

BrainStorm Cell Therapeutics Announces First Quarter 2024 Financial Results and Provides Corporate Update

Company received written agreement from the U.S. FDA under a Special Protocol Assessment (SPA) on the design for a Phase 3b trial of NurOwn®

Conference call planned for later this quarter to provide update on NurOwn program

NEW YORK, May 14, 2024 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced financial results for the First Quarter ended March 31, 2024 and provided a corporate update.

"We recently achieved an important milestone on our Debamestrocel (NurOwn®) development program, reaching agreement with the US FDA on a Special Protocol Assessment for our planned Phase 3b trial of NurOwn. The SPA covers the design and planned analysis of the trial in order to adequately address the objectives necessary to support a regulatory submission," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "We believe that the SPA will substantially derisk the regulatory aspects of our program. This moves us closer to initiating the trial and ensures our approach aligns with the FDA's current views, standards, and guidelines. We are committed to collaborating closely with the ALS community and are grateful for the continued support and collaboration of patients, caregivers, and advocacy groups as we work to bring this potentially valuable new treatment to those affected by this devastating disease."

First Quarter 2024 and Recent Highlights

Clinical and regulatory

- In April 2024, BrainStorm received written agreement from the U.S. Food and Drug Administration (FDA), under a Special Protocol Assessment (SPA), on the design for a Phase 3b trial of NurOwn® in amyotrophic lateral sclerosis (ALS). The SPA agreement validates the clinical trial protocol and statistical analysis of the planned Phase 3b trial of NurOwn, demonstrating their adequacy for addressing objectives that support a future BLA (Biologics License Application) in ALS. BrainStorm anticipates initiating the Phase 3b study in 2024, after reviewing the protocol with investigators, securing study site Institutional Review Board approvals, and engaging with appropriate members of the ALS community.
- In April 2024, Phase 3 biomarker data on NurOwn in ALS were published in *Muscle and Nerve* in a paper entitled "["Debamestrocel multimodal effects on biomarker pathways in amyotrophic lateral sclerosis are linked to clinical outcomes"](#)". The published data show that NurOwn treatment resulted in a positive impact on important CSF biomarkers relevant to ALS compared to placebo. Significant changes in multiple ALS disease pathways support NurOwn's mechanism of action and complement the clinical effects observed in ALS.
- Brainstorm's proposed design for the planned Phase 3b trial of NurOwn ALS was presented in a poster at the [MDA Clinical and Scientific Conference](#) in March, 2024. The design is for a two-part, multicenter, Phase 3b study to assess the efficacy and safety of NurOwn in participants with ALS. The entry criteria will enroll people living with mild-to-moderate ALS. The primary endpoint will be based on the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R).

Corporate

- In April 2024, promoted Dr. Bob Dagher to Executive Vice President and Chief Medical Officer. Dr. Dagher has over 20 years' of experience in clinical research and development, with a proven track record of leading successful clinical trials and fostering innovation in drug development. In addition, after four years of maintaining top executive roles, Dr. Stacy Lindborg is stepping down from the role of Co-CEO and will remain with BrainStorm as a member of its Board of Directors. These strategic management changes are being made as the Company prepares to embark on the registrational Phase 3b trial for NurOwn®.

Upcoming Event – ALS Drug Development Summit

- BrainStorm will participate in the forthcoming 3rd Annual ALS Drug Development Summit, to take place May 21 to 23, 2024 in Boston MA. Dr. Stacy Lindborg will deliver a presentation **Promising Longer-Term Biomarker Data from NurOwn Program in ALS: Spotlight on NfL in EAP Extension Cohort**. The new data to be presented suggest that patients may benefit from longer term treatment with NurOwn, as evidenced by changes in neurofilament light (NfL), an important biomarker associated with clinical outcomes in ALS. Other members of BrainStorm's team, Antonio Trejo, VP of Regulatory Affairs; Mary Kay Turner Senior Vice President, Global Patient Advocacy & Public Affairs; and Kyran Morris, Senior Manager, Patient Advocacy will take part in a workshop and panel at the Summit.

Financial Results for the First Quarter Ended March 31, 2024

- Cash, cash equivalents, and restricted cash amounted to approximately \$1.0 million, as of March 31, 2024.
- Research and development expenses, net, in the first quarter ended March 31, 2024 were approximately \$1.0 million, compared to \$2.9 million for the quarter ended March 31, 2023.
- General and administrative expenses for the first quarters ended March 31, 2024 and 2023 were \$1.5 million and \$2.2 million, respectively.
- Net loss for the first quarter ended March 31, 2024 was \$3.4 million as compared to a net loss of \$5.1 million for the quarter ended March 31, 2023.
- Net loss per share for the quarter ended March 31, 2024 and March 31, 2023 was \$0.05 and \$0.14, respectively.

Conference Call and Webcast

BrainStorm management will host a conference call for the investment community later in the second quarter to provide update on the NurOwn program. Details on the conference call will be provided when available.

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 statements regarding meetings with the U.S. Food and Drug Administration (FDA), Special Protocol Assessment (SPA), ADCOM meeting related to NurOwn, the timing of a PDUFA action date for the BLA for NurOwn, 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)

March 31, 2024	December 31, 2023
Unaudited	Audited

	<u>U.S. \$ in thousands</u>	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 779	\$ 1,300
Other accounts receivable	26	51
Prepaid expenses and other current assets (Note 4)	454	548
Total current assets	<u>\$ 1,259</u>	<u>\$ 1,899</u>
Long-Term Assets:		
Prepaid expenses and other long-term assets	\$ 20	\$ 22
Restricted Cash	182	185
Operating lease right of use asset (Note 5)	1,265	1,416
Property and Equipment, Net	622	686
Total Long-Term Assets	<u>\$ 2,089</u>	<u>\$ 2,309</u>
Total assets	<u>\$ 3,348</u>	<u>\$ 4,208</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payables	\$ 4,690	\$ 4,954
Accrued expenses	636	1,240
Operating lease liability (Note 5)	588	603
Employees related liability	917	1,003
Total current liabilities	<u>\$ 6,831</u>	<u>\$ 7,800</u>
Long-Term Liabilities:		
Operating lease liability (Note 5)	533	672
Warrants liability (Note 6)	1,534	594
Total long-term liabilities	<u>\$ 2,067</u>	<u>\$ 1,266</u>
Total liabilities	\$ 8,898	\$ 9,066
Stockholders' Deficit:		
Stock capital: (Note 7)	13	13
Common Stock of \$0.00005 par value - Authorized: 100,000,000 shares at March 31, 2024 and December 31, 2023 respectively; Issued and outstanding: 68,447,193 and 60,489,208 shares at March 31, 2024 and December 31, 2023 respectively.		
Additional paid-in-capital	212,967	210,258
Treasury stocks	(116)	(116)
Accumulated deficit	(218,414)	(215,013)
Total stockholders' deficit	<u>\$ (5,550)</u>	<u>\$ (4,858)</u>
Total liabilities and stockholders' deficit	<u>\$ 3,348</u>	<u>\$ 4,208</u>

The accompanying notes 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)

	Three months ended	
	March 31,	
	2024	2023
	Unaudited	
Operating expenses:		
Research and development, net	\$ 961	\$ 2,924
General and administrative	1,513	2,227
Operating loss	(2,474)	(5,151)
Financial income, net	13	92
Loss on change in fair value of Warrants liability (Note 6)	(940)	—
Net loss	\$ (3,401)	\$ (5,059)
Basic and diluted net loss per share from continuing operations	\$ (0.05)	\$ (0.14)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	64,738,544	36,735,435

The accompanying notes 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/2024-05-14-BrainStorm-Cell-Therapeutics-Announces-First-Quarter-2024-Financial-Results-and-Provides-Corporate-Update>