# BrainStorm Cell Therapeutics Announces Full Year 2023 Financial Results and Provides Corporate Update

Conference call planned for early April 2024 to provide update on NurOwn program

NEW YORK, April 1, 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 full year ended December 31, 2023 and provided a corporate update.

"Brainstorm's priority for 2024 is to move forward with a confirmatory Phase 3b trial for NurOwn that will potentially support a new Biologics License Application," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "We have been working closely with the FDA with the goal of agreeing on a Special Protocol Assessment (SPA) so that we are aligned on the study design. We believe that an SPA will substantially de-risk the regulatory aspects of our program. Our team is committed to this rigorous planning process, recognizing its critical importance in the potential success and validity of the trial outcomes. We continue to believe that, if approved, NurOwn has the potential to be a valuable treatment option for ALS patients in need. We look forward to providing a further update in the near future."

Stacy Lindborg, Ph.D., co-CEO BrainStorm commented, "We are acutely aware of the challenges faced by those afflicted with ALS. Our planned Phase 3b trial will be conducted with the highest standards of scientific excellence and integrity, driven by our commitment to the ALS community and our goal of expanding the treatment landscape."

**Fourth Quarter 2023 and Recent Highlights**

Clinical and regulatory

- In February 2024, Brainstorm submitted a Special Protocol Assessment (SPA) request to the U.S. Food and Drug Administration (FDA) for a Phase 3b study of NurOwn. An SPA agreement would indicate concurrence by FDA with the adequacy and acceptability of the overall protocol design for a planned Phase 3b study, intended to support a future marketing application. The request is currently under review, and the Company is expecting to have a response from the US FDA very soon as we approach the 45-day SPA review cycle
- Brainstorm's proposed design for the planned Phase 3b trial of NurOwn ALS was presented in a poster at the MDA Clinical and Scientific Conference in March, 2024. The design is for a two-part, multicenter, Phase 3b study to assess the efficacy and safety of NurOwn in participants with ALS, earlier in the disease.
- In December 2023, company management attended an in-person meeting with the FDA to discuss the regulatory path forward for NurOwn in ALS, including plans for an SPA prior to commencing the planned Phase 3b confirmatory trial.
- In November 2023, Bob Dagher, MD, Executive Vice President and Chief Development Officer at BrainStorm, delivered a presentation titled, "NurOwn for ALS: Biomarker exploration of NurOwn multimodal mechanism of action on neuroinflammation, neuroprotection and neurodegeneration" at the 6th Annual ALS Research Symposium hosted by ALS ONE.
- In October 2023, Brainstorm withdrew its Biological License Application (BLA) for NurOwn in ALS. This action was coordinated with FDA and was viewed by the Agency as a withdrawal without prejudice. This decision was made following the U.S. FDA's Cellular, Tissue and Gene Therapies Advisory Committee meeting that took place in September 2023. The Committee voted that NurOwn did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS.

Corporate

- In October 2023, Brainstorm announced a strategic realignment to enable accelerated development of NurOwn for the treatment of ALS. The company reduced and refocusing resources by streamlining clean room operations and undertook a targeted reduction in headcount of approximately 30 percent.

**Financial Results for the Year Ended December 31, 2023**

- Cash, cash equivalents, and restricted cash amounted to $1.45 million, as of December 31, 2023, compared to cash, cash equivalents, and short-term deposits of $3 million as of December 31, 2022.
- Research and development expenses for the twelve months ended December 31, 2023, and 2022 were approximately $10.8 million and $14 million, respectively.
- General and administrative expenses for the twelve months ended December 31, 2023, and 2022 were

approximately $10.7 million and $10.9 million, respectively.
- Net loss for the year ended December 31, 2023 was $17.2 million as compared to a net loss of $24.3 million for the year ended December 31, 2022.
- Net loss per share for the year ended December 31, 2023 and December 31, 2022 was $0.40 and $0.66, respectively.

**Conference Call and Webcast**

BrainStorm management will host a conference call for the investment community in early April 2024 to discuss plans for NurOwn including an update on the SPA. As described above, the Company is expecting to have a response from the US FDA very soon as we approach the 45-day SPA review cycle. Details on the conference call will be provided when available.

**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.
CONSOLIDATED BALANCE SHEETS

**U.S. dollars in THOUSANDS**
**(Except share data)**

| | December 31, | |
|---|---|---|
| | **2023** | **2022** |
| | **U.S. $ in thousands** | |
| **ASSETS** | | |
| **Current Assets:** | | |
| Cash and cash equivalents | $ 1,300 | $ 772 |
| Short-term deposit (Note 8) | - | 2,211 |
| Other accounts receivable | 51 | 91 |
| Prepaid expenses and other current assets (Note 4) | 548 | 32 |
| **Total current assets** | $ 1,899 | $ 3,106 |
| **Long-Term Assets:** | | |
| Prepaid expenses and other long-term assets | $ 22 | $ 23 |
| Restricted Cash | 185 | - |
| Operating lease right of use asset (Note 5) | 1,416 | 4,389 |
| Property and Equipment, Net (Note 6) | 686 | 933 |
| **Total Long-Term Assets** | $ 2,309 | $ 5,345 |
| **Total assets** | $ 4,208 | $ 8,451 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| **Current Liabilities:** | | |
| Accounts payables | $ 4,954 | $ 6,224 |
| Accrued expenses | 1,240 | 84 |
| Operating lease liability (Note 5) | 603 | 1,427 |
| Employees related liability | 1,003 | 1,065 |
| **Total current liabilities** | $ 7,800 | $ 8,800 |
| **Long-Term Liabilities:** | | |
| Operating lease liability (Note 5) | 672 | 2,666 |
| Warrants liability (Note 6) | 594 | - |
| **Total long-term liabilities** | $ 1,266 | $ 2,666 |
| **Total liabilities** | $ 9,066 | $ 11,466 |
| **Stockholders' Equity (deficit):** | | |
| Stock capital: (Note 9) | 13 | 12 |
| Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at December 31, 2023 and December 31, 2022 respectively; Issued and outstanding: 60,489,208 and 36,694,078 shares at December 31, 2023 and December 31, 2022 respectively. | | |
| Additional paid-in-capital | 210,258 | 194,910 |
| Treasury stocks | (116) | (116) |
| Accumulated deficit | (215,013) | (197,821) |
| **Total stockholders' equity (deficit)** | $ (4,858) | $ (3,015) |
| **Total liabilities and stockholders' equity (deficit)** | $ 4,208 | $ 8,451 |

**The accompanying notes are an integral part of the consolidated financial statements.**

BRAINSTORM CELL THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
**U.S. dollars in thousands**
**(Except share data)**

| | Year ended December 31, | |
|---|---|---|
| | **2023** | **2022** |
| | **U.S. $ in thousands** | |
| **Operating expenses:** | | |
| Research and development, net (Note 12) | $ 10,746 | $ 13,956 |
| General and administrative | 10,693 | 10,866 |
| **Operating loss** | (21,439) | (24,822) |
| Financial income (expense), net | (447) | 545 |
| Gain on change in fair value of Warrants liability (Note 9) | 4,694 | - |
| **Net loss** | $ (17,192) | $ (24,277) |
| Basic and diluted net loss per share | $ (0.40) | $ (0.66) |
| Weighted average number of shares outstanding used in computing basic and diluted net loss per share | 43,075,938 | 36,509,060 |

**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.

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Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2024-04-01-BrainStorm-Cell-Therapeutics-Announces-Full-Year-2023-Financial-Results-and-Provides-Corporate-Update