: Tuesday August 13, 2019, 11:00 AM ET
Replay Expiry: Tuesday August 27, 2019, 11:59 PM ET

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, 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)

	June 30, 2 0 1 9	December 31, 2 0 1 8
	U.S. $ in thousands	
ASSETS	Unaudited	Audited
Current Assets:		
Cash and cash equivalents	$ 1,126	$ 942
Short-term deposit	1,575	6,122
Account receivable	1,917	2,009
Prepaid expenses and other current assets	917	1,197
Total current assets	5,535	10,270
Long-Term Assets:		
Prepaid expenses and other long-term assets	31	307
Operating lease right of use asset	2,699	-
Property and Equipment, Net	599	651
Total long-term assets	3,329	958
Total assets	$ 8,864	$ 11,228
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 8,765	$ 4,548
Accrued expenses	1,020	1,042
Other accounts payable	758	622
Total current liabilities	10,543	6,212
Long-Term Liabilities:		
Operating lease liability	2,837	-
Total long-term liabilities	2,837	-
Total liabilities	$ 13,380	$ 6,212

Stockholders' Equity:		
Stock capital:	11	11
Common stock of $0.00005 par value - Authorized: 100,000,000 shares at each of June 30, 2019 and December 31, 2018; Issued and outstanding: 21,708,442 and 20,757,816 shares at June 30, 2019 and December 31, 2018, respectively.		
Additional paid-in-capital	99,423	94,620
Receipts on account of shares	-	4,408
Accumulated deficit	(103,950)	(94,023)
Total stockholders' equity (deficit)	(4,516)	5,016
Total liabilities and stockholders' equity	$ 8,864	$ 11,228

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

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

	Six months ended June 30,		Three months ended June 30,	
	2 0 1 9	2 0 1 8	2 0 1 9	2 0 1 8
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net	$ 7,010	$ 2,458	$ 3,554	$ 1,481
General and administrative	2,775	2,936	1,303	1,606
Operating loss	(9,785)	(5,394)	(4,857)	(3,087)
Financial expenses (income), net	142	(5)	43	4
Net loss	$ (9,927)	$ (5,389)	$ (4,900)	$ (3,091)
Basic and diluted net loss per share from continuing operations	$ (0.47)	$ (0.28)	$ (0.23)	$ (0.16)
Weighted average number of shares outstanding used in	21,312,335	19,277,518	21,703,001	19,505,157

computing
basic and
diluted net
loss per share

Source: BrainStorm Cell Therapeutics Inc.

Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2019-08-13-BrainStorm-Announces-Financial-Results-for-the-Second-Quarter-of-2019-and-Provides-a-Corporate-Update