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

Conference call and webcast scheduled for 8:30 a.m. Eastern Time Today, Thursday, August 14, 2025

NEW YORK, Aug. 14, 2025 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (OTCQB: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced financial results for the second quarter ended June 30, 2025, and provided a corporate update.

"BrainStorm remains focused on executing our clinical development plan for NurOwn®. We reached an important milestone in Q2 with FDA clearance to initiate our Phase 3b trial, designed to generate confirmatory data to support a potential BLA submission," said Chaim Lebovits, President and CEO. "We are also advancing key operational activities, including discussions with clinical sites as well as ongoing engagement with our selected CDMO partners to ensure readiness for clinical drug supply. We are encouraged by the ongoing interest and support from clinicians and the ALS community, and we remain confident that, if approved, NurOwn has the potential to make a meaningful difference for patients and their families."

Mr. Lebovits continued, "We support the FDA's consideration of the Citizen Petition, which may provide a fresh opportunity for an objective evaluation of the scientific evidence. We continue to stand behind the integrity and rigor of our data and will continue to engage with clinicians and the ALS community."

Recent Highlights

NurOwn (MSC-NTF) for ALS

- **FDA has cleared the company to initiate the Phase 3b clinical trial of NurOwn®** The Phase 3b trial, known as ENDURANCE, is expected to enroll approximately 200 participants at leading academic medical centers and will consist of a 24-week randomized, double-blind, placebo-controlled phase, followed by a 24-week open-label extension in which all participants will receive NurOwn. The primary endpoint is the change from baseline to week 24 in the ALS Functional Rating Scale-Revised (ALSFRS-R). Successful completion of the double blind portion of the study (Part A) is expected to generate the clinical data needed to support a new BLA submission. Details of the trial, including a list of anticipated participating clinical sites, are available on ClinicalTrials.gov ID NCT06973629.
- **A Citizens Petition submitted to the FDA by ALS Community requesting a new review of the NurOwn data** The company acknowledges that the FDA's consideration of the petition provides a new opportunity to reaffirm NurOwn's potential as a therapy for ALS. BrainStorm was not involved in drafting or submitting this petition or its contents.
- **New survival data from NurOwn Expanded Access Program** show that 100% of participants (10/10) in the EAP survived more than 5 years from the onset of ALS symptoms, compared to published estimates indicating that approximately 10% of individuals with ALS would survive beyond 5 years. The single death in the cohort occurred following elective euthanasia. The median survival observed in the EAP cohort was 6.8 years (range: 6 to 7 years) from symptom onset. Although the EAP cohort included participants earlier in their disease course, these results are encouraging and support further study.
- **Manufacturing Partnership with Minaris** BrainStorm has signed a Letter of Intent (LOI) with Minaris Advanced Therapies, a global contract development and manufacturing organization (CDMO) specializing in cell and gene therapies, to manufacture NurOwn for the upcoming Phase 3b clinical trial.
- **NurOwn® data selected as Breakthrough Science for Presentation at ISCT 2025 Meeting** The new pharmacogenomic data were delivered in an oral presentation at the International Society for Cell & Gene Therapy (ISCT) 2025 Annual Meeting in May 2025, 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."

Financial Results for the Second quarter Ended June 30, 2025

- Cash, cash equivalents, and restricted cash were approximately $1.03 million as of June 30, 2025.
- Research and development expenditures, net, for the quarter ended June 30, 2025 were $1.1 million, compared to $0.9 million for the quarter ended June 30, 2024.
- General and administrative expenses for the quarter ended June 30, 2025 were approximately $1.4 million, compared to approximately $2.1 million for the quarter ended June 30, 2024.
- Net loss for the quarter ended June 30, 2025, was approximately $2.9 million, as compared to a net loss of approximately $2.5.4 million for the quarter ended June 30, 2024.
- Net loss per share for the three months ended June 30, 2025, and 2024 was $0.34 and $0.60, respectively.

Conference Call and Webcast

Participant Numbers:

Toll Free	877-545-0320
International	973-528-0002
Participant Access Code	601260
Webcast	https://shorturl.at/xrBQQ

The replay of the conference call can be accessed by dialing the numbers below and will be available until August 28.

Replay Numbers:

Toll Free	877-481-4010
International	919-882-2331
Reply Passcode	52831

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. (OTCQB: 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.

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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, 2025	December 31, 2024
	Unaudited	Audited
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 824	$ 187
Other accounts receivable	106	63
Prepaid expenses and other current assets	585	135
Total current assets	$ 1,515	$ 385
Long-Term Assets:		
Prepaid expenses and other long-term assets	$ 24	$ 22
Restricted Cash	201	184
Operating lease right of use asset (Note 3)	495	807
Property and Equipment, Net	331	434
Total Long-Term Assets	$ 1,051	$ 1,447
Total assets	$ 2,566	$ 1,832
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payables	$ 5,997	$ 6,080
Accrued expenses	367	619
Short-term loans (Note 7)	101	300
Operating lease liability (Note 3)	381	549
Employees related liability	1,682	1,430
Total current liabilities	$ 8,528	$ 8,978
Long-Term Liabilities:		
Operating lease liability (Note 3)	95	171
Warrants liability (Note 4)	-	447
Total long-term liabilities	$ 95	$ 618
Total liabilities	$ 8,623	$ 9,596
Stockholders' Deficit:		
Stock capital: (Note 5)	16	14

Common Stock of $0.00005 par value - Authorized: 250,000,000 shares at June 30, 2025 and at December 31, 2024 respectively; Issued and outstanding: 10,120,109 and 6,141,762 shares at June 30, 2025 and December 31, 2024 respectively		
Additional paid-in-capital	226,446	218,974
Treasury stocks	(116)	(116)
Accumulated deficit	(232,403)	(226,636)
Total stockholders' deficit	$ (6,057)	$ (7,764)
Total liabilities and stockholders' deficit	$ 2,566	$ 1,832

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,	
	2025	2024	2025	2024
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net	$ 2,424	$ 1,883	$ 1,120	$ 922
General and administrative	3,238	3,573	1,453	2,060
Operating loss	(5,662)	(5,456)	(2,573)	(2,982)
Financial income (expense), net	(284)	43	(330)	30
Gain (loss) on change in fair value of Warrants liability (Note 4)	179	529	-	(411)
Net loss	$ (5,767)	$ (5,942)	$ (2,903)	$ (2,541)
Basic and diluted net loss per share from continuing operations	$ (0.77)	$ (1.35)	$ (0.34)	$ (0.60)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	7,487,495	4,531,801	8,620,400	4,747,699

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

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