BrainStorm Cell Therapeutics Announces Full Year 2021 Financial Results and Provides a Corporate Update

BrainStorm continues to collect and leverage expert feedback as it pursues the optimal path forward to provide broad access to NurOwn® for patients with ALS
Announced the peer reviewed publication of the full analysis of the NurOwn Phase 3 trial in ALS showing greater treatment effects in participants with less advanced disease
Extended treatment period for NurOwn's Expanded Access Protocol authorized by the United States Food and Drug Administration
Conference call and webcast at 8:00 a.m. Eastern Time today

NEW YORK, March 28, 2022 /PRNewswire/ -- Brainstorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced the financial results for the fiscal year ended December 31, 2021 and provided a corporate update.

"We began 2022 with strong momentum and Phase 3 data showing that NurOwn® appears to deliver meaningful clinical benefits to ALS patients with less advanced disease," said Chaim Lebovits, Chief Executive Officer. "These data have been validated through a manuscript reviewed and accepted by a prestigious peer-reviewed journal and feedback from key opinion leaders at numerous medical conferences. The insights gained from these interactions are invaluable as we pursue the optimal path forward to provide broad access to NurOwn for patients with ALS. We also took important steps to increase our manufacturing capacity and made key additions to our leadership team in preparation for anticipated growth and success. Looking ahead, we believe we are well positioned to execute on our clinical, regulatory, and corporate goals as we pursue NurOwn's continued advancement in ALS and progressive multiple sclerosis (PMS)."

Fourth Quarter 2021 and Recent Highlights

- Full results from NurOwn's Phase 3 trial in ALS published in *Muscle and Nerve*. Although previously announced results showed the trial did not reach statistical significance on the primary or secondary endpoints, pre-specified and post hoc analyses featured in the publication show a treatment effect with NurOwn across both primary and secondary efficacy outcomes in patients with less advanced disease. Additionally, the publication links these clinical results to biomarker changes and confirmed treatment safety.
- Analyses leveraging the validated ENCALS prediction model and the primary endpoint from NurOwn's Phase 3 trial in ALS presented at the 4th Annual ALS ONE Research Symposium. We showed that in participants with less advanced disease (i.e., those predicted to have long to very long survival) there were more responders with NurOwn compared to placebo (33% vs. 14%). The presentation was delivered by Jonathan S. Katz, MD, a co-principal investigator on the trial and Chair of the Neurology Department and Director of the Forbes Norris ALS Clinic at the California Pacific Medical Center.
- In Q1 2022, presented genetic analyses from the NurOwn Phase 3 trial in ALS suggesting that NurOwn treatment may influence disease progression in patients who possess the UNC13A risk allele. The presentation was delivered in a late-breaking oral session at the 2022 MDA Clinical & Scientific Conference by Merit E. Cudkowicz, MD, MSc, Chief of Neurology at Massachusetts General Hospital, Julieanne Dorn Professor of Neurology at Harvard Medical School, Director of the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital.
- Presented biomarker data from NurOwn's Phase 3 trial in ALS at the 32nd International Symposium on ALS/MND and at the 2021 Northeast Amyotrophic Lateral Sclerosis Consortium®. Collectively, these data show significant NurOwn-driven changes across a range of neural biomarkers and suggest the NurOwn's biological activity of NurOwn observed across multiple disease pathways could prove important to impacting the progression of ALS. They also provide an increased understanding of NurOwn's mechanism of action in ALS and additional evidence linking this mechanism of action to NurOwn's potential impact on ALS disease progression. The presentations were delivered by two principal investigators from the NurOwn Phase 3 trial: Robert H. Brown Jr., MD, Director of the Program in Neurotherapeutics at the University of Massachusetts Medical School, and James D. Berry, MD, MPH, Winthrop Family Scholar in ALS Sciences, Director of the Massachusetts General Hospital multidisciplinary ALS clinic and Chief of the Division of ALS

and Motor Neuron Diseases.

- Received authorization from the United States Food and Drug Administration (FDA) for an extension of the dosing period in NurOwn's Expanded Access Protocol (EAP). The Agency recommended that BrainStorm submit the protocol amendment that led to this authorization, which provides patients who completed the EAP with the opportunity to receive up to three additional doses of NurOwn.
- Presented Phase 2 clinical trial data of NurOwn in progressive multiple sclerosis (MS) showing general tolerability, preliminary evidence of efficacy, a reduction in neuroinflammatory biomarkers in the cerebrospinal fluid (CSF), and an increase in neuroprotective biomarkers in the CSF at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). The presentation was delivered by 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.
- Finalized the technology transfer for NurOwn manufacturing at Catalent's world-class, 32,000 square-foot, cell-therapy facility in Houston, Texas.
- Granted a new patent in Brazil covering methods of manufacturing NurOwn.
- Delivered a presentation at the 2021 Cell & Gene Meeting on the Mesa highlighting the expansion of BrainStorm's technology portfolio to include autologous and allogeneic product candidates covering multiple neurological diseases.
- Presented positive preclinical results at the NYSCF 2021 VIRTUAL Meeting. These results suggest that intrathecal administration of small extracellular vesicles (sEVs) isolated from mesenchymal stem cells that were induced to secrete increased levels of regenerative and immunoregulatory factors based on the NurOwn technology platform may have therapeutic potential in acute lung-related pathologies (e.g., acute respiratory distress syndrome).
- Appointed Kim Thacker, MD, as Senior VP, Medical Affairs and Clinical Innovation and Sidney A. Spector, MD, PhD, as Senior VP, Global Strategy and Medical Affairs. Drs. Thacker and Spector are working together to create a formal global medical affairs function as the Company prepares for anticipated growth.
- Expanded the responsibilities of Stacy Lindborg, PhD, with a promotion to the new position of Chief Development Officer.
- Appointed Menghis Bairu, MD, to the Company's Board of Directors.
- Presented a corporate and clinical overview at the 12th Annual California ALS Research Summit.

Financial Results for the Year Ended December 31, 2021

Cash, cash equivalents, and short-term bank deposits were approximately $22.1 million as of December 31, 2021, compared to $41.9 million as of December 31, 2020.

Research and development expenses for the twelve months ended December 31, 2021, and 2020 were approximately $15.2 million and $22.3 million, respectively.

General and administrative expenses for the twelve months ended December 31, 2021, and 2020 were approximately $9.3 million and $9.4 million, respectively.

Net loss for the twelve months ended December 31, 2021, was approximately $24.5 million, as compared to a net loss of approximately $31.8 million for the twelve months ended December 31, 2020.

Net loss per share for the twelve months ended December 31, 2021, and 2020 was $0.68 and $1.07, respectively.

Conference Call and Webcast

Monday March 28, 2022, at 8:00 a.m. Eastern Time

Toll Free: 888-506-0062

International: 973-528-0011

Entry Code: 108732

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

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.

Toll Free: 877-481-4010

International: 919-882-2331

Replay Passcode: 44771

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).

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, prospects for future 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 products and 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; 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.
CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands
(Except share data)

	December 31,	
	2021	**2020**
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 18,856	$ 37,829
Short-term deposit (Note 9)	3,238	4,107
Other accounts receivable (Note 4)	86	304
Prepaid expenses and other current assets (Note 5)	1,100	1,002
Total current assets	$ 23,280	$ 43,242
Long-Term Assets:		
Prepaid expenses and other long-term assets	$ 27	$ 26
Operating lease right of use asset (Note 6)	4,781	6,872
Property and Equipment, Net (Note 7)	1,189	1,119
Total Long-Term Assets	$ 5,997	$ 8,017
Total assets	$ 29,277	$ 51,259
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payables	$ 3,700	$ 5,417
Accrued expenses	83	1,261
Operating lease liability (Note 6)	1,461	2,655
Other accounts payables	1,073	1,900
Total current liabilities	$ 6,317	$ 11,233
Long-Term Liabilities:		
Operating lease liability (Note 6)	3,618	4,562
Total long-term liabilities	$ 3,618	$ 4,562
Total liabilities	$ 9,935	$ 15,795
Stockholders' Equity:		
Stock capital: (Note 10)	12	12
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at December 31, 2021 and December 31, 2020 respectively; Issued and outstanding: 36,401,413 and 35,159,977 shares at December 31, 2021 and December 31, 2020 respectively.		
Additional paid-in-capital	192,990	184,655
Treasury stocks	(116)	(116)
Accumulated deficit	(173,544)	(149,087)
Total stockholders' equity	$ 19,342	$ 35,464
Total liabilities and stockholders' equity	$ 29,277	$ 51,259

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

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

	Year ended December 31,	
	2021	2020
	U.S. $ in thousands	
Operating expenses:		
Research and development, net (Note 11)	$ 15,235	$ 22,329
General and administrative	9,304	9,355
Operating loss	(24,539)	(31,684)
Financial expenses (income), net	(82)	127
Net loss	$ (24,457)	$ (31,811)
Basic and diluted net loss per share	$ (0.68)	$ (1.07)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	36,181,753	29,848,217

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

SOURCE BrainStorm Cell Therapeutics Inc

Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2022-03-28-BrainStorm-Cell-Therapeutics-Announces-Full-Year-2021-Financial-Results-and-Provides-a-Corporate-Update