

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 March 31, 2020

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  
(State or other jurisdiction of  
incorporation or organization)

20-7273918  
(I.R.S. Employer  
Identification No.)

1325 Avenue of Americas, 28<sup>th</sup> 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 May 4, 2020, the number of shares outstanding of the registrant's Common Stock, \$0.00005 par value per share, was 29,440,732.

TABLE OF CONTENTS

	Page Number
<u>PART I – FINANCIAL INFORMATION</u>	<u>3</u>
<u>Item 1. Financial Statements</u>	<u>3</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>23</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>34</u>
<u>Item 4. Controls and Procedures</u>	<u>34</u>
<u>PART II – OTHER INFORMATION</u>	<u>35</u>
<u>Item 1. Legal Proceedings</u>	<u>35</u>
<u>Item 1A. Risk Factors</u>	<u>35</u>
<u>Item 5. Other Information</u>	<u>36</u>
<u>Item 6. Exhibits</u>	<u>36</u>
<u>SIGNATURES</u>	<u>37</u>

**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES**

**INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
AS OF MARCH 31, 2020**

**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 MARCH 31, 2020**

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

**(UNAUDITED)**

**INDEX**

	<b><u>Page</u></b>
<a href="#"><u>Interim Condensed Consolidated Balance Sheets</u></a>	<a href="#"><u>5</u></a>
<a href="#"><u>Interim Condensed Consolidated Statements of Comprehensive Loss</u></a>	<a href="#"><u>6</u></a>
<a href="#"><u>Interim Condensed Statements of Changes in Stockholders' Equity</u></a>	<a href="#"><u>7</u></a>
<a href="#"><u>Interim Condensed Consolidated Statements of Cash Flows</u></a>	<a href="#"><u>9</u></a>
<a href="#"><u>Notes to Interim Condensed Consolidated Financial Statements</u></a>	<a href="#"><u>11</u></a>

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES**

**INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS**

U.S. dollars in thousands  
(Except share data)

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	<u>U.S. \$ in thousands</u>	
	<u>Unaudited</u>	<u>Audited</u>
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 12,471	\$ 536
Short-term deposit (Note 4)	2,020	33
Other accounts receivable	435	2,359
Prepaid expenses and other current assets (Note 5)	279	432
<b>Total current assets</b>	<u>15,205</u>	<u>3,360</u>
<b>Long-Term Assets:</b>		
Prepaid expenses and other long-term assets	31	32
Operating lease right of use asset (Note 6)	1,917	2,182
Property and Equipment, Net	918	960
<b>Total Long-Term Assets</b>	<u>2,866</u>	<u>3,174</u>
<b>Total assets</b>	<u>\$ 18,071</u>	<u>\$ 6,534</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 4,571	\$ 14,677
Accrued expenses	1,303	1,000
Operating lease liability (Note 6)	1,208	1,263
Other accounts payable	1,170	714
<b>Total current liabilities</b>	<u>8,252</u>	<u>17,654</u>
<b>Long-Term Liabilities:</b>		
Operating lease liability (Note 6)	808	1,103
<b>Total long-term liabilities</b>	<u>808</u>	<u>1,103</u>
<b>Total liabilities</b>	\$ 9,060	\$ 18,757
<b>Stockholders' Equity (deficit):</b>		
Stock capital: (Note 7)	12	11
Common Stock of \$0.00005 par value - Authorized: 100,000,000 shares at March 31, 2020 and December 31, 2019 respectively; Issued and outstanding: 28,423,837 and 23,174,228 shares at March 31, 2020 and December 31, 2019 respectively.		
Additional paid-in-capital	134,389	105,042
Receipts on account of shares	-	-
Accumulated deficit	(125,390)	(117,276)
<b>Total stockholders' equity (deficit)</b>	<u>9,011</u>	<u>(12,223)</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 18,071</u>	<u>\$ 6,534</u>

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)

	<u>Three months ended</u>	
	<u>March 31,</u>	
	<u>2 0 2 0</u>	<u>2 0 1 9</u>
	<u>U.S. \$ in thousands</u>	
<b>Operating expenses:</b>		
Research and development, net	\$ 5,948	\$ 3,456
General and administrative	2,360	1,472
<b>Operating loss</b>	<b>(8,308)</b>	<b>(4,928)</b>
Financial expenses (income), net	(194)	99
<b>Net loss</b>	<b>\$ (8,114)</b>	<b>\$ (5,027)</b>
Basic and diluted net loss per share from continuing operations	<u>\$ (0.32)</u>	<u>\$ (0.24)</u>
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	<u>28,423,837</u>	<u>20,917,329</u>

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

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES**

**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in capital	Receipts on account of shares	Accumulated Deficit	Total stockholders' equity (deficit)
	Number	Amount				
<b>Balance as of January 1, 2019</b>	20,757,816	\$ 11	\$ 94,620	\$ 4,408	\$ (94,023)	\$ 5,016
Stock-based compensation related to warrants and stock granted to service providers	5,908	(*)	25	-	-	25
Stock-based compensation related to stock and options granted to directors and employees	107,104	(*)	764	-	-	764
Issuance of shares in at-the-market (ATM) offering (Note 7)	542,736	(*)	2,064	-	-	2,064
Exercise and reissuance of warrants	1,741,999	(*)	7,534	(4,408)	-	3,126
Exercise of options	18,665	(*)	35	-	-	35
Net loss	-	-	-	-	(23,253)	(23,253)
<b>Balance as of December 31, 2019</b>	<u>23,174,228</u>	<u>\$ 11</u>	<u>\$ 105,042</u>	<u>\$ -</u>	<u>\$ (117,276)</u>	<u>\$ (12,223)</u>

\* Represents an amount less than \$1.

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

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES**

**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**

U.S. dollars in thousands  
(Except share data)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Number	Amount			
<b>Balance as of January 1, 2020</b>	23,174,228	\$ 11	\$ 105,042	\$ (117,276)	\$ (12,223)
Stock-based compensation related to stock and options granted to directors and employees	54,956	(*)	390	-	390
Issuance of shares in at-the-market (ATM) offering (Note 7)	3,935,320	1	18,971	-	18,972
Issuance of shares and warrants in Registered Direct Offering (Note 7)	1,250,000	(*)	9,957	-	9,957
Exercise of options	9,333	(*)	29	-	29
Net loss	-	-	-	(8,114)	(8,114)
<b>Balance as of March 31, 2020</b>	<u>28,423,837</u>	<u>\$ 12</u>	<u>\$ 134,389</u>	<u>\$ (125,390)</u>	<u>\$ 9,011</u>

\* Represents an amount less than \$1.

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

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2 0 2 0</b>	<b>2 0 1 9</b>
	<b>U.S. \$ in thousands</b>	
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,114)	\$ (5,027)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation	49	44
Shares and options granted to service providers	-	25
Deferred Stock-based compensation related to options granted to employees and directors	390	312
Finance lease expense (income)	(85)	94
Decrease in other accounts receivable, prepaid expenses and other current assets	2,078	1,449
Increase (decrease) in trade payables'	(10,106)	481
Increase in deferred grant income	-	511
Increase in other accounts payable and accrued expenses	759	1,276
Total net cash used in operating activities	\$ (15,029)	\$ (835)

**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

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2 0 2 0</b>	<b>2 0 1 9</b>
	<b>U.S. \$ in thousands</b>	
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(7)	(4)
Changes in short-term deposit	(1,987)	3,135
Total net cash provided by (used in) investing activities	<u>\$ (1,994)</u>	<u>\$ 3,131</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of options	29	-
Proceeds from issuance of shares in at-the-market (ATM) offering (Note 7)	18,972	-
Proceeds from issuance of shares and warrants in Registered Direct Offering (Note 7)	9,957	-
Total net cash provided by financing activities	<u>\$ 28,958</u>	<u>\$ -</u>
<b>Increase in cash and cash equivalents</b>	<b>11,935</b>	<b>2,296</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>536</b>	<b>942</b>
Cash and cash equivalents at end of the period	<u>\$ 12,471</u>	<u>\$ 3,238</u>

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 of 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 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 Amyotrophic Lateral Sclerosis (ALS, also known as Lou Gherig Disease), Progressive Multiple Sclerosis (PMS) and Parkinson's disease. The Company developed a proprietary process, called NurOwn®, for the propagation of Mesenchymal Stem Cells 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.** NurOwn® is in clinical development for the treatment of ALS. The Company has completed two single dose clinical trials of NurOwn® in Israel, a Phase 1/2 trial with 12 patients and a Phase 2a trial with additional 12 patients. In July 2016 the Company announced the results of its Phase 2 trial which was conducted in three major medical centers in the US. This single dose trial included 48 patients randomized in a 3:1 ratio to receive NurOwn® or placebo.
- D.** The Company made significant progress in 2019 and in Q1, 2020 advancing NurOwn®, its late stage differentiated mesenchymal stem cell therapy, into a 200 patient Phase 3 trial for the treatment of ALS. Enrollment in this randomized, double-blind, placebo-controlled, multi-dose clinical trial of NurOwn® for ALS was completed in October 2019. This Phase 3 trial builds upon the promising efficacy seen in prior trials including the randomized Phase 2 trial conducted in the U.S.
- E.** The Phase 3 ALS trial pre-specified interim safety analysis by an independent Data Safety Monitoring Board (DSMB) was successfully completed in August 2018. The DSMB completed its second pre-specified interim analysis of safety outcomes for 106 participants treated with NurOwn® in the Phase 3 ALS trial on October 28, 2019. Top-data from this trial is still expected in fourth quarter of 2020.
- F.** On December 15, 2018, the Company was granted FDA clearance for its NurOwn® IND Application for Progressive Multiple Sclerosis indication (ClinicalTrials.gov Identifier NCT03799718). As of March 31, 2020, the Progressive Multiple Sclerosis Phase 2 open label clinical trial has enrolled the first 9 study participants.
- G.** The Company received Good Manufacturing Practice (GMP) approval from the Israel Ministry of Health (MoH) for our Israeli contract manufacturing facility at the Hadassah Medical Center in Jerusalem. The GMP certificate confirms the Company's manufacturing site compliance with Israeli GMPs which are recognized as equivalent to EU standards.

**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**

**GOING CONCERN:**

Since its inception, the Company has devoted substantially all of its efforts to research and development, clinical trials, recruiting management and technical staff, acquiring assets and raising capital. The Company is still in its development and clinical stage and has not yet generated revenues. The extent of the Company's future operating losses and the timing of becoming profitable are uncertain. The Company has funded its operations to date primarily through public and private sales of its Common Stock and warrants, the exercise of warrants, the issuance of convertible promissory notes, sales via ATM program and through grants from California Institute for Regenerative Medicine (CIRM) and the Israel Innovation Authority of the Ministry of Economy and Industry (the "IIA") (formerly the Office of the Chief Scientist of the Ministry of Economy and Industry (the "OCS)).

Additional funding will be required to complete the Company's research and development and clinical trials, to attain regulatory approvals, 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, and the issuance of convertible promissory notes, sales with 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. Uncertain market conditions and approval by regulatory bodies and adverse results from clinical trials may (among other reasons) adversely impact the Company's ability to raise capital in the future.

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. This has led management to conclude that substantial doubt about the Company's ability to continue as a going concern exists. The Company's consolidated financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

**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 generally accepted accounting principles 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 year ended December 31, 2019.

Operating results for the three months ended March 31, 2020, are not necessarily indicative of the results that may be expected for the year ended December 31, 2020.

**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.

**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 (Cont.):**

**C. Recent Accounting Standards**

The Company reviews new accounting standards as issued. Although some of these accounting standards issued or effective after the end of the Company's previous fiscal year may be applicable, the Company has not identified any standards that the Company believes merit further discussion. The Company believes that none of the new standards will have a significant impact on the 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**

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.

**NOTE 4 - SHORT TERM DEPOSITS**

Short term deposits on March 31, 2020 and December 31, 2019 include bank deposits bearing annual interest rates varying from 0.15% to 2.00%, with maturities of up to 6 months as of March 31, 2020 and December 31, 2019.

**NOTE 5 - PREPAID EXPENSES**

In November 2017 the Company has contracted with City of Hope's Center for Biomedicine and Genetics ("COH") to produce clinical supplies of NurOwn® adult stem cells for the Company's ongoing Phase 3 clinical study. In 2017 the Company has paid COH \$2,665 advance payment. The advance was recorded as prepaid expense and is amortized over the term of the agreement. As of December 31, 2019, \$276 were recorded as current prepaid expense. As of March 31, 2020, the prepaid expenses were fully reduced.

**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 – LEASES**

On January 1, 2019 the Company adopted ASU 2016-02, Leases (Topic 842) (“ASU 2016-02”) using the modified retrospective approach for all lease arrangements at the beginning of the period of adoption. Leases existing for the reporting period beginning January 1, 2019 are presented under ASU 2016-02. The Company leases facilities, clinical research rooms, and vehicles under operating leases. At March 31, 2020, the Company’s ROU assets and lease liabilities for operating leases totaled \$1,917 and \$2,016, respectively. The impact of adopting the new lease standard was not material to the Company’s condensed consolidated statement of operations for the periods presented.

Supplemental cash flow information related to operating leases was as follows (unaudited):

	<b>Three Months Ended March 31, 2020</b>
Cash payments for operating leases	\$ 327
New operating lease assets obtained in exchange for operating lease liabilities	\$ 1,917

As of March 31, 2020, our operating leases had a weighted average remaining lease term of 1.72 years and a weighted average discount rate of 8.25%. Future lease payments under operating leases as of March 31, 2020 were as follows (unaudited):

	<b>Operating Leases</b>
Remainder of 2020	\$ 955
2021	1,209
<b>Total future lease payments</b>	<b>2,164</b>
Less imputed interest	(148)
<b>Total lease liability balance</b>	<b>\$ 2,016</b>

**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**

**The rights of Common Stock are as follows:**

Holders of 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.

**Private placements and public offerings:**

Warrant Exercise Agreement:

On August 2, 2019, the Company entered into a Warrant Exercise Agreement which generated gross cash proceeds to the Company of approximately \$3.3 million. Pursuant to the agreement, certain holders (the "Holders") of warrants issued by the Company on June 6, 2018 (the "2018 Warrants") agreed to exercise 842,000 shares of Common Stock of their 2018 Warrants, at an amended exercise price of \$3.90 per share, and the Company agreed to issue new warrant shares to the Holders to purchase 842,000 shares of Common Stock (the "New Warrants"), at an exercise price of \$7.00, with an expiration date of December 31, 2021. The 2018 Warrants held by the Holders, to the extent not exercised, were also amended to reduce the exercise price to \$7.00 per share and to extend the expiration date to December 31, 2021.

Subject to limited exceptions, for the 90 days following the date of the Warrant Exercise Agreement, neither the Company nor any Subsidiary will issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock, without the prior written consent of the Holders of a majority of the New Warrant shares. The Company also agreed that during the time the New Warrants are unexercised, the Company will not enter into any agreements with any holder of 2018 Warrants with more favorable terms, without the consent of the Holders of a majority of the warrant shares then exercisable under all outstanding August 2019 Warrant Exercise Agreements.

The New Warrants have not been registered under the Securities Act of 1933, as amended (the Securities Act), or state securities laws. The shares issuable upon exercise of the New Warrants have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-233349). The Exercised Shares have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-225995). The issuance of the Exercised Shares and New Warrants is exempt from the registration requirements of the Securities Act pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act.

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 Securities Act, including, without limitation, by sales made directly on the Nasdaq Capital Market. During the quarter ended March 31, 2020 the Company sold an aggregate of 3,598,833 shares of Common Stock pursuant to the June 11, 2019 ATM, at an average price of \$4.96 per share, raising gross proceeds of approximately \$17.86 million.

**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.):**

At-the-market (ATM) Offerings (Cont.):

On March 6, 2020, the Company entered into a new Distribution Agreement with Raymond James, pursuant to which the Company may 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 are 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 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. During the quarter ended March 31, 2020, the Company sold an aggregate of 336,487 shares of Common Stock pursuant to the March 6, 2020 ATM, at an average price of \$5.23 per share, raising gross proceeds of approximately \$1.76 million.

The Company has no obligation under the March 6, 2020 ATM to sell any shares, and may at any time suspend sales or terminate the March 6, 2020 ATM in accordance with its terms. Raymond James is entitled under each ATM to a fixed commission of 3.0% of the aggregate gross proceeds from the any shares sold. 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 and March 6, 2020 respectively.

Registered Direct Offering:

On March 6, 2020, the Company entered into and closed a \$10.0 million registered direct offering of 1,250,000 shares of Common Stock at a per share purchase price equal to \$8.00. The purchaser also received a three-year warrant to purchase up to 250,000 shares of Common Stock at any exercise price of \$15.00 per share.

Since its inception and as of a quarter ended March 31, 2020 the Company has raised approximately \$94 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.

**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.):**

**Stock Plans:**

As of March 31, 2020, 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. The 2014 Plans have a shared pool of 4,000,000 shares of Common Stock available for issuance.

As of March 31, 2020, 1,623,067 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 administers the Company's stock incentive compensation and equity-based plans.

**Share-based compensation to employees and to directors:**

***Employees:***

Chaim Lebovits, the Company's Chief Executive Officer (i) was granted a stock option under the 2014 Global Plan on September 28, 2015 for the purchase of up to 369,619 shares of the Company's Common Stock at a per share exercise price of \$2.45, which grant is fully vested and exercisable and shall be exercisable for a period of two years after termination of employment; (ii) received on July 26, 2017, July 26, 2018, July 26, 2019, and is entitled to receive on each anniversary thereafter (provided he remains Chief Executive Officer), a grant of 31,185 shares of restricted stock, each of which vests as to twenty-five percent (25%) of the award on the first, second, third and fourth anniversary of the date of grant and is subject to accelerated vesting upon a Change of Control (as defined in the Lebovits employment agreement) of the Company; and (iii) was granted on July 26, 2017 a fully vested and exercisable option to purchase up to 41,580 shares of Common Stock, with an exercise price per share of \$4.81. The option was fully-vested and exercisable until the 2nd anniversary of the date of grant, when it expired unexercised.

Dr. Ralph Kern, President and Chief Medical Officer of the Company, received on March 6, 2017, March 6, 2018, March 6, 2019 and March 6, 2020, and is entitled to receive on each anniversary thereafter (provided he remains employed by the Company), a grant of 35,885 shares of restricted stock, each of which vests as to twenty-five percent (25%) of the award on the first, second, third and fourth anniversary of the date of grant and is subject to accelerated vesting upon a Change of Control (as defined in the agreement) of the Company.

On March 6, 2017, Dr. Kern received an option under the 2014 U.S. Plan to purchase up to 47,847 shares of Common Stock with an exercise price per share of \$4.18. The option was fully vested and exercisable until the 2nd anniversary of the date of grant, when it expired unexercised.

**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 (Cont.):**

***Employees (Cont.):***

On March 9, 2020, Dr. Kern received an option under the 2014 U.S. Plan to purchase up to 80,000 shares of Common Stock with an exercise price per share of \$7.33. The option becomes vested and exercisable as to 25% of the number of shares on each of the first four anniversaries of the grant date until fully vested and exercisable on the fourth anniversary of the grant date. Notwithstanding the foregoing, immediately prior to a Change of Control (as defined in Dr. Kern's employment agreement with the Company) any outstanding unvested Shares shall vest and become exercisable in full.

Uri Yablonka, the Company's Executive Vice President, Chief Business Officer and director is granted a stock option for the purchase of up to 13,333 shares of Common Stock on the first business day after each annual meeting of stockholders (or special meeting in lieu thereof) of the Company (including on November 10, 2017, November 30, 2018 and December 12, 2019), each with an exercise price per share of \$0.75, and each of which vests and becomes exercisable in 12 monthly installments. The Company also granted Mr. Yablonka 5,543 shares of restricted Common Stock on July 13, 2017.

On November 20, 2017, the Company granted to Eyal Rubin, the Company's Chief Financial Officer, 25,000 shares of restricted Common Stock, which fully vested on April 1, 2018. On November 20, 2017 the Company also granted to Mr. Rubin an option to purchase up to 93,686 shares of Common Stock, at an exercise price per share equal to \$4.30 per share, which shall vest and become exercisable as to 25% of the shares underlying the Option on each of the first, second, third and fourth anniversary of the date of grant, subject to accelerated vesting upon a Change of Control of the Company or a Material Secondary Public Offering of the Company (each as defined in Mr. Rubin's employment agreement). Mr. Rubin resigned effective September 18, 2019 and all unvested and unexercised shares were forfeited in accordance with the 2014 Global Plan.

On August 28, 2018, the Company granted Arturo Araya, Chief Commercial Officer of the Company an option to purchase 200,000 shares of Common Stock, at an exercise price of \$3.98 per share. 25% of the grant shall vest and become exercisable on each of the first, second, third and fourth anniversaries of the grant date and subject to accelerated vesting upon a Change of Control (as defined in the agreement). On August 28, 2018, Mr. Araya resigned from the GNC Committee, and the restricted stock previously granted to him in connection with his service on the Board and the GNC Committee ceased vesting and the unvested shares were forfeited.

On September 6, 2019, the Company granted Preetam Shah, Executive Vice President, Chief Financial Officer and Treasurer of the Company, stock options (i) to purchase up to 100,000 shares of Common Stock, at an exercise price of \$3.96 per share, and (ii) to purchase up to 100,000 shares of Common Stock at an exercise price per share equal to \$6.00 per share. Each option shall vest and become exercisable as follows: 25% of the shares underlying the option shall vest and become exercisable on the first anniversary of the date of grant, and the remaining shares underlying the option shall vest and become exercisable in equal quarterly installments thereafter, until fully vested and exercisable on the fourth anniversary of the date of grant, and is subject to accelerated vesting upon a Change of Control (as defined in Dr. Shah's employment agreement) of the Company.

On September 6, 2019, the Company granted Dr. Shah 25,000 shares of restricted common stock of the Company, which shall vest as to 100% of the award on the one year anniversary of the grant date, and is subject to accelerated vesting upon a Change of Control (as defined in Dr. Shah's employment agreement) of the Company.

The Company granted Mary Kay Turner, an employee, 9,924 shares of restricted Common Stock on August 17, 2017, 11,198 shares of restricted Common Stock on August 1, 2018 and 11,533 on August 1, 2019, each of which vests as to 25% of the grant yearly over the course of four (4) years.

**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: (Cont.):**

On July 9, 2018, the Company granted Susan Ward, an employee, an option to purchase 150,000 shares of Common Stock at an exercise price of \$4.21 per share, which vests and becomes exercisable as to 20% of the option on each of the first, second, third, fourth and fifth anniversaries of the date of grant.

***Directors:***

From 2005 through 2015, the Company granted its directors options to purchase an aggregate of 402,778 shares of Common Stock at an average exercise price of \$1.34 per share.

The Company's Second Amended and Restated Director Compensation Plan was approved in July 9, 2014 and amended on April 29, 2015, February 26, 2017 and July 13, 2017 (as amended, the "Director Compensation Plan"). The Director Compensation Plan governs Company compensation of eligible non-employee director of the Company, except that certain non-employee directors have individualized compensation and are not entitled receive annual director awards under the Director Compensation Plan, but are entitled to committee compensation under the Director Compensation Plan in the event that they qualify for and serve as a member of any committee of the Board. The Director Compensation Plan also determines the annual awards to be granted to qualified directors for their services in future periods, which annual awards have had the same terms since 2014, as further detailed in the Director Compensation Plan.

During the 3 months ended March 31, 2020, the following grants were made under the 2014 Plans to eligible directors:

- On February 1, 2020, Dr. Anthony J. Polverino received 3,071 shares of restricted stock for his service as a director

***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.

**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: (Cont.):**

	<b>Number of Shares of Restricted Stock</b>	<b>Weighted Average Grant Date Fair Value</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>
Nonvested as of December 31, 2019	201,385	4.00	1.95
Granted	54,956	6.94	
Vested	31,753	3.77	
Forfeitures	-	-	
Nonvested as of March 31, 2020	224,588	4.75	1.95

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 three months ended March 31, 2020 amounted to \$122.

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

	<b>For the Three months ended March 31, 2020</b>		
	<b>Amount of options *</b>	<b>Weighted average exercise price</b>	<b>Aggregate intrinsic value</b>
		<b>\$</b>	<b>\$</b>
Outstanding at beginning of period	1,293,007	3.0142	
Granted	468,666	6.7871	
Exercised	(9,333)	3.1286	
Cancelled	(2,000)	4.8000	
Outstanding at end of period	1,750,340	4.0218	1,082,037
Vested and expected-to-vest at end of period	821,340	1.7561	2,368,627

\* Represents Employee Stock Options only (not including RSUs).

**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: (Cont.):**

**Directors (Cont.):**

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 March 31, 2020, 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.

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 three months ended March 31, 2020 and 2019 amounted to \$390 and \$312, respectively.

**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:

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
Research and development	105	28
General and administrative	285	309
Total stock-based compensation expense	<u>390</u>	<u>337</u>

**NOTE 8 - SUBSEQUENT EVENTS**

On April 6, 2020, Mr. Sankesh Abbhi received 4,657 shares of restricted Common Stock under the 2014 Plans, which shall vest in 12 monthly installments, for his service as a director.

On April 6, 2020, Dr. Jacob Frankel received stock options under the 2014 Plans for the purchase of up to 50,000 shares of Common Stock each with an exercise price per share of \$0.75, and each of which vests and becomes exercisable in 12 monthly installments, for his service as director.

On April 7, 2020, the Company granted Dr. David Setboun 50,000 shares of restricted Common Stock under the 2014 Plans, which shall vest as to 100% of the award on the one year anniversary of the grant date, and is subject to accelerated vesting upon a change of control of the Company. On April 7, 2020, the Company also granted Mr. Setboun a one-time issuance of performance based restricted stock units (the "RSU") with the following terms: upon the occurrence of specified milestones Mr. Setboun shall receive, within 10 business days, 250,000 shares of restricted Common Stock which shall vest immediately as to 100% of the award. The RSU is not subject to acceleration upon change in control. The milestone for the RSU is as follows: the Company had entered into a definitive commercialization agreement - prior to its phase 3 ALS trial data unblinding for its lead investigational product - with a third party that is not an affiliate or subsidiary of the Company, with respect to the Company's primary targeted indication - Amyotrophic Lateral Sclerosis.

**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 8 - SUBSEQUENT EVENTS**

In December 2019, a novel strain of coronavirus (“COVID-19”), surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States and Israel, where the Company conducts its operations, as well as its clinical trials for NurOwn®. In response to the spread of COVID-19, to ensure the safety of employees and continuity of business operations, the Company closed its offices, with its administrative employees continuing their work remotely and limited the number of staff in any given research and development laboratory. The Company’s research and development laboratory in Israel and manufacturing sites in the U.S. remain open.

As of the date of this report, the Company’s business operations and clinical trials have continued with delays in the pace of enrollment in its Phase 2 PMS clinical trial due to site access restrictions related to the global COVID-19 pandemic. Scheduled March and April 2020 new patient enrollments were deferred to May 2020 due to site closures related to COVID-19, when some of affected healthcare sites anticipate their access restrictions will be mitigated. Enrollment will proceed in 2020 subject to any site access restrictions related to COVID-19.

The Phase 3 ALS clinical trial continues to provide necessary treatments to study participants despite severe constraints in the affected healthcare institutions due to COVID-19. Non-treatment study visits are now performed by telephone.

Because of the COVID-19 outbreak, the Company may, in the future, experience disruptions that could severely impact its business, including clinical trial activities; participant enrollment; or any currently unforeseen delays in completion of study timelines. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company’s business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted at this time, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. The Company’s management team is actively monitoring this situation and the possible effects on the financial condition, liquidity, operations, suppliers, industry, and workforce.

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.

### 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 ALS, the sufficiency of our existing capital resources for continuing operations in 2020 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 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 broad acceptance as a treatment option for ALS 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, health reform legislation, demand for our services, currency exchange rates and product liability claims and litigation, the impact on BrainStorm of the COVID-19 pandemic, 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, 2019. 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, 2019, in addition to the other information set forth herein and elsewhere in our other public filings with the Securities and Exchange Commission (“SEC”).*

### 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: Amyotrophic Lateral Sclerosis (“ALS”, also known as Lou Gehrig’s disease); Progressive Multiple Sclerosis (“PMS”); and Parkinson’s disease (“PD”).
- NurOwn® leverages innovative and proprietary cell culture methods to induce autologous bone marrow-derived mesenchymal stem cells (MSCs) to secrete high levels of neurotrophic factors (NTFs), modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival and improve neurological function.
- NurOwn® is currently being evaluated in Phase 3 ALS and Phase 2 PMS clinical trials. Enrollment for the U.S. Phase 3 ALS trial was completed in October 2019 and the trial continues to provide necessary treatments to study participants despite severe constraints in the affected healthcare institutions due to COVID-19. The Phase 3 ALS trial is still expected to generate top-line data in the fourth quarter of 2020. The U.S. Phase 2 PMS trial has faced delays in enrollment due to the COVID-19 pandemic. Scheduled March and April 2020 new participant enrollments were deferred to May 2020 due to site closures related to COVID-19, when some of affected healthcare sites anticipate their access restrictions will be mitigated. Enrollment will proceed in 2020 subject to any site access restrictions related to COVID-19. Top-line results may still be possible in the fourth quarter of 2020, if enrollment continues without COVID-19 disruptions.

- Our wholly owned Israeli subsidiary, BrainStorm Cell Therapeutics Ltd. (“Israeli Subsidiary”), holds exclusive rights to commercialize NurOwn® technology through a licensing agreement with Ramot (“Ramot”), the technology transfer company of Tel Aviv University, Israel.
- The Israeli Subsidiary was granted approval by the Israeli Ministry of Health (“MoH”) to treat ALS patients with NurOwn® under the Hospital Exemption Pathway (“HE”).
- NurOwn® has a strong and comprehensive intellectual property portfolio.
- NurOwn® was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) and Orphan Drug status by the FDA and the European Medicines Agency (EMA) for ALS. For more information, visit BrainStorm’s website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com).
- BrainStorm Cell Therapeutics Inc. currently employs 34 employees in the United States and in Israel. Most of the senior management team is based in the United States, and all of BrainStorm’s current clinical trial sites are located in the United States. BrainStorm’s R&D center is located in Petach Tikva, Israel.
- *The Outbreak of the Novel Strain of Coronavirus, SARS-CoV-2 (COVID-19) Disease and its Impact:*

The Outbreak of the novel strain of coronavirus, SARS-CoV-2 (COVID-19) disease has currently impacted and may continue to adversely impact our business, including our preclinical studies and clinical trials. In December 2019, a novel strain of coronavirus, surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States and Israel, where the Company conducts its operations, as well as its clinical trials for NurOwn®. In response to the spread of COVID-19 and to ensure safety of employees and continuity of business operations, we closed our offices, with our administrative employees continuing their work remotely and limited the number of staff in any given research and development laboratory. Our research and development laboratory in Israel and manufacturing sites in U.S. remain open.

As of the date of this report, our business operations and clinical trials have continued with delays in the pace of enrollment in our Phase 2 PMS clinical trial due to site access restrictions related to the global COVID-19 pandemic. Scheduled March and April 2020 new patient enrollments were deferred to May 2020 due to site closures related to COVID-19, when some of affected healthcare sites anticipate their access restrictions will be mitigated. Enrollment will proceed in 2020 subject to any site access restrictions related to COVID-19. The Phase 3 ALS clinical trial continues to provide necessary treatments to study participants despite severe constraints in the affected healthcare institutions due to COVID-19. Non-treatment study visits are now performed by telephone.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted at this time, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Our management team is actively monitoring this situation and the possible effects on our financial condition, liquidity, operations, suppliers, industry, and workforce. For additional information on risks posed by the COVID-19 pandemic, please see Part II, Item 1A – Risk Factors – Risks Related to the COVID-19 Pandemic.

### **Recent Highlights**

- The Company has made significant progress in the past 12 months advancing the NurOwn® ALS Phase 3 clinical trial at all 6 U.S. investigative sites (Mass General Hospital, UMass, Mayo Clinic, CPMC, Cedars Sinai and UC Irvine). This clinical trial builds upon promising efficacy seen in three prior early-stage ALS clinical trials, including a U.S. randomized placebo-controlled Phase 2 trial. We completed enrollment for NurOwn® ALS Phase 3 trial in October 2019 and the trial is still expected to generate top-line data in the fourth quarter to support an FDA BLA filing.
- On February 11, 2020, the Company announced that it recently held a high-level meeting with the U.S. Food and Drug Administration (FDA) to discuss potential NurOwn® regulatory pathways for approval in ALS. In the planned meeting with senior Center for Biologics Evaluation and Research (CBER) leadership and several leading U.S. ALS experts, the FDA confirmed that the fully enrolled Phase 3 ALS trial is 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. Furthermore, based on their detailed data assessment, they are committed to work collaboratively with BrainStorm to identify a regulatory pathway forward, including opportunities to expedite statistical review of data from the Phase 3 trial.

- The Company was granted FDA approval in December 2018 for the IND Application of NurOwn® in Progressive Multiple Sclerosis (PMS) ([www.clinicalTrials.gov](http://www.clinicalTrials.gov) Identifier: NCT03799718). The study entitled ‘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 Progressive Multiple Sclerosis (MS)’ is ongoing at 5 leading U.S. Multiple Sclerosis centers. On February 27, 2020, the Company announced Partners MS Center at Brigham and Women’s Hospital, a leading research and clinical care center, as the fifth and final Site for BrainStorm’s PMS Phase 2 clinical trial. As of the quarter ended March 31, 2020, the first nine (9) study participants have been enrolled in the study. The trial has faced delays in enrollment due to the COVID-19 pandemic. Scheduled March and April 2020 new patient enrollments were deferred to May 2020 due to site closures related to COVID-19, when some of affected healthcare sites anticipate their access restrictions will be mitigated. Enrollment will proceed in 2020 subject to any site access restrictions related to COVID-19. The Company is currently collecting the clinical and biomarker data from treated patients and plans to perform an interim analysis after 50% of the patients in the trial have been treated.
- On February 21, 2020, we completed the sale of all remaining shares issuable under the June 11, 2019, \$20 million ATM Distribution Agreement (the “June 19, 2020 ATM”) with Raymond James & Associates, Inc. and exhausted its full capacity. During the quarter ended March 31, 2020, the Company sold an aggregate of 3,598,833 shares of Common Stock pursuant to the June 11, 2019 ATM at an average price of \$4.96 per share, raising gross proceeds of approximately \$17.86 million. Since the initiation of the June 11, 2019 ATM through February 21, 2020, the Company sold an aggregate of 4,141,569 shares of Common Stock at an average price of \$4.83 per share, raising gross proceeds of approximately \$20 million.
- On March 6, 2020, we entered into a new Distribution Agreement (the “March 6, 2020 ATM”) with Raymond James & Associates, Inc. (the “Agent”). Under the March 6, 2020 ATM, the Company may sell from time to time or through the Agent shares of Common Stock, having an aggregate offering amount of up to \$50 million. The Company filed a prospectus supplement, on March 6, 2020, with the U.S. Securities and Exchange Commission (the “SEC”) in connection with the March 6, 2020 ATM. During the quarter ended March 31, 2020, the Company sold an aggregate of 336,487, shares of Common Stock pursuant to the March 6, 2020 ATM at an average price of \$5.23 per share, raising gross proceeds of approximately \$1.76 million.
- On March 6, 2020 we entered into a definitive agreement with Abbhi Investments, LLC, a healthcare-focused family office based in Miami, Florida, in connection with a privately negotiated sale of Company common stock, \$0.00005 par value per share (“Common Stock”) and a warrant to purchase shares of Common Stock (collectively, the “Securities”). Upon the closing of this registered direct offering, the Company received gross proceeds of approximately \$10.0 million, resulting from the issuance and sale of 1,250,000 shares of Common Stock at a price per share of \$8.00, a 4.9% premium to the Company’s closing share price of \$7.62 on March 5, 2020, and a 35.6% premium to the Company’s 30 day volume-weighted average share price of \$5.90. The purchaser also received a warrant to purchase up to 250,000 shares of Common Stock at an exercise price of \$15.00 per share. The warrant was exercisable immediately and has a term of three years.
- On March 7, 2019, the Israeli MoH approved the Company’s treatment of up to 13 ALS patients with NurOwn® under the Israeli Hospital Exemption (HE) regulatory pathway. This approval expired on March 7, 2020. Based on this approval, the Company enrolled twelve (12) patients under the HE regulatory pathway as of March 31, 2020 and intends to enroll the maximum number of patients that have been approved. The Hospital has received approval from the MoH for the extension of this program and to expand the HE regulatory pathway to include an additional 13 patients. Currently, the Company has not finished treating all the first 13 patients as non-Israeli patients are unable to travel to Israel at the present time due to COVID-19 travel restrictions. The Company is currently collecting HE clinical data for the patients who already received treatment at the Ichilov Hospital. Once the complete data for the first 13 treated patients is available, the Company will perform a detailed analysis. Thus far, the Company has received \$3.4 million in gross proceeds in connection with the treatment of the aforementioned patients.
- On March 16, 2020, the Company announced that it had received a \$2.2 million non-dilutive grant from CIRM for completing it predetermined milestones. With the receipt of this grant the Company has now received \$14.75 million of the total available \$15.91 million grant funding awarded by CIRM.
- On March 30, 2020, the Board of Directors of the Company (the “Board”) appointed Jacob Frenkel, Ph.D., as Chairman of the Board. Prof. Frenkel is a world-renowned economist and former Governor of the Bank of Israel. On March 30, 2020, the Board also appointed Sankesh Abbhi as a member of the Board. Mr. Abbhi is the President and CEO of ArisGlobal, a leading provider of cloud-based, end-to-end, drug development technology solutions. Mr. Abbhi replaces Chen Schor as member of the Board.

- On April 7, 2020, the Company appointed David Setboun, Pharm.D., MBA, as its Executive Vice President and Chief Operating Officer. Dr. Setboun, has directed commercial development, business strategy, and product launches for 2 decades at 3 major biopharmaceutical companies. Most recently, Dr. Setboun served as Chief Business Officer, Corporate Development & Strategy at Life Biosciences. In connection with Dr. Setboun's hiring, Dr. Ralph Kern was appointed the Company's President and Chief Medical Officer and ceased to serve as the Company's Chief Operating Officer, and Mr. Chaim Lebovits ceased serving as President and continues to serve as Chief Executive Officer of the Company.
- On April 3, 2020, the Company announced that its wholly owned subsidiary, BrainStorm Cell Therapeutics Ltd., has been awarded a non-dilutive grant of approximately \$1.5 million by the Israel Innovation Authority (IIA). The grant enables the Company to continue development of advanced cellular manufacturing capabilities, furthers the development of MSC-derived exosomes as a novel therapeutic platform, and will ultimately enable BrainStorm to expand the therapeutic pipeline in neurodegenerative disorders.

### **NurOwn® Proprietary Technology**

NurOwn® technology is based on an innovative manufacturing protocol, which induces the differentiation of purified and expanded bone marrow-derived mesenchymal stem cells ("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"); and hepatocyte growth factor ("HGF"), among others. GDNF is one of the most potent survival factors for peripheral motoneurons. VEGF and HGF have demonstrated important neuroprotective effects in ALS and other neurodegenerative diseases. Neuroinflammation is a prominent and early feature of ALS and other neurodegenerative diseases, as well as of Progressive MS.

NurOwn® manufacturing involves a multi-step process that includes: 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 ("IT") injection 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 safe and well tolerated in multiple CNS clinical trials to date. The ongoing NurOwn® U.S. Phase 3 ALS study is evaluating the therapeutic potential of repeated dosing (three doses at bi-monthly intervals).

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

### ***The NurOwn® Transplantation 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
- Autologous transplantation into the patient's cerebrospinal fluid by IT injection (standard lumbar puncture).

### ***Differentiation before Transplantation***

The ability to induce autologous adult mesenchymal stem cells 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 (Self-transplantation)***

The NurOwn® technology platform is autologous, using the patient's own bone-marrow derived stem cells for "self-transplantation." In autologous transplantation, 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 stem cells is free of several ethical concerns associated with the use of embryonic-derived stem cells in some countries.

### **The ALS Clinical Program**

NurOwn® is currently in a Phase 3 late stage clinical development program for the treatment of ALS. It has been granted Fast Track designation by the U.S. Food and Drug Administration ("FDA") for this indication, and has been granted Orphan Drug Status, in the U.S. and Europe, which provides the potential for an extended period of exclusivity.

### ***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 ("Hadassah") 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 and investigation 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 safety of NurOwn® by both routes of administration and showed preliminary signs of efficacy.

In January 2016, the results of the two completed Phase 1/2 study and Phase 2 open label trials were published in JAMA Neurology. This demonstrated a slower rate of disease progression following MSC-NTF cell transplantation as measured by the ALS Functional Rating Score ("ALSFRS-R"), the gold standard for the evaluation of ALS functional status, and Forced Vital Capacity ("FVC"), a measure of pulmonary function, as well as positive trends in the rate of decline of muscle volume and the compound motor axon potential ("CMAPs"). This was the first published clinical data using autologous mesenchymal stem cells, 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 ("IND") 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 Massachusetts General Hospital (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 entitled 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® transplantation was safe and well-tolerated. There were no discontinuations from the trial due to AEs and there were no deaths in the study. The most common adverse events (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 (change/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 beneficial treatment effects were greater in the rapid progressor subgroup (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 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-transplantation. 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 post-treatment vs. pre-treatment ALSFRS-R slope change. ***These are new and meaningful ALS clinical observations that are being evaluated in the ongoing Phase 3 study using repeat dosing in ALS rapid progressors.***

### ***Phase 3 ALS Clinical Trial***

Following successful completion of the Phase 2 study, the Company is currently conducting a Phase 3 trial (a multi-dose double-blind, placebo-controlled, multicenter trial protocol) that has been designed to generate data to support a Biologic License Application ("BLA") for NurOwn® in ALS. The clinical trial has completed enrolment of an enriched patient population of rapid progressors (~50% of ALS patients) based on superior outcomes observed in the Phase-2 pre-specified sub-group.

The primary clinical efficacy outcome measure is the ALSFRS-R score responder analysis, an outcome that evaluates the proportion of treated participants who achieve a prespecified level of improvement in the ALSFRS-R post-treatment slope. The Phase 3 trial expands biomarker evaluations to further understand their potential to predict ALS disease progression, treatment response and confirm the biology of NurOwn® in a larger study population. The study is being conducted at 6 leading U.S. medical centers, 3 of which participated in the prior Phase 2 study. Patient enrollment commenced in October 2017, at Massachusetts General Hospital followed by the other 5 study sites, including University of California Irvine Medical Center, University of Massachusetts Medical Center, Mayo Clinic in Rochester, Minnesota, the California Pacific Medical Center in San Francisco, and Cedars Sinai Medical Center in Los Angeles. All 6 sites are actively enrolling study participants. As of October 2019, the study is fully enrolled.

The independent Data Safety Monitoring Board ("DSMB") for the study completed its pre-specified interim analysis of safety outcomes for the first 31 participants treated with NurOwn® in the Phase 3 trial in ALS (NCT03280056) in August 2018. The DSMB indicated there were no significant safety concerns and recommended that the trial continue, as planned without any modifications to the study protocol.

The DSMB completed the second pre-specified interim analysis of safety outcomes for 106 participants treated with NurOwn® in the Phase 3 ALS trial on October 28, 2019. The DSMB indicated that the trial should continue without any modifications to the study protocol, and the DSMB chair indicated that they did not identify any significant safety concerns.

The Phase 3 ALS clinical trial continues to provide necessary treatments to study participants despite severe constraints in the affected healthcare institutions due to COVID-19. Non-treatment study visits are now performed by telephone. Top-line efficacy data is still expected in the fourth quarter of 2020. The study is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (ClinicalTrials.gov Identifier: NCT03280056).

The Company has 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 trial 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.

The Company has contracted with City of Hope's Center for Biomedicine and Genetics to produce clinical supplies of NurOwn® adult stem cells for the ongoing Phase 3 clinical study. City of Hope is currently supporting the production of NurOwn® and placebo for the participants treated in the Phase 3 trial. The Connell and O'Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute (DFCI) in Boston has also been contracted to manufacture NurOwn® and placebo for Phase 3 ALS clinical study participants and commenced manufacturing in October 2018. As of March 2019, The DFCI core manufacturing facility is also supplying NurOwn for the Phase 2 PMS study.

### **Special meeting with 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's 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 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 (Massachusetts General Hospital, 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, the Company announced that it recently held a high-level meeting with the U.S. Food and Drug Administration (FDA) to discuss potential NurOwn® regulatory pathways for approval in ALS. In the planned meeting with senior Center for Biologics Evaluation and Research (CBER) leadership and several leading U.S. ALS experts, the FDA confirmed that the fully enrolled Phase 3 ALS trial is 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. Furthermore, based on their detailed data assessment, they are committed to work collaboratively with BrainStorm to identify a regulatory pathway forward, including opportunities to expedite statistical review of data from the Phase 3 trial.

### **Patient Access Programs (ALS)**

The Company, working collaboratively with the Tel Aviv Sourasky Medical Center (Ichilov Hospital), was approved on March 7, 2019 to treat up to 13 ALS patients with NurOwn®, under the Israel Hospital Exemption regulatory pathway for Advanced Therapy Medicinal Products (ATMP), which was adopted by the Israeli Ministry of Health (MoH) from the European Medicine Agency (EMA) regulation. This pathway enables the Company to make NurOwn® accessible to ALS patients in Israel, for a fee. This approval expired on March 7, 2020. Based on this approval, the Company enrolled twelve (12) patients under the HE regulatory pathway as of March 31, 2020 and intends to enroll the maximum number of patients that have been approved. The Hospital has received approval from the MoH for the extension of this program and to expand the HE regulatory pathway to include an additional 13 patients. Currently, the Company has not finished treating all the first 13 patients as non-Israeli patients are unable to travel to Israel at the present time due to COVID-19 travel restrictions. The Company is currently collecting HE clinical data for the patients who already received treatment at the Ichilov Hospital. Once the complete data set for the first 13 treated patients is available, the Company will perform a detailed analysis. Thus far, the Company has received \$3.4 million in gross proceeds in connection with the treatment of the aforementioned patients.

### **NurOwn in Progressive Multiple Sclerosis**

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 progressive MS (PMS. [www.clinicaltrials.gov](http://www.clinicaltrials.gov) Identifier NCT03799718). The study entitled '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 Progressive Multiple Sclerosis (MS)' will recruit 20 progressive MS patients at 5 leading US MS centers. As of the quarter ended March 31, 2020, the first nine (9) study participants have been enrolled in the study.

On December 18, 2019, the clinical trial independent Data Safety Monitoring Board (DSMB) for the 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".

On November 14, 2019 the Company also received a \$495,330 grant from the National Multiple Sclerosis Society, 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 progressive Multiple Sclerosis.

The trial has faced delays in enrollment due to the COVID-19 pandemic. Scheduled March and April 2020 new patient enrollments were deferred to May 2020 due to site closures related to COVID-19, when some of affected healthcare sites anticipate their access restrictions will be mitigated. Enrollment will proceed in 2020 subject to any site access restrictions related to COVID-19. Top-line results may still be possible in the fourth quarter of 2020, if enrollment continues without COVID-19 disruptions.

The Company is currently collecting the clinical and biomarker data from treated patients and plans to perform an interim analysis after 50% of the patients in the trial have been treated.

### **Non-Dilutive Funding**

In July 2017, the Company was 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. The Company 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, the Company announced that it had received an additional \$2,200,000 from CIRM for achieving its pre-determined milestones. With the receipt of this grant, the Company has now received \$14,750,000 of the total available \$15,912,390 grant funding awarded by CIRM. The grant does not bear a royalty payment commitment nor is the grant otherwise refundable. The Company expects to receive approximately \$1,162,390 in additional grant funding from CIRM upon achieving certain milestones.

On April 3, 2020, the Company announced that its wholly owned subsidiary, BrainStorm Cell Therapeutics Ltd., has been awarded a new non-dilutive grant of approximately \$1.5 million by the Israel Innovation Authority ("IIA"). The grant enables the Company to continue development of advanced cellular manufacturing capabilities, furthers development of MSC-derived exosomes as a novel therapeutic platform, and will ultimately enable BrainStorm to expand the therapeutic pipeline in neurodegenerative disorders.

### **Intellectual Property**

A key element of the Company's 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 15 granted patents 4 allowed patents and 22 patent applications in the United States, Europe, and Israel, as well as in additional countries worldwide, including countries in the Far East and South America (in calculating the number of granted patents, each European patent validated in multiple jurisdictions was counted as a single patent).

In March 2019, the European Patent Office ("EPO") granted a European-wide patent titled 'Mesenchymal Stem Cells for the treatment of CNS Diseases.' The European Patent Application published in the European Patent Bulletin 19/13 on March 27, 2019, under Patent No. 2620493. The allowed claims cover the isolated cells as well as their use in the manufacture of a medicament for treating a CNS disease or disorder, selected from the group consisting of: Parkinson's, multiple sclerosis, epilepsy, amyotrophic lateral sclerosis, stroke, autoimmune encephalomyelitis, diabetic neuropathy, glaucomatous neuropathy, Alzheimer's disease and Huntington's disease.

On August 27, 2019, the Canadian Intellectual Property Office granted Canadian Patent No. 2,877,223 entitled 'Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors'. The allowed claims cover the method for generating the Mesenchymal Stem Cells Secreting Neurotrophic Factors (MSC-NTF cells).

On September 16, 2019, the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance for BrainStorm's new US Patent Application, number: 15/113,105, titled: 'Method of Qualifying Cells'. 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 October 21, 2019, the Japan Patent Office (JPO) issued a decision to Grant Japanese Patent Application, number: 2016-548691, titled: 'Method of Qualifying Cells.' The patent covers cell populations which are therapeutic for the treatment of ALS and the method of qualifying the cells for therapeutic use.

On December 6, 2019, the Hong Kong Patent Office sealed patent No. HK1182133 titled 'Mesenchymal Stem Cells for the treatment of CNS Diseases'.

On January 27, 2020, the Israeli patent Office allowed application number 246943 titled 'Method of Qualifying Cells'. The allowed claims cover a method of qualifying whether a cell population is a suitable therapeutic for treating Amyotrophic Lateral Sclerosis (ALS) and an isolated population of cells that secrete neurotrophic factors which are qualified useful as a therapeutic for treating ALS.

On January 29, 2020, the European Patent Office (EPO) communicated its intention to grant a European patent titled 'Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors'. Allowed claims cover the method for manufacturing MSC-NTF cells (NurOwn®).

On February 18, 2020, the US Patent and Trademark Office (USPTO) issued US 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.

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

For a complete list of our patent portfolio, please refer to the [Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#).

### **Scientific and industry presentations in 2020**

On January 12, 2020, Mr. Chaim Lebovits presented at 3rd Annual Neuroscience Innovation Forum at the Marines' Memorial Club in San Francisco, California.

On January 12, 2020, Dr. Ralph Kern MD, MHSc, participated on a Rare & Orphan Diseases Panel at the 3rd Annual Neuroscience Innovation Forum at the Marines' Memorial Club in San Francisco, California.

On January 24, 2020, Dr. Ralph Kern MD, MHSc, delivered a podium presentation entitled "CIRM funded Stem Cell Clinical Trials in California – Updates" at the 10th Annual California ALS Research Summit hosted at the Cedars-Sinai Medical Center, Los Angeles, California.

On February 11, 2020, Mr. Chaim Lebovits presented at BIO CEO & Investor Conference at the Marriott Marquis in New York City, New York.

On February 17, 2020, Dr. Ralph Kern MD, MHSc, presented at the Noble Capital Markets' Sixteenth Annual Investor Conference at the Hard Rock Hotel & Casino, Hollywood, Florida.

### **Research and Development**

The Company is also reviewing the potential for clinical development of NurOwn® in other neurodegenerative disorders, such as Parkinson's disease, and Alzheimer's disease and neurodegenerative eye disease. Research is currently ongoing to develop additional specialized derivative cell products such as MSC-NTF derived Exosomes. 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 research efforts are primarily focused on:

1. Manufacturing of MSC-NTF exosomes from bone marrow derived MSC and umbilical cord derived MSC:
  - a. Developing and optimizing large scale cell culture processes using bioreactors, to generate exosomes.
  - b. Developing advanced scalable purification GMP methods that can be applied to commercial use.
2. Quantification, characterization of phenotype and exosome cargo.
3. Assessment of MSC-NTF exosomes potency and stability.
4. Establishment of a method for exosomes modification

For the ongoing multidose clinical studies in ALS and MS, 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 offices at 12 N State Route 17, Suite 201, Paramus, NJ 07652, and in Petach Tikva, Israel. We maintain an Internet 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) through March 31, 2020, the Company has not earned any revenue from operations. The Company does not expect to earn revenue from operations in the near-term. The Company has incurred operating costs and other expenses of approximately \$8,308,000 during the three months ended March 31, 2020 compared to \$4,928,000 during the three months through March 31, 2019. The increase of \$3,380,000 is due to higher expenses in connection with the ongoing U.S. Phase 3 and Phase 2 Clinical Trials.

### *Research and Development Expenses:*

Research and development expenses, net for the three months ended March 31, 2020 and 2019 were 5,948,000 and \$3,456,000, respectively, representing an increase of \$2,492,000. This increase is due to (i) an increase of \$1,929,000 in connection with the Phase 3 and Phase 2 Clinical Trials; (ii) an increase of \$103,000 for costs related to payroll and stock-based compensation expenses and (iii) a decrease of \$1,457,000 in participation of the Israel Innovation Authority (“IIA”) and CIRM in 2020, under various awarded grants. This increase was partially offset by (i) \$816,000 received in connection with the treatment of patients under the hospital exemption regulatory pathway and (ii) a decrease of \$181,000 in connection with materials, patents, travel, rent and other activities.

Excluding participation from IIA and CIRM under the grants and proceeds received under the hospital exemption regulatory pathway, research and development expenses increased by \$1,935,000 from \$5,200,000 in the first quarter of 2019 to \$7,135,000 in the first quarter of 2020.

### *General and Administrative Expenses:*

General and administrative expenses for the three months ended March 31, 2020 and 2019 were \$2,360,000 and \$1,472,000, respectively. The increase in general and administrative expenses of \$888,000 is primarily due to an increase of \$636,000 in payroll and stock-based compensation, an increase of \$107,000 in PR and IR costs and an increase of \$145,000 in rent, consultants and travel.

### *Other Income and Expenses:*

Financial income for the three months ended March 31, 2020 was \$194,000 as compared to financial expense of \$99,000 for the three months ended March 31, 2019 as a result of the adoption of the Accounting Standard Update ASU 2016-02 “Leases” and due to conversion exchange rates.

### *Net Loss:*

Net loss for the three months ended on March 31, 2020 was \$8,114,000, as compared to a net loss of \$5,027,000 for the three months ended March 31, 2019. Net loss per share for the three months ended March 31, 2020 and 2019 was \$0.32 and \$0.24, 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 March 31, 2020 was 28,423,837, compared to 20,917,329 for the three months ended March 31, 2019.

## Liquidity and Capital Resources

The Company has financed its operations since inception primarily through public and private sales of its Common Stock and warrants, the exercise of warrants, the issuance of convertible promissory notes, sales via ATM program and through various grants.

Cash, Cash equivalents (including short-term bank deposits) amounted to approximately \$14,491,000 as of March 31, 2020.

Net cash used in operating activities was \$15,029,000 for the three months ended March 31, 2020. Cash used for operating activities was primarily attributed to significant reduction in outstanding trades payables, cost of payroll, rent of clean rooms and materials for clinical trials, rent, legal expenses and public relations expenses. Net cash used in investing activities was \$1,994,000 for the three months ended March 31, 2020, representing net increase in short-term interest-bearing bank deposits. Net cash provided by financing activities was \$28,958,000 for the three months ended March 31, 2020 and is attributable to the exercise of options and exercise and sales of shares under our ATM Program and registered direct offering.

On June 8, 2018, we filed a shelf registration statement on Form S-3 (File No. 333-225517) (the “Shelf Registration Statement”), which was declared effective by the SEC on June 29, 2018, relating to Common Stock, warrants and units that we may sell from time to time in one or more offerings, up to a total dollar amount of \$100,000,000. Other than the supplements filed on June 11, 2019 and on March 6, 2020 in connection with the ATM offerings discussed below, and the prospectus supplement filed on March 6, 2020 in connection with the registered direct offering discussed below, we have not filed any supplemental prospectus defining particular terms of securities to be offered under the shelf registration statement.

*At-the-market (ATM) Offerings:*

On June 11, 2019, the Company entered into a Distribution Agreement with Raymond James & Associates, Inc. (“Agent”), pursuant to which the Company sold, through the Agent, shares of Common Stock having an aggregate offering price of \$20,000,000 (the “June 11, 2019 ATM”) in an “at the market” offering as defined in Rule 415 promulgated under the Securities Act, including, without limitation, by sales made directly on the Nasdaq Capital Market. On February 21, 2020, the Company completed the sale of all remaining shares issuable under the June 11, 2019, \$20 million Distribution Agreement with Raymond James & Associates, Inc. and exhausted its full ATM capacity. During the quarter ended March 31, 2020, the Company sold an aggregate of 3,598,833 shares of Common Stock pursuant to the June 11, 2019 ATM at an average price of \$4.96 per share, raising gross proceeds of approximately \$17.86 million. Since the initiation of the June 11, 2019 ATM through February 21, 2020, the Company sold an aggregate of 4,141,569 shares of Common Stock at an average price of \$4.83 per share, raising gross proceeds of approximately \$20 million.

On March 6, 2020, the Company entered into a new Distribution Agreement with Raymond James & Associates, Inc. (“Agent”), pursuant to which the Company may 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 will 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 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 Agent. During the quarter ended March 31, 2020, the Company sold an aggregate of 336,487, shares of Common Stock pursuant to the March 6, 2020 ATM at an average price of \$5.23 per share, raising gross proceeds of approximately \$1.76 million.

The Company has no obligation under the March 6, 2020 ATM to sell any shares and may at any time suspend sales or terminate the March 6, 2020 ATM in accordance with its terms. Agent is entitled under each ATM to a fixed commission of 3.0% of the aggregate gross proceeds from the any shares sold. 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 and March 6, 2020, respectively.

*Registered Direct Offering:*

On March 6, 2020, the Company entered into and closed a \$10.0 million registered direct offering of 1,250,000 shares of Common Stock at a per share purchase price equal to \$8.00. Purchaser also received a three-year warrant to purchase up to 250,000 shares of Common Stock at any exercise price of \$15.00 per share.

*Company Cash Needs*

Our material cash needs for the next 24 months, assuming we do not expand our clinical trials beyond the current Phase 3 ALS and Phase 2 PMS trials in the United States, will include (i) costs of the clinical trial in the U.S., (ii) employee salaries, (iii) payments for rent and operation of the GMP facilities, and (iv) fees to our consultants and legal advisors, patents, and fees for facilities to be used in our research and development.

Over the longer term if we are not able to raise additional capital, we may not be able to continue to function as a going concern and may have to cease operations or the Company will reduce its costs, including curtailing its current plan to move new indications into clinical testing. We will be required to raise a substantial amount of capital in the future in order to reach profitability and to complete the commercialization of our products. Our ability to fund these future capital requirements will depend on many factors, including the following:

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

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, financial condition, liquidity and capital resources will depend on future developments that are highly uncertain and cannot be accurately predicted at this time, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Our management team is actively monitoring this situation and the possible effects on our financial condition and liquidity.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements 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 continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, our expected course of development, historical experience and other factors we believe are reasonable based on the circumstances, the results of which form our management’s basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There were no significant changes to our critical accounting policies during the quarter ended March 31, 2020. For information about critical accounting policies, see the discussion of critical accounting policies in our [Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#).

### **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 Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on this evaluation, our 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 Officer 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 March 31, 2020 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. We currently are not a party to any material legal proceedings, the adverse outcome of which, in management's opinion, would have a material adverse effect on our business, results of operation or financial condition.

### Item 1A. Risk Factors.

Other than the additional risk factor 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, 2019](#).

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, 2019, 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, 2019 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.

#### Risks Related to Our Business Operations and Commercialization of Stem Cell Therapies:

***The coronavirus outbreak has the potential to cause disruptions in our business, including our clinical development activities.***

*The Outbreak of the novel strain of coronavirus, SARS-CoV-2 (COVID-19) disease, has currently impacted and may continue to adversely impact our business, including our preclinical studies and clinical trials.* In December 2019, a novel strain of coronavirus, surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States and Israel, where the Company conducts its operations, as well as its clinical trials of NurOwn®. In response to the spread of COVID-19, to ensure the safety of our employees and continuity of business operations, we have closed our offices, with our administrative employees continuing their work remotely, restricted on-site staff, and limited the number of staff in any given research and development laboratory. Our research and development laboratory in Israel and manufacturing sites in U.S. remain open.

As of the date of this report, our business operations and clinical trials have continued with delays in the pace of enrollment in our Phase 2 PMS clinical trial due to site access restrictions related to the global COVID-19 pandemic. Scheduled March and April 2020 new patient enrollments were deferred to May 2020 due to site closures related to COVID-19, when some of affected healthcare sites anticipate their access restrictions will be mitigated. Enrollment will proceed in 2020, subject to any site access restrictions related to COVID-19.

The Phase 3 ALS clinical trial continues to provide necessary treatments to study participants despite severe constraints in the affected healthcare institutions due to COVID-19. Non-treatment study visits are now performed by telephone. Top-line efficacy data is still expected in the fourth quarter of 2020.

Because of the COVID-19 outbreak, we may in the future experience disruptions that could severely impact our business, including clinical trial activities; participant enrollment; or any currently unforeseen delays in completion of study timelines. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted at this time, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

In addition, the trading prices for our common stock and other biotechnology companies have been highly volatile as a result of the COVID-19 epidemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs, business closures or business disruptions and the effectiveness of actions taken to contain and treat the disease.

**Item 5. Other Information.**

During the quarter ended March 31, 2020, we made no material changes to the procedures by which stockholders may recommend nominees to our Board of Directors, as described in our most recent proxy statement.

**Item 6. Exhibits.**

The following documents are filed as exhibits to this report:

Exhibit Number	Description	Filed (or Furnished) with this Form 10-Q	Incorporated by Reference Herein		
			Form	Exhibit & File No.	Date Filed
<a href="#">10.1</a>	<a href="#">Distribution Agreement, dated March 6, 2020, by and between BrainStorm Cell Therapeutics Inc. and Raymond James &amp; Associates, Inc.</a>		<a href="#">8-K</a>	<a href="#">1.1</a>	<a href="#">March 6, 2020</a>
<a href="#">10.2</a>	<a href="#">Securities Purchase Agreement dated March 6, 2020, by and between BrainStorm Cell Therapeutics Inc. and Abbhi Investments, LLC.</a>		<a href="#">8-K</a>	<a href="#">10.1</a>	<a href="#">March 6, 2020</a>
<a href="#">10.3</a>	<a href="#">Common Stock Purchase Warrant for the purchase of Common Stock, issued March 6, 2020 by BrainStorm Cell Therapeutics Inc. to Abbhi Investments, LLC.</a>		<a href="#">8-K</a>	<a href="#">4.1</a>	<a href="#">March 6, 2020</a>
<a href="#">10.4</a>	<a href="#">Employment Agreement by and between BrainStorm Cell Therapeutics Inc. and David Setboun, effective April 7, 2020.</a>		<a href="#">8-K</a>	<a href="#">10.1</a>	<a href="#">April 3, 2020</a>
<a href="#">31.1</a>	<a href="#">Certification by the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	*			
<a href="#">31.2</a>	<a href="#">Certification by the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	*			
<a href="#">32.1</a>	<a href="#">Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	‡			
<a href="#">32.2</a>	<a href="#">Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	‡			
101.INS	XBRL Instance Document	*			
101.SCH	XBRL Taxonomy Extension Schema Document	*			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	*			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	*			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	*			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	*			

\* Filed herewith

‡ Furnished herewith

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: May 7, 2020

By: /s/ Preetam Shah  
Name: Preetam Shah  
Title: EVP, Chief Financial Officer  
(Principal Financial Officer)

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 officer 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 officer 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.

Date: May 7, 2020

/s/ Chaim Lebovits

Name: Chaim Lebovits

Title: Chief Executive Officer

(Principal Executive Officer)

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, Preetam Shah, 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 officer 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 officer 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.

Date: May 7, 2020

/s/ Preetam Shah

Name: Preetam Shah

Title: EVP, Chief Financial Officer  
(Principal Financial Officer)

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. for the period ended March 31, 2020, 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) the Quarterly Report on Form 10-Q for the period ended March 31, 2020 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 the Quarterly Report on Form 10-Q for the period ended March 31, 2020 fairly presents, in all material respects, the financial condition and results of operations.

May 7, 2020

/s/ Chaim Lebovits

\_\_\_\_\_  
Name: Chaim Lebovits

Title: Chief Executive Officer

(Principal Executive Officer)

*The foregoing certification is not deemed filed with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and is not to be incorporated by reference into any filing of BrainStorm Cell Therapeutics Inc. under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.*

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. for the period ended March 31, 2020, 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) the Quarterly Report on Form 10-Q for the period ended March 31, 2020 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 the Quarterly Report on Form 10-Q for the period ended March 31, 2020 fairly presents, in all material respects, the financial condition and results of operations.

May 7, 2020

/s/ Preetam Shah

Name Preetam Shah

Title: EVP, Chief Financial Officer

(Principal Financial Officer)

*The foregoing certification is not deemed filed with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and is not to be incorporated by reference into any filing of BrainStorm Cell Therapeutics Inc. under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.*