BrainStorm Cell Therapeutics Announces Third Quarter 2021 Financial Results and Provides a Corporate Update

BrainStorm remains committed to pursuing the best and most expeditious path forward to facilitate access to NurOwn® for people living with ALS
Presented important new ALS biomarker data at NEALS meeting showing significant NurOwn-driven changes across neural biomarkers and that treatment response to NurOwn can be predicted in the trial using biomarker data and innovative statistical models
Expanded leadership by naming Stacy R. Lindborg, PhD, EVP and Chief Development Officer and appointment of Sidney A. Spector, MD, PhD, as SVP, Global Strategy and Medical Affairs and Kim Thacker, MD, as SVP, Medical Affairs and Clinical Innovation
Conference call and webcast at 8:00 a.m. Eastern Time today

NEW YORK, Nov. 15, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, today announced financial results for the quarter ended September 30, 2021, and provided a corporate update.

"We made strong progress towards our goal of advancing NurOwn in ALS and MS over the past months," said Chaim Lebovits, Chief Executive Officer, Brainstorm Cell Therapeutics. "Our productive discussions with leading clinical experts continue, and we continue to bring forward new evidence of NurOwn's effectiveness in the scientific domain, as highlighted by our recent NEALS presentation of Phase 3 ALS data showing that NurOwn drove significant changes in important neural biomarkers that could be used to predict treatment outcomes within the trial. The insights we have gained from these discussions have generated strong momentum in our pursuit of the best and most expeditious path forward to bring NurOwn to patients. We also strengthened our leadership team and increased our manufacturing capacity, supporting our readiness to provide broad patient access as we seek paths for potential regulatory approval. The devastating and progressive nature of ALS creates an urgent unmet need for patients, and one that we are fully committed to addressing through NurOwn's continued advancement."

Third Quarter 2021 and Subsequent Corporate Highlights

- Presented important new Phase 3 ALS Biomarker data showing significant NurOwn-driven changes across a range of neural biomarkers, and that treatment response in the trial can be predicted using biomarker data and an innovative statistical model at the 2021 Northeast Amyotrophic Lateral Sclerosis Consortium® (NEALS) conference. This data furthers our understanding of NurOwn's mechanism of action in ALS and provides additional evidence linking the mechanism of action to NurOwn's impact on ALS disease progression. Data were presented by Dr. James Berry, MD, Director of the Mass General Hospital (MGH) multidisciplinary ALS clinic and Principal Investigator in the NurOwn ALS Phase 3 trial.
- Presented Phase 2 clinical trial data of NurOwn in progressive multiple sclerosis (MS) showing safety, preliminary evidence of efficacy, a reduction in neuroinflammatory biomarkers in the cerebrospinal fluid (CSF), and an increase in neuroprotective biomarkers in the CSF in an oral presentation at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). Data were presented by Dr. Jeffrey Cohen, MD, Director of Experimental Therapeutics at the Cleveland Clinic Mellen Center for MS and Principal Investigator in the NurOwn MS phase 2 trial.
- Highlighted the expansion of BrainStorm's technology portfolio to include autologous and allogeneic product candidates covering multiple neurological diseases at the 2021 Cell & Gene Meeting on the Mesa.
- Presented positive preclinical results suggesting that intrathecal administration of small extracellular vesicles (sEVs) isolated from MSCs which were induced to secrete increased levels of regenerative and immunoregulatory factors based on the NurOwn technology platform may have clinical potential as a therapy for acute lung related pathologies (ARDS) at the NYSCF 2021 VIRTUAL Meeting.
- Appointed Sidney A. Spector, MD, PhD, as Senior VP, Global Strategy and Medical Affairs and Kim Thacker, MD, as Senior VP, Medical Affairs and Clinical Innovation.
    - Drs. Spector and Thacker will work together to create a formal global Medical Affairs function as the Company prepares for anticipated growth.
- Expanded the responsibilities of Stacy Lindborg, PhD, Executive Vice President, named to the new position of Chief Development Officer.
- Appointed Menghis Bairu, MD, to the Company's Board of Directors.
- Increased commercial manufacturing capacity with the receipt of Good Manufacturing Practice (GMP) approval from the Israel Ministry of Health for three state-of-the-art cleanrooms leased by the Company at the Tel Aviv Sourasky Medical Center ("Sourasky Hospital") in Tel Aviv, Israel.

Financial Results for the Three Months Ended September 30, 2021

Cash, cash equivalents, and short-term bank deposits were approximately $28 million as of September 30, 2021, compared to approximately $35 million on June 30, 2021.

Research and development expenses, for the three months ended September 30, 2021 and 2020 were approximately $3.6 million and $4.1 million, respectively.

General and administrative expenses for the three months ended September 30, 2021 and 2020 were approximately $1.7 million and $2.6 million, respectively.

Net loss for the three months ended September 30, 2021 was approximately $5.3 million, as compared to a net loss of approximately $4.5 million for the three months ended September 30, 2020.

Net loss per share for the three months ended September 30, 2021 and 2020 was $0.15 and $0.14, respectively.

Conference Call and Webcast

Monday, November 15, 2021, at 8:00 a.m. Eastern Time	
From the U.S.:	888-506-0062
International:	973-528-0011
Entry Code:	837509

Webcast URL: https://www.webcaster4.com/Webcast/Page/2354/43351

Those that wish to listen to the replay of the conference call can do so by dialing the numbers below. The replay will be available for 14 days.

From the U.S.:	
	877-481-4010
International:	919-882-2331
Replay Passcode:	43351

About NurOwn®

The NurOwn® technology platform (autologous MSC-NTF cells) represents 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 (NTFs). Autologous MSC-NTF cells are designed to 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.

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 designation status from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of amyotrophic lateral sclerosis (ALS). BrainStorm has completed a Phase 3 pivotal trial in ALS (NCT03280056); this trial investigated the safety and efficacy of repeat-administration of autologous MSC-NTF cells and was supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). BrainStorm completed under an investigational new drug application a Phase 2 open-label multicenter trial (NCT03799718) of autologous MSC-NTF cells in progressive multiple sclerosis (MS) and was supported by a grant from the National MS Society (NMSS).

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 NurOwn® manufacturing and clinical development plans, 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, the prospects for regulatory approval of BrainStorm's NurOwn® treatment candidate, the initiation, completion, and 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, or to use third parties 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:

Contacts
Investor Relations:
John Mullaly
LifeSci Advisors, LLC
Phone: +1 617-429-3548
jmullaly@lifesciadvisors.com

Media:
Mariesa Kemble
kemblem@mac.com

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands
(Except share data)

	September 30, 2021	December 31, 2020
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 25,695	$ 37,829

Short-term deposit (Note 4)	2,114	4,107
Other accounts receivable	85	304
Prepaid expenses and other current assets (Note 5)	50	1,002
Total current assets	27,944	43,242
Long-Term Assets:		
Prepaid expenses and other long-term assets	32	26
Operating lease right of use asset (Note 6)	5,338	6,872
Property and Equipment, Net	1,224	1,119
Total Long-Term Assets	6,594	8,017
Total assets	$ 34,538	$ 51,259
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,739	$ 5,417
Accrued expenses	387	1,261
Operating lease liability (Note 6)	1,735	2,655
Other accounts payable	985	1,900
Total current liabilities	5,846	11,233
Long-Term Liabilities:		
Operating lease liability (Note 6)	3,766	4,562
Total long-term liabilities	3,766	4,562
Total liabilities	$ 9,612	$ 15,795
Stockholders' Equity:		
Stock capital: (Note 7)	12	12
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at September 30, 2021 and December 31, 2020 respectively; Issued and outstanding: 36,277,953 and 35,159,977 shares at September 30, 2021 and December 31, 2020 respectively.		
Additional paid-in-capital	192,384	184,655
Treasury stocks	(116)	(116)
Accumulated deficit	(167,354)	(149,087)
Total stockholders' equity	24,926	35,464
Total liabilities and stockholders' equity	$ 34,538	$ 51,259

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,	
	2021	2020	2021	2020
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net (Note 8)	$ 11,558	$ 13,509	$ 3,618	$ 1,867
General and administrative	6,769	6,684	1,659	2,618
Operating loss	(18,327)	(20,193)	(5,277)	(4,485)
Financial expenses (income), net	(60)	(197)	59	3
Net loss	$ (18,267)	$ (19,996)	$ (5,336)	$ (4,488)
Basic and diluted net loss per share from continuing operations	$ (0.51)	$ (0.70)	$ (0.15)	$ (0.14)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	36,140,130	28,695,540	36,304,878	31,154,101

SOURCE Brainstorm Cell Therapeutics Inc

Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2021-11-15-BrainStorm-Cell-Therapeutics-Announces-Third-Quarter-2021-Financial-Results-and-Provides-a-Corporate-Update