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

- Conference Call and Webcast at 8am ET Today
- ALS Phase 3 Clinical Trial Remains on Track for Q4'20 Top-line Data Readout
- All Participants Enrolled in Phase 2 Progressive MS trial with Dosing to be Completed in Q4'20

NEW YORK, Aug. 5, 2020 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, announced today financial results for the second quarter and first half ended June 30, 2020, and provided a corporate update.

"Despite the impact of COVID-19 on healthcare access, we completed enrollment and dosing of our Phase 3 ALS clinical trial and expanded our pipeline across new indications," stated Chaim Lebovits, Chief Executive Officer of BrainStorm Cell Therapeutics. "We want to recognize and thank the relentless dedication of the trial participants, their loved ones, our investigators and the team here at BrainStorm for this outstanding achievement. We expect a topline data readout by the end of November this year."

The application of NurOwn® as a platform technology in neurodegenerative disease has great potential and we are actively investing in clinical trials to evaluate the product in other conditions beyond ALS. The Phase 2 clinical trial ongoing in progressive multiple sclerosis (PMS) is expected to complete dosing by the end of 2020. In addition, we recently unveiled a clinical development program in Alzheimer's disease and are planning a Phase 2 proof-of-concept clinical trial at several leading AD centers in the Netherlands and France. We believe that leveraging the NurOwn platform and potentially bringing much needed innovative treatment options to patients across multiple diseases will result in value creation for our various stakeholders.

Second Quarter 2020 and Recent Corporate Highlights:

- Completed dosing of all patients in the ongoing NurOwn Phase 3 clinical trial in amyotrophic lateral sclerosis (ALS).
- NurOwn is being investigated in a Phase 2 clinical trial in patients with progressive multiple sclerosis (PMS) which is ongoing at 5 leading U.S. MS centers. As of August 4, 2020, all 20 study participants have been enrolled in the study and dosing is expected to be completed by the end of 2020.
- Announced a new clinical program focused on NurOwn as a treatment for Alzheimer's disease (AD). The Company is planning a multi-national Phase 2 clinical trial in Europe in patients with prodromal to mild AD.
- The Alzheimer's disease program and Phase 2 trial were featured in a Key Opinion Leader (KOL) webinar on July 8.
- Announced groundbreaking pre-clinical study of NurOwn derived exosome-based treatment for Covid-19 ARDS.
- Granted Small and Medium-Sized Enterprise (SME) status by the European Medicines Agency
- Announced leasing of three state-of-the-art cleanrooms, at the Tel Aviv Sourasky Medical Center to increase manufacturing capability for EU and the local Israeli market
- Awarded $0.5 Million by The ALS Association and IAMALS for ALS Biomarker Study
- Professor Jacob Frankel appointed as Chairman of the Board of Directors
- Appointed Stacy R. Lindborg Ph.D. as Executive Vice President, Head of Global Clinical Research
- Appointed David Setboun as Executive Vice President and Chief Operating Officer
- Presented new data highlighting NurOwn immunomodulation in Neurology Journal
- Awarded $1.5 million grant for 2020 by the Israel Innovation Authority
- Received non-dilutive bonus payment of $700,000 from CIRM for treating more California participants than originally proposed in our Phase 3 ALS clinical trial.
- Joined the Russell 2000® and Russel 3000® Indexes

Presented at the following Investor Conferences:

- Raymond James Human Health Innovations Conference
- BIO Digital 2020

Cash and Liquidity as of July 31, 2020

Total available funding as of July 31, 2020, which includes cash on hand of approximately $34.7 million as well as remaining non-dilutive funding from CIRM, IIA and other grants, amounts to approximately $37.5 million.

Financial Results for the Three Months Ended June 30, 2020

- Cash, cash equivalents, and short-term bank deposits were approximately $16.2 million as of June 30, 2020, compared to $6.2 million on March 31, 2019.
- Research and development expenses, net for the three months ended June 30, 2020 and 2019 were $5.69 million and $3.55 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 $520,000 from $6.54 million in the second quarter of 2019 to $6.02 million in the second quarter of 2020.
- General and administrative expenses for the three months ended June 30, 2020 and 2019 were $1.71 million and $1.30 million, respectively.
- Net loss for the three months ended June 30, 2020 was $7.39 million, as compared to a net loss of $4.90 million for the three months ended June 30, 2019.
  - Net loss per share for the three months ended June 30, 2020 and 2019 was $0.25 and $0.23, respectively.

Conference Call & Webcast

Wednesday, August 5, 2020 at 8am Eastern Time

From the US: 877-407-9205
International: 201-689-8054
Webcast: https://bit.ly/2DciAC9

Replays, available through August 19

From the US: 877-481-4010
International: 919-882-2331
Replay Passcode: 36017

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. 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 U.S. FDA acceptance to initiate a Phase 2 open-label multicenter trial in progressive MS and enrollment began in March 2019.

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 (U.S. FDA) and the European Medicines Agency (EMA) in 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. The Phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) started enrollment in March 2019. 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)

	June 30, 2020	December 31, 2019
	U.S. $ in thousands	
ASSETS	**Unaudited**	**Audited**
Current Assets:		
Cash and cash equivalents	$ 12,153	$ 536
Short-term deposit (Note 4)	4,040	33
Other accounts receivable	259	2,359
Prepaid expenses and other current assets (Note 5)	176	432
Total current assets	16,628	3,360
Long-Term Assets:		
Prepaid expenses and other long-term assets	26	32
Operating lease right of use asset (Note 6)	1,649	2,182
Property and Equipment, Net	918	960
Total Long-Term Assets	2,593	3,174
Total assets	$ 19,221	$ 6,534

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 4,604	$ 14,677
Accrued expenses	2,022	1,000
Operating lease liability (Note 6)	1,224	1,263
Other accounts payable	990	714
Total current liabilities	8,840	17,654
Long-Term Liabilities:		
Operating lease liability (Note 6)	559	1,103
Total long-term liabilities	559	1,103
Total liabilities	$ 9,399	$ 18,757
Stockholders' Equity (deficit):		
Stock capital: (Note 7)	12	11
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at June 30, 2020 and December 31, 2019 respectively; Issued and outstanding: 29,669,855 and 23,174,228 shares at June 30, 2020 and December 31, 2019 respectively.		
Additional paid-in-capital	142,594	105,042
Receipts on account of shares	-	-
Accumulated deficit	(132,784)	(117,276)
Total stockholders' equity (deficit)	9,822	(12,223)
Total liabilities and stockholders' equity	$ 19,221	$ 6,534

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

	Six months ended June 30,		Three months ended June 30,	
	2020	2019	2020	2019
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net	$ 11,642	$ 7,010	$ 5,694	$ 3,554
General and administrative	4,066	2,775	1,706	1,303
Operating loss	(15,708)	(9,785)	(7,400)	(4,857)
Financial expenses (income), net	(200)	142	(6)	43
Net loss	$ (15,508)	$ (9,927)	$ (7,394)	$ (4,900)
Basic and diluted net loss per share from continuing operations	$ (0.56)	$ (0.47)	$ (0.25)	$ (0.23)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	27,452,750	21,312,335	29,274,130	21,703,001

SOURCE Brainstorm Cell Therapeutics Inc

Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2020-08-05-BrainStorm-Announces-Financial-Results-for-the-Second-Quarter-of-2020-and-Provides-a-Corporate-Update