BrainStorm Cell Therapeutics Announces First Quarter 2023 Financial Results and Provides Corporate Update

Biologics License Application for NurOwn® for the treatment of ALS to be subject of an upcoming FDA Advisory Committee Meeting

Conference call and webcast at 8:00 a.m. Eastern Time today

NEW YORK, May 15, 2023 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced financial results for the quarter ended March 31, 2023 and provided a corporate update.

"We continue to diligently prepare for NurOwn's upcoming ADCOM supported by a robust dataset providing compelling evidence of its efficacy in ALS, as well as a talented team that was recently bolstered by the addition of Dr. Kirk Taylor as our EVP, Chief Medical Officer," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "Kirk's appointment is part of a strategic initiative to build our medical, regulatory, advocacy, and commercial teams as we prepare for anticipated growth and a potential transition to a commercial organization. On the strength of the data we have generated, and the feedback received from leading ALS experts, we believe we are well positioned to achieve a successful outcome at the upcoming ADCOM. We recognize that time is of the essence for patients with ALS and remain fully committed to working expeditiously towards our goal of making NurOwn widely available to those in need."

"We are equally excited by the addition of Antonio Trejo, VP of Regulatory Affairs, and Robin Wallace, VP of Clinical Operations to our leadership team," said Stacy Lindborg, Ph.D., co-CEO BrainStorm. "As we add to the depth of expertise and capacity of our entire team we will prioritize activities for the upcoming ADCOM and additional tasks that will aide FDA approval, while keeping the horizon of opportunities that lay ahead for Brainstorm. Opportunities such as expanding geographies where NurOwn is approved to treat ALS, expanding the scope of diseases we target as part of our clinical portfolio for NurOwn, in addition to allowing for the development of our next technology platform based on exosomes. We are excited about the multitude of upcoming challenges and opportunities that lay ahead."

First Quarter 2023 and Recent Highlights

- The U.S. Food and Drug Administration (FDA) notified BrainStorm in a written communication that the Agency will hold an Advisory Committee Meeting to review the Biologics License Application (BLA) for NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). The FDA noted that it will provide a date for the ADCOM and a Prescription Drug User Fee Act (PDUFA) target action date for the BLA in due course.
- In April 2023, BrainStorm announced the appointment of Dr. Kirk Taylor as Executive Vice President and Chief Medical Officer, continuing a targeted capability build that was launched with the promotion of Dr. Stacy Lindborg to Co-CEO in January 2023. The capability build is being implemented to hire and bring expertise inside BrainStorm in preparation for anticipated growth.
- A presentation at the 2023 MDA Clinical and Scientific Conference featured post hoc sensitivity analyses that suggest a floor effect of the ALSFRS-R resulted in measurement challenges in participants with advanced ALS enrolled in NurOwn's Phase 3 trial and in historical studies included in the PRO-ACT database. Analyses of data from participants from NurOwn's Phase 3 trial who were not impacted by the floor effect at baseline revealed statistically significant, clinically meaningful effects with NurOwn on the primary and key secondary endpoints. The presentation was delivered by Dr. Lindborg.
- A presentation delivered by Dr. Lindborg at the 13th Annual California ALS Research Summit included Phase 3 results showing that, in analyses controlling for the ALSFRS-R floor effect, participants treated with NurOwn had significantly better outcomes compared to participants treated with placebo. These findings aligned with historical data and power calculations of the Phase 3 trial.
- In January 2023, BrainStorm announced a partnership with the Northeast Amyotrophic Lateral Sclerosis (NEALS) Consortium, The ALS Association and I AM ALS to make biospecimens from NurOwn's placebo-controlled Phase 3 ALS trial available for use by the research community. This partnership is in connection to a $500,000 grant previously awarded to BrainStorm by The ALS Association and I AM ALS to support biomarker research. The specimens have been received by the biorepository and access to them will be governed by NEALS.

Financial Results for the Quarter Ended March 31, 2023

Cash, cash equivalents, and short-term bank deposits were approximately $2.2 million as of March 31, 2023, compared to $3 million as of December 31, 2022.

Research and development expenses for the three months ended March 31, 2023 and 2022 were approximately $2.9 million and $2.6 million, respectively.

General and administrative expenses for the three months ended March 31, 2023 and 2022 were approximately $2.2 million and $2.9 million, respectively.

Net loss for the three months ended March 31, 2023 was approximately $5.1 million, as compared to a net loss of approximately $5.4 million for the three months ended March 31, 2022.

Net loss per share for the three months ended March 31, 2023 and 2022 was $0.14 and $0.15, respectively.

Conference Call and Webcast

May 15, 2023, at 8:00 a.m. Eastern Time

Participant Numbers:
Toll Free: 877 545 0523
International: 973 528 0016
Entry Code: 771387

Webcast URL: https://shorturl.at/knox2

Those interested in listening to the conference call live via the internet may do so by using the webcast link above or by visiting the "Investors & Media" page of BrainStorm's website at https://ir.brainstorm-cell.com/events-and-presentations and clicking on the conference call link.

Those that wish to listen to the replay of the conference call can do so by dialing the numbers below. The replay will be available for 14 days.

Replay Numbers:

Toll Free: 877 481 4010
International: 919 882 2331
Replay Passcode: 48424

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. is a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases. The Company 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 pivotal 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). 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).

Safe-Harbor Statement

Statements in this announcement other than historical data and information, including statements regarding BrainStorm's Type A meeting with the FDA and the clinical development of NurOwn® as a therapy for the treatment of ALS, constitute "forward-looking statements" and involve risks and uncertainties that could cause BrainStorm Cell Therapeutics Inc.'s actual results to differ materially from those stated or implied by such forward-looking statements. Terms and phrases such as "intend," "should," "could," "will," "believe," "potential," and similar terms and phrases are intended to identify these forward-looking statements. The 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, the impacts of the COVID-19 pandemic on our clinical trials, supply chain, and operations, 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

Investor Relations:
John Mullaly
LifeSci Advisors, LLC
Phone: +1 617-429-3548
jmullaly@lifesciadvisors.com

Media:
Lisa Guiterman
Phone: +1 202-330-3431
lisa.guiterman@gmail.com

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands
(Except share data)

	March 31, 2023	December 31, 2022
	Unaudited	Audited
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 2,021	$ 772
Short-term deposit (Note 4)	206	2,211
Other accounts receivable	44	91
Prepaid expenses and other current assets (Note 5)	658	32
Total current assets	2,929	3,106
Long-Term Assets:		
Prepaid expenses and other long-term assets	23	23
Operating lease right of use asset (Note 6)	4,054	4,389
Property and Equipment, Net	866	933
Total Long-Term Assets	4,943	5,345
Total assets	$ 7,872	$ 8,451
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		

Accounts payables	$ 7,802	$ 6,224
Accrued expenses	171	84
Operating lease liability (Note 6)	1,389	1,427
Other accounts payables	1,060	1,065
Total current liabilities	10,422	8,800
Long-Term Liabilities:		
Operating lease liability (Note 6)	2,290	2,666
Total long-term liabilities	2,290	2,666
Total liabilities	$ 12,712	$ 11,466
Stockholders' Equity:		
Stock capital: (Note 7)	12	12
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares March 31, 2023 and December 31, 2022 respectively; Issued and outstanding: 38,475,251 and 36,694,078 shares at March 31, 2023 and December 31, 2022 respectively.		
Additional paid-in-capital	198,144	194,910
Treasury stocks	(116)	(116)
Accumulated deficit	(202,880)	(197,821)
Total stockholders' equity (deficit)	(4,840)	(3,015)
Total liabilities and stockholders' equity (deficit)	$ 7,872	$ 8,451

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,	
	2023	**2022**
	Unaudited	
Operating expenses:		
Research and development, net	$ 2,924	$ 2,616
General and administrative	2,227	2,859
Operating loss	(5,151)	(5,475)
Financial income, net	92	115
Net loss	$ (5,059)	$ (5,360)
Basic and diluted net loss per share from continuing operations	$ (0.14)	$ (0.15)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	36,735,435	36,436,882

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/2023-05-15-BrainStorm-Cell-Therapeutics-Announces-First-Quarter-2023-Financial-Results-and-Provides-Corporate-Update