BrainStorm Announces Financial Results for the Third Quarter of 2018 and Provides a Corporate Update

Highlights Scientific Advances and Continued Progress for NurOwn® in ALS Towards U.S. FDA Approval;
Following Successful FDA Pre-IND Meeting, BrainStorm will File an IND for NurOwn® in a Second Clinical Indication
Conference Call and Webcast Today at 8:30am Eastern Time

NEW YORK, Oct. 29, 2018 (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 and nine months ended September 30, 2018.

“We continue to enroll participants in our Phase 3 trial of NurOwn® in ALS, and were delighted by the successful interim safety analysis conducted by the Data Safety Monitoring Board (DSMB),” commented Chaim Lebovits, President and Chief Executive Officer of BrainStorm Cell Therapeutics. “Moving forward, we are completely focused on taking the steps necessary to cross the finish line towards a potential U.S. FDA approval for NurOwn® in ALS, and we expect successful completion of enrollment in the ongoing pivotal trial in the first half of 2019. Our goal is to bring this potentially life-changing innovative cellular therapy to patients with ALS, who are in desperate need of new treatment options.”

“Our NurOwn® cellular technology platform has the potential to address the unmet need in other serious neurodegenerative diseases and we are excited to report that following a successful FDA Pre-IND Meeting we are now on track to file an IND in a second clinical indication,” added Mr. Lebovits.

Recent Corporate Highlights:

- The Connell and O’Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute in Boston, recently commenced the production of NurOwn® and placebo for the Phase 3 ALS pivotal trial as an additional manufacturing site.
- On August 23, 2018, BrainStorm announced a successful interim safety analysis in the ongoing Phase 3 pivotal trial of NurOwn® in ALS (ClinicalTrials.gov Identifier: NCT03280056).
  o The Data Safety Monitoring Board (DSMB) completed the pre-specified interim analysis of safety outcomes. The DSMB concluded there were no significant safety concerns and that the trial should continue as planned.
  The DSMB Chairperson, Carlayne Jackson MD, FAAN, Professor of Neurology and Otolaryngology at the University of Texas Health Science Center San Antonio (UTHSCSA), stated: “The DSMB appreciates the continued commitment of BrainStorm and the research teams to conducting this trial in such an exemplary manner. We commend them on their outstanding enrollment and the quality of data collection.”
- On September 4, Arturo O. Araya, M.A., M.B.A., was hired as Chief Commercial Officer.
  o Mr. Araya was previously Global Head of Commercial for the Novartis Cell & Gene Therapies Unit. Mr. Araya led the initial efforts to build the infrastructure for the subsequent FDA approval and U.S. commercialization of KYMRIAH®.
- On September 12, Dr. Ralph Kern, Brainstorm’s CMO and COO, presented at the FDA Rare disease workshop in Washington, D.C. on the “ALS Case Study: Clinical Trial Designs for Small Patient Populations.”
- On October 3, Dr. James Berry of Massachusetts General Hospital (one of the Principal Investigators for the ALS pivotal trial), presented a clinical poster entitled, “*MicroRNA Changes in the NurOwn® Phase 2 ALS Randomized Clinical Trial: Relationship to Neuroprotection and Innate Immunity*” at the Annual Northeast Amyotrophic Lateral Sclerosis (NEALS) conference.
  o The clinical poster received the “Best clinical abstract award” at the NEALS conference.
- Strengthened intellectual property estate around NurOwn:
  o Japanese Patent Office (JPO) issued a Decision to Grant notice on a patent that is expected to provide protection in Japan until 2033.
  o European Patent Office granted European-wide patent that is expected to provide protection in Europe until 2029.
  o U.S. Patent & Trademark Office (PTO) granted a patent that covers the method for generating NurOwn® in industrial amounts for clinical practice.

Financial Results for the Three Months Ended September 30, 2018

- Cash, cash equivalents, and short-term bank deposits were $10.9 million at September 30, 2018, compared with $7.8 million at December 31, 2017.

o Cash, Cash equivalents (including short-term bank deposits) and cash commitments (including the remaining commitments of $7 million from the CIRM grant and approximately $1 million under the IIA 2018 grant) amounted to approximately $19 million.
- Research and development expenses, net, for the three months ended September 30, 2018 were $2.0 million, compared to $1.2 million, net for the three months ended September 30, 2017.
  o Excluding participation from IIA and CIRM under the grants, research and development expenses increased by $2.5 million from $1.6 in the third quarter of 2017 to $4.1 million in the third quarter of 2018.
- General and administrative expenses for the three months ended September 30, 2018 were $1.3 million, in line with the $1.2 million reported in the three months ended September 30, 2017.
- Net loss for the three months ended September 30, 2018 was $3.2 million, or ($0.15) per share, as compared to a net loss of $2.4 million, or ($0.13) per share for the three months ended September 30, 2017.

For further details on Brainstorm's financials, including financial results for the nine months ended September 30, 2018, refer to form 10Q filed with the SEC.

Conference Call – Monday, October 29, 2018 @ 8:30am Eastern Time

USA Toll Free:	888-220-8451
International Investors:	323-794-2588
Israel Investors:	1809 212 909
Conference ID:	5255627
Webcast:	https://goo.gl/m4sF8n

Replays, Available through November 12, 2018:

Domestic:	844-512-2921
International:	412-317-6671
Replay PIN:	5255627

About BrainStorm Cell Therapeutics Inc.
BrainStorm Cell Therapeutics Inc. is a leading cellular therapy biotechnology company engaged in the development of first-of-its-kind adult stem cell therapies derived from autologous bone marrow cells for the treatment of neurodegenerative diseases. The Company holds the rights to clinical development and commercialization of the NurOwn® technology platform through an exclusive, worldwide licensing agreement. NurOwn® has received Fast Track designation from the U.S. Food and Drug Administration (U.S. FDA) in ALS and has additionally been granted Orphan Status by the U.S. FDA and the European Medicines Agency (EMA). For more information, visit BrainStorm's website at www.brainstorm-cell.com.

About NurOwn® Phase 3 Clinical Program in ALS
BrainStorm is currently enrolling a Phase 3 pivotal trial investigating repeat-administration of NurOwn® in ALS at six clinical sites in the U.S., supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The study will enroll 200 ALS patients, randomized 1:1 to receive NurOwn® or placebo, and will evaluate the ALS functional rating scale (ALSFRS-R) responder analysis as a primary efficacy outcome measure (NCT03280056). On August 23, 2018, BrainStorm announced a successful pre-specified interim safety analyses by an independent Data Safety Monitoring Board (DSMB). The completion of Phase 3 enrollment is anticipated in first half of 2019 and is expected to support a BLA filing for FDA approval of NurOwn® in ALS.

About U.S. Sites for NurOwn® Phase 3 Trial in ALS

- University of California Irvine; Principal Investigator: Namita Goyal, M.D.
- Cedars-Sinai Medical Center; Principal Investigator: Robert Baloh, M.D.
- California Pacific Medical Center; Principal Investigator: Robert Miller, M.D.
- Massachusetts General Hospital; Principal Investigator: James Berry, M.D.
- University of Massachusetts Medical School; Principal Investigator: Robert Brown, M.D.
- Mayo Clinic; Principal Investigator: Anthony Windebank, M.D.

Safe-Harbor Statement
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)

	September 30, 2018	December 31, 2017
	U.S. $ in thousands	
ASSETS	Unaudited	Audited
Current Assets:		
Cash and cash equivalents	$ 697	$ 2,483
Short-term deposit	10,194	5,273
Account receivable	492	672
Prepaid expenses and other current assets	1,238	1,195
Total current assets	12,621	9,623
Long-Term Assets:		
Prepaid expenses and other long-term assets	584	1,408
Property and Equipment, Net	564	392
Total long-term assets	1,148	1,800
Total assets	$ 13,769	$ 11,423
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		

Accounts payable	$ 2,602	$ 1,424
Accrued expenses	428	817
Deferred grant income	130	2,625
Other accounts payable	631	677
Total current liabilities	3,791	5,543
Total liabilities	$ 3,791	$ 5,543
Stockholders' Equity:		
Stock capital:	11	11
Common stock of $0.00005 par value - Authorized: 100,000,000 shares at each of September 30, 2018 and December 31, 2017; Issued and outstanding: 20,700,713 and 18,976,169 shares at September 30, 2018 and December 31, 2017, respectively.		
Additional paid-in-capital	94,199	85,944
Receipts on account of shares	4,408	-
Accumulated deficit	(88,640)	(80,075)
Total stockholders' equity	9,978	5,880
Total liabilities and stockholders' equity	$ 13,769	$ 11,423

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,	
	2018	2017	2018	2017
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net	$ 4,433	$ 2,544	$ 1,975	$ 1,168
General and administrative	4,193	2,693	1,257	1,224
Operating loss	(8,626)	(5,237)	(3,232)	(2,392)
Financial expenses (income), net	(61)	(9)	(56)	11
Net loss	$ (8,565)	$ (5,228)	$ (3,176)	$ (2,403)

Basic and diluted net loss per share from continuing operations	$ (0.43)	$ (0.28)	$ (0.15)	$ (0.13)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	19,754,159	18,737,307	20,691,900	18,783,997

BrainStorm Cell Therapeutics Inc.

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Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2018-10-29-BrainStorm-Announces-Financial-Results-for-the-Third-Quarter-of-2018-and-Provides-a-Corporate-Update