# BrainStorm Announces First Quarter 2021 Financial Results and Provides a Corporate Update

**- Positive Phase 2 data demonstrate the potential of NurOwn® as a treatment for progressive MS**
**- Regulatory strategy progressing to advance NurOwn's approval in ALS**
**- Conference call and webcast at 8:00 a.m. Eastern Time today**

NEW YORK, April 26, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, announced today financial results for the first quarter ended March 31, 2021 and provided a corporate update.

"In the first quarter we were excited to announce positive top line data from our Phase 2 trial evaluating NurOwn® as a treatment for progressive multiple sclerosis (MS). These data expand the body of evidence supporting the NurOwn® technology platform across neurodegenerative diseases," said Chaim Lebovits, Chief Executive Officer of BrainStorm. "In our ALS program, we intend to submit a manuscript for peer review shortly and are delivering scientific presentations. We are currently in active discussions with various experts including principal investigators, ALS physicians, statisticians, regulatory advisors as well as patient advocacy groups, in addition to potential strategic partners. Based on all feedback received, we will assess the best path forward to enable patients access to NurOwn including FDA BLA submission and/or other regulatory and business options."

**First Quarter 2021 Corporate Highlights**

- Announced positive top-line data from the open label Phase 2 trial evaluating NurOwn® as a treatment for progressive multiple sclerosis (MS). The trial achieved the primary endpoint of safety and demonstrated clinically meaningful improvements in multiple endpoints.
    - Consistent improvement across all functional measures were observed, in comparison to the matched clinical cohort from the Comprehensive Longitudinal Investigations in MS at the Brigham & Woman's Hospital (CLIMB Study).
    - Pre-specified responder analysis demonstrated consistent improvements in functional measures including walking, vision and cognition. These improvements were not seen in any of the matched CLIMB patients.
    - Consistent increases in delivered neurotrophic factors and a reduction across key inflammatory biomarkers were observed
- Following FDA feedback on the Phase 3 NurOwn ALS clinical data, and enacting FDA advice, we have made great progress in the important steps needed to develop and then act on our regulatory strategy. These include submission of a manuscript for a peer-reviewed publication of NurOwn's Phase 3 clinical trial results and conducting ongoing consultations with key ALS stakeholders in the U.S. and other jurisdictions confirming the strength of the data and providing feedback and valuable guidance on next steps.
- Published data from a preclinical study showing 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. The study, entitled, "MSC-NTF (NurOwn) exosomes: a novel therapeutic modality in the mouse LPS-induced ARDS model," was published in the peer-reviewed journal *Stem Cell and Research Therapy*.

**Presented at the following investor conferences:**

- 10th Annual SVB Leerink Global Healthcare Conference

**Cash and Liquidity as of March 31, 2021**

Total available funding as of March 31, 2021, which includes cash, cash equivalents and short-term bank deposits of approximately $40.0 million, an untapped ATM capacity of approximately $16 million, as well as remaining non-dilutive funding from grants, amounts to approximately $57 million.

**Financial Results for the Three Months Ended March 31, 2021**

Cash, cash equivalents, and short-term bank deposits were approximately $40.0 million as of March 31, 2021, compared to approximately $42.0 million on December 31, 2020.

Research and development expenses, net for the three months ended March 31, 2021 and 2020 were approximately $4.3 million and $5.9 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 approximately $2.3 million from $7.1 million in the first quarter of 2020 to $4.8 million in the first quarter of 2021.

General and administrative expenses for the three months ended March 31, 2021 and 2020 were approximately $2.6 million and $2.4 million, respectively.

Net loss for the three months ended March 31, 2021 was approximately $6.6 million, as compared to a net loss of approximately $8.1 million for the three months ended March 31, 2020.

Net loss per share for the three months ended March 31, 2021 and 2020 was $0.19 and $0.32, respectively.

**Conference Call & Webcast**

Monday, April 26, 2021 at 8:00 a.m. Eastern Time

From the U.S.: 877-407-9205
International: 201-689-8054
Webcast URL: https://www.webcaster4.com/Webcast/Page/2354/40513

Replays, available through May 10, 2021
From the U.S.: 877-481-4010
International: 919-882-2331
Replay Passcode: 40513

**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).

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.

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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, 2021 | December 31, 2020 |
|---|---|---|
| | U.S. $ in thousands | |
| **ASSETS** | | |
| **Current Assets:** | | |
| Cash and cash equivalents | $ 35,933 | $ 37,829 |
| Short-term deposit (Note 4) | 4,114 | 4,107 |
| Other accounts receivable | 255 | 304 |
| Prepaid expenses and other current assets (Note 5) | 728 | 1,002 |
| **Total current assets** | 41,030 | 43,242 |
| **Long-Term Assets:** | | |
| Prepaid expenses and other long-term assets | 27 | 26 |
| Operating lease right of use asset (Note 6) | 6,426 | 6,872 |
| Property and Equipment, Net | 1,088 | 1,119 |
| **Total Long-Term Assets** | 7,541 | 8,017 |
| **Total assets** | $ 48,571 | $ 51,259 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current Liabilities:** | | |
| Accounts payable | $ 2,552 | $ 5,417 |
| Accrued expenses | 1,748 | 1,261 |
| Operating lease liability (Note 6) | 2,299 | 2,655 |
| Other accounts payable | 1,592 | 1,900 |
| **Total current liabilities** | 8,191 | 11,233 |
| **Long-Term Liabilities:** | | |

| | | |
|---|---|---|
| Operating lease liability (Note 6) | 4,179 | 4,562 |
| **Total long-term liabilities** | 4,179 | 4,562 |
| **Total liabilities** | $ 12,370 | $ 15,795 |
| **Stockholders' Equity:** | | |
| Stock capital: (Note 7) | 12 | 12 |
| Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at March 31, 2021 and December 31, 2020 respectively; Issued and outstanding: 36,318,561 and 35,159,977 shares at March 31, 2021 and December 31, 2020 respectively. | | |
| Additional paid-in-capital | 192,054 | 184,655 |
| Treasury stocks | (116) | (116) |
| Accumulated deficit | (155,749) | (149,087) |
| **Total stockholders' equity** | 36,201 | 35,464 |
| **Total liabilities and stockholders' equity** | $ 48,571 | $ 51,259 |

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, | |
|---|---|---|
| | **2021** | **2020** |
| | **Unaudited** | |
| **Operating expenses:** | | |
| Research and development, net (Note 8) | $ 4,341 | $ 5,948 |
| General and administrative | 2,588 | 2,360 |
| **Operating loss** | (6,929) | (8,308) |
| Financial income, net | 267 | 194 |
| **Net loss** | $ (6,662) | $ (8,114) |
| Basic and diluted net loss per share from continuing operations | $ (0.19) | $ (0.32) |
| Weighted average number of shares outstanding used in computing basic and diluted net loss per share | 35,791,309 | 28,423,837 |

SOURCE BrainStorm Cell Therapeutics Inc.

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Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2021-04-26-BrainStorm-Announces-First-Quarter-2021-Financial-Results-and-Provides-a-Corporate-Update