

BrainStorm Cell Therapeutics Announces Third quarter 2023 Financial Results and Provides Corporate Update

Conference call and webcast at 8:30 a.m. Eastern Time today

NEW YORK, Nov. 14, 2023 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced financial results for the third quarter ended September 30, 2023 and provided a corporate update.

"We are committed to our goal of making NurOwn® available to the ALS community and intend to work with the FDA to agree on a path forward," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "We acknowledge that approval will require a confirmatory Phase 3b trial and look forward to meeting with the FDA to align on the details. The recently announced strategic realignment is a necessary step to conserve and refocus resources, and we believe this will position us better to accelerate our ALS development program."

Stacy Lindborg, Ph.D., co-CEO BrainStorm commented, "We believe we have generated a compelling body of clinical data that support the utility of NurOwn in ALS. We intend to harness the learnings from our prior studies to conduct a Phase 3b trial as efficiently as possible. We will also continue to engage with the academic community to share new data with our goal of leveraging the latest results to contribute to new insights into ALS and NurOwn."

Third quarter 2023 and Recent Highlights

Clinical and regulatory

- In October 2023, Brainstorm withdraw its Biological License Application (BLA) for NurOwn in ALS. This action was coordinated with FDA and is viewed by the Agency as a withdrawal without prejudice. This decision was made following the U.S. FDA's Cellular, Tissue and Gene Therapies Advisory Committee meeting that took place on September 27. The Committee voted that NurOwn did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS.
- The FDA has invited Brainstorm to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS.
- In July 2023, [new biomarker data from the Phase 3 trial of NurOwn were presented at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference](#). These data show that treatment with NurOwn significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration over time, including neurofilament light (NfL) compared to placebo in all trial participants. It is believed that reductions in plasma NfL are reasonably likely to predict clinical benefit in ALS.

Corporate

- In October 2023, Brainstorm announced a strategic realignment to enable accelerated development of NurOwn® for the treatment of ALS. The company is actively exploring various options to raise capital including non-dilutive grants and capitalizing on its exosome technology. At the same time, it is reducing and refocusing resources by streamlining clean room operations and undertaking a targeted reduction in headcount of approximately 30 percent. The strategic realignment is expected to cut total resource consumption by approximately half.
- In July 2023, Brainstorm closed a registered direct offering with a single institutional investor raising gross proceeds, before deducting the placement agent's fees and other offering expenses, of approximately \$7.5 million.
- [In July 2023, Brainstorm appointed Bob Dagher, MD, as Executive Vice President and Chief Development Officer.](#)

Financial Results for the Quarter Ended September 30, 2023

Cash, cash equivalents, and short-term bank deposits were approximately \$1.4 million as of September 30, 2023, compared to \$3 million as of December 31, 2022.

Research and development expenses for the three months ended September 30, 2023 and 2022 were approximately \$3.3 million and \$3.8 million, respectively.

General and administrative expenses for the three months ended September 30, 2023 and 2022 were approximately \$2.7 million and \$3.1 million, respectively.

Net loss for the three months ended September 30, 2023 was approximately \$1.2 million, as compared to a net loss of approximately \$6.9 million for the three months ended September 30, 2022.

Net loss per share for the three months ended September 30, 2023 and 2022 was \$0.03 and \$0.19, respectively.

For more details on the financials, including results for the 9 month period ended September 30, 2023, refer to Form 10Q filed with the SEC.

Conference Call and Webcast, 8:30 a.m. Eastern Time Today

The investment community may participate in the conference call by dialing the following numbers:

Participant Numbers:

Toll Free: 888-506-0062

International: 973-528-0011
Access Code: 944879
Webcast URL: <https://rb.gy/875eq4>

Those interested in listening to webcast may do so by using the link above or by visiting the "Investors & Media" page of BrainStorm's website at

<https://ir.brainstorm-cell.com/overview> and clicking on the webcast link.

The replay of the conference call can do so by dialing the numbers below and will be available until November 28, 2023.

Replay Numbers:

Toll Free: 877-481-4010
International: 919-882-2331
Replay Passcode: 49431

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 harvested from each person with ALS and are manufactured using an innovative and proprietary process to secrete neurotrophic factors to target specific neurodegenerative diseases. The lead program for NurOwn is for the treatment of ALS. BrainStorm's long-term commitment to ALS is demonstrated in preclinical research and a series of clinical studies, all of which have been published in peer-reviewed journals.

The NurOwn clinical program has generated valuable insights into the pathology of ALS, as well as disease progression and treatment. Since the initial Phase 3 readout, BrainStorm has shared the full dataset through rigorous peer-reviewed analysis, including: quantification of Floor Effect, which had been noted, but never before explored in depth; evaluation of multiple pre-specified biomarkers, collected at seven different points across 20 weeks during the trial, allowing a longitudinal view; and analysis of genetic data, which represents one of the first ALS trials to prospectively invoke pharmacogenomic analysis of clinical outcome, offering great promise for the development of future treatments for ALS.

About BrainStorm Cell Therapeutics Inc.

BrainStorm Cell Therapeutics Inc. is a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases. BrainStorm 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 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), and another grant from the ALS Association and I AM ALS. BrainStorm completed under an investigational new drug application a Phase 2 open-label multicenter trial (NCT03799718) of autologous MSC-NTF cells in progressive MS and was supported by a grant from the National MS Society (NMSS).

Notice Regarding Forward-Looking Statements

This press release contains "forward-looking statements" that are subject to substantial risks and uncertainties, including the clinical development of NurOwn as a therapy for the treatment of ALS, the future availability of NurOwn to patients, and the future success of BrainStorm. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on BrainStorm's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. These potential risks and uncertainties include, without limitation, management's ability to successfully achieve its goals, BrainStorm's ability to raise additional capital.

BrainStorm's ability to continue as a going concern, prospects for future regulatory approval of NurOwn, whether BrainStorm's future interactions with the FDA will have productive outcomes, 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, 2023 Unaudited U.S. \$ in thousands	December 31, 2022 Audited U.S. \$ in thousands
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 1,222	\$ 772
Short-term deposit (Note 4)	196	2,211
Other accounts receivable	66	91
Prepaid expenses and other current assets	55	32
Total current assets	<u>1,539</u>	<u>3,106</u>
Long-Term Assets:		
Prepaid expenses and other long-term assets	21	23
Operating lease right of use asset (Note 6)	3,370	4,389
Property and Equipment, Net	752	933
Total Long-Term Assets	<u>4,143</u>	<u>5,345</u>
Total assets	<u>\$ 5,682</u>	<u>\$ 8,451</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payables	\$ 3,926	\$ 6,224
Accrued expenses	63	84
Operating lease liability (Note 5)	1,306	1,427
Other accounts payables	1,026	1,065
Total current liabilities	<u>6,321</u>	<u>8,800</u>
Long-Term Liabilities:		
Operating lease liability (Note 5)	1,585	2,666
Warrants liability (Note 6)	358	—
Total long-term liabilities	<u>\$ 1,943</u>	<u>\$ 2,666</u>
Total liabilities	<u>\$ 8,264</u>	<u>\$ 11,466</u>
Stockholders' Equity:		
Stock capital: (Note 7)	12	12
Common Stock of \$0.00005 par value - Authorized: 100,000,000 shares September 30, 2023 and December 31, 2022 respectively; Issued and outstanding: 45,314,961 and 36,694,078 shares at September 30, 2023 and December 31, 2022 respectively.		
Additional paid-in-capital	206,957	194,910
Treasury stocks	(116)	(116)
Accumulated deficit	(209,435)	(197,821)
Total stockholders' equity (deficit)	<u>(2,582)</u>	<u>(3,015)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 5,682</u>	<u>\$ 8,451</u>

The accompanying notes in Form 10Q are an integral part of the consolidated financial statements.

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, 2023	2022	Three months ended September 30, 2023	2022
	Unaudited		Unaudited	
Operating expenses:				

Research and development, net	\$ 9,048	\$ 11,505	\$ 3,330	\$ 3,776
General and administrative	7,587	8,402	2,705	3,065
Operating loss	(16,635)	(19,907)	(6,035)	(6,841)
Financial income (expenses), net	91	648	(121)	(17)
Gain on change in fair value of Warrants liability (Note 6)	4,930	—	4,930	—
Net loss	<u>\$ (11,614)</u>	<u>\$ (19,259)</u>	<u>\$ (1,226)</u>	<u>\$ (6,858)</u>
Basic and diluted net loss per share from continuing operations	<u>\$ (0.29)</u>	<u>\$ (0.53)</u>	<u>\$ (0.03)</u>	<u>\$ (0.19)</u>
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	<u>40,255,502</u>	<u>36,472,372</u>	<u>44,251,809</u>	<u>36,493,432</u>

The accompanying notes in Form 10Q are an integral part of the consolidated financial statements.

Logo - https://mma.prnewswire.com/media/1166536/BrainStorm_Logo.jpg

SOURCE BrainStorm Cell Therapeutics Inc.

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

<https://ir.brainstorm-cell.com/2023-11-14-BrainStorm-Cell-Therapeutics-Announces-Third-quarter-2023-Financial-Results-and-Provides-Corporate-Update>