# BrainStorm Announces Financial Results for the Third Quarter of 2020 and Provides a Corporate Update

## Pivotal Phase 3 ALS trial remains on track for top-line data readout by the end of November 2020

## New senior executives strengthen regulatory and market access capabilities as the Company prepares to transition to a commercial organization

## Conference Call and Webcast at 8 a.m. ET Today

NEW YORK, Oct. 15, 2020 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, announced today financial results for the third quarter ended September 30, 2020, and provided a corporate update.

"The most important near-term event for BrainStorm will be the upcoming top-line data readout for the NurOwn® Phase 3 trial in ALS, expected by the end of November. A successful outcome will set us on the path to filing a Biologic License Application (BLA) for what we believe will be a valuable new treatment for ALS," said Chaim Lebovits, Chief Executive Officer of BrainStorm Cell Therapeutics. "In parallel to our preparations for upcoming data read out, we are very busy planning and executing on other pre-BLA activities. On the management front, we appointed William K. White and Dr. Anthony Waclawski, adding valuable commercial and regulatory expertise to our leadership team. This expertise will be crucial as we work towards obtaining regulatory approval for NurOwn and ensuring that, if approved, it will be readily accessible to ALS patients in need of new treatment options for this devastating disease."

NurOwn has an innovative mechanism of action that is broadly applicable across neurodegenerative diseases and BrainStorm continues to invest in clinical trials evaluating the product in conditions beyond ALS to maximize value creation for its various stakeholders. The company remains on track to complete dosing in its Phase 2 clinical trial in progressive multiple sclerosis (PMS) by the end of 2020. In addition, the Company recently unveiled a clinical development program in Alzheimer's' disease (AD) and is planning a Phase 2 proof-of-concept clinical trial at several leading AD centers in the Netherlands and France.

**Third Quarter 2020 and Recent Corporate Highlights:**

- Completed dosing of all patients in the ongoing NurOwn Phase 3 clinical trial in ALS and plans remains on track to report top-line data by the end of November 2020.
- Announced the publication of a manuscript titled "*Effects of MSC-NTF cells on T and B regulatory cell function in ALS*" in the journal Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration. The manuscript describes NurOwn's immunomodulatory effects on T and B regulatory cell function, suggesting that its mechanism of action is broadly applicable in ALS, PMS and Alzheimer's disease.
- Presented a scientific poster titled "*Advancing NurOwn® for ALS: Phase 3 Clinical Trial Design*" at the Annual Northeast ALS (NEALS) Meeting.
- A Phase 2 trial evaluating NurOwn® as a treatment for progressive multiple sclerosis (PMS) is ongoing at 5 leading U.S. multiple sclerosis centers. The Company remains on track to complete dosing by year end 2020.
- Presented progressive MS natural history data at the MSVirtual2020 meeting documenting an association between magnetic resonance imaging (MRI) measures and functional improvement in patients matched to the phase 2 NurOwn clinical trial.
- Hosted a Key Opinion Leader (KOL) webinar on the Alzheimer's disease program and the planned European Phase 2 trial. The webinar featured presentations by two lead investigators in the trial: Philip Scheltens, M.D., Ph.D., Professor of Cognitive Neurology and Director of the Alzheimer Centre at the VU University Medical Center in Amsterdam, Netherlands; and Bruno Dubois, M.D., Ph.D., Professor of Neurology at the Neurological Institute of the Salpétrière University Hospital in Paris, France.
- Announced a groundbreaking pre-clinical study of a NurOwn® derived exosome-based treatment for COVID-19 acute respiratory distress syndrome (ARDS).
- Appointed Anthony Waclawski Ph.D. as Executive Vice President, Global Head of Regulatory Affairs.
- Appointed William K. White as Senior Vice President, Head of Market Access and Pricing.
- Received a non-dilutive bonus payment of $700,000 from California Institute for Regenerative Medicine (CIRM) for treating more California participants than originally proposed in the Phase 3 ALS trial.
- Announced the grant of Japanese Patent No. 6,753,887, titled: "*Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors*".

**Presented at the following Investor Conferences:**

- 40th Annual Canaccord Genuity Growth Conference

**Cash and Liquidity as of October 14, 2020**

Total available funding as of October 14, 2020, which includes cash, cash equivalents and short-term bank deposits of approximately $33.1 million as well as remaining non-dilutive funding from CIRM, IIA and other grants, amounts to approximately $36 million.

**Financial Results for the Three Months Ended September 30, 2020**

- Cash and cash equivalents, and short-term bank deposits amounted to approximately $28.8 million at September 30, 2020 compared to $16.2 million at June 30, 2020.
- Research and development expenses, net for the three months ended September 30, 2020 and 2019 were $1.87 million and $4.01 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 $1.68 million from $5.66 million in the third quarter of 2019 to $3.98 million in the third quarter of 2020.
- General and administrative expenses for the three months ended September 30, 2020 and 2019 were $2.62 million and $1.54 million, respectively.
- Net loss for the three months ended on September 30, 2020 was $4.49 million, as compared to a net loss of $5.63 million for the three months ended September 30, 2019.
    - Net loss per share for the three months ended September 30, 2020 and 2019 was $0.14 and $0.25, respectively.

**Conference Call & Webcast**
**Thursday, October 15, 2020 at 8 a.m. Eastern Time**
From the US: 877-407-9205
International: 201-689-8054
Webcast: https://www.webcaster4.com/Webcast/Page/2354/37811

Replays, available through October 29, 2020
From the US: 877-481-4010
International: 919-882-2331
Replay Passcode: 37811

**About NurOwn®**

NurOwn (autologous MSC-NTF) cells represent 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 can 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. BrainStorm has fully enrolled a Phase 3 pivotal trial of autologous MSC-NTF cells for the treatment of amyotrophic lateral sclerosis (ALS). BrainStorm also recently received acceptance from the U.S. Food and Drug Administration (FDA) to initiate a Phase 2 open-label multicenter trial in progressive multiple sclerosis (MS) and completed enrollment in August 2020.

**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 fully enrolled a Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of autologous MSC-NTF cells at six U.S. sites supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The pivotal study is intended to support a filing for U.S. FDA approval of autologous MSC-NTF cells in ALS. BrainStorm also recently received U.S. FDA clearance to initiate a 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 enrollment in August 2020. 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, 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 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,; 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, 2020 | December 31, 2019 |
|---|---|---|
| | U.S. $ in thousands | |
| | Unaudited | Audited |
| **ASSETS** | | |
| **Current Assets:** | | |
| Cash and cash equivalents | $ 24,770 | $ 536 |
| Short-term deposit (Note 4) | 4,038 | 33 |
| Other accounts receivable | 1,473 | 2,359 |
| Prepaid expenses and other current assets (Note 5) | 56 | 432 |
| **Total current assets** | 30,337 | 3,360 |
| | | |
| **Long-Term Assets:** | | |
| Prepaid expenses and other long-term assets | 27 | 32 |
| Operating lease right of use asset (Note 6) | 1,377 | 2,182 |

| | | |
|---|---|---|
| Property and Equipment, Net | 950 | 960 |
| **Total Long-Term Assets** | 2,354 | 3,174 |
| **Total assets** | $ 32,691 | $ 6,534 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| **Current Liabilities:** | | |
| Accounts payable | $ 3,283 | $ 14,677 |
| Accrued expenses | 917 | 1,000 |
| Operating lease liability (Note 6) | 1,216 | 1,263 |
| Other accounts payable | 1,013 | 714 |
| **Total current liabilities** | 6,429 | 17,654 |
| **Long-Term Liabilities:** | | |
| Operating lease liability (Note 6) | 284 | 1,103 |
| **Total long-term liabilities** | 284 | 1,103 |
| **Total liabilities** | $ 6,713 | $ 18,757 |
| **Stockholders' Equity (deficit):** | | |
| Stock capital: (Note 7) Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at September 30, 2020 and December 31, 2019 respectively; Issued and outstanding: 31,567,592 and 23,174,228 shares at September 30, 2020 and December 31, 2019 respectively. | 12 | 11 |
| Additional paid-in-capital | 163,238 | 105,042 |
| Receipts on account of shares | — | — |
| Accumulated deficit | (137,272) | (117,276) |
| **Total stockholders' equity (deficit)** | 25,978 | (12,223) |
| **Total liabilities and stockholders' equity** | $ 32,691 | $ 6,534 |

**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, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | Unaudited | | Unaudited | |
| **Operating expenses:** | | | | |
| Research and development, net | $ 13,509 | $ 11,018 | $ 1,867 | $ 4,008 |
| General and administrative | 6,684 | 4,318 | 2,618 | 1,543 |
| **Operating loss** | (20,193) | (15,336) | (4,485) | (5,551) |
| Financial expenses (income), net | (197) | 225 | 3 | 83 |
| **Net loss** | $ (19,996) | $ (15,561) | $ (4,488) | $ (5,634) |
| Basic and diluted net loss per share from continuing operations | $ (0.70) | $ (0.72) | $ (0.14) | $ (0.25) |

| | | | | |
|---|---|---|---|---|
| Weighted average number of shares outstanding used in computing basic and diluted net loss per share | 28,695,540 | 21,630,007 | 31,154,101 | 22,254,993 |

SOURCE Brainstorm Cell Therapeutics Inc

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Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2020-10-15-BrainStorm-Announces-Financial-Results-for-the-Third-Quarter-of-2020-and-Provides-a-Corporate-Update