

BrainStorm Announces Second Quarter 2021 Financial Results and Provides a Corporate Update

Continuing to assess regulatory strategy for advancing NurOwn® towards potential approval in ALS

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

NEW YORK, Aug. 5, 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 June 30, 2021 and provided a corporate update.

"We continue to take important steps to advance NurOwn in ALS and progressive MS and position ourselves for sustained success," said Chaim Lebovits, Chief Executive Officer of BrainStorm. "Our discussions with leading ALS experts have provided invaluable insights that we will leverage as we assess NurOwn's potential regulatory pathways in major markets. We also doubled our capacity to supply NurOwn® across Israel and Europe, supporting our readiness to provide broad patient access following any potential approval. Looking ahead, we will continue to work expeditiously with key opinion leaders and the broader ALS community to address the urgent unmet needs of ALS patients, who remain our greatest inspiration."

Second Quarter 2021 and Subsequent Corporate Highlights

- Increased commercial manufacturing capacity with the receipt of Good Manufacturing Practice (GMP) approval from the Israel Ministry of Health for three state-of-the-art cleanrooms leased by the Company at the Tel Aviv Sourasky Medical Center ("Sourasky Hospital") in Tel Aviv, Israel.
- Announced the expansion of the NurOwn® intellectual property portfolio with the grant and allowance of multiple patents and applications in key territories including the U.S., European Union, Canada, Israel, and Hong Kong.
- Presented preclinical data showing that intrathecal administration of NurOwn-derived exosomes resulted in statistically significant improvements in multiple lung parameters in a mouse model of acute respiratory distress syndrome (ARDS) at the [ISCT 2021 New Orleans VIRTUAL Meeting](#).

Cash and Liquidity as of June 30, 2021

The Company's cash, cash equivalents and short-term bank deposits as of June 30, 2021, totaled approximately \$35.0 million.

During the quarter ended June 30, 2021, the Company did not sell any ordinary shares pursuant to its ATM offering established in September 2020. Since commencement of the ATM offering in September 2020, the Company has raised gross proceeds, before payment of commissions and offering expenses, of approximately \$29.1 million under this facility.

Financial Results for the Three Months Ended June 30, 2021

Cash, cash equivalents, and short-term bank deposits were approximately \$35.0 million as of June 30, 2021, compared to approximately \$40.0 million on March 31, 2021.

Research and development expenses, net for the three months ended June 30, 2021 and 2020 were approximately \$3.6 million and \$5.7 million, respectively.

Excluding participation from IIA and other grants, research and development expenses decreased by approximately \$2.2 million from \$6.0 million in the second quarter of 2020 to \$3.8 million in the second quarter of 2021.

General and administrative expenses for the three months ended June 30, 2021 and 2020 were approximately \$2.5 million and \$1.7 million, respectively.

Net loss for the three months ended June 30, 2021 was approximately \$6.3 million, as compared to a net loss of approximately \$7.4 million for the three months ended June 30, 2020.

Net loss per share for the three months ended June 30, 2021 and 2020 was \$0.17 and \$0.25, respectively.

Conference Call & Webcast

Thursday, August 5, 2021 at 8:00 a.m. Eastern Time

From the U.S.: 888-506-0062

International: 973-528-0011

Entry Code: 298566

Webcast URL: <https://www.webcaster4.com/Webcast/Page/2354/41929>

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.

From the U.S.: 877-481-4010

International: 919-882-2331

Replay Passcode: 41929

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; the prospects for regulatory approval of BrainStorm's NurOwn® treatment candidates for the treatment of ALS and MS; the initiation, completion, and results of BrainStorm's preclinical and clinical development programs; research, regulatory and personnel issues; if approved, development of a global market for our treatment candidates; the ability to secure and maintain research institutions to conduct our clinical trials; if approved and commercialized, the ability to generate any 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, if approved, commercialize the NurOwn® treatment candidates; obtaining patents that provide meaningful protection, competition and market developments; BrainStorm's ability to protect our intellectual property from infringement by third parties; health reform legislation; 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.

Contacts

Investor Relations:

Eric Goldstein

LifeSci Advisors, LLC

Phone: +1 646.791.9729

egoldstein@lifesciadvisors.com**Media:**

Paul Tyahla

SmithSolve

Phone: + 1.973.713.3768

Paul.tyahla@smithsolve.com**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES**
INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

(Except share data)


	June 30, 2021	December 31, 2020
	<u>U.S. \$ in thousands</u>	
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 30,565	\$ 37,829
Short-term deposit (Note 4)	4,047	4,107
Other accounts receivable	183	304
Prepaid expenses and other current assets (Note 5)	392	1,002
Total current assets	<u>35,187</u>	<u>43,242</u>
Long-Term Assets:		
Prepaid expenses and other long-term assets	108	26
Operating lease right of use asset (Note 6)	5,886	6,872
Property and Equipment, Net	1,054	1,119
Total Long-Term Assets	<u>7,048</u>	<u>8,017</u>
Total assets	<u>\$ 42,235</u>	<u>\$ 51,259</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 3,000	\$ 5,417
Accrued expenses	1,712	1,261
Operating lease liability (Note 6)	2,037	2,655
Other accounts payable	1,310	1,900
Total current liabilities	<u>8,059</u>	<u>11,233</u>
Long-Term Liabilities:		
Operating lease liability (Note 6)	4,004	4,562
Total long-term liabilities	<u>4,004</u>	<u>4,562</u>
Total liabilities	<u>\$ 12,063</u>	<u>\$ 15,795</u>
Stockholders' Equity:		
Stock capital: (Note 7)	12	12
Common Stock of \$0.00005 par value - Authorized: 100,000,000 shares at June 30, 2021 and December 31, 2020 respectively; Issued and outstanding: 36,318,561 and 35,159,977 shares at June 30, 2021 and December 31, 2020 respectively.		
Additional paid-in-capital	192,294	184,655

Treasury stocks	(116)	(116)
Accumulated deficit	(162,018)	(149,087)
Total stockholders' equity	<u>30,172</u>	<u>35,464</u>
Total liabilities and stockholders' equity	<u>\$ 42,235</u>	<u>\$ 51,259</u>

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		Three months ended	
	June 30,		June 30,	
	2021	2020	2021	2020
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net (Note 8)	\$ 7,940	\$ 11,642	\$ 3,599	\$ 5,694
General and administrative	5,110	4,066	2,522	1,706
Operating loss	(13,050)	(15,708)	(6,121)	(7,400)
Financial expenses (income), net	(119)	(200)	148	(6)
Net loss	<u>\$ (12,931)</u>	<u>\$ (15,508)</u>	<u>\$ (6,269)</u>	<u>\$ (7,394)</u>
Basic and diluted net loss per share from continuing operations	<u>\$ (0.36)</u>	<u>\$ (0.56)</u>	<u>\$ (0.17)</u>	<u>\$ (0.25)</u>
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	<u>36,056,391</u>	<u>27,452,750</u>	<u>36,318,561</u>	<u>29,274,130</u>

SOURCE BrainStorm Cell Therapeutics Inc.

Additional assets available online:  [Photos \(1\)](#)

<https://ir.brainstorm-cell.com/2021-08-05-BrainStorm-Announces-Second-Quarter-2021-Financial-Results-and-Provides-a-Corporate-Update>