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

BrainStorm continues to gain insights and perspectives from leading ALS experts as it seeks the optimal path forward to provide broad patient access to NurOwn®

Strengthened executive team in preparation for anticipated growth and corporate development, with the appointment of Netta Blondheim-Shraga, PhD, as VP of Research & Development and Antal Pearl-Lendner, Avd, as Chief Legal Counsel

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

NEW YORK, May 16, 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 first quarter ended March 31, 2022 and provided a corporate update.

"We remain firmly committed to addressing the urgent needs of ALS patients by working expeditiously towards our goal of enabling broad access to NurOwn®," said Chaim Lebovits, Chief Executive Officer. "Our efforts here are bolstered by peer-reviewed Phase 3 data that provide evidence of NurOwn's greater treatment effects for ALS patients with less advanced disease, and by our ongoing interactions with the broader physician and patient community. These have allowed us to gain valuable perspective from the world's most prominent thought leaders as we seek NurOwn's optimal path forward. Looking ahead, we will continue to leverage expert feedback as we work with the regulatory authorities to enable NurOwn's advancement. We believe our strong clinical and biomarker data and highly talented leadership team has us poised for sustained success."

First Quarter 2022 and Recent Highlights

- Biomarker analyses from NurOwn's Phase 3 trial in ALS were presented by James 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, in an abstract at the American Academy of Neurology 2022 Virtual Congress. These results demonstrated significant changes across multiple cerebrospinal fluid biomarkers following NurOwn treatment, with the strongest effects observed in biomarkers related to neuroprotection and neuroinflammation.
- Presented a prospective genetic analyses from NurOwn's Phase 3 ALS trial suggesting that NurOwn treatment may influence disease progression in patients carrying the ALS UNC13A risk allele. The presentation was featured in a late-breaking oral session at the 2022 Muscular Dystrophy and Association (Clinical & Scientific Conference) and delivered by Merit E. 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.
- Presented preclinical data demonstrating greater macrophage immunomodulation of NurOwn-derived exosomes (Exo MSC-NTF) compared to naïve mesenchymal stem cell-derived exosomes (Exo MSC) against acute lung injury at the International Society of Cell & Gene Therapy (ISCT) 2022 Meeting. The presentation was delivered by Dr. Kim Thacker, Senior Vice President, Medical Affairs and Clinical Innovation, BrainStorm Cell Therapeutics.
- Announced upcoming presentations at the ALS Drug Development Summit (May 25, 2022) and the ISEV 2022 Annual Meeting (May 26, 2022). The ALS Drug Development Summit presentation by Ralph Kern MD MHSc, President and Chief Medical Officer Brainstorm Cell Therapeutics, will focus on the use of cerebrospinal fluid biomarkers to interrogate multiple neuroinflammatory, neurodegenerative and neuroprotection pathways in NurOwn's Phase 3 ALS trial and how this information may be leveraged to confirm ALS target engagement and improve therapeutic outcomes. The ISEV presentation features the results of a preclinical study examining the advantages of Exo MSC-NTF over Exo MSC in models of acute lung injury and will be presented by Haggai Kaspi PhD, Brainstorm R&D.
- Strengthened the Company's executive team in preparation for anticipated growth and corporate development, with the appointments of Netta Blondheim-Shraga, PhD, as VP of Research & Development and Antal Pearl-Lendner, Adv, as Chief Legal Counsel.
- Granted a new Brazilian patent covering methods of manufacturing NurOwn titled - *A method of generating cells which secrete Brain Derived Neurotrophic Factor (BDNF), Glial Derived Neurotrophic Factor (GDNF), Hepatocyte Growth Factor (HGF) And Vascular Endothelial Growth Factor (VEGF), wherein said cells do not Secrete Nerve Growth Factor (NGF)*.
- Presented a corporate and Phase 3 ALS clinical overview at the 12th Annual California ALS Research Summit on January 27, 2022 by Ralph Kern MD MHSc, President and Chief Medical Officer Brainstorm Cell Therapeutics.

Financial Results for the First Quarter Ended March 31, 2022

Cash, cash equivalents, and short-term bank deposits were approximately $18.4 million as of March 31, 2022, compared to $22.1 million as of December 31, 2021.

Research and development expenses for the three months ended March 31, 2022, and 2021 were approximately $2.6 million and $4.3 million, respectively.

General and administrative expenses for the three months ended March 31, 2022, and 2021 were approximately $2.9 million and $2.6 million, respectively.

Net loss for the three months ended March 31, 2022, was approximately $5.4 million, as compared to a net loss of approximately $6.7 million for the three months ended March 31, 2021.

Net loss per share for the three months ended March 31, 2022, and 2021 was $0.15 and $0.19 respectively.

Conference Call and Webcast

May 16, 2022, at 8:00 a.m. Eastern Time

Participant Numbers:
Toll Free: 888-506-0062
International: 973-528-0011
Entry Code: 476792
Webcast URL: https://www.webcaster4.com/Webcast/Page/2354/45459

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: 45459

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

	March 31, 2022	December 31, 2021
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 15,151	$ 18,856
Short-term deposit (Note 4)	3,246	3,238
Other accounts receivable	61	86
Prepaid expenses and other current assets (Note 5)	802	1,100
Total current assets	19,260	23,280
Long-Term Assets:		
Prepaid expenses and other long-term assets	27	27
Operating lease right of use asset (Note 6)	5,380	4,781
Property and Equipment, Net	1,124	1,189
Total Long-Term Assets	6,531	5,997
Total assets	$ 25,791	$ 29,277
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payables	$ 4,570	$ 3,700
Accrued expenses	71	83
Operating lease liability (Note 6)	1,629	1,461
Other accounts payables	1,102	1,073
Total current liabilities	7,372	6,317
Long-Term Liabilities:		
Operating lease liability (Note 6)	3,932	3,618
Total long-term liabilities	3,932	3,618
Total liabilities	$ 11,304	$ 9,935
Stockholders' Equity:		
Stock capital: (Note 7)	12	12
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at December 31, 2021 and March 31, 2022 respectively; Issued and outstanding: 36,486,180 and 36,277,953 shares at September 30, 2021 and December 31, 2020 respectively.		
Additional paid-in-capital	193,495	192,990
Treasury stocks	(116)	(116)
Accumulated deficit	(178,904)	(173,544)
Total stockholders' equity	14,487	19,342
Total liabilities and stockholders' equity	$ 25,791	$ 29,277

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

	Three months ended March 31,	
	2022	2021
	Unaudited	
Operating expenses:		

Research and development, net (Note 8)	$ 2,616	$ 4,341
General and administrative	2,859	2,588
Operating loss	(5,475)	(6,929)
Financial income, net	115	267
Net loss	$ (5,360)	$ (6,662)
Basic and diluted net loss per share from continuing operations	$ (0.15)	$ (0.19)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	36,436,882	35,791,309

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/2022-05-16-BrainStorm-Cell-Therapeutics-Announces-First-Quarter-2022-Financial-Results-and-Provides-a-Corporate-Update