BrainStorm Cell Therapeutics Announces Third Quarter 2022 Financial Results and Provides a Corporate Update

BrainStorm to request Type A meeting with FDA to facilitate NurOwn's advancement following receipt of a refusal to file letter regarding the company's new Biologics License Application

Conference call and webcast at 8:00 a.m. Eastern Time today

NEW YORK, Nov. 14, 2022 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced financial results for the third quarter ended September 30, 2022, and provided a corporate update.

"Our commitment to ALS patients and our belief in NurOwn's potential to address their unmet medical needs remains unchanged, despite our receipt of a refusal to file letter regarding our new Biologics License Application," said Chaim Lebovits, Chief Executive Officer of Brainstorm. "Our next step is to request a Type A meeting with the FDA, which will help us explore the best path forward to accomplish our goal of providing ALS patients with broad access to NurOwn. We believe that an important part of the regulatory process will be an FDA Advisory Committee meeting to discuss NurOwn, as this will allow a fair hearing in an open and transparent setting. We are grateful for the support we are receiving and look forward to providing more information on our Earnings Call around the FDA feedback we have received, and our next steps."

Third Quarter 2022 and Recent Highlights

- BrainStorm intends to request a Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss the contents of a refusal to file letter issued by the FDA regarding the company's New Biologics License Application (BLA) for NurOwn for the treatment of ALS. As part of the Type A meeting, the company plans to discuss with the FDA a path to an FDA Advisory Committee meeting.
- Additional analyses from NurOwn's Phase 3 ALS trial that account for measurement limitations in the lower part of the Revised ALS Functional Rating Scale (ALSFRS-R) were presented at the 21st Annual NEALS Meeting. These analyses add to the robust body of evidence supporting a clinically meaningful treatment effect with NurOwn in ALS, as two complementary post-hoc sensitivity analysis methods showed that, after controlling for the impact of the ALSFRS-R floor effect, participants treated with NurOwn had a higher rate of clinical response and less function lost across 28 weeks compared to placebo. The presentation was jointly delivered by Stacy Lindborg, PhD, Executive Vice President and Chief Development Officer at BrainStorm and Merit Cudkowicz, MD, MSC, Chief of Neurology at Massachusetts General Hospital, Julieanne Dorn Professor of Neurology at Harvard Medical School, and Director of the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital.
- Biomarker analyses from NurOwn's Phase 3 ALS trial presented at the 5th Annual ALS ONE Research Symposium confirmed the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints. The new biomarker data presented indicate that NurOwn had similar biological effects on Phase 3 trial participants regardless of the level of disease progression at baseline, providing further evidence confirming NurOwn's multifaceted mechanism of action. Furthermore, biomarkers spanning the 3 key pathways of neurodegeneration, neuroinflammation and neuroprotection were identified by a pre-specified model linking the changes in biomarkers in participants treated with NurOwn to the clinical outcomes observed in the trial. The presentation was delivered by Dr. Stacy Lindborg, Executive Vice President and Chief Development Officer at Brainstorm.
- Full results from a single-arm, Phase 2 trial of NurOwn were published in the peer-reviewed *Multiple Sclerosis Journal*. The results demonstrate NurOwn's safety and provide preliminary evidence of efficacy in patients with progressive multiple sclerosis (MS). Treatment with NurOwn resulted in large, clinically meaningful improvements in some progressive MS patients, as defined by response criteria, across all endpoints measured. These observed improvements diverged from what was seen in matched patients with progressive MS from the Comprehensive Longitudinal Investigation of Multiple Sclerosis (CLIMB) registry. In addition, biomarker analyses confirmed NurOwn's proposed mechanism of action in progressive MS by showing consistent treatment effects in neuroinflammation and neuroprotection pathways.
- Biomarker data from the Phase 2 trial of NurOwn in progressive MS was presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) by Jeffrey Cohen, MD, Hazel Prior Hostetler Endowed Chair and Professor of Neurology, Cleveland Clinic Lerner College of Medicine, Director, Experimental Therapeutics, Mellen Center for MS Treatment and Research. The presented data provide important biological context for the trial's observed clinical outcomes, as they showed NurOwn treatment resulting in robust increases in neuroprotective biomarkers in cerebrospinal fluid.

Financial Results for the Third Quarter Ended September 30, 2022

Cash, cash equivalents, and short-term bank deposits were approximately $7.4 million as of September 30, 2022, compared to $12.2 million as of June 30, 2022.

Research and development expenses for the three months ended September 30, 2022, and 2021 were approximately $3.8 million and $3.6 million, respectively.

General and administrative expenses for the three months ended September 30, 2022, and 2021 were approximately $3.1 million and $1.7 million, respectively.

Net loss for the three months ended September 30, 2022, was approximately $6.9 million, as compared to a net loss of approximately $5.3 million for the three months ended September 30, 2021.

Net loss per share for the three months ended September 30, 2022, and 2021 was $0.19 and $0.15, respectively.

Conference Call and Webcast

November 14, 2022, at 8:00 a.m. Eastern Time

Participant Numbers:

Toll Free: 877-545-0523
International: 973-528-0016
Entry Code: 710870

Webcast URL: https://bit.ly/3AeRBkr

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.

Replay Numbers:

Toll Free: 877-481-4010
International: 919-882-2331
Replay Passcode: 47063

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 MS and was supported by a grant from the National MS Society (NMSS).

Safe-Harbor Statement

Statements in this announcement other than historical data and information, including statements regarding BrainStorm's intent to request a Type A meeting with the FDA and the clinical development of NurOwn® as a therapy for the treatment of ALS, 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 "intend," "should," "could," "will," "believe," "potential," and similar terms and phrases are intended to identify these forward-looking statements. The potential risks and uncertainties include, without limitation, management's ability to successfully achieve its goals, BrainStorm's ability to raise additional capital, BrainStorm's ability to continue as a going concern, prospects for future regulatory approval of NurOwn®, whether the FDA will grant BrainStorm's request for a Type A meeting and whether BrainStorm's future interactions with the FDA will have productive outcomes, , the impacts of the COVID-19 pandemic on our clinical trials, supply chain, and operations, 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, 2022	December 31, 2021
	Unaudited	Audited
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,144	$ 18,856
Short-term deposit (Note 4)	3,249	3,238
Other accounts receivable	58	86
Prepaid expenses and other current assets (Note 5)	51	1,100
Total current assets	7,502	23,280
Long-Term Assets:		
Prepaid expenses and other long-term assets	23	27
Operating lease right of use asset (Note 6)	4,726	4,781
Property and Equipment, Net	1,003	1,189
Total Long-Term Assets	5,752	5,997
Total assets	$ 13,254	$ 29,277
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payables	$ 6,395	$ 3,700
Accrued expenses	58	83
Operating lease liability (Note 6)	1,460	1,461
Other accounts payables	1,035	1,073
Total current liabilities	8,948	6,317
Long-Term Liabilities:		
Operating lease liability (Note 6)	2,918	3,618
Total long-term liabilities	2,918	3,618
Total liabilities	$ 11,866	$ 9,935
Stockholders' Equity:		
Stock capital: (Note 7) Common Stock of $0.00005 par value - Authorized: 100,000,000 shares September 30, 2022 and December 31, 2021 respectively; Issued and outstanding: 36,541,779 and 36,401,413 shares at September 30, 2022 and December 31, 2021 respectively.	12	12
Additional paid-in-capital	194,295	192,990
Treasury stocks	(116)	(116)
Accumulated deficit	(192,803)	(173,544)
Total stockholders' equity	1,388	19,342
Total liabilities and stockholders' equity	$ 13,254	$ 29,277

The accompanying notes are an integral part of the consolidated financial statements.

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,	
	2022	2021	2022	2021
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net (Note 8)	$ 11,505	$ 11,558	$ 3,776	$ 3,618
General and administrative	8,402	6,769	3,065	1,659
Operating loss	(19,907)	(18,327)	(6,841)	(5,277)
Financial expenses (income), net	(648)	(60)	17	59
Net loss	$ (19,259)	$ (18,267)	$ (6,858)	$ (5,336)

Basic and diluted net loss per share from continuing operations	$ (0.53)	$ (0.51)	$ (0.19)	$ (0.15)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	36,472,372	36,140,130	36,493,432	36,304,878

The accompanying notes are an integral part of the consolidated financial statements.

Logo - https://mma.prnewswire.com/media/1166536/BrainStorm_Logo.jpg

SOURCE BrainStorm Cell Therapeutics Inc.

Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2022-11-14-BrainStorm-Cell-Therapeutics-Announces-Third-Quarter-2022-Financial-Results-and-Provides-a-Corporate-Update