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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024.
or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-36641

BRAINSTORM CELL THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	20-7273918
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1325 Avenue of Americas, 28th Floor New York, NY (Address of principal executive offices)	10019 (Zip Code)

(201) 488-0460
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00005 par value	BCLI	NASDAQ Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes☐ No ☒

As of November 12, 2024, the number of shares outstanding of the registrant's Common Stock, $0.00005 par value per share, was 5,703,426(*).

* Retroactively adjusted (See Note 7).

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report contains numerous statements, descriptions, forecasts and projections, regarding Brainstorm Cell Therapeutics Inc. (together with its consolidated subsidiaries, the "Company," "Brainstorm," "we," "us" or "our") and its potential future business operations and performance, including financial results for the most recent fiscal quarter, statements regarding the market potential for treatment of neurodegenerative disorders such as amyotrophic lateral sclerosis ("ALS"), the sufficiency of our existing capital resources for continuing operations in 2024 and beyond, the safety and clinical effectiveness of our NurOwn® technology, our clinical trials of NurOwn® and its related clinical development, and our ability to develop collaborations and partnerships to support our business plan. In some cases you can identify such "forward-looking statements" by the use of words like "may," "will," "should," "could," "expects," "hopes," "anticipates," "believes," "intends," "plans," "projects," "targets," "goals," "estimates," "predicts," "likely," "potential," or "continue" or the negative of any of these terms or similar words. These statements, descriptions, forecasts and projections constitute "forward-looking statements," and as such involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance and achievements to be materially different from any results, levels of activity, performance and achievements expressed or implied by any such "forward-looking statements." These risks and uncertainties include, but are not limited to the potential consequences of the Nasdaq Stock Market's (the "Nasdaq") notice of noncompliance with the minimum market value of listed securities requirement, our reputation and business generally, whether we will be able to meet Nasdaq's minimum market value of $35 million in time for Nasdaq's January 14, 2025 deadline, the outcomes of the putative securities class action and derivative lawsuits filed by five of our shareholders, the potential for more derivative lawsuits to be brought, our need to raise additional capital, our ability to continue as a going concern, regulatory approval of our NurOwn® treatment candidate, the success of our product development programs and research, regulatory and personnel issues, development of a global market for our services, the ability to secure and maintain research institutions to conduct our clinical trials, the ability to generate significant revenue, the ability of our NurOwn® treatment candidate to achieve broader acceptance as a treatment option for ALS, progressive multiple sclerosis ("PMS"), Alzheimer's disease ("AD") or other neurodegenerative diseases, our ability to manufacture and commercialize our NurOwn® treatment candidate, obtaining patents that provide meaningful protection, competition and market developments, our ability to protect our intellectual property from infringement by third parties, heath reform legislation, demand for our services, currency exchange rates and product liability claims and litigation, adverse developments affecting the financial services industry, political instability, unrest and wars, such as the conflicts involving Ukraine and Russia and Israel and its surrounding regions, including our clinical development activities, and other factors described under "Risk Factors" in this report and in our annual report on Form 10-K for the fiscal year ended December 31, 2023. These "forward-looking statements" are based on certain assumptions that we have made as of the date hereof. To the extent these assumptions are not valid, the associated "forward-looking statements" and projections will not be correct. Although we believe that the expectations reflected in these "forward-looking statements" are reasonable, we cannot guarantee any future results, levels of activity, performance, or achievements. It is routine for our internal projections and expectations to change as the year or each quarter in the year progresses, and therefore it should be clearly understood that the internal projections and beliefs upon which we base our expectations may change prior to the end of each quarter or the year. Although these expectations may change, we may not inform you if they do and we undertake no obligation to do so, except as required by applicable securities laws and regulations. We caution investors that our business and financial performance are subject to substantial risks and uncertainties. In evaluating our business, prospective investors should carefully consider the information set forth under the caption "Risk Factors" in this report and in our annual report on Form 10-K for the fiscal year ended December 31, 2023 in addition to the other information set forth herein and elsewhere in our other public filings with the Securities and Exchange Commission ("SEC").

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
As of September 30, 2024

U.S. DOLLARS IN THOUSANDS
(Except share data and exercise prices)

(UNAUDITED)

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

As of September 30, 2024
U.S. DOLLARS IN THOUSANDS
(Except share data and exercise prices)

(UNAUDITED)

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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, 2024 Unaudited	December 31, 2023 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 September 30,		Three months ended 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.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT (UNAUDITED)
U.S. dollars in thousands
(Except share data)

	Common stock		Additional paid-in capital	Treasury stocks	Accumulated deficit	Total stockholders' equity
	Number(**)	Amount				
Balance as of January 1, 2023	**2,446,272**	**12**	**194,910**	**(116)**	**(197,821)**	**(3,015)**
Stock-based compensation related to stock and options granted to directors and employees	(1,255)	*	4	—	—	4
Issuance of shares in at-the-market (ATM) offering (Note 7)	120,000	*	3,230	—	—	3,230
Net loss	—	—	—	—	(5,059)	(5,059)
Balance as of March 31, 2023	**2,565,017**	**12**	**198,144**	**(116)**	**(202,880)**	**(4,840)**
Stock-based compensation related to stock and options granted to directors and employees	21,000	*	988	—	—	988
Issuance of shares in at-the-market (ATM) offering (Note 7)	142,433	*	5,299	—	—	5,299
Net loss	—	—	—	—	(5,329)	(5,329)
Balance as of June 30, 2023	**2,728,450**	**12**	**204,431**	**(116)**	**(208,209)**	**(3,882)**
Stock-based compensation related to stock and options granted to directors and employees	22,277	*	548	—	—	548
Issuance of shares for private placement (Note 7)	270,270	*	1,978	—	—	1,978
Net loss	—	—	—	—	(1,226)	(1,226)
Balance as of September 30, 2023	**3,020,997**	**12**	**206,957**	**(116)**	**(209,435)**	**(2,582)**

* Represents an amount less than $1.

** Retroactively adjusted (See Note 7).

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT (UNAUDITED)
U.S. dollars in thousands
(Except share data)

	Common stock		Additional paid-in capital	Treasury stocks	Accumulated deficit	Total stockholders' deficit
	Number	Amount				
Balance as of January 1, 2024	**4,032,614 (**)**	**13**	**210,258**	**(116)**	**(215,013)**	**(4,858)**
Stock-based compensation related to stock and options granted to directors and employees	—	*	170	—	—	170
Issuance of shares in at-the-market (ATM) offering (Note 7)	530,532	*	2,539	—	—	2,539
Net loss	—	—	—	—	(3,401)	(3,401)
Balance as of March 31, 2024	**4,563,146 (**)**	**13**	**212,967**	**(116)**	**(218,414)**	**(5,550)**
Stock-based compensation related to stock and options granted to directors and employees	111,721 (**)	*	194	—	—	194
Issuance of shares in at-the-market (ATM) offering (Note 7)	107,011 (**)	*	725	—	—	725
Issuance of shares for private placement (Note 7)	527,918 (**)	1	3,644	—	—	3,645
Net loss	—	—	—	—	(2,541)	(2,541)
Balance as of June 30, 2024	**5,309,796 (**)**	**14**	**217,530**	**(116)**	**(220,955)**	**(3,527)**
Stock-based compensation related to stock and options granted to directors and employees	—	*	178	—	—	178
Net loss	—	—	—	—	(2,708)	(2,708)
Balance as of September 30, 2024	**5,309,796**	**14**	**217,708**	**(116)**	**(223,663)**	**(6,057)**

* Represents an amount less than $1.

** 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 CASH FLOWS (UNAUDITED)
U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2024	2023	2024	2023
Cash flows from operating activities:				
Net loss	$ (8,650)	$ (11,614)	$ (2,708)	$ (1,226)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	187	199	59	65
Stock-based compensation related to options granted to employees and directors	542	1,540	178	548
Change in operating lease liability	23	(183)	30	(58)
Decrease in other accounts receivable and prepaid expenses	403	4	149	345
Increase (decrease) in trade payables	(351)	(298)	(737)	(1,264)
Loss (gain) on change in fair value of warrants (Note 6)	135	(4,761)	(394)	(4,761)
Increase (decrease) in other accounts payable and accrued expenses	(334)	(60)	124	(58)
Total net cash used in operating activities	$ (8,045)	$ (17,173)	$ (3,299)	$ (6,409)

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2024	2023	2024	2023
Cash flows from investing activities:		(18)		(18)
Changes in short-term deposit	—	2,015	—	6
Total net cash provided by investing activities	$ —	$ 1,997	$ —	$ (12)
Cash flows from financing activities:				
Proceeds from issuance of shares in at-the-market (ATM) offering (Note 7)	3,264	8,529	—	—
Proceeds from Issuance of shares for private placement (Note 7) (*)	3,645	7,097	—	7,097
Total net cash provided by financing activities	$ 6,909	$ 15,626	$ —	$ 7,097
Increase (decrease) in cash, cash equivalents and restricted cash	(1,136)	450	(3,299)	676
Cash, cash equivalents and restricted cash at the beginning of the period	$ 1,485	$ 772	$ 3,648	$ 546
Cash, cash equivalents and restricted cash at end of the period	$ 349	$ 1,222	$ 349	$ 1,222

(*) Presented after neutralizing costs of issuance.

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to the Interim Condensed Consolidated Financial Statements

NOTE 1 - GENERAL

A. The Company was incorporated in the State of Delaware on November 15, 2006, and previously was incorporated in the State of Washington. In October 2004, the Company formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics Ltd. ("BCT") in Israel, which currently conducts all the research and development activities of the Company. BCT formed wholly-owned subsidiaries Brainstorm Cell Therapeutics UK Ltd., in the United Kingdom on February 19, 2013 (currently inactive), Advanced Cell Therapies Ltd. in Israel on June 21, 2018 and Brainstorm Cell Therapeutics Limited in Ireland on October 1, 2019. The Company formed a wholly-owned subsidiary in Delaware, Brainstorm Cell Manufacturing LLC, in August 21, 2024.

The Company's common stock, $0.00005 par value per share (the "Common Stock") is publicly traded on the Nasdaq Capital Market under the symbol "BCLI".

B. The Company, through BCT, holds rights to commercialize certain stem cell technology developed by Ramot of Tel Aviv University Ltd. ("Ramot"), (see Note 3). Using this technology, the Company has been developing novel adult stem cell therapies for debilitating neurodegenerative disorders such as ALS, also known as Lou Gherig Disease, PMS and Parkinson's disease. The Company developed a proprietary process, called NurOwn®, for the propagation of MSCs and their differentiation into neurotrophic factor secreting cells. These cells are then transplanted at or near the site of damage, offering the hope of more effectively treating neurodegenerative diseases. The process is currently autologous, or self-transplanted.

C. A reverse stock split of the Company's shares of Common Stock by a ratio of one-for-fifteen (the "Reverse Stock Split") was effected on September 30, 2024 at 11:59 p.m. pursuant to an amendment to the Company's Certificate of Incorporation approved by the stockholders of the Company on September 16, 2024. The Company adjusted all ordinary shares, options, warrants, per share data and exercise prices included in these financial statements for all periods presented to reflect the Reverse Stock Split.

D. Since its inception, the Company has devoted substantially all its efforts to research and development. The Company is still in its development and clinical stage and has not yet generated revenues. The Company has incurred operating losses since its inception and expects to continue to incur operating losses for the near-term. As of September 30, 2024, the Company had an accumulated deficit of approximately $224,000. The extent of the Company's future operating losses and the timing of becoming profitable are uncertain. As of September 30, 2024 the cash balance is $349.

The Company's primary sources of cash have been proceeds from the issuance and sale of its Common Stock and warrants, the exercise of warrants, sales of Common Stock via its at-the-market ("ATM") program and other funding transactions. While the Company has been successful in raising financing recently and in the past, there can be no assurance that it will be able to do so in the future on a timely basis on terms acceptable to the Company, or at all. The Company has not yet commercialized any of its product candidates. Even if the Company commercializes one or more of its product candidates, it may not become profitable in the near-term. The Company's ability to achieve profitability depends on several factors, including its ability to obtain regulatory approval for its product candidates, successfully complete any post-approval regulatory obligations and successfully commercialize its product candidates alone or in partnership.

Such conditions raise substantial doubts about the Company's ability to continue as a going concern. Management's plan includes raising funds from outside potential investors via its ATM program and other potential funds as mentioned. However, as mentioned above, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. These interim condensed financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
U.S. dollars in thousands
(Except share data and exercise prices)
Notes to the Interim Condensed Consolidated Financial Statements

NOTE 2 - BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

A. Unaudited Interim Financial Statements

The accompanying unaudited interim condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of U.S. Securities and Exchange Commission Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation have been included (consisting only of normal recurring adjustments except as otherwise discussed). For further information, reference is made to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Operating results for the three and nine months ended September 30, 2024, are not necessarily indicative of the results that may be expected for the year ending December 31, 2024.

B. Significant Accounting Policies

The significant accounting policies followed in the preparation of these unaudited interim condensed consolidated financial statements are identical to those applied in the preparation of the latest annual financial statements.

C. Recent Accounting Standards

Management does not believe that any recently issued, but not yet effective, accounting standards, if currently adopted, would have a material effect on the Company's condensed financial statements.

D. Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

NOTE 3 - RESEARCH AND LICENSE AGREEMENT

In 2004, the Company entered into a Research and License Agreement, as amended and restated, with Ramot (the "License Agreement"). Pursuant to the remuneration terms of the License Agreement, the Company has agreed to pay Ramot royalties on Net Sales of the Licensed Product as follows:

a) So long as the making, producing, manufacturing, using, marketing, selling, importing or exporting (collectively, the "Commercialization") of such Licensed Product is covered by a Valid Claim or is covered by Orphan Drug Status, the Company shall pay Ramot a royalty of 5% of the Net Sales received by the Company and resulting from such Commercialization; and

b) In the event the Commercialization of the Licensed Product is neither covered by a Valid Claim nor by Orphan Drug status, the Company shall pay Ramot a royalty of 3% of the Net Sales received by the Company resulting from such Commercialization. This royalty shall be paid from the First Commercial Sale of the Licensed Product and for a period of fifteen (15) years thereafter.

Capitalized terms set forth above which are not defined shall have the meanings attributed to them under the License Agreement.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
U.S. dollars in thousands
(Except share data and exercise prices)
Notes to the Interim Condensed Consolidated Financial Statements

NOTE 4 - PREPAID EXPENSES

As of September 30, 2024, the prepaid expenses balance was $156, none of which was related to director's insurance. Whereas, as of December 31, 2023 the prepaid expenses balance mostly included director's insurance of $428.

NOTE 5 - LEASES

As of September 30, 2024, and December 31, 2023, total right-of-use assets was approximately $ 959 and $1,416 and the operating lease liabilities for remaining long term lease was approximately $841 and $1,275, respectively. In the nine months period ended September 30, 2024 and in the nine months period ended September 30, 2023, the Company recognized approximately $324 and $619, respectively, in total lease costs. Variable lease costs for these periods were immaterial.

Supplemental cash flow and total lease cost information was as follows:

	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Cash payments for operating leases	496	1,100
Operating lease expense	492	1,209
Finance lease income	28	(293)

As of September 30, 2024, the Company's operating leases had a weighted average remaining lease term of 1.67 years and a weighted average discount rate of 8.50%. Future lease payments under operating leases as of September 30, 2024 were as follows:

	Operating Leases
2024	149
2025	563
2026	185
Total future lease payments	897
Less imputed interest	(56)
Total lease liability balance	841

NOTE 6 - WARRANTS LIABILITY

In July 2023, the Company issued 270,270 shares of Common Stock and 270,270 private placement warrants ("July 2023 warrants") to purchase shares of Common Stock. The gross proceeds from this transaction were approximately $7.5 million. The Common Warrants contain provisions regarding settlement in the event of a fundamental transaction that calculate the fair value of the warrants using a prespecified volatility assumption that was not consistent with the input used to value the warrants at issuance which causes the warrants to be classified as liabilities. The Common Warrants will be measured at fair value at inception and in subsequent reporting periods with changes in fair value recognized as financial income or expense as change in fair value of warrant liabilities in the period of change in the condensed consolidated statements of comprehensive loss. July 2023 warrants are classified as Level 3 financial instruments in the fair value hierarchy (refer to Note 8, *Fair Value Measurement*). As of September 30, 2024, the July 2023 warrants were outstanding with fair values of $729. The fair value of the warrant liability for the nine – month period ended September 30, 2024 increased by $ 135. The change has been recognized as loss on change in fair value of derivatives in the Company's Consolidated Statements of Comprehensive Loss.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to the Interim Condensed Consolidated Financial Statements

NOTE 6 - WARRANTS LIABILITY (Cont.):

In connection with the June 2024 public offering (the "Offering") (refer to Note 7), the Company also entered into a warrant amendment agreement regarding July 2023 warrants (the "Warrant Amendment Agreement") with the Purchaser. Under the Warrant Amendment Agreement, the Company agreed to amend its existing warrants to purchase up to an aggregate of 270,270 shares of Common Stock (collectively, the "Existing Warrants") that were previously issued to the investor in July 2023, such that, effective upon the closing of the Offering, the amended Existing Warrants will have an exercise price of $5.868 per share and a termination date of June 28, 2029.

NOTE 7 – STOCK CAPITAL

The rights of Common Stock are as follows:

Holders of the Common Stock have the right to receive notice to participate and vote in general meetings of the Company, the right to a share in the excess of assets upon liquidation of the Company and the right to receive dividends, if declared.

The Common Stock is publicly traded on The Nasdaq Capital Market under the symbol "BCLI".

On September 30, 2024 the Company effected the Reverse Stock Split of the Company's ordinary shares at the one-for-fifteen ratio, such that every fifteen shares of Common Stock were consolidated into one ordinary share. As a result, all share amounts were adjusted retroactively for all periods presented in these financial statements.

Private placements and public offerings:

At-the-market (ATM) Offering:

On August 9, 2021, the Company entered into an Amended and Restated Distribution Agreement (the "New Distribution Agreement") with the Agents (as defined in the New Distribution Agreement) pursuant to which the Company may sell from time to time, through the Agents, shares of Common Stock (the "Shares"), having an aggregate offering price of up to $100,000,000 (the "August 9, 2021 ATM"). Sales under the August 9, 2021 ATM are to be made by any method permitted by law that is deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), including, without limitation, sales made directly on The Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and the Agents. In connection with the New Distribution Agreement, the Company terminated the previous Distribution Agreement and the September 25, 2020, ATM. During the nine months ended September 30, 2024, the Company has sold 637,543 shares of Common Stock for gross proceeds of approximately $ 3,342,413 under the August 9, 2021, ATM.

Securities Purchase Agreement:

On July 17, 2023, the Company entered into a Securities Purchase Agreement with the purchaser named therein, pursuant to which the Company agreed to sell, in the Offering, an aggregate of 270,270 shares of Common Stock, together with accompanying warrants (the "Common Warrants") to purchase 270,270 shares of Common Stock, at a purchase price of $27.75 per share and accompanying warrants for gross proceeds to the Company of approximately $ 7.5 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Offering closed on July 19, 2023. The Common Warrants are immediately exercisable, expire five years following the date of issuance and have an exercise price of $30.00 per share. Please refer to Note 6.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to the Interim Condensed Consolidated Financial Statements

NOTE 7 – STOCK CAPITAL (Cont.):

Securities Purchase Agreement: (Cont.):

On June 27, 2024, the Company entered into a Securities Purchase Agreement with the purchaser, pursuant to which the Company agreed to sell, (i) an aggregate of 527,918 registered shares of the Company's Common Stock, (ii) registered pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 212,823 shares of Common Stock and (iii) unregistered warrants to purchase up to 1,111,111 shares of Common Stock, at a purchase price of $ 5.4 per share of Common Stock and accompanying Common Warrant, or $5.399 per Pre-Funded Warrant and accompanying Common Warrant. The Offering of the Securities yielded gross proceeds to the Company of approximately $4.0 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Offering closed on June 28, 2024. The Warrants will be exercisable six months after the issuance date, will expire five years following the date of issuance and have an exercise price of $5.868 per share. Each Pre-Funded Warrant is immediately exercisable for one share of Common Stock (the "Pre-Funded Warrant Shares") at an exercise price of $0.00005 per share and will remain exercisable until the Pre-Funded Warrants are exercised in full.

Capital Raised Since Inception:

Since its inception through September 30, 2024, the Company has raised approximately $ 178 million gross in cash in consideration for issuances of Common Stock and warrants in private placements and public offerings as well as proceeds from warrants exercises.

Stock Plans:

During the nine months ended September 30, 2024, the Company had outstanding awards for stock options under four stockholder approved plans: (i) the 2004 Global Stock Option Plan and the Israeli Appendix thereto (the "2004 Global Plan") (ii) the 2005 U.S. Stock Option and Incentive Plan (the "2005 U.S. Plan," and together with the 2004 Global Plan, the "Prior Plans"); (iii) the 2014 Global Share Option Plan and the Israeli Appendix thereto (which applies solely to participants who are residents of Israel) (the "2014 Global Plan"); and (iv) the 2014 Stock Incentive Plan (the "2014 U.S. Plan" and together with the 2014 Global Plan, the "2014 Plans").

The 2004 Global Plan and 2005 U.S. Plan expired on November 25, 2014 and March 28, 2015, respectively. Grants that were made under the Prior Plans remain outstanding pursuant to their terms. The 2014 Plans were approved by the stockholders on August 14, 2014 (at which time the Company ceased to issue awards under each of the 2005 U.S. Plan and 2004 Global Plan) and amended on June 21, 2016 and November 29, 2018. Unless otherwise stated, option grants prior to August 14, 2014 were made pursuant to the Company's Prior Plans, and grants issued on or after August 14, 2014 were made pursuant to the Company's 2014 Plans, and expire on the tenth anniversary of the grant date.

On September 16, 2024, the Company held its 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting"), and the stockholders of the Company approved Amendment No. 4 to the 2014 U.S. Plan, as amended, and Amendment No. 4 to the 2014 Global Option Plan, as amended (collectively, the "Amendments to the 2014 Plans"). The Amendments to the 2014 Plans amend each of the U.S. Plan, as amended, and 2014 Global Option Plan, as amended, respectively (collectively, the "Original 2014 Plans") to (i) increase the shared pool of shares of the Common Stock available for issuance under the Company's Original 2014 Plans by 533,333 shares of Common Stock, resulting in a shared pool of 906,666 shares of Common Stock, and (ii) extend the term of each of the Original 2014 Plans by an additional ten years. This extension applies solely to future grants and does not affect any grants made under the original terms.

The 2014 Plans now have a shared pool of 906,666 shares of Common Stock available for issuance. As of September 30, 2024, 585,379 shares were available for future issuances under the 2014 Plans. The exercise price of the options granted under the 2014 Plans may not be less than the nominal value of the shares into which such options are exercised. Any options under the 2014 Plans that are canceled or forfeited before expiration become available for future grants. The Governance, Nominating and Compensation Committee (the "GNC Committee") of the Board of Directors of the Company (the "Board") administers the Company's stock incentive compensation and equity-based plans.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
U.S. dollars in thousands
(Except share data and exercise prices)
Notes to the Interim Condensed Consolidated Financial Statements

NOTE 7 – STOCK CAPITAL (Cont.):

Share-based compensation to employees and to directors:

Under the 2014 Plans, the Company may award stock options to certain employees, officers, directors, and/or service providers. The stock options vest in accordance with such conditions and restrictions determined by the GNC Committee.

Stock options:

These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with the Company through a specified period. Stock options awarded are valued based upon the Black-Scholes option pricing model and the Company recognizes this value as stock compensation expense over the periods in which the options vest. Use of the Black Scholes option-pricing model requires that the Company make certain assumptions, including expected volatility, risk-free interest rate, expected dividend yield, and the expected life of the options. The Company didn't grant stock options during the nine months ended September 30, 2024.

A summary of the Company's option activity related to options to employees and directors, and related information as of September 30, 2024, is as follows:

	For the Nine months ended September 30, 2024		
	Amount of options *	Weighted Average Exercise Price	Aggregate intrinsic value
		$	$
Outstanding at December 31, 2023	107,052	55.4481	—
Granted	—	—	—
Forfeited	(17,448)	127.0191	—
Outstanding at September 30, 2024	89,604	33.8151	—
Exercisable at September 30, 2024	70,428	31.7924	—

* Represents Employee Stock Options only (not including restricted stock units).

** Retroactively adjusted (See Note 7).

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the fair market value of the Company's shares on September 30, 2024, multiplied by the number of in-the-money options on those dates) that would have been received by the option holders had all option holders exercised their options on those dates.

As of September 30, 2024, there was $ 219 of total unrecognized compensation cost related to non-vested options under the Plan. The cost is expected to be recognized over a weighted average period of 1.78 years. Compensation expense recorded by the Company in respect of its stock-based employees and directors compensation awards in accordance with ASC 718-10 for the nine months ended September 30, 2024 amounted to $224. For the nine months ended September 30, 2023 the Company recorded compensation income amounted to $229.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
U.S. dollars in thousands
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Notes to the Interim Condensed Consolidated Financial Statements

NOTE 7 – STOCK CAPITAL (Cont.):

Restricted Stock:

The Company awards stock and restricted stock to certain employees, officers, directors, and/or service providers. The restricted stock vests in accordance with such conditions and restrictions determined by the GNC Committee. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with the Company through a specified restricted period. The purchase price (if any) of shares of restricted stock is determined by the GNC Committee. If the performance goals and other restrictions are not attained, the grantee will automatically forfeit their unvested awards of restricted stock to the Company. Compensation expense for restricted stock is based on fair market value at the grant date.

	Number of Shares of Restricted Stock	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)
Nonvested as of December 31, 2023	20,326 (*)	42.92	1.32
Granted	115,210 (*)	4.95	—
Vested	(6,679)(*)	38.73	—
Forfeited	(7,572)(*)	31.11	—
Nonvested as of September 30, 2024	121,285	6.69	0.97

* Retroactively adjusted (See Note 7).

Compensation expense recorded by the Company in respect of its stock and restricted stock awards to certain employees, officers, directors, and/or service providers for the nine months ended September 30, 2024 and September 30, 2023 amounted to $318 and $1,310, respectively.

As of September 30, 2024, there was $ 399 of total unrecognized compensation cost related to non-vested restricted stock under the Plan. The cost is expected to be recognized over a weighted average period of 1.22 years.

Total Stock-Based Compensation Expense

The total stock-based compensation expense, related to shares, options and warrants granted to employees, directors and service providers was comprised, at each period, as follows:

	Nine months ended September 30,	
	2024	2023
Research and development	$ 272	$ 1,108
General and administrative	270	432
Total stock-based compensation expense	$ 542	$ 1,540

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NOTE 8 – FAIR VALUE MEASUREMENT

The Company's financial instruments consist of cash and cash equivalents, accounts payable and warrants.

Accounting standards establish a hierarchy, which prioritizes the inputs to valuation techniques used to measure fair value into three levels. The fair value hierarchy gives the highest priority to quoted market prices (unadjusted) in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Accounting standards require financial assets and liabilities to be classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and the exercise of this judgment may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The carrying value of cash and cash equivalents, restricted cash, accounts receivable, contract assets, contract liabilities and accounts payable are considered to be representative of their fair value due to the short maturity of these instruments.

Warrants Liabilities

The July 2023 warrants are classified as Level 3 financial instruments. The Company estimated the fair value of the July 2023 warrants using the Black-Scholes model at inception and on subsequent valuation dates. This model incorporates inputs such as the stock price of the Company, risk-free interest rate, volatility, and time to expiration. The volatility involves unobservable inputs classified as Level 3 of the fair value hierarchy. The assumptions used to determine the fair value of the July 2023 warrants are as follows:

	September 30, 2024	June 30, 2024	March 31, 2024	December 31,2023
Time to expiration	4.74 years	5 years	4.31 years	4.56 years
Common stock price	$ 3.45	$ 5.1	$ 8.4	$ 4.05
Risk-free interest rate	3.58	4.33	4.28	3.88
Volatility	122 %	118 %	123 %	116 %

For the Warrant Amendment Agreement please refer to Note 7.

NOTE 9 – MATERIAL EVENTS DURING THE PERIOD

A. On November 1, 2023, a purported shareholder of the Company filed a putative securities class action complaint against the Company and certain of its officers, captioned *Sporn v. Brainstorm Cell Therapeutics Inc., et al.* , Case No. 1:23-cv-09630 (the "Securities Complaint"), in the United States District Court for the Southern District of New York (the "Securities Action"). The Lead Plaintiff filed an Amended Complaint on April 1, 2024; the Amended Complaint adds a former officer as an individual defendant. The Company and individual defendants moved to dismiss the Amended Complaint on May 31, 2024; plaintiffs opposed the motion to dismiss on July 31, 2024; and the Company and individual defendants' filed a reply in support of their motion to dismiss on September 17, 2024. The court may, in its discretion, either hold an oral argument or issue a ruling on the motion to dismiss based upon the parties' briefing.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands
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NOTE 9 – MATERIAL EVENTS DURING THE PERIOD (Cont.):

B. On February 14, 2024, February 15, 2024, March 21, 2024, and April 12, 2024 four purported shareholders of the Company filed derivative action complaints against the Company as nominal defendant and certain of its officers, current and former directors, and members of its scientific advisory board, captioned Porteous v. Lebovits, et al., Case No. 1:24-cv-01095; Andrev v. Lebovits, et al., Case No. 1:24-cv-1101; and Holtzman v. Lebovits, et al., Case No. 1:24-cv-02139, and Hamby v. Lebovits, et al., Case No. 1:24-cv-02811 (the "Derivative Complaints") in the United States District Court for the Southern District of New York (the "Derivative Actions"). On April 25, 2024, the Court consolidated the Derivative Actions into a consolidated action captioned In Re Brainstorm Cell Therapeutics, Inc. Derivative Litigation, Case No. 1:24-cv-01095-DEH (the "Consolidated Derivative Action"), and appointed Co-Lead Counsel.

C. All substantive deadlines in the Consolidated Derivative Action are currently stayed pending the court's decision on the motion to dismiss in the Securities Action. Plaintiffs have not yet filed a consolidated complaint; the Derivative Actions, brought on behalf of the Company, each assert state law claims for breach of fiduciary duty and unjust enrichment against the individual defendants. The complaints in Holtzman and Hamby also assert state law claims against the individual defendants for abuse of control, gross mismanagement, corporate waste, a claim against the individual defendants for violations of Section 14(a) of the Exchange Act, and a claim against two officer defendants for contribution under Sections 10(b) and 21D of the Exchange Act. The Derivative Complaints allege that the individual defendants breached their fiduciary duties and duties under the Exchange Act in connection with the Company's internal controls relating to, as with the allegations in the Securities Complaint, NurOwn® for the treatment of ALS, the Company's submissions to and communications with the FDA in support of the approval of NurOwn® for the treatment of ALS, and the prospects of future approval of NurOwn® by the FDA their actions or omissions could not have been a good faith exercise of prudent business. The Derivative Actions seek among other things, monetary damages and disgorgement of performance-based compensation granted in connection with an allegedly inflated stock price between August 15, 2022 and September 27, 2023, as well as attorneys' fees and costs.

The Company intends to vigorously defend against the lawsuits.

D. On November 1, 2023, the Company was notified by Nasdaq of non-compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market. On May 1, 2024, Nasdaq informed the Company of a potential delisting, effective May 10, 2024, unless the Company requested a hearing. The Company appealed on May 2, 2024, and on June 3, 2024, Nasdaq granted a temporary exception until October 21, 2024, to regain compliance. To meet the requirement, the Company implemented a one-for-fifteen reverse stock split on September 30, 2024. As of October 15, 2024, the Common Stock closed above $1.00 for ten consecutive trading days, achieving compliance.

On October 29, 2024, the Company received written notice from the Nasdaq stating that the Company has regained compliance with the Minimum Bid Price Requirement and the Nasdaq Hearing Panel has decided to continue the listing of the Company's securities on Nasdaq. Accordingly, the Common Stock will continue to trade on The Nasdaq Capital Market, subject to the Company's compliance with Nasdaq's continued listing requirements.

E. On July 18, 2024, the Company received a letter (the "MVLS Deficiency Notice") from the listing qualifications department staff (the "Staff") of Nasdaq notifying the Company that from June 2, 2024 to July 17, 2024, the Company's Market Value of Listed Securities ("MVLS") was below the minimum of $35 million required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "MVLS Requirement").

The MVLS Deficiency Notice has no immediate effect on the listing of the Common Stock, and the Common Stock continues to trade on the Nasdaq Capital Market under the symbol "BCLI."
In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has 180 calendar days from the date of the MVLS Deficiency Notice, or until January 14, 2025 (the "Compliance Date"), to regain compliance with respect to the MVLS Requirement. The MVLS Deficiency Notice states that to regain compliance with the MVLS Requirement, the Company's MVLS must close at $35 million or more for a minimum of ten consecutive business days during the compliance period ending on the Compliance Date.

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NOTE 9 – MATERIAL EVENTS DURING THE PERIOD (Cont.):

If the Company does not regain compliance by the Compliance Date, Nasdaq will provide written notice to the Company that its securities are subject to delisting. At that time, the Company may appeal any such delisting determination. However, there can be no assurance that, if the Company receives a delisting notice from the Staff and appeals the delisting determination, such appeal would be successful.

The Company intends to actively monitor the Company's MVLS between now and the Compliance Date and will take all reasonable measures available to the Company to regain compliance with the MVLS Requirement. While the Company is exercising diligent efforts to maintain the listing of its Common Stock on Nasdaq, there can be no assurance that the Company will be able to regain or maintain compliance with the applicable continued listing standards set forth in the Nasdaq Listing Rules.

NOTE 10 – SUBSEQUENT EVENTS

A. The Common Stock began trading on a post-Reverse Stock Split basis on The Nasdaq Capital Market on October 1, 2024. To regain compliance, the Common Stock needed to close at above $1.00 for at least ten consecutive trading days. As of the close of trading on October 15, 2024, as a result of the Reserve Stock Split, the Common Stock had closed at above $1.00 for ten consecutive trading days.

On October 29, 2024, the Company received written notice from the Nasdaq stating that the Company has regained compliance with the Minimum Bid Price Requirement and the Nasdaq Hearing Panel has decided to continue the listing of the Company's securities on Nasdaq. Accordingly, the Common Stock will continue to trade on The Nasdaq Capital Market, subject to the Company's compliance with Nasdaq's continued listing requirements.

In accordance with ASC 855 "Subsequent Events" the Company evaluated subsequent events through the date the condensed consolidated financial statements were issued. The Company concluded that no other subsequent events have occurred that would require recognition or disclosure in the condensed consolidated financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Company Overview

Brainstorm Cell Therapeutics Inc. is a leading biotechnology company committed to the development and commercialization of best-in-class autologous cellular therapies for the treatment of neurodegenerative diseases, including ALS, also known as Lou Gehrig's disease); PMS; AD; and other neurodegenerative diseases. NurOwn®, our proprietary cell therapy platform, leverages cell culture methods to induce autologous bone marrow-derived MSCs to secrete high levels of neurotrophic factors ("NTFs"), modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival and improve neurological function.

NurOwn® has completed its Phase 3 ALS and Phase 2 PMS clinical trials. On November 17, 2020, we announced top-line data from our Phase 3 ALS trial. On March 24, 2021, we announced positive top-line data from our Phase 2 trial evaluating three repeated intrathecal administrations of NurOwn®, each given 2 months apart, as a treatment for PMS. On June 24, 2020, we announced a new clinical program focused on the development of NurOwn® as a treatment for AD. On August 15, 2022, we announced our decision to submit a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for NurOwn® for the treatment of ALS. On September 9, 2022, we filed a BLA to the FDA for NurOwn® for the treatment of ALS. On November 10, 2022, we announced that we had received a refusal to file ("RTF") letter from the FDA regarding our BLA. The FDA indicated that we may request a Type A meeting to discuss the content of the RTF letter. On December 12, 2022, we announced the submission of a Type A meeting request with the FDA to discuss the contents of the RTF letter previously issued by the FDA regarding the BLA for NurOwn® for the treatment of ALS. On December 27, 2022, we announced that the FDA granted a Type A meeting to discuss the contents of the RTF letter previously issued regarding our BLA for NurOwn® for the treatment of ALS. The Type A Meeting was held on January 11, 2023. The perspective shared by the FDA review team reflected what was in the previously issued RTF letter. Conversations with the FDA on the best pathway to resolve the outstanding questions that remained continued, following the Type A meeting. During these discussions, Brainstorm was presented with multiple options to return the BLA to regulatory review, which included the regulatory procedure to File over Protest. Additionally, within these discussions, the FDA committed to review amendments that were filed to address items raised in the RTF letter. These discussions resulted in Brainstorm requesting the FDA to file our BLA over Protest, as this was the regulatory procedure that would allow us to reach an ADCOM in the shortest amount of time. Brainstorm notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn® BLA for ALS over Protest. We received confirmation from the FDA that the BLA was re-filed on February 7, 2023. We received the FDA Type A meeting minutes on February 9, 2023. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. Written feedback was received on March 22, 2023, from the FDA project manager associated with the BLA confirming the FDA's decision to grant an ADCOM for the NurOwn® BLA for ALS. On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company's BLA for NurOwn® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 22, 2023, we submitted an amendment to our BLA to revise the indication to NurOwn® for the treatment of mild to moderate ALS. On September 27, 2023, we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that FDA invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS. Brainstorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the BLA for NurOwn® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision to withdraw the BLA was coordinated with FDA and is viewed by FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a Special Protocol Assessment ("SPA") with FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS. On April 9, 2024, the Company announced that it received written agreement from the FDA, under a SPA, on the design for a Phase 3b trial of NurOwn® in ALS. The SPA agreement with the FDA validates the clinical trial protocol and statistical analysis of the planned Phase 3b trial of NurOwn, demonstrating the Company's adequacy in addressing objectives that support a future BLA in ALS. On June 26, 2024, the Company announced that it has reached alignment with FDA on the Chemistry, Manufacturing, and Controls (CMC) aspects of Brainstorm's Phase 3b clinical trial for NurOwn (R), its investigational therapy for ALS. This Type C meeting builds upon the positive momentum established in April 2024, when the FDA granted BrainStorm a SPA agreement for its NurOwn Phase 3b trial.

Our wholly owned Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. ("Israeli Subsidiary"), holds exclusive rights to commercialize NurOwn® technology through a licensing agreement with Ramot, the technology transfer company of Tel Aviv University, Israel.

NurOwn® has a strong and comprehensive intellectual property portfolio and was granted Fast Track designation by the FDA and Orphan Drug status by the FDA and the European Medicines Agency ("EMA") for ALS.

Our human capital resource objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors and consultants to accomplish our goal of developing and launching a novel cell therapy for neurodegenerative diseases. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and our success by motivating such individuals to perform to the best of their abilities and achieve our objectives. We currently employ 29 employees in the United States and in Israel. Most of the senior management team are based in the United States, and all of our clinical trial sites for ALS and PMS from our late phase trials are in the United States. Our R&D center is located in Petach Tikva, Israel. In addition, we currently lease the GMP manufacturing center in Tel Aviv at the Sourasky Medical Center ("Sourasky Hospital") to manufacture NurOwn®. This center increases our capacity and expand our ability to manufacture and ship NurOwn® into the EU and local Israeli markets.

Recent Highlights

- On February 23, 2024, we announced the submission of a SPA request to the FDA for a planned Phase 3b clinical trial of NurOwn® for treatment of ALS.
- On February 28, 2024, Dr. Stacy Lindborg, former Co-Chief Executive Officer at Brainstorm Cell Therapeutics, provided a corporate update at 17th Annual European Life Sciences CEO Forum in Zurich, Switzerland. Dr. Lindborg also participated in a panel discussion entitled "Neuro Advances Panel: Highlighting the Main Opportunities".
- On March 4, 2024, Dr. Bob Dagher, Brainstorm Cell Therapeutics' then EVP and Chief Development Officer and current EVP and Chief Medical Officer, presented a scientific poster titled "Design of A Phase 3B Trial of Debamestrocel (NurOwn®) in ALS" the 2024 Muscular Dystrophy Association Clinical and Scientific Conference in Orlando, Florida held March 3-6, 2024. The presentation provided an overview into the key features of the phase 3b trial design.
- On April 9, 2024, the Company announced that it received written agreement from the FDA, under a SPA, on the design for a Phase 3b trial of NurOwn® in ALS. The SPA agreement with the FDA validates the clinical trial protocol and statistical analysis of the planned Phase 3b trial of NurOwn, demonstrating the Company's adequacy in addressing objectives that support a future BLA in ALS.
- On April 10, 2024, the Company announced the peer-reviewed publication of Phase 3 biomarker data in Muscle and Nerve. The paper, entitled "Debamestrocel multimodal effects on biomarker pathways in amyotrophic lateral sclerosis are linked to clinical outcomes", can be found online through the Muscle and Nerve website. This study suggests that debamestrocel or NurOwn®, an investigational cell therapy, may impact key biomarkers in ALS that are predictive of disease progression.
- On April 16, 2024, the Company announced the promotion of Dr. Bob Dagher to Executive Vice President and Chief Medical Officer. In addition, after four years of maintaining top executive roles, Dr. Stacy Lindborg stepping down from the role of Co-Chief Executive Officer and will remain with BrainStorm as a member of its Board. These strategic management changes are being made as the Company prepares to embark on a registrational Phase 3b trial for NurOwn®, its investigational cell therapy treatment for ALS.
- In May 2024, the Company presented new biomarker data suggesting that ALS patients may benefit from longer - term treatment with NurOwn (R). The Company shared the data with an international audience of patient advocacy groups, physicians, research organizations, industry representatives, key thought leaders and decision makers dedicated to ALS research at the 3rd Annual ALS Drug Development Summit in Boston. Dr. Stacy Lindborg delivered a presentation on new biomarker data from the NurOwn Expanded Access Program ("EAP") along with data from the Phase 3 trial.

- On June 20, 2024, the Company announced the appointment of Hartoun Hartounian, Ph.D. as its new EVP and COO, effective as of June 24, 2024. 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. His career highlights include founding and leading BioCentriq, a state - of - the - art cell and gene therapy CDMO facility, which was successfully acquired for $73 million in 2022.

- On June 26, 2024, the Company announced that it has reached alignment with FDA on the CMC aspects of Brainstorm's Phase 3b clinical trial for NurOwn (R), its investigational therapy for ALS. This Type C meeting builds upon the positive momentum established in April 2024, when the FDA granted BrainStorm a SPA agreement for its NurOwn Phase 3b trial.

- On October 7, 2024, the Company announced its participation in the 2024 Maxim Healthcare Virtual Summit. On October 15, Chaim Lebovits joined Jason McCarthy, Ph.D., Senior Managing Director and Head of Biotechnology Research at Maxim Group for a Fireside Chat. During the session, Mr. Lebovits provided an update on the planned Phase 3b clinical trial for NurOwn®, the company's investigational cell therapy for ALS. This event presents a valuable opportunity to engage with the investment community and share in-depth insights into the upcoming trial.

- On October 28, 2024, the Company announced the presentation of two posters featuring NurOwn® (MSC-NTF0 or debamestrocel) at the 2024 Annual Northeastern Amyotrophic Lateral Sclerosis Consortium (NEALS) Meeting, which took place virtually October 21 – 24. The posters 'Debamestrocel Long-Term Benefits on Survival and Neurodegeneration in ALS Expanded Access Program' and 'An Overview of The Phase 3b Clinical Trial of Debamestrocel in ALS' highlight the results achieved with ALS patients who participated in the Expanded Access Program (EAP) for NurOwn and summarize the details of BrainStorm's upcoming Phase 3b trial in ALS.

- On October 30, 2024, the Company announced that on October 29, 2024, the Company received written notice from The Nasdaq Stock Market stating that the Company has regained compliance with the minimum closing bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.

- Accordingly, the Company's common stock will continue to trade on The Nasdaq Capital Market, subject to the Company's compliance with Nasdaq's continued listing requirements.

- On November 11, 2024, the Company announced that it has entered into a Memorandum of Understanding (MOU) with Pluri Inc. (NASDAQ: PLUR) through its wholly owned subsidiary ("Pluri"), an established global leader in the development and manufacturing of cell-based therapeutics, to manufacture NurOwn® for use in BrainStorm's planned Phase 3b trial in amyotrophic lateral sclerosis (ALS). This MOU enables BrainStorm to begin transfer of its manufacturing technology and start producing NurOwn at Pluri's manufacturing facility upon finalizing the binding definitive agreement.

NurOwn® Proprietary Technology

NurOwn® technology is based on an innovative manufacturing protocol, which induces the differentiation of purified and expanded bone marrow-derived MSC and consistently generates cells that release high levels of multiple neurotrophic factors ("MSC-NTF" cells) to modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival and improve neurological function. These factors are known to be critical for the growth, survival and differentiation of neurons, including: glial-derived neurotrophic factor ("GDNF"); brain-derived neurotrophic factor ("BDNF"); vascular endothelial growth factor ("VEGF"); hepatocyte growth factor ("HGF"), and Galectin-1 among others. VEGF is one of the most potent neuronal and motor neuron survival factors and has demonstrated important neuroprotective effects in ALS and several other neurodegenerative diseases.

NurOwn® manufacturing involves a multi-step process that includes the following: harvesting and isolating undifferentiated stem cells from the patient's own bone marrow; processing of cells at the manufacturing site; cryopreservation of MSC to enable multiple treatments from a single bone marrow sample; and intrathecal administration of MSC-NTF cells into the same patient by standard lumbar puncture. This administration procedure does not require hospitalization and has been shown to be generally well tolerated in multiple CNS clinical trials to date. The completed NurOwn® U.S. Phase 3 ALS and the NurOwn® U.S. Phase 2 PMS trials evaluated the therapeutic potential of repeated intrathecal MSC-NTF cell administration (three doses at bi-monthly intervals). Our highest priority is to obtain regulatory approval of NurOwn® for ALS. We are also strategically focused on fully executing the clinical development of NurOwn® in PMS, reviewing the optimal approach in AD and will consider the best course of action based on recent scientific and regulatory insights.

The proprietary technology and manufacturing processing of NurOwn® (MSC-NTF cells) for clinical use is conducted in full compliance with current Good Manufacturing Practice. The NurOwn® proprietary technology is fully owned or developed by our Israeli Subsidiary. All granted patents related to NurOwn® (MSC-NTF cells) manufacturing process are fully assigned to or owned by our Israeli Subsidiary (please see Intellectual Property section for details).

The NurOwn® Treatment Process

- Bone marrow aspiration from the patient;
- MSC Isolation and propagation;
- MSC Cryopreservation;
- MSC thawing and differentiation into neurotrophic-factor secreting (MSC-NTF; NurOwn®) cells; and
- Intrathecal administration into the patient's cerebrospinal fluid by standard lumbar puncture.

Differentiation before Treatment

We believe that the ability to induce autologous adult MSCs into differentiated MSC-NTF cells makes NurOwn® uniquely suited for the treatment of neurodegenerative diseases.

The specialized MSC-NTF cells secrete multiple neurotrophic factors and immunomodulatory cytokines that may result in:

- Protection of existing neurons;
- Promotion of neuronal repair;
- Neuronal functional improvement; and
- Immunomodulation and reduced neuroinflammation.

Autologous treatment

The NurOwn® technology platform is autologous, using the patient's own bone-marrow derived stem cells for treatment. In autologous cellular treatment, there is no introduction of unrelated donor antigens that may lead to alloimmunity, no risk of rejection, and no need for treatment with immunosuppressive agents, which can cause severe and/or long-term side effects. In addition, the use of adult, autologous stem cells is free of several ethical concerns associated with the use of embryonic-derived stem cells in some countries.

NurOwn® ALS Clinical Program

We announced top-line data from the Phase 3 clinical trial of NurOwn® in ALS on November 17, 2020. We have been granted Fast Track designation by the FDA for this indication, and have been granted Orphan Drug Status, in the U.S. and Europe, which provides us the potential for an extended period of exclusivity. On August 15, 2022, we announced our decision to submit a BLA to the FDA for NurOwn® for the treatment of ALS. The BLA was filed on September 9, 2022. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA. The FDA indicated that we could request a Type A meeting to discuss the content of the RTF letter, and Type A meeting was held on January 11, 2023. On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company's BLA for NurOwn® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 22, 2023, we submitted an amendment to our BLA to revise the indication to NurOwn® for the treatment of mild to moderate ALS. On September 27, 2023 we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that the FDA invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS. Brainstorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the BLA for NurOwn® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision to withdraw the BLA was coordinated with the FDA and is viewed by the FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company

a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a SPA with the FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS. On April 9, 2024, the Company announced that it received written agreement from the FDA, under a SPA, on the design for a Phase 3b trial of NurOwn® in ALS. The SPA agreement with the FDA validates the clinical trial protocol and statistical analysis of the planned Phase 3b trial of NurOwn, demonstrating the Company's adequacy in addressing objectives that support a future BLA in ALS. On June 26, 2024, the Company announced that it has reached alignment with FDA on the CMC aspects of Brainstorm's Phase 3b clinical trial for NurOwn (R), its investigational therapy for ALS. This Type C meeting builds upon the positive momentum established in April 2024, when the FDA granted BrainStorm a SPA agreement for its NurOwn Phase 3b trial.

Phase 1/2 ALS Open Label Trials

We have completed two early stage Phase 1/2 and 2 open-label clinical trials of NurOwn® in patients with ALS at the Hadassah Medical Center in Jerusalem, Israel, as well as a Phase 2 double-blind, placebo-controlled, multicenter clinical trial at three prestigious U.S. Medical centers - the Massachusetts General Hospital ("MGH") in Boston, Massachusetts Memorial Hospital in Worcester, Massachusetts, and the Mayo Clinic in Rochester, Minnesota - all highly experienced in the management, investigation, and treatment of ALS.

The first two open-label trials were approved by the Israeli Ministry of Health ("MoH"). The first-in-human trial, a Phase 1 safety and efficacy trial of NurOwn® administered either intramuscularly or intrathecally in 12 ALS patients, was initiated in June 2011. In the Phase 2 dose-escalating study, 14 ALS patients were administered NurOwn® by a combined route of intramuscular and intrathecal administration. These studies demonstrated the tolerability of NurOwn® by both routes of administration and showed preliminary signs of activity.

In January 2016, the results of the two completed Phase 1/2 study and Phase 2 open label trials were published in JAMA Neurology. The results demonstrated a slower rate of disease progression following MSC-NTF cell treatment as measured by the ALSFRS-R, the gold standard for the evaluation of ALS functional status, and Forced Vital Capacity, a measure of pulmonary function, as well as positive trends in the rate of decline of muscle volume and the compound motor axon potential. This was the first published clinical data using autologous MSCs induced under culture conditions to produce NTFs, with the potential to deliver a combined neuroprotective and immunomodulatory therapeutic effect in ALS and potentially modify the course of this disease.

Phase 2 ALS Randomized Trial

The Phase 2 U.S. study was conducted under an FDA Investigational New Drug application. This randomized, double-blind, placebo-controlled multi-center U.S. Phase 2 clinical trial evaluating NurOwn® in ALS patients was conducted at three clinical sites: (i) the MGH in Boston, (ii) Massachusetts Memorial Hospital in Worcester, Massachusetts, and (iii) the Mayo Clinic in Rochester, Minnesota. For this trial, NurOwn® was manufactured at the Connell and O'Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute in Boston and at the Human Cellular Therapy Lab at the Mayo Clinic. In this study, 48 patients were randomized 3:1 to receive NurOwn® or placebo.

Results of this Phase 2 Study were published in the peer reviewed Journal 'Neurology'. The publication titled "NurOwn, Phase 2, Randomized, Clinical Trial in Patients with ALS: Safety, Clinical, and Biomarker Results" was published in December 2019.

Key findings from the trial were as follows:

The study achieved its primary objective, demonstrating that NurOwn® treatment was well-tolerated. There were no discontinuations from the trial due to adverse events ("AEs") and there were no deaths in the study. The most common AEs of mild or moderate severity, were transient procedure-related AEs such as headache, back pain, pyrexia arthralgia and injection-site discomfort, which were more commonly seen in the NurOwn®-treated participants compared to placebo.

NurOwn® achieved multiple secondary efficacy endpoints, showing evidence of a clinically meaningful benefit. Notably, response rates in the ALS functional rating scale (48-point ALSFRS-R outcome measure) were higher in NurOwn®-treated participants, compared to placebo, at all study timepoints over 24 weeks.

A pre-specified responder analysis examined percentage improvements in the post treatment ALSFRS-R slope (in points change per month) compared to pre-treatment slope and demonstrated that a higher proportion of NurOwn® treated participants achieved a 100% improvement in the post-treatment vs. pre-treatment slope, compared to the placebo group. This analysis also demonstrated that a higher proportion of the NurOwn® treated participants achieved a 1.5 point per month or greater improvement in the post-treatment vs. pre-treatment ALSFRS-R slope, compared to the placebo group.

The treatment effects were greater in the rapid progressor subgroup (a pre-specified definition, in which pretreatment ALSFRS-R declined by 2 or more points in the three months pre-treatment).

As an important confirmation of NurOwn®'s mechanism of action, levels of neurotrophic factors and inflammatory markers were measured in the cerebrospinal fluid ("CSF") samples collected from participants pre-treatment and two weeks post treatment. In the samples of those participants treated with NurOwn®, statistically significant increases in levels of neurotrophic factors VEGF, HGF and LIF and a statistically significant reduction in inflammatory markers MCP-1, SDF-1 and CHIT-1 were observed post-treatment. Furthermore, the observed reduction in inflammatory markers correlated with ALS functional improvements. These clinical-biomarker correlations were not seen in placebo-treated participants, consistent with the proposed combined neuroprotective and immunomodulatory mechanism of action of NurOwn® in ALS.

In summary, a higher proportion of NurOwn® treated participants, particularly those with more rapid disease progression, experienced stabilization or improvement in ALS function, as measured by the change in post-treatment vs. pre-treatment ALSFRS-R rate of decline or slope.

Phase 3 ALS Clinical Trial

Following successful completion of the Phase 2 study, we conducted a Phase 3 trial (a multi-dose double-blind, placebo-controlled, multicenter trial protocol) that was designed to generate data to potentially support a BLA submission in the U.S. for NurOwn® in ALS. In October 2019, the clinical trial completed enrollment of an enriched patient population of rapid progressors based on superior outcomes observed in the Phase-2 pre-specified sub-group. The study is registered at www.clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT03280056).

We announced top-line data from our Phase 3 ALS trial on November 17, 2020. Results from the trial showed that NurOwn® was generally well tolerated in the population of rapidly progressing ALS patients. However, the trial did not reach statistically significant results. No new safety concerns were identified. On February 9, 2021, we announced feedback from our Type-C Meeting with the FDA to review specific aspects of our planned manufacturing modifications to support the development of a semi-automated commercial manufacturing process for NurOwn® (MSC-NTF cell). On February 22, 2021, we announced high-level FDA feedback on NurOwn® ALS clinical development program. The FDA concluded from their initial review that the clinical data provided at the time did not provide the threshold of substantial evidence that the FDA seeks to support a BLA. In addition, the FDA advised that this recommendation did not preclude the Company from proceeding with a BLA submission.

Key findings from the trial were as follows (which include the update to the data published in Muscle & Nerve 65(3):291-302 on August 12, 2022):

- NurOwn® was generally well tolerated in this population of rapidly progressing ALS patients.
- While showing a numerical improvement in the treated group compared to placebo across the primary and key secondary efficacy endpoints, the trial did not reach statistically significant results.
- The primary efficacy endpoint, a responder analysis evaluating the proportion of participants who experienced at least a 1.25 points per month improvement in the post-treatment ALSFRS-R slope compared to pre-treatment, was powered on assumed treatment response rates of 35% on NurOwn® versus 15% on Placebo. These estimates were based on available historical clinical trial data and the NurOwn® Phase 2 data. The response definition for the primary endpoint was met by 32.6% of NurOwn® participants versus 27.7% for Placebo (p=0.453). Therefore, the trial met the expected ~35% NurOwn® treatment group efficacy response assumption, however the high rate of response in placebo participants exceeded the placebo response expected based on contemporary ALS trials.

- The secondary efficacy endpoint measuring average change in ALSFRS-R total score from baseline to Week 28, was -5.52 with NurOwn® versus -5.88 on Placebo, a difference of 0.36 (p= 0.693).

- In an important, pre-specified subgroup early in the disease course based on an ALSFRS-R baseline score of 35 or greater, NurOwn® demonstrated a clinically meaningful treatment response across the primary and key secondary endpoints and remained consistent with our pre-trial, data-derived assumptions. In this subgroup, there were 34.6% responders who met the primary endpoint definition on NurOwn® and 15.6% on Placebo (p=0.305), and the average change from baseline to week 28 in ALSFRS-R total score was -1.56 on NurOwn® and -3.65 on Placebo (p=0.050), an improvement of 2.09 ALSFRS-R points favoring NurOwn®.

- Additional sensitivity analyses have demonstrated consistent treatment effects with NurOwn® after accounting for the impact of the ALSFRS-R floor effect. Two methods include: (1) Total Score Threshold ("TST"), which removed participants with ALSFRS-R scores ≤ 25; and (2) Item Level Threshold ("ITL"), which removed participants with a baseline score of 0 or 1 in at least 5 of 6 of the ALSFRS-R's Fine and Gross Motor scale items. Applying the TST and ITL sensitivity analysis methods resulted in the exclusion of 23% (n=44) and 16% (n=30) of trial participants from analyses, respectively. Both the TST and ILT sensitivity analysis methods show that, after controlling for the impact of the ALSFRS-R floor effect, participants treated with NurOwn® had a higher rate of clinical response (primary endpoint) and less function lost across 28 weeks (secondary endpoint), compared to placebo. Additional post-hoc analyses published for the secondary endpoint (average change from baseline in ALSFRS-R), showed a statistically significant benefit following treatment with NurOwn® in all subgroups with ALSFRS-R baseline total score of at least 26 to 35 (p≤0.050).

- The NurOwn® Phase 3 trial enrolled a broad set of participants, including some with advanced ALS disease (ALSFRS-R≤25) at baseline, making this trial subject to the impact of floor effects of the ALSFRS-R and reduced ALSFRS-R sensitivity. A post-hoc analysis was done using participants with baseline ALSFRS-R>25 for the primary endpoint and the % response for NurOwn® was 34.7% and 20.5% for Placebo, p=0.053. This analysis suggests a treatment effect with NurOwn® in participants with less advanced disease. CSF biomarker analyses confirmed that treatment with NurOwn® resulted in a statistically significant increase of neurotrophic factors (VEGF) and reduction in neurodegenerative (neurofilament) and neuroinflammatory biomarkers (MCP-1) that was not observed in the placebo treatment group.

- Pre-specified statistical modeling designed to predict clinical response with high sensitivity and specificity based on ALS biomarkers and ALS Function confirmed that NurOwn® treatment outcomes could be predicted by baseline ALS function as well as key CSF neurodegenerative and neuroinflammatory biomarkers. Additional analyses focused on the trajectory of biomarkers for the subgroups of participants with baseline ALSFRS-R scores >25 and ≤25, those most likely to be impacted by the floor effect of the scale, indicate that NurOwn® had similar biological effects on ALS participants regardless of the level of disease progression at baseline. Specifically, we observe decreases in neuroinflammatory and neurodegenerative markers and increases in neuroprotective markers in NurOwn® treated participants compared to placebo in both subgroups.

Decision to Submit BLA

New clinical analyses of NurOwn's® Phase 3 clinical trial in ALS published August 12, 2022, led to a correction of data originally published in Muscle & Nerve in December 2021 and strengthened the Company's original conclusions from the trial. The correction resulted in a statistically significant treatment difference (p=0.050) of more than 2 points for an important secondary endpoint, average change from baseline in ALSFRS-R, in the pre-specified efficacy subgroup of participants with a baseline score of at least 35. Analyses reported in the original publication utilized an efficacy model that unintentionally deviated from the trial's pre-specified statistical analysis plan by erroneously incorporating interaction terms between the subgroup and treatment. The newly published results employ the efficacy model as pre-specified in the trial's statistical analysis plan, correcting the analyses. The correction also relates to the other subgroup analyses published for this endpoint, demonstrating that all subgroups with ALSFRS-R baseline scores of greater than 26 to 35 showed a statistically significant benefit following treatment with NurOwn® (p≤0.050).

On August 15, 2022, we announced the decision to submit a BLA to the FDA for NurOwn® for the treatment of ALS. The BLA was filed on September 9, 2022. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA for NurOwn® for the treatment of ALS. The FDA informed us that the BLA is not sufficiently complete to enable a substantive review and that the FDA would therefore not file the BLA. The RTF letter contained a list of topics the FDA provided to Brainstorm as rationale for the BLA file being not sufficiently complete to enable a substantive review. According to the FDA, these reasons included one item

related to the trial not meeting the standard for substantial evidence of effectiveness and CMC related items. The FDA indicated that we may request a Type A meeting to discuss the content of the RTF letter. On December 12, 2022, we announced the submission of a Type A meeting request with the FDA to discuss the contents of the RTF letter previously issued by the FDA regarding the BLA for NurOwn® for the treatment of ALS. On December 27, 2022, we announced that the FDA granted a Type A meeting to discuss the contents of the RTF letter previously issued regarding our BLA for NurOwn® for the treatment of ALS. The Type A Meeting was held on January 11, 2023.

The perspective shared by the FDA review team reflected what was in the previously issued RTF letter. Conversations on the best pathway to resolve the outstanding questions that remained continued, following the Type A meeting. During these discussions, Brainstorm was presented with multiple options to return the BLA to regulatory review, which included the regulatory procedure to File over Protest. Additionally, within these discussions, the FDA committed to review amendments that were filed to address items raised in the RTF letter. These discussions resulted in Brainstorm requesting the FDA to file our BLA over Protest, as this was the regulatory procedure that would allow us to reach an ADCOM in the shortest amount of time. Brainstorm notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn® BLA for ALS over Protest. We received confirmation from the FDA that the BLA was re-filed on February 7, 2023.

We received the FDA Type A meeting minutes on February 9, 2023. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. Written feedback was received on March 22, 2023, from the FDA project manager associated with the BLA confirming the FDA's decision to grant an ADCOM for the NurOwn® BLA for ALS. On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company's BLA for NurOwn® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 22, 2023, we submitted an amendment to our BLA to revise the indication to NurOwn® for the treatment of mild to moderate ALS. On September 27, 2023 we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that the FDA invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS. Brainstorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the BLA for NurOwn® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision to withdraw the BLA was coordinated with the FDA and is viewed by the FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a SPA with the FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS. On April 9, 2024, the Company announced that it received written agreement from the FDA, under a SPA, on the design for a Phase 3b trial of NurOwn® in ALS. The SPA agreement with the FDA validates the clinical trial protocol and statistical analysis of the planned Phase 3b trial of NurOwn, demonstrating the Company's adequacy in addressing objectives that support a future BLA in ALS. On June 26, 2024, the Company announced that it has reached alignment with FDA on the CMC aspects of Brainstorm's Phase 3b clinical trial for NurOwn (R), its investigational therapy for ALS. This Type C meeting builds upon the positive momentum established in April 2024, when the FDA granted BrainStorm a SPA agreement for its NurOwn Phase 3b trial.

NurOwn® Clinical Manufacturing

We have developed a validated cryopreservation process for the long-term storage of MSC, that allows multiple doses of NurOwn® to be created from a single bone marrow harvest procedure in the multi-dose clinical trials and to avoid the need for patients to undergo repeated bone marrow aspiration. A validation study was conducted in 2017 comparing NurOwn® derived from fresh MSC to those derived from cryopreserved MSC. Company scientists were successful in showing that the MSC can be stored in the vapor phase of liquid nitrogen for prolonged periods of time, while maintaining their characteristics. Cryopreserved MSC are capable of differentiating into NurOwn®, similar to the NurOwn® derived from fresh MSC from the same patient/donor, prior to cryopreservation and maintain their key functional properties including immunomodulation and neurotrophic factor secretion.

We contracted with City of Hope's Center for Biomedicine and Genetics to manufacture clinical supplies of NurOwn® adult stem cells for our Phase 3 clinical study. City of Hope supported the manufacturing of NurOwn® and placebo for the participants treated in the Phase 3 study. The Connell and O'Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute ("DFCI") in Boston was also contracted to manufacture NurOwn® and placebo for our Phase 3 ALS clinical study participants and commenced manufacturing in October 2018. DFCI core manufacturing facility also supplied NurOwn® for our Phase 2 PMS study.

On October 22, 2020, we announced a partnership with Catalent, the leading global provider of advanced delivery technologies, to manufacture NurOwn®, which has been evaluated for the treatment of ALS in our Phase 3 clinical trial. If we receive FDA approval for NurOwn® in ALS, Catalent will be our partner for manufacturing commercial quantities of NurOwn® to treat patients with ALS. Our technology transfer to Catalent Houston was successfully completed and enabled continuous supply of NurOwn® for the EAP.

As of November 1, 2023, the Company optimized its manufacturing capabilities, particularly in the production of NurOwn®, by strategically leveraging partnerships and optimizing operational resources. The Company currently leases a GMP-certified cleanroom manufacturing center located at Sourasky Hospital, which serves as a critical hub for the production and distribution of NurOwn®. This facility significantly enhances the Company's capacity to manufacture and distribute NurOwn® within both the European Union (EU) and local Israeli markets.

On December 7, 2021, we and Catalent announced completion of technology transfer for NurOwn® manufacturing at the Catalent's cell therapy facility in Houston, Texas.

Catalent Houston manufactured NurOwn® for the EAP. As of December 31, 2022, seven participants have completed treatment with NurOwn® that was manufactured at the Catalent facility as well as all Expanded Access protocol follow-up visits. We are currently negotiating a contract with a leading manufacturing contract development organization.

Meetings with the FDA and FDA Senior Management

In July 2019, the Brainstorm management team was invited to participate in a special in-person, high-level meeting with the senior management of the FDA Drug and Biologics Centers and, 'I AM ALS', a grassroots ALS advocacy group advocating for an ALS cure. FDA's Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research ("CBER") and Dr. Janet Woodcock Director, former of the Center for Drug Evaluation and Research ("CDER") were in attendance with senior FDA staff. Brainstorm's Phase 3 ALS principal Investigators Dr. Robert Brown (Massachusetts Memorial Hospital, Worcester, Massachusetts) and Dr. Merit Cudkowicz (MGH, Boston) joined by teleconference. The meeting's purpose was to discuss Brainstorm's ongoing Phase 3 ALS clinical trial as well as efforts to speed treatment access to the ALS patient community. The meeting enabled an open and effective dialogue between the FDA and Brainstorm, setting the stage for future meetings to explore practical options to quickly bring our investigational treatment to those living with ALS.

On February 11, 2020, we announced that we held a high-level meeting with the FDA to discuss potential NurOwn® regulatory pathways for approval in ALS. In the planned meeting with senior CBER leadership and several leading U.S. ALS experts, the FDA confirmed that the Phase 3 ALS trial was collecting relevant data critical to the assessment of NurOwn® efficacy. The FDA indicated that they would look at the "totality of the evidence" in the expected Phase 3 clinical trial data.

On February 9, 2021, we announced feedback on a Type-C Meeting with the FDA on future NurOwn® manufacturing plans and to review specific aspects of our planned manufacturing modifications to support the development of a semi-automated commercial manufacturing process for NurOwn® (MSC-NTF cell). The meeting included a detailed review of the requirements for comparability testing to support future modifications along with geographic considerations in the sourcing of starting materials and future manufacturing production. We plan to incorporate feedback from the FDA meeting in 2021, our experience from Phase 3 manufacturing, in addition to feedback received in recent interactions with FDA including the Type A meeting on December 6, 2023, to formalize our plan to satisfy FDA's expectations for CMC for a product in Phase 3 development.

On February 22, 2021, we announced high-level FDA feedback on NurOwn® ALS Clinical Development Program. The FDA concluded from their initial review that the current level of clinical data does not provide the threshold of substantial evidence that the FDA is seeking to support a BLA. In addition, the FDA advised that this recommendation does not preclude the Company from proceeding with a BLA submission. Following extensive consultations with principal investigators, ALS experts, expert statisticians, regulatory advisors, and ALS advocacy groups to discuss the best path forward to provide NurOwn® for ALS patients, Brainstorm filed a BLA on September 9, 2022. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA, which informed us that the BLA was not sufficiently complete to enable a substantive review and that the FDA. The RTF letter contained a list of topics the FDA provided to BrainStorm as rationale for the BLA file being not sufficiently complete to enable a substantive review. According to the FDA, these reasons included one item related to the trial not meeting the standard for substantial evidence of effectiveness and CMC related items. The FDA indicated that we could request a Type A meeting to discuss the content of the RTF letter, and the Type A meeting was held on January 11, 2023. We notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn® BLA for ALS over Protest. Written feedback was received on March 22, 2023 from the FDA project manager associated with the BLA confirming the FDA's decision to grant an ADCOM for the NurOwn® BLA for ALS. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. The BLA for NurOwn® to treat ALS is currently under active review by the FDA.

On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company's BLA for NurOwn® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 22, 2023, we submitted an amendment to our BLA to revise the indication to NurOwn® for the treatment of mild to moderate ALS. On September 27, 2023 we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that the FDA invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS. Brainstorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the BLA for NurOwn® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision to withdraw the BLA was coordinated with the FDA and is viewed by the FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a SPA with the FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS. On April 9, 2024, the Company announced that it received written agreement from the FDA, under a SPA, on the design for a Phase 3b trial of NurOwn® in ALS. The SPA agreement with the FDA validates the clinical trial protocol and statistical analysis of the planned Phase 3b trial of NurOwn, demonstrating the Company's adequacy in addressing objectives that support a future BLA in ALS. On June 26, 2024, the Company announced that it has reached alignment with FDA on the CMC aspects of Brainstorm's Phase 3b clinical trial for NurOwn (R), its investigational therapy for ALS. This Type C meeting builds upon the positive momentum established in April 2024, when the FDA granted BrainStorm a SPA agreement for its NurOwn Phase 3b trial.

ALS Expanded Access Program

On December 14, 2020, we announced the NurOwn® EAP through which NurOwn® would be made available for ALS patients who completed all Phase 3 scheduled treatments and follow-up assessments and meet specific eligibility criteria.

The protocol for the EAP was developed in partnership with the FDA to provide access to NurOwn® for Phase 3 clinical trial participants who meet specific eligibility criteria. Initially, participants less severely affected by ALS, as measured by ALSFRS-R, were the first to receive treatment. This approach is informed by recently announced top-line data from the Company's Phase 3 clinical trial. According to the FDA, EAPs, alternatively known as "compassionate use" programs, provide a pathway for patients to receive an investigational medicine for a serious disease or condition outside of a clinical trial.

Through the EAP, the six clinical centers participating in the Phase 3 NurOwn® trial each had the opportunity to treat ALS participants who completed the trial. These six centers are: University of California, Irvine; Cedars-Sinai Medical Center; California Pacific Medical Center; MGH; University of Massachusetts Medical School; and the Mayo Clinic. EAP treatment of ALS participants who have completed the Phase 3 clinical trial did not interfere with data or regulatory timelines. The Cell Manipulation Core Facility ("CMCF") at the Dana Farber Cancer Institute manufactured the investigational therapy, assisted by on-site Brainstorm personnel.

In the course of 2021, 10 eligible patients that had completed the Phase 3 study, were enrolled in the EAP at the six participating medical centers to receive three additional doses of NurOwn® eight weeks apart. Eight patients completed the program receiving all three treatment doses. Two participants withdrew consent after receiving two treatment doses. There were no serious adverse events AEs in the treated participants.

On December 27, 2021, we announced plans for a dosing extension of NurOwn® for participants who completed the EAP. The FDA recommended that Brainstorm submit an EAP protocol amendment to provide additional dosing for these participants. Under the original EAP protocol, participants who had completed the Phase 3 NurOwn® trial and who met specific eligibility criteria had the opportunity to receive 3 doses of NurOwn®. Under the amended EAP protocol, these eligible participants will receive up to 3 additional doses. Data collected from the original EAP treatments informed the decision to move forward with additional doses for participants who completed it. Seven participants completed treatment with NurOwn® manufactured at the Catalent Houston manufacturing site and all follow-up visits.

Patient Access Programs (ALS)

The Company, had worked collaboratively with the Sourasky Hospital, to treat ALS patients with NurOwn®, under the Israel Hospital Exemption ("HE") regulatory pathway for Advanced Therapy Medicinal Products ("ATMP"), which was adopted by the Israeli MoH from the EMA regulation. Between the first quarter of 2019 and the fourth quarter of 2020, the Company enrolled and treated 12 ALS patients with NurOwn®, under the HE pathway. The Company received $3.4 million in gross proceeds in connection with the treatment of the aforementioned patients, which did not cover the costs of the trial. The remaining cost associated with the HE pathway were paid by Brainstorm.

NurOwn® in Progressive Multiple Sclerosis (PMS)

On December 15, 2018, the FDA approved the Company's IND to conduct a Phase 2 open-label trial of repeated intrathecal administration of NurOwn® in PMS (www.clinicaltrials.gov Identifier NCT03799718). The study titled "A Phase 2, open-label, multicenter study to evaluate the safety and efficacy of repeated administration of NurOwn® (Autologous Mesenchymal Stem Cells Secreting Neurotrophic Factors; MSC-NTF cells) in participants with PMS was designed to recruit 20 PMS participants at 5 leading U.S. Multiple Sclerosis centers.

On December 18, 2019, the clinical trial independent Data Safety Monitoring Board ("DSMB") for the U.S. Phase 2 PMS study completed the first, pre-specified interim analysis, of safety outcomes for the first 9 participants enrolled in the study. After careful review of all available clinical trial data, the DSMB unanimously concluded "the study should continue as planned without any protocol modification".

In August 2021, the clinical trial independent DSMB for the U.S. Phase 2 PMS study issued an end-of-study statement concluding that, based on the data, the procedures and treatment involved in BCT-101-US were relatively safe and tolerable. Given that the study was "open-label" with no active comparator arm(s), it was not possible to evaluate efficacy, except through comparison to non-contemporaneous natural history data sets or to prior clinical trials of similar populations.

Phase 2 PMS Clinical Trial

On March 24, 2021, the Company announced positive top-line data in the Phase 2 study evaluating three repeated administrations of NurOwn®, each given 2 months apart, as a treatment for PMS. The 28-week open-label Phase 2 clinical trial enrolled 20 primary and secondary PMS patients based on the 2017 revised McDonald Criteria, ages 18-65, with baseline Expanded Disability Status Scale ("EDSS") scores between 3-6.5, without evidence of relapse within 6 months of enrollment, able to walk 25 feet in 60 seconds or less and were permitted to be on a stable dose of disease modifying therapy. Of the 20 patients enrolled, 18 were treated and 16 (80)% completed the study. Two patients discontinued related to procedure-related AEs. There were no study deaths or AEs related to multiple sclerosis ("MS") worsening. The mean age of study patients was 47, 56% were female, and mean baseline EDSS score was 5.4. The clinical trial compared clinical efficacy outcomes with a 48-patient matched clinical cohort from the Comprehensive Longitudinal Investigations in MS at the Brigham & Woman's Hospital (CLIMB Study). MS Function and Cognition measures in the top-line results included the timed 25-foot walk (T25FW); 9-hole peg test (9-HPT); Low Contrast Letter Acuity (LCLA); Symbol Digit Modality Test (SDMT); and the 12 item MS Walking Scale (MSWS-12).

Key findings from the trial were as follows:

- Prespecified 25% improvements in the timed T25FW and 9-HPT (combined average) from baseline to 28 weeks were observed in 14% and 13% of NurOwn® treated patients, respectively, and improvement in 9-HPT (combined average) was observed in 0% of the pre-specified matched historical controls in the CLIMB registry.

- 38% of NurOwn® treated patients showed at least a 10-point improvement in the MSWS-12 from baseline to week 28, a patient reported outcome that evaluates walking function.

- 47% of NurOwn® treated patients showed at least an 8-letter improvement across 28 weeks in the LCLA binocular 1.25%, a visual function test. Additionally, 27% of NurOwn® treated patients showed at least an 8-letter improvement across 28 weeks in the LCLA binocular 2.5%,

- 67% of NurOwn® treated patients showed at least a 3-point improvement in the SDMT, a measure of cognitive processing.

- NurOwn® treated patients showed a mean improvement from baseline of 10% in T25FW and a 4.8% improvement from baseline on the 9-HPT dominant hand, compared to 1.8% and 1.4% worsening respectively in matched historical controls from the CLIMB registry.

- NurOwn® treated patients showed a 6% improvement from baseline in MSWS-12.

All results reported are based on observed data. Cerebrospinal fluid (CSF) biomarkers were obtained at 3 consecutive time points, just prior to each intrathecal administration of NurOwn®. We observed increases in neuroprotective molecules (VEGF, HGF) and decreases in neuroinflammatory biomarkers (MCP-1, and Osteopontin).

Additionally, we completed secondary efficacy data and detailed CSF and blood biomarker analyses. We presented a detailed summary of the study outcomes at the 37th Congress of the ECTRIMS on October 14, 2021 and published our findings in the peer reviewed journal Multiple Sclerosis Journal in September 15, 2022. We are currently considering how best to advance NurOwn® as an innovative treatment option in PMS.

NurOwn® in Alzheimer's Disease (AD)

On June 24, 2020, we announced a new clinical program focused on the development of NurOwn® as a treatment for AD. We are currently evaluating next steps based on emerging scientific insights and the changing regulatory landscape for AD following the recent FDA decision to grant accelerated approval of Aducanumab and pending regulatory reviews of other investigational anti-amyloid therapies.

While many AD therapies have focused on a single target such as tau or beta-amyloid, we believe NurOwn® has the capability to simultaneously target multiple relevant biological pathways and bring a comprehensive approach to this multifactorial disease. Importantly, NurOwn®'s mechanism of action may allow the therapy to enable synergistic combinations with anti-tau or anti-beta-amyloid treatments, further underscoring its potential to address critical unmet needs in AD. In such a complex disease, addressing inflammation and neuroprotection is an innovative approach and a first in the world for this technology.

Non-Dilutive Funding

In July 2017, we were awarded a grant in the amount of $15,912,390 from the California Institute for Regenerative Medicine (CIRM) to aid in funding the Company's pivotal Phase 3 study of NurOwn®, for the treatment of ALS. We received $12,550,000 of the CIRM grant from 2017 2019: $9,050,000 from 2017 through 2018, and an additional $3,500,000 in 2019. On March 16, 2020, we received $2,200,000 from CIRM for achieving our pre-determined milestones. In July 2020, we received an additional $700,000 for making further progress in our Phase 3 study. On December 1, 2020, we received our final payment of $462,390. We have now received in full the total amount of the $15,912,390 grant funding awarded by CIRM. The grant does not bear a royalty payment commitment nor is the grant otherwise refundable.

On November 14, 2019, we were awarded a $495,330 grant from the National Multiple Sclerosis Society (NMSS), through its Fast Forward program, for serum and CSF biomarkers analysis in Brainstorm's Phase 2 open-label, multicenter clinical trial of repeated intrathecal administration of NurOwn® in participants with PMS. As of September 30, 2024, we have received $352,156 out of the $495,330 awarded.

On June 9, 2020, we announced that The ALS Association and I AM ALS have awarded us a combined grant of $500,000 to support an ALS biomarker research study. The grant will be used to draw insights from data and samples collected from patients who participated in Brainstorm's Phase 3 clinical trial and treated with NurOwn®, and to further the understanding of critical biomarkers associated with treatment response for people with ALS. As of September 30, 2024, we have received $400,000 out of $500,000 awarded.

Intellectual Property

A key element of our overall strategy is to establish a broad portfolio of patents and other methods described below to protect its proprietary technologies and products. Brainstorm is the sole licensee or assignee of 27 granted patents, and 23 patent applications in the United States, Canada, Europe, Israel and Brazil, as well as in additional countries worldwide, including countries in the Far East and South America (in calculating the number of granted patents and patent applications, each European patent validated in multiple jurisdictions was counted as a single patent).

On February 18, 2020, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 10,564,149 titled 'Populations of Mesenchymal Stem Cells That Secrete Neurotrophic Factors'. The allowed claims cover a pharmaceutical composition for MSC-NTF cells secreting neurotrophic factors (NurOwn®) comprising a culture medium as a carrier and an isolated population of differentiated bone marrow-derived MSCs that secrete neurotrophic factors.

On June 3, 2020, the European Patent Office ("EPO") granted European patent No. 2880151 titled 'Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors'. The allowed claims cover the method for manufacturing MSC-NTF cells (NurOwn®).

On September 1, 2020, the Israeli Patent Office issued Israeli Patent No. 246943 titled 'Method of Qualifying Cells'. The granted claims cover a method of qualifying whether a cell population is a suitable therapeutic for treating ALS and an isolated population of cells that secrete neurotrophic factors which are qualified useful as a therapeutic for treating ALS.

On September 16, 2020, the Company announced that the Japanese Patent Office has granted Brainstorm's Japanese Patent No. 6,753,887, titled 'Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors'. The allowed claims cover a method of generating cells which secrete neurotrophic factors from human undifferentiated MSCs derived from the bone marrow of a single donor. The said neurotrophic factors includes: BDNF; GDNF; HGF; and VEGF.

On December 15, 2020, the Canadian Patent office sealed Patent No. 2,937,305 titled 'Pharmaceutical composition comprising bone-marrow derived mesenchymal stem cells'. The granted claims include a pharmaceutical composition for NurOwn® (MSC-NTF cells, MSCs secreting neurotrophic factors), comprising a culture medium as a carrier and an isolated population of differentiated bone marrow-derived MSCs that secrete neurotrophic factors.

On December 22, 2020 the USPTO issued U.S. Patent No. 10,869,899 titled 'Isolated cells and populations comprising same for the treatment of CNS diseases'. Granted claims cover an isolated cell population secreting GDNF, a pharmaceutical composition comprising the isolated cells, and a device comprising the pharmaceutical composition, including a device that is adapted for administration of the isolated cell population into the spinal cord.

On February 19, 2021, the Hong Kong patent office sealed Patent No. HK1209453 titled 'Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors'. Allowed claims cover the method for manufacturing MSC-NTF cells (NurOwn®).

On November 30, 2021, the USPTO issued US Patent No. 11,185,572 titled 'Mesenchymal stem cells for the treatment of CNS diseases'. The granted claims are for a method of treating a disease selected from the group consisting of Parkinson's disease, ALS, AD, stroke and Huntington's disease using MSC-NTF cells (NurOwn).

On February 15, 2022, we announced that the Brazilian Patent Office granted patent application BR112015001435-6 titled 'A method of generating cells which secrete Brain Derived Neurotrophic Factor (BDNF), Glial Derived Neurotrophic Factor (GDNF), Hepatocyte Growth Factor (HGF) and Vascular Endothelial Growth Factor (VEGF), wherein said cells do not Secrete Nerve Growth Factor (NGF)'. The granted claims cover a method of manufacturing MSC-NTF cells (NurOwn®).

On April 6, 2023, the EPO accepted European Patent Application No.: 15710010.8 titled 'Method of Qualifying cells'. Allowed claims include a method of qualifying whether a cell population is a suitable therapeutic for treating ALS and an isolated population of MSCs for use in treating ALS.

On June 2, 2023, the Australian Patent Office accepted Application No. 2019252987 titled 'Cell-Type Specific Exosomes and Use Thereof'. Accepted claims include an isolated Exosomes population derived form MSC-NTF cells as well as a pharmaceutical composition for the treatment of neurodegenerative diseases.

On August 22, 2023 The Israel Patent Office accepted Application No. 277447 titled 'Cell-Type Specific Exosomes and Use Thereof'. Accepted claims include an isolated Exosomes population derived from MSC-NTF cells as well as a pharmaceutical composition for the treatment of neurodegenerative diseases.

On Dec. 26, 2023, we announced the European grant for NurOwn® as well as the Australian grant and Israeli allowance for the NurOwn® exosomes.

Patents protecting NurOwn® have been issued in the United States, Canada, Japan, Europe, Hong Kong, Brazil and Israel.

Recent Scientific and Industry Presentations

- On February 28, 2024, Dr. Stacy Lindborg, former Co-Chief Executive Officer at Brainstorm Cell Therapeutics, provided a corporate update at 17th Annual European Life Sciences CEO Forum in Zurich, Switzerland. Dr. Lindborg also participated in a panel discussion entitled "Neuro Advances Panel: Highlighting the Main Opportunities".

- On March 4, 2024, Dr. Bob Dagher, then Brainstorm Cell Therapeutics EVP and Chief Development and current EVP and Chief Medical Officer, presented a scientific poster titled "Design of A Phase 3B Trial of Debamestrocel (NurOwn®) in ALS" the 2024 Muscular Dystrophy Association Clinical and Scientific Conference in Orlando, Florida held March 3-6, 2024. The presentation provided an overview into the key features of the phase 3b trial design.

- In May 2024, the Company presented new biomarker data suggesting that ALS patients may benefit from longer - term treatment with NurOwn (R). The Company shared the data with an international audience of patient advocacy groups, physicians, research organizations, industry representatives, key thought leaders and decision makers dedicated to ALS research at the 3rd Annual ALS Drug Development Summit in Boston. Dr. Stacy Lindborg delivered a presentation on new biomarker data from the NurOwn EAP along with data from the Phase 3 trial.

Stock Split

On September 30, 2024, the Company filed a Certificate of Amendment with the Secretary of State of the State of Delaware to effect the one-for-fifteen Reverse Stock Split of the Company's Common Stock, effective as of 11:59 p.m., Eastern time. The Reverse Stock Split had been approved by the Board on September 23, 2024 and by the Company's stockholders at the 2024 Annual Meeting. Pursuant to the Reverse Stock Split, each fifteen shares of Common Stock of the Company were combined and were reclassified into one share of Common Stock of the Company, and the number of issued and outstanding shares of Common Stock of the Company was proportionally reduced, in both cases without any change to the authorized number of shares of Common Stock or in the par value of such shares. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who were entitled to fractional shares received cash in lieu of receiving fractional shares at a rate of $4.2405 per share (the average of the closing trading prices of the Common Stock (as adjusted to reflect the reverse stock split) during regular trading hours for the five trading days immediately preceding the effective time of the Reverse Stock Split). The number of shares of the Company's Common Stock subject to outstanding options and warrants issued by the Company were reduced proportionately and the respective exercise prices were increased proportionately to reflect the Reverse Stock Split. The number of shares reserved for issuance under the Company's equity compensation plans were also reduced proportionately.

Research and Development

We are actively engaged in research and development to evaluate the potential for clinical development of NurOwn® and MSC-NTF derived Exosomes in various neurodegenerative disorders, neurodegenerative eye disease and acute respiratory distress syndrome ("ARDS"). MSC-NTF derived Exosomes are an example of ongoing research in additional specialized derivative cell products. Exosomes are extracellular nano-vesicles (secreted by the cells) that carry various molecular components of their cell of origin, including nucleic acids, proteins and lipids. Exosomes can transfer molecules from one cell to another, thereby mediating cell-to-cell communication, ultimately regulating many cell processes, which are suitable for clinical applications in multiple neurodegenerative diseases. NurOwn® derived exosomes may possess unique features for the enhanced delivery of therapeutics to the brain, due to their ability to cross the blood brain barrier and to penetrate the brain and spinal cord.

The exosome research efforts are primarily focused on manufacturing of MSC-NTF exosomes from bone marrow derived MSC:

1. Developing and optimizing large scale cell culture processes using bioreactors, to generate exosomes.
2. Developing advanced scalable purification GMP methods that can be applied to commercial use.
3. Quantification, characterization of phenotype and exosome cargo.
4. Assessment of MSC-NTF exosomes potency and stability.
5. Establishment of a method for exosomes modification.
6. Preclinical experiments in neurodegenerative and lung injury models.

NurOwn® derived exosomes have the potential to treat ARDS due to their ability to penetrate deep tissues and decrease the inflammatory response. ARDS is a type of respiratory failure associated with widespread inflammation and lung damage mediated by dysregulated cytokine production and is one of the severe features of COVID-19.

MSC exosomes may be delivered intravenously or directly into the lungs via intratracheal administration have several practical advantages over cellular therapy including ease of storage, stability, formulation and low immunogenicity.

In a preclinical study, we evaluated MSCs and NurOwn® derived exosomes in an LPS ARDS-mouse model, relevant to severe acute lung injury. The results from the study showed that intratracheal administration of NurOwn® derived exosomes resulted in a statistically significant improvement in multiple lung parameters. These included the clinically relevant factors: functional lung recovery, reduction in pro-inflammatory cytokines and most importantly, attenuation of lung damage. Moreover, MSC-NTF cell derived exosomes exhibited a superior effect when compared to treatment with exosomes derived from naïve MSCs from the same donor. On January 20, 2021, we announced the peer-reviewed publication of this preclinical study in the journal Stem Cell and Research Therapy. The study, entitled "MSC-NTF (NurOwn®) exosomes: a novel therapeutic modality in the mouse LPS-induced ARDS model," evaluated the use of NurOwn® (MSC-NTF cell) derived exosomes in a mouse model of ARDS.

On May 4, 2022, we made a presentation titled "MSC-NTF derived small extracellular vesicles display superior macrophage immunomodulation compared with vesicles derived from naïve MSCs" at the International Society of Cell & Gene Therapy ("ISCT") 2022 Meeting in San Francisco, CA May 4-7. The presentation highlighted results of a preclinical study undertaken to understand the mechanisms underlying the superior preclinical efficacy of Exo MSC-NTF versus Exo-MSC in acute lung injury models.

On May 25, 2021, we made a scientific presentation of NurOwn® Exosome preclinical ARDS data at the ISCT 2021 New Orleans Virtual Meeting demonstrating that intrathecal administration of NurOwn-derived exosomes resulted in statistically significant improvements in multiple lung parameters in a mouse model of ARDS.

On May 26, 2022, we presented a poster titled "Therapeutic effect of MSC-NTF exosomes in experimental bleomycin-induced lung injury" at the ISEV 2022 Annual Meeting, Lyon France. Results from a preclinical study demonstrating superior outcomes of exosomes derived from MSC-NTF cells compared to exosomes derived from MSC cells were presented.

A poster titled, "Therapeutic Benefits of MSC-NTF (NurOwn®) Exosomes in Acute Lung Injury Models" was presented on October 19, 2021 at the NYSCF 2021 Virtual Meeting, which was held on October 19-20, 2021. Results in two different acute lung injury models showed that the beneficial effects of intratracheal administration of Exo MSC-NTF (MSC-NTF derived exosomes) were more active than Exo MSC (MSC-derived Exosomes) in multiple parameters, including increase in blood oxygen saturation and reduction in lung pathology, inflammatory infiltration and levels of proinflammatory cytokines in bronchoalveolar lavage fluid ("BALF"), in addition to reduction of lung fibrosis in the Bleomycin model.

The observed positive preclinical results suggest that intratracheal administration of Exo MSC-NTF may have clinical potential as a therapy for acute lung related pathologies and has the potential to modify physiological, pathological, and biochemical outcomes with greater activity than sEVs isolated from naïve MSCs.

For the completed multidose clinical studies in ALS and PMS, the Company has improved the efficiency of NurOwn® production and improved its stability, allowing manufacturing to take place at centralized clean room facilities from which NurOwn® is distributed to the clinical trial sites, where the cells are then administered to patients. The Company is also engaged in several research initiatives to further improve and scale-up manufacturing capacity and extend the shelf life of NurOwn®.

Corporate Information

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 1325 Avenue of Americas, 28th Floor, New York, NY 10019, and our telephone number is (201) 488-0460. We also maintain an office in Petach Tikva, Israel and in Burlington, Massachusetts. We maintain a website at http://www.brainstorm-cell.com. The information on our website is not incorporated into this Quarterly Report on Form 10-Q.

Results of Operations

For the period from inception (September 22, 2000) until September 30, 2024, we did not generate any revenues from operations. In addition, we incurred operating costs and expenses of approximately $3,048,000 during the three months ended September 30, 2024, compared to $6,035,000 during the three months ended September 30, 2023. We incurred operating costs and expenses of approximately $8,504,000 during the nine months ended September 30, 2024, compared to $16,635,000 during the nine months ended September 30, 2023.

Research and Development, net

Our business model calls for significant investments in research and development. Our research and development expenditures, net in the three months ended September 30, 2024 were $1,045,000, a decrease of $2,285,000 compared to $3,330,000 for the three months ended September 30, 2023.

This decrease is due to: (i) a decrease of $1,182,000 in costs related to the Phase 3 clinical trial; (ii) decrease of $377,000 in connection with payroll and stock-based compensation expenses; and (iii) decrease of $726,000 in connection with travel, materials, depreciation, and other activities.

Our research and development expenditures, net for the nine months ended September 30, 2024 were $2,928,000, a decrease of $6,120,000 compared to $9,048,000 for the nine months ended September 30, 2023.

This decrease is due to: (i) a decrease of $2,640,000 in costs related to the Phase 3 clinical trial; (ii) decrease of $1,383,000 in connection with payroll and stock-based compensation expenses; and (iii) a decrease of $2,097,000 in connection with patents, rent, travel, materials, depreciation and other activities.

General and Administrative

General and administrative expenses for the three months ended September 30, 2024 and 2023 were $2,003,000 and $2,705,000, respectively. The decrease in general and administrative expenses of $702,000 is primarily due to decrease in payroll, stock-based compensation expenses, PR activities, travel and consultants' costs. This decrease was partially offset by an increase in rent, stock management costs and other cost-related changes.

General and administrative expenses for the nine months ended September 30, 2024 and 2023 were $5,576,000 and $7,587,000, respectively. The decrease in general and administrative expenses of $2,011,000 is primarily due to a decrease for costs related to payroll, stock-based compensation expenses, PR activities, travel, rent and other activities. This decrease was partially offset by an increase in consultants' costs and stock management costs.

Financial Expenses

Financial expense for the three months ended September 30, 2024 was $54,000 compared to financial expense of $121,000 for the three months ended September 30, 2023, as a result of interest earned on our cash, cash equivalents and short-term deposits and due to conversion exchange rates.

Financial expense for the nine months ended September 30, 2024 was $11,000 compared to financial income of $91,000 for the nine months ended September 30, 2023 as a result of interest earned on our cash, cash equivalents and short-term deposits and due to conversion exchange rates.

Net Loss

Net loss for the three months ended on September 30, 2024 was $2,708,000, compared to a net loss of $1,226,000 for the three months ended September 30, 2023. Net loss per share for the three months ended September 30, 2024 and 2023 was $0.51 and $0.45, respectively.

The weighted average number of shares of Common Stock used in computing basic and diluted net loss per share for the three months ended September 30, 2024 was 5,309,796, compared to 2,950,121 for the three months ended September 30, 2023.

Net loss for the nine months ended on September 30, 2024 was $8,650,000, compared to a net loss of $11,614,000 for the nine months ended September 30, 2023. Net loss per share for the nine months ended September 30, 2024 and 2023 was $1.80 and $4.35, respectively.

The weighted average number of shares of Common Stock used in computing basic and diluted net loss per share for the nine months ended September 30, 2024 was 4,793,026, compared to 2,683,700 for the nine months ended September 30, 2023.

Additional funding will be required to begin the commercialization efforts and to achieve a level of sales adequate to support the Company's cost structure.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional public and private sales of its Common Stock and warrants, the exercise of warrants, the issuance of convertible promissory notes, sales of Common Stock via its August 9, 2021 ATM program and other funding transactions. While the Company has been successful in raising financing recently and in the past, there can be no assurance that it will be able to do so in the future on a timely basis on terms acceptable to the Company, or at all.

Management expects that the Company will continue to generate losses from the clinical development and regulatory activities, which will result in a negative cash flow from operating activity. The Company has completed regulatory review of the BLA for NurOwn for the treatment of ALS with the withdrawal of the BLA on November 3, 2023. The decision to withdraw the BLA was coordinated with FDA and is viewed by FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for an SPA with FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS. On April 9, 2024, the Company announced that it received written agreement from the FDA, under an SPA, on the design for a Phase 3b trial of NurOwn® in ALS. The SPA agreement with the FDA validates the clinical trial protocol and statistical analysis of the planned Phase 3b trial of NurOwn, demonstrating the Company's adequacy in addressing objectives that support a future BLA in ALS.

If the Company is not able to raise additional capital for these purposes, the Company may not be able to continue to function as a going concern. The Company's consolidated financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

Liquidity and Capital Resources

Since inception, the Company has financed its operations primarily through public and private sales of its Common Stock and warrants, the exercise of warrants, the issuance of convertible promissory notes, sales via the ATM programs and through various grants. On September 30, 2024 cash, cash equivalents and restricted cash amounted to $349,000.

Net cash used in operating activities for the nine months ended September 30, 2024 was $8,045,000. Cash used for operating activities was primarily attributed to cost of clinical trials, rent of clean room and materials for clinical trials, payroll costs, rent, outside legal fee expenses and public relations expenses.

Net cash provided by financing activities for the nine months ended September 30, 2024 was $6,909,000 from sales of common stock under the August 9, 2021 ATM programs and June 2024 Sales of Unregistered Securities.

On August 9, 2021, the Company entered into the New Distribution Agreement with the Agents pursuant to which the Company may sell from time to time, through the Agents, shares of Common Stock, having an aggregate offering price of up to $100,000,000 (the "August 9, 2021, ATM"). Sales under the August 9, 2021, ATM are to be made by any method permitted by law that is deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Exchange Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and the Agents. In connection with the New Distribution Agreement, the Company terminated the previous Distribution Agreement and the September 25, 2020, ATM. During the nine months ended September 30, 2024, the Company has sold 637,543 shares of Common Stock for gross proceeds of approximately $3,342,413 under the August 9, 2021, ATM.

At-the-market (ATM) Offerings:

On June 11, 2019, the Company entered into a distribution agreement with Raymond James & Associates, Inc. (“Raymond James”), pursuant to which the Company sold, through the Raymond James, shares of Common Stock having an aggregate offering amount of $20,000,000 (the “June 11, 2019 ATM”) in an “at the market” offering as defined in Rule 415 promulgated under the Exchange Act, including, without limitation, by sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and Raymond James.

On March 6, 2020, the Company entered into a new distribution agreement with Raymond James (the “Agent”), pursuant to which the Company was able to sell from time to time, through the Agent, shares of Common Stock, having an aggregate offering price of up to $50,000,000 (the “March 6, 2020, ATM”). Sales under the March 6, 2020. ATM were made by any method permitted by law that is deemed to be an “at the market” offering as defined in Rule 415 promulgated under the Exchange Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and Raymond James. Under the March 6, 2020, ATM, the Company sold an aggregate of 163,109 shares of Common Stock at an average price of $141.75 per share, raising gross proceeds of approximately $23.11 million.

On September 25, 2020, the Company entered into an Amended and Restated Distribution Agreement (the “Distribution Agreement”) with SVB Leerink LLC (“Leerink”) and Raymond James & Associates (together with Leerink, the “Agents”) pursuant to which the Company may sell from time to time, through the Agents, shares of Common Stock, having an aggregate offering price of up to $45,000,000, which aggregate amount includes amount unsold pursuant to the March 6, 2020, ATM (the “September 25, 2020, ATM”). Sales under the September 25, 2020, ATM are to be made by any method permitted by law that is deemed to be an “at the market” offering as defined in Rule 415 promulgated under the Exchange Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and the Agents. The Distribution Agreement amends and restates in its entirety the Company’s prior agreement with Raymond James entered into on March 6, 2020 (the “March 6, 2020, ATM”). The Company previously sold 163,109 shares of Common Stock for gross proceeds of approximately $23.11 million of Common Stock under the March 6, 2020, ATM. During the quarter ended September 30, 2021, the Company did not sell any additional shares of its Common Stock pursuant to the September 25, 2020, ATM. Since inception and as of September 30, 2021, the Company had sold 314,752 shares of Common Stock for gross proceeds of approximately $29.1 million under the September 25, 2020, ATM.

The Company has no obligation under the September 25, 2020, ATM to sell any shares and may at any time suspend sales or terminate the September 25, 2020, ATM in accordance with its terms. Subject to the terms and conditions of the Distribution Agreement, the Agents will use their commercially reasonable efforts to sell on the Company’s behalf, from time to time consistent with its normal sales and trading practices, such Shares based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company has provided the Agents with customary indemnification rights, and the Agents will be entitled to a fixed commission of 3.0% of the aggregate gross proceeds from the Shares sold. The Distribution Agreement contains customary representations and warranties, and the Company is required to deliver customary closing documents and certificates in connection with sales of the Shares. Shares sold under the ATMs are issued pursuant to the Company’s existing Shelf Registration Statement, and the Prospectus Supplement to the Registration Statements filed June 11, 2019, March 6, 2020, and September 25, 2020, respectively.

On August 9, 2021, the Company entered into the New Distribution Agreement with the Agents pursuant to which the Company may sell from time to time, through the Agents, shares of Common Stock, having an aggregate offering price of up to $100,000,000 (the “August 9, 2021, ATM”). Sales under the August 9, 2021, ATM are to be made by any method permitted by law that is deemed to be an “at the market” offering as defined in Rule 415 promulgated under the Exchange Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and the Agents. In connection with the New Distribution Agreement, the Company terminated the previous Distribution Agreement and the September 25, 2020, ATM. During the nine months ended September 30, 2024, the Company has sold 637,543 shares of Common Stock for gross proceeds of approximately $3,342,413 under the August 9, 2021, ATM. On April 2, 2024, we entered into Amendment No. 1 to the New Distribution Agreement (“Amendment No. 1”) pursuant to which Leerink Partners ceased to be an agent.

Recent Sales of Unregistered Securities:

On July 17, 2023, the Company entered into a Securities Purchase Agreement with the purchaser named therein, pursuant to which the Company agreed to sell, in the Offering, an aggregate of 270,270 shares of Common Stock, together with the Common Warrants to purchase 270,270 shares of Common Stock, at a purchase price of $27.75 per share and accompanying warrants for gross proceeds to the Company of approximately $7.5 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Offering closed on July 19, 2023. The Common Warrants are immediately exercisable, expire five years following the date of issuance and have an exercise price of $30.00 per share.

On June 27, 2024, the Company entered into a Securities Purchase Agreement with the purchaser, pursuant to which the Company agreed to sell, (i) an aggregate of 527,918 registered shares of the Company's common stock, (ii) the Pre-Funded Warrants to purchase up to 212,823 shares of Common Stock and (iii) unregistered warrants to purchase up to 1,111,111 shares of Common Stock, at a purchase price of $5.4 per share of Common Stock and accompanying Common Warrant, or $5.399 per Pre-Funded Warrant and accompanying Common Warrant. The Offering of the Securities yielded gross proceeds to the Company of approximately $4.0 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Offering closed on June 28, 2024. The Warrants will be exercisable six months after the issuance date, will expire five years following the date of issuance and have an exercise price of $5.868 per share. The Pre-Funded Warrant Shares are immediately exercisable at an exercise price of $0.00005 per share and will remain exercisable until the Pre-Funded Warrants are exercised in full.

We expect that we will continue to generate losses from the clinical development and regulatory activities, which will result in a negative cash flow from operating activity. If we are granted an SPA with the FDA, additional capital raise will be needed to conduct a Phase 3b trial in ALS, to commercialize NurOwn® for ALS, and for future trials that may be needed for other indications. The actual amount of cash that the Company will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our product candidates, along with cost to commercialize these product candidates.

We anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may incur debt, license certain intellectual property, and seek to sell additional equity or convertible securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of equity or convertible securities, these securities could have rights or preferences senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our future capital requirements will depend on many factors, including:

- our ability to obtain funding from third parties, including any future collaborative partners;
- the scope, rate of progress and cost of our clinical trials and other research and development programs;
- the time and costs required to gain regulatory approvals;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of filing, prosecuting, defending and enforcing patents, patent applications, patent claims, trademarks and other intellectual property rights;
- any product liability or other lawsuits related to our product candidates;
- the expenses needed to attract and retain skilled personnel;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the general and administrative expenses related to being a public company;

- the effect of competition and market developments; and
- future pre-clinical and clinical trial results.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S. The preparation of our consolidated financial statements and disclosures requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accounting for stock-based compensation:

We grant equity-based awards under share-based compensation plans. We estimate the fair value of share-based payment awards using the Black-Scholes option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected life of the option. Share-based compensation expense is based on awards ultimately expected to vest, and therefore is reduced by expected forfeitures. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Off Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

This information has been omitted as the Company qualifies as a smaller reporting company.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this quarterly report, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on this evaluation, our Chief Executive Officer, former Co-Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective, as of the end of the period covered by this report, to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in such reports is accumulated and communicated to our management, including our Chief Executive Officers and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising out of operations in the normal course of business, which we consider routine and incidental to our business.

Between November 1, 2023 and April 12, 2024, five lawsuits were filed in the U.S. District Court for the Southern District of New York by purported shareholders of the Company.

On November 1, 2023, a purported shareholder of the Company filed the Securities Complaint against the Company and certain of its officers, captioned *Sporn v. Brainstorm Cell Therapeutics Inc., et al.* , Case No. 1:23-cv-09630, in the United States District Court for the Southern District of New York. The Lead Plaintiff filed an Amended Complaint on April 1, 2024; the Amended Complaint adds a former officer as an individual defendant. The Amended Complaint in the Securities Action alleges violations of Sections 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder against all defendants and control person violations of Section 20(a) against the individual defendants, relating to NurOwn® for the treatment of ALS, the Company's submissions to and communications with the FDA in support of the approval of NurOwn® for the treatment of ALS, and the prospects of future approval of NurOwn® by the FDA. The Securities Action seeks, among other things, damages in connection with an allegedly inflated stock price between February 18, 2020 and September 27, 2023, as well as attorneys' fees and costs. The Company and individual defendants moved to dismiss the Amended Complaint on May 31, 2024; plaintiffs opposed the motion to dismiss on July 31, 2024; and the Company and individual defendants' filed a reply in support of their motion to dismiss on September 17, 2024. The court may, in its discretion, either hold an oral argument or issue a ruling on the motion to dismiss based upon the parties' briefing.

On February 14, 2024, February 15, 2024, March 21, 2024 and April 12, 2024 four purported shareholders of the Company filed the Derivative Complaints against the Company as nominal defendant and certain of its officers, current and former directors, and members of its scientific advisory board, captioned *Porteous v. Lebovits, et al.* , Case No. 1:24-cv-01095; *Andrev v. Lebovits, et al.* , Case No. 1:24-cv-1101; and *Holtzman v. Lebovits, et al.* , Case No. 1:24-cv-02139, and *Hamby v. Lebovits, et al.* , Case No. 1:24-cv-02811 in the United States District Court for the Southern District of New York. On April 25, 2024, the Court consolidated the Derivative Actions into a consolidated action captioned *In Re Brainstorm Cell Therapeutics, Inc. Derivative Litigation* , Case No. 1:24-cv-01095-DEH (the "Consolidated Derivative Action"), and appointed Co-Lead Counsel. All substantive deadlines in the Consolidated Derivative Action are currently stayed pending the court's decision on the motion to dismiss in the Securities Action. Plaintiffs have not yet filed a consolidated complaint; the Derivative Actions, brought on behalf of the Company, each assert state law claims for breach of fiduciary duty and unjust enrichment against the individual defendants. The complaints in *Holtzman* and *Hamby* also assert state law claims against the individual defendants for abuse of control, gross mismanagement, corporate waste, a claim against the individual defendants for violations of Section 14(a) of the Exchange Act, and a claim against two officer defendants for contribution under Sections 10(b) and 21D of the Exchange Act. The Derivative Complaints allege that the individual defendants breached their fiduciary duties and duties under the Exchange Act in connection with the Company's internal controls relating to, as with the allegations in the Securities Complaint, NurOwn® for the treatment of ALS, the Company's submissions to and communications with the FDA in support of the approval of NurOwn® for the treatment of ALS, and the prospects of future approval of NurOwn® by the FDA their actions or omissions could not have been a good faith exercise of prudent business. The Derivative Actions seek among other things, monetary damages and disgorgement of performance-based compensation granted in connection with an allegedly inflated stock price between August 15, 2022 and September 27, 2023, as well as attorneys' fees and costs.

The Company intends to vigorously defend against the lawsuits.

Item 1A. Risk Factors.

Other than the additional risk factors below, there have not been any material changes from the risk factors previously disclosed in the "Risk Factors" section of our Annual Report on Form 10 - K for the fiscal year ended December 31, 2023.

In addition to the other information set forth in this Quarterly Report on Form 10 - Q, you should carefully consider the risk factors in our Annual Report on Form 10 - K for the fiscal year ended December 31, 2023, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10 - K for the fiscal year ended December 31, 2023, and in this Quarterly Report on Form 10 - Q, are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

If we fail to regain compliance with the continued listing requirements of Nasdaq, our Common Stock may be delisted, and the price and liquidity of our common stock may be negatively impacted.

On July 18, 2024, we received a letter from the Staff indicating that we have not maintained Nasdaq's MVLS of $35 million from June 2, 2024 to July 17, 2024. Under Nasdaq's listing rules, we have 180 calendar days from this notice, until January 14, 2025, to regain compliance with Nasdaq's MVLS. If at any time during this compliance period the Company's MVLS closes at $35 million or more for a minimum of ten consecutive business days, the Staff will notify the Company that it has regained compliance with the MVLS requirement. However, if the Company fails to comply with the MVLS requirement for ten consecutive business days prior to the expiration of the compliance period on January 14, 2025, then the Staff will send the Company a notice of delisting.

If we are unsuccessful in our efforts to regain compliance with the MVLS requirement, delisting from the Nasdaq market could make trading the Common Stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have difficulty obtaining a quote for the sale or purchase of the Common Stock, the sale or purchase of the Common Stock would likely be made more difficult and the trading volume and liquidity of the Common Stock could decline. Delisting from Nasdaq could also result in negative publicity, make it more difficult for us to raise additional capital through alternative financing sources on terms acceptable to us, or at all, result in potential loss of confidence by investors and employees, and result in fewer business development opportunities. We cannot assure you that the Common Stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system.

We are and could be further subject to securities class action litigation and other types of stockholder litigation.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. For example, in November 2023, a purported stockholder filed a lawsuit against us and certain of our officers captioned *Sporn v. Brainstorm Cell Therapeutics, Inc. et al.* in the U.S. District Court for the Southern District of New York, and in February 2024, March 2024, and April 2024, four derivative actions were filed in the same court, consolidated and captioned *In Re Brainstorm Cell Therapeutics, Inc. Derivative Litigation* (see *"Item 3. Legal Proceedings"* for a more detailed description of these matters). We could also be subject to other types of litigation, which may involve claims of breach of fiduciary duties by our directors or officers for misuse/mismanagement of company assets/resources or conflicts of interest. Any such litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the quarter ended September 30, 2024, none of the Company's directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 6. Exhibits.

The following documents are filed as exhibits to this report:

			Incorporated by Reference Herein		
Exhibit Number	**Description**	**Filed (or Furnished) with this Form 10-Q**	**Form**	**Exhibit & File No.**	**Date Filed**
3.1	Certificate of Incorporation of Brainstorm Cell Therapeutics Inc.		Definitive Schedule 14A	Appendix B File No. 333-61610	November 20, 2006
3.2	Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc., dated September 15, 2014.		Form 8-K	Exhibit 3.1 File No. 000-54365	September 16, 2014
3.3	Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc., dated August 31, 2015.		Form 8-K	Exhibit 3.1 File No. 001-366641	September 4, 2015
3.4	Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc., dated September 16, 2024.		Form 8-K	Exhibit 3.1 File No. 001-366641	September 16, 2024
3.5	Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc., dated September 30, 2024.		Form 8-K	Exhibit 3.1 File No. 001-366641.	October 1, 2024
3.5	ByLaws of Brainstorm Cell Therapeutics Inc.		Definitive Schedule 14A	Appendix C File No. 333-61610	November 20, 2006
3.6	Amendment No. 1 to ByLaws of Brainstorm Cell Therapeutics Inc., dated as of March 21, 2007.		Form 8-K	Exhibit 3.1 File No. 333-61610	March 27, 2007
10.1¥	Amendment No. 4 to the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan		Form 8-K	Exhibit 10.5 File No. 001-36641	September 16, 2024
10.2¥	Amendment No. 4 to Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan		Form 8-K	Exhibit 10.10 File No. 001-36641	September 16, 2024
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	*			
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	*			
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	‡			
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	‡			
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	*			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	*			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	*			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*			

* *Filed herewith*
‡ *Furnished herewith*
¥ Indicates a management contract or any compensatory plan, contract or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BRAINSTORM CELL THERAPEUTICS INC.

Date: November 14, 2024

By: /s/ Chaim Lebovits
Name: Chaim Lebovits
Title: Chief Executive Officer
(Principal Executive Officer)

By: /s/ Alla Patlis
Name: Alla Patlis
Title: Controller, Interim Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

I, Chaim Lebovits, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Brainstorm Cell Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 14, 2024

/s/ Chaim Lebovits

Name: Chaim Lebovits

Title: Executive Officer (Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

I, Alla Patlis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Brainstorm Cell Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 14, 2024

/s/ Alla Patlis

Name: Alla Patlis

Title: Interim Chief Financial Officer and Controller
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

In connection with the accompanying Quarterly Report on Form 10-Q of Brainstorm Cell Therapeutics Inc. (the "Company") for the period ended September 30, 2024, the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) such Quarterly Report on Form 10-Q for the period ended September 30, 2024 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in such Quarterly Report on Form 10-Q for the period ended September 30, 2024 fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 14, 2024

/s/ Chaim Lebovits

Name: Chaim Lebovits
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

In connection with the accompanying Quarterly Report on Form 10-Q of Brainstorm Cell Therapeutics Inc. (the "Company") for the period ended September 30, 2024 the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) such Quarterly Report on Form 10-Q for the period ended September 30, 2024 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in such Quarterly Report on Form 10-Q for the period ended September 30, 2024 fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 14, 2024

/s/ Alla Patlis

Name: Alla Patlis
Title: Interim Chief Financial Officer and Controller
(Principal Financial and Accounting Officer)