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

- Company reached alignment with the U.S. FDA on the Chemistry, Manufacturing, and Controls (CMC) aspects of its planned Phase 3b clinical trial for NurOwn® in ALS

- SPA in place for Phase3b NurOwn® trial in ALS

- Enhanced leadership team with appointment of Hartoun Hartounian Ph.D. as EVP and Chief Operating Officer, and promotion of Dr. Bob Dagher to EVP and Chief Medical Officer

- Conference call and webcast at8.30am ET today

NEW YORK, Aug. 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 Second Quarter ended June 30, 2023 and provided a corporate update.

"We continue to make excellent progress in our preparations for the planned Phase3b trial of NurOwn in ALS, with important recent developments on regulatory and operational fronts," said Chaim Lebovits, President and CEO of BrainStorm. "We believe that the regulatory aspects of the program have been substantially derisked, having secured agreement with the FDA on a Special Protocol Assessment and also reached alignment on the CMC aspects. We have selected a leading Clinical Research Organization and are actively working to establish multiple trial sites. If successful, this trial has the potential to significantly improve the lives of ALS patients by providing a much-needed therapeutic option."

Second Quarter 2024 and Recent Highlights

Clinical and regulatory

- In June 2024, BrainStorm reached alignment with the U.S. Food and Drug Administration (FDA) on the Chemistry, Manufacturing, and Controls (CMC) aspects of its planned Phase 3b clinical trial for NurOwn®, its investigational therapy for amyotrophic lateral sclerosis (ALS). This followed the announcement, in April 2024, that the FDA had granted BrainStorm a Special Protocol Assessment (SPA) agreement for the Phase 3b trial. The SPA agreement validates the clinical trial protocol and statistical analysis of the trial, demonstrating their adequacy for addressing objectives that support a future BLA (Biologics License Application) in ALS.

- The Company has selected a leading Clinical Research Organization (CRO) to support the initiation and execution of the Phase 3b trial. We are actively engaging with over 12 leading ALS centers of excellence to establish trial sites. Manufacturing processes are well-advanced and on track to meet production timelines.

- In May 2024, new biomarker data on NurOwn from the prior Phase 3 study and Expanded Access Program (EAP) were featured in a presentation at the 3rd Annual ALS Drug Development Summit, which took place in Boston MA. The data suggested that patients who received extended treatment with NurOwn continued to see benefits. The summit was attended by advocacy groups, physicians, research organizations, industry representatives, key thought leaders and decision makers dedicated to ALS research.

- 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".

Corporate

- In June 2024, BrainStorm completed a successful registered direct offering, with a single institutional investor, raising gross proceeds of $4.0 million.

- In June 2024, appointed Hartoun Hartounian Ph.D. as EVP and Chief Operating Officer. Dr. Hartounian brings a distinguished track record with over 32 years of experience in the biopharmaceutical industry, with a focus on cell and gene therapy.

- 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.

Financial Results for the Second Quarter Ended June 30, 2024

- Cash, cash equivalents, and restricted cash amounted to approximately $3.65 million, as of June 30, 2024.
- Research and development expenses, net, in the second quarter ended June 30, 2024 were $0.9 million, compared to $2.8 million for the quarter ended June 30, 2023.
- General and administrative expenses for the second quarter ended June 30, 2024 and 2023 were $2.0 million and $2.7 million, respectively.
- Net loss for the second quarter ended June 30, 2024 was $2.5 million as compared to a net loss of $5.3 million for the quarter ended June 30, 2023.
- Net loss per share for the second quarter ended June 30, 2024 and June 30, 2023 was $0.04 and $0.13, respectively.

Conference Call and Webcast

BrainStorm management will discuss the second quarter results and recent progress in a conference call and webcast for the investment community at 830am ET today. Investors may participate by dialing the following numbers:

Toll Free: 877-545-0523
International: 973-528-0016
Participant Access Code: 308245
Webcast URL: https://www.webcaster4.com/Webcast/Page/2354/51009

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

Replay Numbers
Toll Free: 877-481-4010
International: 919-882-2331
Replay Passcode: 51009

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

	June 30, 2024 Unaudited	December 31, 2023 Audited
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,469	$ 1,300
Other accounts receivable	33	51
Prepaid expenses and other current assets (Note 4)	314	548
Total current assets	$ 3,816	$ 1,899
Long-Term Assets:		
Prepaid expenses and other long-term assets	$ 20	$ 22
Restricted Cash	179	185
Operating lease right of use asset (Note 5)	1,110	1,416
Property and Equipment, Net	558	686
Total Long-Term Assets	$ 1,867	$ 2,309
Total assets	$ 5,683	$ 4,208
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payables	$ 5,340	$ 4,954
Accrued expenses	718	1,240
Operating lease liability (Note 5)	566	603
Employees related liability	1,067	1,003
Total current liabilities	$ 7,691	$ 7,800
Long-Term Liabilities:		
Operating lease liability (Note 5)	396	672
Warrants liability (Note 6)	1,123	594
Total long-term liabilities	$ 1,519	$ 1,266
Total liabilities	$ 9,210	$ 9,066
Stockholders' Deficit:		
Stock capital: (Note 7)	14	13

Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at June 30, 2024 and December 31, 2023 respectively; Issued and outstanding: 79,646,942 and 60,489,208 shares at June 30, 2024 and December 31, 2023 respectively.		
Additional paid-in-capital	217,530	210,258
Treasury stocks	(116)	(116)
Accumulated deficit	(220,955)	(215,013)
Total stockholders' deficit	$ (3,527)	$ (4,858)
Total liabilities and stockholders' deficit	$ 5,683	$ 4,208

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)

	Six months ended June 30,		Three months ended June 30,	
	2024	2023	2024	2023
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net	$ 1,883	$ 5,718	$ 922	$ 2,794
General and administrative	3,573	4,882	2,060	2,655
Operating loss	(5,456)	(10,600)	(2,982)	(5,449)
Financial income, net	43	212	30	120
Gain (loss) on change in fair value of Warrants liability (Note 6)	529	-	(411)	-
Net loss	$ (5,942)	$ (10,388)	$ (2,541)	$ (5,329)
Basic and diluted net loss per share from continuing operations	$ (0.09)	$ (0.27)	$ (0.04)	$ (0.13)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	67,977,012	38,224,230	71,215,481	39,696,665

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/2024-08-14-BrainStorm-Cell-Therapeutics-Announces-Second-Quarter-2024-Financial-Results-and-Provides-Corporate-Update