

BrainStorm Cell Therapeutics Announces First Quarter 2025 Financial Results and Provides Corporate Update

Conference call and webcast rescheduled for 8:30 a.m. Eastern Time on Monday, May 19

NEW YORK, May 15, 2025 /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, 2025, and provided a corporate update.

"BrainStorm continues to make meaningful progress in advancing our NurOwn® development program. Our priority continues to be initiation of a Phase 3b trial, designed to confirm the product's efficacy in early stage ALS patients and support a new BLA," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "We have a clear path forward and ongoing support from the ALS community. We recently submitted an amendment to our IND, which includes updated documentation that is essential for regulatory compliance and trial integrity. We are in the process of finalization clinical trial agreements with leading academic centers and completing other necessary steps on trial execution and manufacturing. We believe that NurOwn, if approved, has the potential to become a valuable treatment option for ALS patients. Our team is fully aligned and executing with discipline to position BrainStorm for success."

Recent Highlights

NurOwn (MSC-NTF) for ALS

- **IND amendment on NurOwn submitted to FDA** BrainStorm submitted an Investigational New Drug (IND) amendment to the U.S. Food and Drug Administration for NurOwn. This important milestone sets the stage for the initiation of the planned Phase 3b clinical trial, which has been designed in collaboration with the FDA under a Special Protocol Assessment (SPA). The trial will have a primary efficacy endpoint assessing changes in ALSFRS-R scores from baseline to week 24, and is designed to enroll approximately 200 ALS participants with early stage disease. Successful completion of the double blind part of the study (Part A) is expected to generate the clinical data to support a new BLA submission.
- **Phase 3b trial listed on Clinicaltrials.gov.** Details of the trial, known as ENDURANCE, are now available on ClinicalTrials.gov ID NCT06973629. Included is a list of 15 clinical trial sites that are expected to participate in the trial.
- **NurOwn® data selected as Breakthrough Science for Presentation at ISCT 2025 Meeting** The new pharmacogenomic were delivered in a oral presentation at the International Society for Cell & Gene Therapy (ISCT) 2025 Annual Meeting, in New Orleans. The data highlight the impact of the UNC13A genotype on clinical outcomes for ALS patients treated with NurOwn. The presentation was featured in the ISCT public announcement regarding the meeting, which indicated that the data were "carefully reviewed and selected by the ISCT 2025 Planning Faculty, to explore the latest breakthroughs in the clinical translation of Mesenchymal Stem/Stromal Cells and how they will shape the future of cell therapies."
- **Biomarker insights supporting NurOwn's mechanism and clinical impact presented at the 2025 ALS Drug Development Summit** BrainStorm's senior leadership team (Dr. Bob Dagher, Dr. Netta Blondheim-Shraga and May Kay Turner) participated in sessions at the summit that highlighted insights and expertise gained throughout the NurOwn® development program. These sessions included a presentation on cerebrospinal fluid (CSF) biomarker pathways associated with NurOwn treatment, including their relationship to clinical outcomes and disease heterogeneity in ALS.

Financial Results for the First Quarter Ended March 31, 2025

- Cash, cash equivalents, and restricted cash were approximately \$1.8 million as of March 31, 2025.
- Research and development expenditures, net, for the quarter ended March 31, 2025 were \$1.3 million, compared to \$1.0 million for the quarter ended March 31, 2024.
- General and administrative expenses for the quarter ended March 31, 2025 were approximately \$1.8 million, compared to approximately \$1.5 million for the quarter ended March 31, 2024.
- Net loss for the quarter ended March 31, 2025, was approximately \$2.9 million, as compared to a net loss of approximately \$3.4 million for the quarter ended March 31, 2024.
- Net loss per share for the three months ended March 31, 2025, and 2024 was \$0.45 and \$0.75, respectively.

Conference Call and Webcast

Monday, May 19, 2025, at 8:30 a.m. U.S. Eastern Time

Participant Numbers:

U.S. dial in: 888-506-0062

International: 973-528-0011

Participant Access Code: 621608

Webcast URL: <https://www.webcaster4.com/Webcast/Page/2354/52457>

The replay of the conference call can be accessed by dialing the numbers below and will be available for 14 days.

Teleconference Replay Number:

Toll Free: 877-481-4010

International: 919-882-2331

Passcode: 52457

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. (NASDAQ: BCLI) is a leading developer of autologous adult stem cell therapies for debilitating neurodegenerative diseases. The company's proprietary NurOwn® platform uses autologous mesenchymal stem cells (MSCs) to produce neurotrophic factor-secreting cells (MSC-NTF cells), designed to deliver targeted biological signals that modulate neuroinflammation and promote neuroprotection.

NurOwn® is BrainStorm's lead investigational therapy for amyotrophic lateral sclerosis (ALS) and has received Orphan Drug designation from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). A Phase 3 trial in ALS (NCT03280056) has been completed, and a second Phase 3b trial is set to launch under a Special Protocol Assessment (SPA) agreement with the FDA. The NurOwn clinical program has generated valuable insights into ALS disease biology, including pharmacogenomic response associated with the UNC13A genotype, biomarker data collected at seven longitudinal time points, and a comprehensive analysis of the "Floor Effect" — a critical challenge in measuring clinical outcomes in advanced ALS. BrainStorm has published its findings in multiple peer-reviewed journals. In addition to ALS, BrainStorm has completed a Phase 2 open-label multicenter trial (NCT03799718) of MSC-NTF cells in progressive multiple sclerosis (MS), supported by a grant from the National MS Society. BrainStorm is also advancing a proprietary, allogeneic exosome-based platform designed to deliver therapeutic proteins and nucleic acids. The company recently received a Notice of Allowance from the U.S. Patent and Trademark Office for a foundational patent covering its exosome technology, further strengthening BrainStorm's growing IP portfolio in this emerging area of regenerative medicine. To learn more, visit www.brainstorm-cell.com.

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), 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.

CONTACTS

Investors:

Michael Wood

Phone: +1 646-597-6983

mwood@lifesciadvisors.com

Media:

Uri Yablonka, Chief Business Officer

Phone: +1 917-284-2911

uri@brainstorm-cell.com

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES **INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS**

U.S. dollars in thousands

(Except share data)

	March 31,	December
	2025	31,
	Unaudited	2024
	U.S. \$ in thousands	Audited
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 1,644	\$ 187
Other accounts receivable	67	63
Prepaid expenses and other current assets	621	135
Total current assets	\$ 2,332	\$ 385
Long-Term Assets:		
Prepaid expenses and other long-term assets	\$ 22	\$ 22
Restricted Cash	182	184
Operating lease right of use asset (Note 4)	653	807
Property and Equipment, Net	382	434
Total Long-Term Assets	\$ 1,239	\$ 1,447
Total assets	\$ 3,571	\$ 1,832
<u>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</u>		
Current Liabilities:		
Accounts payables	\$ 6,797	\$ 6,080
Accrued expenses	538	619
Short-term loans (Note 7)	1,200	300
Operating lease liability (Note 4)	443	549
Employees related liability	1,923	1,430
Total current liabilities	\$ 10,901	\$ 8,978
Long-Term Liabilities:		
Operating lease liability (Note 4)	127	171
Warrants liability (Note 5)	-	447
Total long-term liabilities	\$ 127	\$ 618

Total liabilities	\$ 11,028	\$ 9,596
Stockholders' Deficit:		
Stock capital: (Note 6)	15	14
Common Stock of \$0.00005 par value - Authorized: 250,000,000 shares at March 31, 2025 and at December 31, 2024 respectively; Issued and outstanding: 7,911,204 and 6,141,762 shares at March 31, 2025 and December 31, 2024 respectively (*)		
Additional paid-in-capital	222,144	218,974
Treasury stocks	(116)	(116)
Accumulated deficit	(229,500)	(226,636)
Total stockholders' deficit	<u>\$ (7,457)</u>	<u>\$ (7,764)</u>
Total liabilities and stockholders' deficit	<u>\$ 3,571</u>	<u>\$ 1,832</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,	
	2025	2024
	Unaudited	
Operating expenses:		
Research and development, net	\$ 1,304	\$ 961
General and administrative	1,785	1,513
Operating loss	(3,089)	(2,474)
Financial income, net	46	13
Loss on change in fair value of Warrants liability (Note 6)	(179)	(940)
Net loss	<u>\$ (2,864)</u>	<u>\$ (3,401)</u>
Basic and diluted net loss per share from continuing operations	<u>\$ (0.45)</u>	<u>\$ (*) (0.75)</u>
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	<u>6,342,002</u>	<u>(*) 4,315,903</u>

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/2025-05-15-BrainStorm-Cell-Therapeutics-Announces-First-Quarter-2025-Financial-Results-and-Provides-Corporate-Update>