

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

Conference call planned for later in Q4 2024 to provide updates on NurOwn® program

NEW YORK, Nov. 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 third quarter ended September 30, 2024 and provided a corporate update.

"BrainStorm's primary focus continues to be preparing for the upcoming Phase3b registration trial of NurOwn in ALS," said Chaim Lebovits, President and CEO of Brainstorm. "We have carefully refined the trial design based on the learnings from our previous study, and we believe this will increase the probability of demonstrating a treatment effect. We are partnering with Pluri Inc., an established global leader in the development and manufacturing of cell-based therapeutics, to support the clinical supply needs. We have also selected a leading Clinical Research Organization and continue to work with investigators to establish multiple trial sites. We remain committed to the ALS community as we work to advance NurOwn and deliver a therapeutic option that we believe will make a difference for patients and their families."

Third Quarter 2024 and Recent Highlights

- In November 2024, BrainStorm entered into a Memorandum of Understanding (MOU) with Pluri Inc. (Pluri) to manufacture NurOwn® for use in the planned Phase 3b ALS trial. This MOU enables Brainstorm to begin the immediate transfer of its manufacturing technology and start producing NurOwn at Pluri's facility while the binding definitive agreement is being finalized.
- In October 2024, Brainstorm announced further details of the Phase3b trial at the [Annual Northeastern Amyotrophic Lateral Sclerosis Consortium \(NEALS\) Meeting](#).
- Up to approximately 200 participants with ALS are expected to enroll in the two-part Phase3b trial, to receive 3 doses of either NurOwn (debamestrocel) or placebo for 24 weeks (Part-A), followed by an open label period during which all patients will receive 3 doses of NurOwn for another 24 weeks (Part B). Successful completion of Part A is expected to support a Biologic License Application (BLA).
- The primary efficacy endpoint will be a comparison of change in ALSFRS-R from baseline to week-24 (i.e. at the end of Part A) for NurOwn vs. placebo. Other outcome assessments will include CAFS (Clinical Assessment of Function & Survival), SVC, HHD (Hand-Held Dynamometry), survival, ALSAQ-40 questionnaire, the ZBI (Zarit Burden Interview), and disease biomarkers.
- The entry criteria are specifically targeting people living with ALS in the early stage of their disease. Key entry criteria will include: age 18 to 75 years old, ALS diagnosis defined by the revised El Escorial criteria as laboratory-supported probable, clinically probable, or definite, symptom onset within 24 months of screening, ≥ 2 points on each item of the ALSFRS-R, ALSFRS-R total score ≤ 45 , and upright Slow Vital Capacity (SVC) $\geq 65\%$ of predicted.
- Participants in both treatment arms will be able to receive standard of care while on study.
- Also at the NEALS meeting, Brainstorm presented a poster "Debamestrocel Long-Term Benefits on Survival and Neurodegeneration in ALS Expanded Access Program" featuring the results from 10 participants (6 NurOwn, 4 placebo) from the company's prior Phase 3 clinical trial (BCT-002-US) who enrolled in an open label Expanded Access Program (EAP). The EAP spanned two 28-week periods, with a break in time between the periods. Participants received a dose of NurOwn every 8 weeks, for a maximum of 6 doses over the 2 periods.
- Promising long term survival benefits were observed in NurOwn treated patients compared to matched controls in the PRO-ACT database. The survival curves revealed a statistically significant difference in favor of NurOwn (LRT, $p=0.0379$) with a median survival time of 46.6 months for the treated group compared to 41.1 months for the matched control.
- Consistent reductions in neurofilament light (NfL) were observed both during the randomized Phase 3 trial and in the subsequent EAP period, indicating that patients treated with NurOwn continued to see benefits from extended treatment. NfL is an important biomarker in ALS, measuring neurodegeneration and neural cell death. These data align with the understanding of NurOwn's mechanism of action.

Investor Conference Call and Webcast

BrainStorm is planning to host a conference call and webcast for the investment community later in Q4 2024 to provide further updates on the NurOwn Phase 3 program. Details will be provided in the near future.

Financial Results for the Third Quarter Ended September 30, 2024

- Cash, cash equivalents, and restricted cash amounted to approximately \$0.35 million, as of September 30, 2024.

- Research and development expenses, net, in the third quarter ended September 30, 2024 were \$1 million, compared to \$3.3 million for the quarter ended September 30, 2023.
- General and administrative expenses for the third quarter ended September 30, 2024 and 2023 were \$2 million and \$2.7 million, respectively.
- Net loss for the third quarter ended September 30, 2024 was \$2.7 million as compared to a net loss of \$1.2 million for the quarter ended September 30, 2023.
- Net loss per share for the third quarter ended September 30, 2024 and September 30, 2023 was \$0.51 and \$0.45, respectively.

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 probability of NurOwn demonstrating a treatment effect in ALS, the patient enrollment and dosing in the Phase 3b trial for NurOwn®, and 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,	December 31,
	2024	2023
	Unaudited	Audited
	U.S. \$ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 168	\$ 1,300
Other accounts receivable	40	51
Prepaid expenses and other current assets (Note 4)	156	548
Total current assets	\$ 364	\$ 1,899
Long-Term Assets:		
Prepaid expenses and other long-term assets	\$ 22	\$ 22
Restricted Cash	181	185
Operating lease right of use asset (Note 5)	959	1,416
Property and Equipment, Net	499	686
Total Long-Term Assets	\$ 1,661	\$ 2,309
Total assets	\$ 2,025	\$ 4,208
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payables	\$ 4,603	\$ 4,954
Accrued expenses	865	1,240
Operating lease liability (Note 5)	570	603
Employees related liability	1,044	1,003
Total current liabilities	\$ 7,082	\$ 7,800
Long-Term Liabilities:		
Operating lease liability (Note 5)	271	672
Warrants liability (Note 6)	729	594
Total long-term liabilities	\$ 1,000	\$ 1,266
Total liabilities	\$ 8,082	\$ 9,066
Stockholders' Deficit:		
Stock capital: (Note 7)	14	13
Common Stock of \$0.00005 par value - Authorized: 250,000,000 shares at September 30, 2024 and 100,000,000 shares at December 31, 2023 respectively; Issued and outstanding: 5,309,796 and 4,032,614 shares at September 30, 2024 and December 31, 2023 respectively (*)		
Additional paid-in-capital	217,708	210,258
Treasury stocks	(116)	(116)
Accumulated deficit	(223,663)	(215,013)
Total stockholders' deficit	\$ (6,057)	\$ (4,858)
Total liabilities and stockholders' deficit	\$ 2,025	\$ 4,208

* Retroactively adjusted (See Note 7).

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)

	Nine months ended		Three months ended	
	September 30,		September 30,	
	2024	2023	2024	2023
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net	\$ 2,928	\$ 9,048	\$ 1,045	\$ 3,330
General and administrative	5,576	7,587	2,003	2,705
Operating loss	(8,504)	(16,635)	(3,048)	(6,035)
Financial (expense) income, net	(11)	91	(54)	(121)
Gain (loss) on change in fair value of Warrants liability (Note 6)	135	4,930	(394)	4,930
Net loss	\$ (8,650)	\$ (11,614)	\$ (2,708)	\$ (1,226)
Basic and diluted net loss per share from continuing operations	\$ (1.80)	\$ (4.35) (*)	\$ (0.51)	\$ (*) (0.45)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	4,793,026	2,683,700(*)	5,309,796	2,950,121(*)

* Retroactively adjusted (See Note 7).

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/2024-11-14-BrainStorm-Cell-Therapeutics-Announces-Third-Quarter-2024-Financial-Results-and-Provides-Corporate-Update>