BrainStorm Announces Full Year 2020 Financial Results and Provides a Corporate Update

- Company met with the FDA to present phase 3 data and is in ongoing discussions with the FDA to identify agreed upon regulatory pathways that may support NurOwn's future approval in ALS
- Progressive MS Phase 2 trial remains on track for top-line data readout in Q1 2021
- Conference call and webcast at 8 a.m. ET today

NEW YORK, Feb. 4, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, announced today financial results for the fiscal year ended December 31, 2020, and provided a corporate update.

"In 2020 we achieved several important company milestones, the most significant of which was the timely completion of our pivotal Phase 3 ALS trial," said Chaim Lebovits, Chief Executive Officer of BrainStorm Cell Therapeutics. "The trial generated robust data suggesting that NurOwn® has a clinically meaningful treatment effect and the FDA is actively reviewing these data following a recent meeting with our clinical team. The unmet needs of ALS patients continue to be our greatest inspiration and foremost priority, and we will keep the market updated as we receive formal feedback from the FDA and diligently pursue next steps to advance NurOwn's development in this devastating disease."

Mr. Lebovits continued, "Beyond our lead ALS program, we continue to make progress and are poised for a catalyst rich 2021 for our NurOwn technology platform. In progressive MS, our Phase 2 top-line data are expected by the end of the first quarter, which we believe will highlight the broad applicability of NurOwn's mechanism of action (MOA). We plan to further advance our pipeline through our clinical development program in Alzheimer's disease, a highly prevalent disease with enormous societal impact and limited treatment options. These clinical programs will be complemented by the expansion of our manufacturing capabilities and advancement of our exosome-based platform technology, which has demonstrated the potential to treat COVID-19 acute respiratory distress syndrome in a recently published preclinical study. We believe that execution of these milestones will help move us toward our ultimate goal of addressing the critical unmet needs of patients with neurodegenerative diseases while simultaneously positioning the company to generate shareholder value."

Fourth Quarter 2020 and Recent Corporate Highlights:

- Announced top-line results from the NurOwn® Phase 3 amyotrophic lateral sclerosis (ALS) trial. Though the trial did not meet statistical significance in the primary efficacy endpoint, pre-specified analyses suggest that NurOwn® has a clinically meaningful treatment effect, which we seek to further explore in ongoing discussions with the FDA.
- Presented the NurOwn® Phase 3 results in a platform session at the 31st International Symposium on ALS/MND.
- Initiated a NurOwn® Expanded Access Program for patients who completed the Phase 3 ALS trial and meet specific eligibility requirements.
- Completed dosing of all patients in the ongoing Phase 2 clinical trial evaluating NurOwn® as a treatment for adults with progressive multiple sclerosis (MS). Top-line data from the trial are expected by the end of the first quarter 2021.
- Announced a partnership with Catalent for NurOwn® manufacturing. The partnership is designed to support a continuous supply of NurOwn® for future clinical trials and initial commercialization.
- Selected Rapid Reshore & Development (RR&D) as our partner to expedite site selection and design services for a state-of-the-art manufacturing facility for NurOwn® in the U.S.
- Announced the publication of a preclinical study entitled "MSC-NTF (NurOwn®) exosomes: a novel therapeutic modality in the mouse LPS-induced ARDS model," in the peer-reviewed journal *Stem Cell and Research Therapy*. Data from the study showed that intrathecal administration of NurOwn® derived exosomes significantly improved lung function and histology in a mouse model of acute respiratory distress syndrome (ARDS), a type of respiratory failure frequently associated with COVID-19.
- Presented preclinical NurOwn® derived exosome ARDS data at the Virtual New York Stem Cell Foundation Conference.
- Presented an on-demand webinar at the 2020 Cell & Gene Meeting on the Mesa.

Cash and Liquidity as of January 31, 2021

Total cash and liquidity as of January 31, 2021 was approximately $45.0 million.

Financial Results for the Year Ended December 31, 2020

- Cash, cash equivalents, and short-term bank deposits were approximately $41.9 million as of December 31, 2020, compared to approximately $0.6 million on December 31, 2019.
- Research and development expenses, net for year ended December 31, 2020 and 2019 were approximately $22.3 million and $17.2 million, respectively.
    - Excluding participation from IIA and CIRM under the grants and proceeds received under the hospital exemption regulatory pathway, research and development expenses decreased by $133,000 from approximately $24.7 million in the year ended December 31, 2019 to approximately $24.6 million in the year ended December 31, 2020.
- General and administrative expenses for the year ended December 31, 2020 and 2019 were approximately $9.4 million and $5.8 million, respectively.
- Net loss for the year ended on December 31, 2020 was $31.8 million, as compared to a net loss of $23.3 million for the year ended December 31, 2019.
    - Net loss per share for the year ended December 31, 2020 and 2019 was $1.07 and $1.06, respectively.

For further details on BrainStorm's financials, including financial results for the year ended December 31, 2020, refer to the Form 10-K filed with the SEC today.

Conference Call & Webcast

Thursday, February 4, 2021 at 8 a.m. Eastern Time
From the US: 877-407-9205
International: 201-689-8054
Webcast: https://cutt.ly/vjBvkTp

Replays, available through February 18, 2021
From the US: 877-481-4010
International: 919-882-2331
Replay Passcode: 39495

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 status designation 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 is in active discussions with the FDA to identify regulatory pathways that may support NurOwn's future approval in ALS. BrainStorm is also conducting an FDA-approved Phase 2 open-label multicenter trial in progressive multiple sclerosis (MS). The Phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) completed dosing in December 2020, and topline results are expected by the end of the first quarter 2021.

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 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,	
	2020	2019
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 37,829	$ 536
Short-term deposit (Note 9)	4,107	33
Other accounts receivable (Note 4)	304	2,359
Prepaid expenses and other current assets (Note 5)	1,002	432
Total current assets	43,242	3,360
Long-Term Assets:		
Prepaid expenses and other long-term assets	26	32
Operating lease right of use asset (Note 6)	6,872	2,182
Property and Equipment, Net (Note 7)	1,119	960
Total Long-Term Assets	8,017	3,174

Total assets	$ 51,259	$ 6,534
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 5,417	$ 14,677
Accrued expenses	1,261	1,000
Operating lease liability (Note 6)	2,655	1,263
Other accounts payable	1,900	714
Total current liabilities	11,233	17,654
Long-Term Liabilities:		
Operating lease liability (Note 6)	4,562	1,103
Total long-term liabilities	4,562	1,103
Total liabilities	$ 15,795	$ 18,757
Stockholders' Equity (deficit):		
Stock capital: (Note 11)	12	11
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at December 31, 2020 and December 31, 2020 respectively; Issued and outstanding: 35,159,977 and 23,174,228 shares at December 31, 2020 and December 31, 2019 respectively.		
Additional paid-in-capital	184,655	105,042
Treasury stocks	(116)	—
Accumulated deficit	(149,087)	(117,276)
Total stockholders' equity (deficit)	35,464	(12,223)
Total liabilities and stockholders' equity	$ 51,259	$ 6,534

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,	
	2020	**2019**
	U.S. $ in thousands	
Operating expenses:		
Research and development, net (Note 12)	$ 22,329	$ 17,204
General and administrative	9,355	5,797
Operating loss	(31,684)	(23,001)
Financial expenses, net	127	252
Net loss	$ (31,811)	$ (23,253)
Basic and diluted net loss per share	$ (1.07)	$ (1.06)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	29,848,217	21,906,257

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/2021-02-04-BrainStorm-Announces-Full-Year-2020-Financial-Results-and-Provides-a-Corporate-Update