

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 June 30, 2019

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, 28th Floor
New York, NY
(Address of principal executive offices)

10019
(Zip Code)

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

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

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

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)

As of August 7, 2019, the number of shares outstanding of the registrant's Common Stock, \$0.00005 par value per share, was 22,550,442.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES
INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF JUNE 30, 2019

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 JUNE 30, 2019

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

(UNAUDITED)

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	<u>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	U.S. \$ in thousands	
	<u>Unaudited</u>	<u>Audited</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 1,126	\$ 942
Short-term deposit (Note 4)	1,575	6,122
Account receivable	1,917	2,009
Prepaid expenses and other current assets (Note 5)	917	1,197
Total current assets	<u>5,535</u>	<u>10,270</u>
Long-Term Assets:		
Prepaid expenses and other long-term assets (Note 5)	31	307
Operating lease right of use asset	2,699	-
Property and Equipment, Net	599	651
Total long-term assets	<u>3,329</u>	<u>958</u>
Total assets	<u>\$ 8,864</u>	<u>\$ 11,228</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 8,765	\$ 4,548
Accrued expenses	1,020	1,042
Other accounts payable	758	622
Total current liabilities	<u>10,543</u>	<u>6,212</u>
Long-Term Liabilities:		
Operating lease liability	2,837	-
Total long-term liabilities	<u>2,837</u>	<u>-</u>
Total liabilities	<u>\$ 13,380</u>	<u>\$ 6,212</u>
Stockholders' Equity:		
Stock capital: (Note 8)	11	11
Common stock of \$0.00005 par value - Authorized: 100,000,000 shares at each of June 30, 2019 and December 31, 2018; Issued and outstanding: 21,708,442 and 20,757,816 shares at June 30, 2019 and December 31, 2018, respectively.		
Additional paid-in-capital	99,423	94,620
Receipts on account of shares	-	4,408
Accumulated deficit	(103,950)	(94,023)
Total stockholders' equity (deficit)	<u>(4,516)</u>	<u>5,016</u>
Total liabilities and stockholders' equity	<u>\$ 8,864</u>	<u>\$ 11,228</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>Six months ended</u>		<u>Three months ended</u>	
	<u>June 30,</u>		<u>June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	<u>Unaudited</u>		<u>Unaudited</u>	
Operating expenses:				
Research and development, net	\$ 7,010	\$ 2,458	\$ 3,554	\$ 1,481
General and administrative	2,775	2,936	1,303	1,606
Operating loss	(9,785)	(5,394)	(4,857)	(3,087)
Financial expenses (income), net	142	(5)	43	4
Net loss	<u>\$ (9,927)</u>	<u>\$ (5,389)</u>	<u>\$ (4,900)</u>	<u>\$ (3,091)</u>
Basic and diluted net loss per share from continuing operations	<u>\$ (0.47)</u>	<u>\$ (0.28)</u>	<u>\$ (0.23)</u>	<u>\$ (0.16)</u>
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	<u>21,312,335</u>	<u>19,277,518</u>	<u>21,703,001</u>	<u>19,505,157</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				
Balance as of January 1, 2018	18,976,169	\$ 11	\$ 85,944	\$ -	\$ (80,075)	\$ 5,880
Stock-based compensation related to warrants and stock granted to service providers	42,293	(*)	102	-	-	102
Stock-based compensation related to stock and options granted to directors and employees	147,820	(*)	917	-	-	917
Exercise of options	33,332	(*)	25	-	-	25
Exercise and reissuance of warrants	1,558,202	(*)	7,632	4,408	-	12,040
Net loss	-	-	-	-	(13,948)	(13,948)
Balance as of December 31, 2018	<u>20,757,816</u>	<u>\$ 11</u>	<u>\$ 94,620</u>	<u>\$ 4,408</u>	<u>\$ (94,023)</u>	<u>\$ 5,016</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	Receipts on account of shares	Accumulated deficit	Total stockholders' equity (deficit)
	Number	Amount				
Balance as of January 1, 2019	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	39,386	(*)	365	-	-	365
Exercise and reissuance of warrants	899,999	(*)	4,408	(4,408)	-	-
Exercise of options	5,333	(*)	5	-	-	5
Net loss	-	-	-	-	(9,927)	(9,927)
Balance as of June 30, 2019	<u>21,708,442</u>	<u>\$ 11</u>	<u>\$ 99,423</u>	<u>\$ 0</u>	<u>\$ (103,950)</u>	<u>\$ (4,516)</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

	<u>Six months ended</u>		<u>Three months ended</u>	
	<u>June 30,</u>		<u>June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Cash flows from operating activities:				
Net loss	\$ (9,927)	\$ (5,389)	\$ (4,900)	\$ (3,091)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	77	56	33	31
Shares and options granted to service providers	25	-	-	-
Stock-based compensation related to options granted to employees and directors	365	363	53	136
Change in lease liability	138	-	44	-
Decrease (Increase) in accounts receivable and prepaid expenses	648	295	(801)	411
Increase in accounts payables	4,217	2,758	3,736	921
Increase (decrease) in deferred grant income	-	(740)	(511)	683
Increase (decrease) in other accounts payable and accrued expenses	114	586	(1,162)	964
Total net cash provided by (used in) operating activities	\$ (4,343)	\$ (2,071)	\$ (3,508)	\$ 55

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

	Six months ended		Three months ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Cash flows from investing activities:				
Purchase of property and equipment	(25)	(260)	(21)	(215)
Changes in short-term deposit	4,547	(9,904)	1,412	(12,818)
Investment in lease deposit	-	(5)	-	-
Total net cash provided by (used in) investing activities	\$ 4,522	\$ (10,169)	\$ 1,391	\$ (13,033)
Cash flows from financing activities:				
Proceeds from exercise of options	5	25	5	-
Exercise and reissuance of warrants	-	11,994	-	11,994
Total net cash provided by financing activities	\$ 5	\$ 12,019	\$ 5	\$ 11,994
Increase (decrease) in cash and cash equivalents	184	(221)	(2,112)	(984)
Cash and cash equivalents at the beginning of the period	\$ 942	\$ 2,483	\$ 3,238	\$ 3,246
Cash and cash equivalents at end of the period	\$ 1,126	\$ 2,262	\$ 1,126	\$ 2,262

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. The Israeli Subsidiary formed a wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd. in the United Kingdom on February 19, 2013, which is currently inactive, and also formed wholly owned subsidiary, Advanced Cell Therapies Ltd. in Israel on June 21, 2018.

The Common Stock is publicly traded on the NASDAQ Capital Market under the symbol "BCLF".

- 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 2018 advancing NurOwn®, its late stage differentiated mesenchymal stem cell therapy, into a Phase 3 trial for the treatment of ALS. Enrollment in this randomized, double-blind, placebo-controlled, multi-dose clinical trial of NurOwn® for ALS is now ongoing. 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.
- F. The Company was granted FDA clearance for its NurOwn® IND Application for Progressive Multiple Sclerosis indication (ClinicalTrials.gov Identifier NCT03799718).
- 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.

GOING CONCERN:

To date the Company has not generated revenues from its operational activities and has incurred substantial operating losses. Management expects the Company to continue to generate substantial operating losses and to continue to fund its operations primarily through utilization of its current financial resources and through additional raises of capital.

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 (Cont.):

GOING CONCERN (Cont.):

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

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, 2018.

Operating results for the three months ended June 30, 2019, are not necessarily indicative of the results that may be expected for the year ending December 31, 2019.

B. Significant Accounting Policies

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

C. Recent Accounting Standards

In June 2016, the FASB issued a new standard requiring measurement and recognition of expected credit losses on certain types of financial instruments. It also modifies the impairment model for available-for-sale debt securities and provides for a simplified accounting model for purchased financial assets with credit deterioration since their origination. This standard is effective for the Company in the first quarter of 2020; early adoption is permitted beginning in the first quarter of 2019. It is required to be applied on a modified-retrospective approach with certain elements being adopted prospectively. The Company does not expect that the adoption of this standard will have a significant impact on the financial position or results of operations.

In June 2018, the FASB issued ASU No. 2018-07 "Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting." These amendments expand the scope of Topic 718, Compensation - Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity - Equity-Based Payments to Non-Employees. The guidance is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The ASU 2018-07 does not have a material impact on the Company's 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 2 - BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES (Cont.):

C. Recent Accounting Standards (Cont.):

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 period of adoption. Results for the reporting period beginning January 1, 2019 are presented under ASU 2016-02, which requires, among other items, lessees to recognize a right-of-use asset ("ROU assets") and lease liability for most leases. Upon adoption of the new lease standard, the Company recorded right of use assets of \$3,197 and lease liabilities of \$3,197 in connection with its operating leases. See Note 6 for additional information regarding our commitments under various lease obligations.

Arrangements that are determined to be leases at inception are recognized in long-term ROU assets and long-term lease liabilities in the condensed consolidated balance sheet at lease commencement. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future fixed lease payments over the lease term at commencement date. As most of the Company's leases do not provide an implicit rate, the Company applies its incremental borrowing rate based on the economic environment at commencement date in determining the present value of future payments. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases or payments are recognized on a straight-line basis over the lease term.

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.

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 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 INVESTMENTS

Short term investments on June 30, 2019 and December 31, 2018 include bank deposits bearing annual interest rates varying from 0.05% to 3.15%, with maturities of up to 4 months as of June 30, 2019 and December 31, 2018.

NOTE 5 - PREPAID EXPENSES

In November 2017, the Company 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 made an advance payment to COH of \$2,665. The advance payment was recorded as prepaid expense and is amortized over the term of the agreement. As of December 31, 2018, \$1,103 and \$276 were recorded as current and long-term prepaid expense, respectively. As of June 30, 2019, \$827 were recorded as current prepaid expense.

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 June 30, 2019, the Company’s ROU assets and lease liabilities for operating leases totaled \$2,699 and \$2,837, 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):

	Six Months Ended June 30, 2019
Cash payments for operating leases	\$ 638
New operating lease assets obtained in exchange for operating lease liabilities	\$ 2,699

As of June 30, 2019, the Company’s operating leases had a weighted average remaining lease term of 2.46 years and a weighted average discount rate of 8.25%. Future lease payments under operating leases as of June 30, 2019 were as follows (unaudited):

	Operating Leases
Remainder of 2019	\$ 647
2020	1,277
2021	1,208
Total future lease payments	3,132
Less imputed interest	(295)
Total lease liability balance	\$ 2,837

NOTE 7 - DEFERRED GRANT INCOME

In July 2017 the Company received an award in the amount of \$15,912 from CIRM to aid in funding the Company’s Phase 3 study of NurOwn®, for the treatment of ALS. An aggregate amount of \$12,550 and \$9,050 related to the project was received through June 30, 2019 and December 31, 2018, respectively. The award does not bear a royalty payment commitment nor is the award otherwise refundable. \$3,290 and \$6,267 was recorded as participation by CIRM in research and development expenses during the six months ended in June 30, 2019 and during the year ended December 31, 2018, respectively.

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 - 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 stockholder meetings of the Company, the right to a share in the excess of assets upon liquidation of the Company and the right to receive dividends, if declared.

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

Private placements and public offerings:

Warrant Exercise Agreement: On June 6, 2018, the Company entered into a Warrant Exercise Agreement (the “Warrant Exercise Agreement”) with certain holders (the “Holders”) of warrants (the “2015 Warrants”) to purchase Company Common Stock, which 2015 Warrants were originally issued in the Company’s January 8, 2015 private placement. Pursuant to the Warrant Exercise Agreement, the Holders exercised their 2015 Warrants for a total of 2,458,201 shares of Common Stock (the “Exercised Shares”) at an amended exercise price of \$5 per share. The warrant exercises generated gross cash proceeds to the Company of \$12,291 (\$12,040 net of issuance expenses). In addition, the Company issued new warrants to the Holders to purchase an aggregate 2,458,201 unregistered shares of Common Stock, at an exercise price of \$9, with an expiration date of December 31, 2020 (the “New Warrants”).

The Warrant Exercise Agreement also requires that to the extent that a Holder’s exercise of 2015 Warrants would result in such Holder exceeding the Beneficial Ownership Limitation (as defined in the 2015 Warrants), such excess warrant shares shall be held for the benefit of such Warrant Holder until such time as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation.

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. 333-225995). The Exercised Shares have been registered for resale on the Company’s registration statement on Form S-3 (File No. 333-201704). The issuance of the Exercised Shares and New Warrants was 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) Offering: On June 11, 2019, the Company entered into a 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 (the “Shares”), having an aggregate offering price of up to \$20,000 (the “ATM Offering”). Sales of the Shares, if any, 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 Distribution Agent.

The Company has no obligation to sell any of the Shares, and may at any time suspend sales under the Distribution Agreement or terminate the Distribution Agreement in accordance with its terms. Agent will be entitled to a fixed commission of 3.0% of the aggregate gross proceeds from the Shares sold. The Shares will be issued pursuant to the Company’s existing shelf registration statement on Form S-3 (File No. 333-225517) (the “Registration Statement”), which was filed with the SEC and declared effective by the SEC on June 29, 2018, and the Prospectus Supplement to the Registration Statement filed June 11, 2019.

As of June 30, 2019, no Shares were issued or sold under the Distribution Agreement.

Since its inception the Company has raised approximately \$59,000, net 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 8 - STOCK CAPITAL (Cont.):

Stock Plans:

As of June 30, 2019, 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. 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 June 30, 2019, 2,283,308 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 and President (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, 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, which shall remain exercisable until the 2nd anniversary of the date of grant, regardless of whether Mr. Lebovits remains employed by the Company, with an exercise price per share of \$4.81.

Dr. Ralph Kem, Chief Operating Officer and Chief Medical Officer of the Company, received on March 6, 2017, March 6, 2018 and March 6, 2019, 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. Kem also 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 8 - STOCK CAPITAL (Cont.):

Share-based compensation to employees and to directors: (Cont.):

Employees (Cont.):

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 and November 30, 2018), 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).

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.

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 - STOCK CAPITAL (Cont.):

Share-based compensation to employees and to directors: (Cont.):

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 directors of the Company, except that certain non-employee directors receive 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 6 months ended June 30, 2019, the following equity grants were made under the 2014 Plans to eligible directors:

- On February 22, 2019 Dr. Anthony J. Polverino received 3,501 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.

	Number of Shares of Restricted Stock	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)
Nonvested as of December 31, 2018	152,908	3.96	1.56
Granted	45,294	3.91	
Vested	34,695	3.67	
Forfeitures	-	-	
Nonvested as of June 30, 2019	163,507	4.01	1.52

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 six months ended June 30, 2019 amounted to \$84.

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 - STOCK CAPITAL (Cont.):

Share-based compensation to employees and to directors: (Cont.):

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

	For the Six months ended June 30, 2019		
	Amount of options *	Weighted average exercise price	Aggregate intrinsic value
	\$	\$	
Outstanding at beginning of period	1,496,287	3.0581	
Granted	-	-	
Exercised	(5,333)	1.0050	
Cancelled	(247,847)	4.1235	
Outstanding at end of period	<u>1,243,107</u>	<u>2.8545</u>	<u>1,361,805</u>
Vested and expected-to-vest at end of period	<u>806,731</u>	<u>2.2396</u>	<u>1,379,842</u>

* 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 8 - 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 June 30, 2019, 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 six months ended June 30, 2019 and 2018 amounted to \$365 and \$363, respectively.

Shares and options to service providers:

On March 26, 2019, the Company issued to its legal advisor 5,908 shares of Common Stock under the 2014 U.S. Plan for certain 2018 legal services. The related compensation expense was recorded as general and administrative expense in 2018.

On May 23, 2019, the Company granted to a former director, in consideration for services rendered to the Company, an option under the 2014 Global Plan to purchase up to 4,167 shares of Common Stock with an exercise price per share of \$0.75. The option was fully vested and exercisable as of the date of grant.

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:

	Six months ended	
	June 30,	
	2019	2018
Research and development	60	48
General and administrative	330	315
Total stock-based compensation expense	<u>390</u>	<u>363</u>

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 9 - SUBSEQUENT EVENTS

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 Company also agreed to file a registration statement covering the resale of the additional shares of Common Stock underlying the New Warrants. The New Warrants have not been registered under the Securities Act of 1933, as amended (the Securities Act), or state securities laws. 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.

As of August 5, 2019, total Cash and Cash equivalents was approximately \$4.5 million.

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 2019 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, 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, 2018. 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, 2018, 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. Both clinical trials are actively enrolling participants in the U.S. and are expected to generate top-line data in the second half of 2020.
- Our wholly-owned Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. (“Israeli Subsidiary”), holds exclusive rights to commercialize NurOwn® technology through a licensing agreement with Ramot, the technology transfer company of Tel Aviv University, Israel.
- The Israeli Subsidiary was granted approval by the Israeli Ministry of Health (“MOH”) to treat ALS patient access 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.
- Brainstorm Cell Therapeutics Inc. currently employs 32 employees in the United States and in Israel. Brainstorm's R&D center is in Petach Tikva, Israel.

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). Over 75% of the participants in this randomized, double-blind, placebo-controlled, repeat-dose clinical trial has been enrolled. This clinical trial builds upon promising efficacy seen in 3 prior early-stage ALS clinical trials, including a U.S. randomized placebo-controlled Phase 2 trial. We expect to complete NurOwn® ALS Phase 3 study enrollment by the end of the third quarter of 2019 and the trial is expected to generate data to support the FDA BLA filing of NurOwn® in ALS in the second half of 2020.
- The Company was granted FDA approval in December 2018 for the IND Application of NurOwn® in Progressive Multiple Sclerosis (PMS) (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 be conducted at 5 leading U.S. MS centers. As of the quarter ending June 30 2019, the first three (3) study participants have been enrolled in the study. Enrollment will proceed through the fourth quarter of 2019 as planned.
- On April 30, 2019, the Company announced that it has expanded its proprietary cellular technology platform to include NurOwn®-derived exosomes (extracellular vesicles) for potential development across a broad range of CNS (Central Nervous System) disorders.
- Since May 2019, following the approval by the MOH to support the treatment of 13 ALS patients with NurOwn® under the Israeli Hospital Exemption (HE) regulatory pathway, the Company has enrolled six (6) patients under the HE pathway. Thus far, the Company received approximately \$1 million in connection with the treatment for the aforementioned patients.
- On June 11, 2019, we established an at-the-market Common Stock offering program (the "ATM Program") to sell shares of our Common Stock, having an aggregate offering price of up to \$20 million. This program provides additional financial flexibility and an alternative mechanism to access the capital markets at an efficient cost as and when the Company needs financing.
- 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 their 2018 Warrants to purchase 842,000 shares of Common Stock, at an amended exercise price of \$3.90 per share, and the Company agreed to issue new warrants to the Holders to purchase 842,000 shares of Common Stock, at an exercise price of \$7.00, with an expiration date of December 31, 2021, and to amend the 2018 Warrants held by the Holders, to the extent not exercised, to reduce the exercise price to \$7.00 per share and to extend the expiration date to December 31, 2021.

NurOwn® Proprietary Technology

NurOwn® technology is based on an innovative and proprietary 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 neurotrophic factors, that are known to be critical for the growth, survival and differentiation of neurons, include: 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 motor neurons. 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 the patient's own bone marrow; processing and isolating the undifferentiated stem cells at the manufacturing site and cryopreserving the MSC to enable multiple treatments from a single bone marrow aspiration. In advance of each treatment cycle, the MSC are thawed differentiation is induced; and MSC-NTF cells are injected by intrathecal (“IT”) administration of into the same patient by a standard lumbar puncture. This administration procedure has been shown to be safe and well tolerated in multiple CNS clinical trials to date. The ongoing NurOwn® U.S. Phase 3 ALS and Phase 2 MS studies are evaluating the therapeutic potential of repeated IT 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 licensed to and developed by Brainstorm Cell Therapeutics Ltd., our wholly-owned subsidiary (the “Israeli Subsidiary”).

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. We have completed two early stage Phase 1/2 and Phase 2 open-label clinical trials of NurOwn® in patients with ALS at the Hadassah Medical Center (“Hadassah”) in Jerusalem as well as a Phase 2 double-blind, placebo-controlled, clinical trial at three prestigious U.S. Medical centers, all highly experienced in the management and investigation of ALS.

Phase 1/2 ALS Open Label Trials

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 (“ALSFRRS-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) 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.

Topline data from this Phase 2 Study were announced by the Company in July 2016. Further details were presented by investigators Dr. Robert Brown and Dr. James Berry, at the 15th Annual Meeting of the Northeast ALS Consortium (NEALS) in October 2016 and by Dr. Berry at the 27th International Symposium on ALS/MND, in Dublin, Ireland, in December 2016. 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 (rate of disease progression as measured by ALSFRS-R 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 enrolling 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 is actively enrolling an enriched clinical trial population of rapid progressors (~50% of ALS patients) based on superior outcomes observed in Phase-2 in this 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: 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.

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 (www.clinicaltrials.gov Identifier 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.

Top-line efficacy data is expected in the second half of 2020.

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 aspirate 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 in Boston has also been contracted to manufacture NurOwn® and placebo for Phase 3 clinical study participants, and commenced manufacturing in October 2018. The two manufacturing facilities are also manufacturing NurOwn® for the Phase 2 study in progressive MS.

Patient Access Programs (ALS)

The Company collaboratively with the Tel Aviv Sourasky Medical Center (Ichilov Hospital), was approved to treat 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 will enable the Company to make NurOwn® accessible to ALS patients in Israel, for a fee.

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 (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. The trial enrolled the first 4 study participants in the first half of 2019 and is expected to generate top line data in the second half of 2020.

Non-Dilutive Funding

In July 2017, the Company was awarded a grant in the amount of \$15,912,000 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. To date, the Company has received \$12,550,000 of the CIRM grant: \$9,050,000 from 2017 through 2018, and an additional \$3,500,000 in 2019. The grant does not bear a royalty payment commitment nor is the grant otherwise refundable.

In 2018 and 2019, the Company was awarded aggregate grants of approximately \$3 million from the Israel Innovation Authority (“IIA”). To date the Company has received approximately \$2.5 million from IIA, made under the 2019 as well as under previous IIA grants.

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 14 granted patents, 2 allowed patents and 24 patent applications in the United States, Europe, and Israel, as well as in additional countries worldwide, including countries in East Asia and South America (in calculating the number of granted patents, each European patent validated in multiple jurisdictions is 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 27 March 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 April 9, 2019 The Canadian Intellectual Property Office issued a Notice of Allowance for Canadian Patent Application 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).

Scientific presentations in 2019

On January 11, 2019, Dr. Ralph Kern provided an update on the Phase 3 pivotal trial of the autologous MSC-NTF Cellular Therapy (NurOwn®) in ALS at the 9th Annual California ALS Research Summit in Irvine, CA. The California ALS Research Summit is an annual meeting of researchers, investigators, clinicians, biotech companies, government representatives, partner organizations, and advocates in ALS and related fields in California

Two scientific abstracts were presented at the 71st American Academy of Neurology (AAN) Annual Meeting in Philadelphia, PA, May 4-10, 2019. The scientific abstracts included: a detailed molecular characterization of enhanced neurotrophic factor production by NurOwn® (MSC-NTF cells); and correlations of cerebrospinal fluid biomarkers with clinical improvement that was selected by the AAN Science Committee, for a platform presentation at the prestigious Emerging Science Session. These findings contribute to our overall understanding of the mechanism of action of NurOwn® and provide further evidence linking ALS clinical outcomes to highly relevant disease biomarkers.

On May 31, 2019, the World Multiple Sclerosis (MS) Day, a global event that raises awareness of the invisible symptoms of MS, Brainstorm presented a poster of the Company's Phase 2 Open-Label, Multicenter Study of Repeated Intrathecal Administration of Autologous MSC-NTF cells in Progressive MS at the Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC), in Seattle. CMSC is the largest North American gathering for healthcare professionals and researchers engaged in MS care. The poster presented the Phase 2 study design and population, as well as the study endpoints and its current status.

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 Huntington's disease. Research is currently ongoing to develop additional specialized derivative cell products such as MSC-NTF derived Exosomes. Exosomes are extracellular 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 via membrane vesicle trafficking, thereby mediating cell-to-cell communication, ultimately regulating many cell processes, which are suitable for clinical applications in multiple neurodegenerative diseases. The research efforts focused on three levels:

1. Manufacturing of MSC-NTF exosomes: Develop and optimize cell culture processes to generate exosomes and develop scalable purification methods that can be applied to commercial use.
2. Characterization of MSC-NTF exosomes: Quantification, characterization of phenotype and exosome cargo.
3. Examination of MSC-NTF exosomes potency.

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 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 June 30, 2019, the Company has not earned any revenue from operations. The Company does not expect to earn revenue from operations until the second half of 2019, if ever. The Company has incurred operating costs and other expenses of approximately \$4,857,000 during the three months ended June 30, 2019 compared to \$3,087,000 during the three months through June 30, 2018. The increase of \$1,770,000 is due to higher expenses in connection with the ongoing U.S. Phase 3 Clinical Trial.

Research and Development Expenses:

Research and development expenses, net for the three months ended June 30, 2019 and 2018 were \$3,554,000 and \$1,481,000, respectively, representing an increase of \$2,073,000. This increase is due to (i) an increase of \$3,050,000 in connection with the Phase 3 Clinical Trial; (ii) an increase of \$220,000 in connection with materials, payroll and stock-based compensation expenses patents, and other activities. This increase was partially offset by (i) \$900,000 received in connection with the treatment of patients under the hospital exemption regulatory pathway; (ii) an increase of \$253,000 in participation of the Israel Innovation Authority (“IIA”) and CIRM in 2019, under various awarded grants; and (iii) a decrease of \$44,000 for costs related to consultants, travel, rent and other costs.

Excluding participation from IIA and CIRM under the grants and proceeds received under the hospital exemption regulatory pathway, research and development expenses increased by \$3,226,000 from \$3,308,000 in the second quarter of 2018 to \$6,535,000 in the second quarter of 2019.

General and Administrative Expenses:

General and administrative expenses for the three months ended June 30, 2019 and 2018 were \$1,303,000 and \$1,606,000, respectively. The decrease in general and administrative expenses of \$303,000 is primarily due to a decrease of \$411,000 in payroll, stock-based compensation, consultants and rent partially offset by an increase of \$108,000 in travel and PR costs.

Other Income and Expenses:

Financial expense for the three months ended June 30, 2019 was \$43,000 as compared to financial expense of \$4,000 for the three months ended June 30, 2018 as a result of the adoption of the Accounting Standard Update ASU 2016-02 “Leases”.

Net Loss:

Net loss for the three months ended on June 30, 2019 was \$4,900,000, as compared to a net loss of \$3,091,000 for the three months ended June 30, 2018. Net loss per share for the three months ended June 30, 2019 and 2018 was \$0.23 and \$0.16, 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 June 30, 2019 was 21,703,001, compared to 19,505,157 for the three months ended June 30, 2018.

Liquidity and Capital Resources

The Company has financed its operations since inception primarily through public and private sales of its Common Stock and warrants and the issuance of convertible promissory notes.

Cash, Cash equivalents (including short-term bank deposits) amounted to approximately \$2,701,000.

Net cash used in operating activities was \$3,508,000 for the three months ended June 30, 2019. Cash used for operating activities was primarily attributed to cost of payroll, rent of clean rooms and materials for clinical trials, rent, legal expenses and public relations expenses. Net cash provided by investing activities was \$1,391,000 for the three months ended June 30, 2019, representing net decrease in short-term interest-bearing bank deposits. Net cash provided by financing activities was \$5,000 for the three months ended June 30, 2019 and is attributable to the exercise of options.

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 trials 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.

We have an effective shelf registration statement on file with the SEC (the “Registration Statement”) to offer and sell various securities from time to time. Under the Registration Statement, we have established an at-the-market common stock offering program (the “ATM Program”) to sell shares of common stock having an aggregate offering price of up to \$20.0 million. During the quarter ended June 30, 2019, no sales were made under the ATM Program. This program provides additional financial flexibility and an alternative mechanism to access the capital markets at an efficient cost as and when we need financing. While we have not sold shares under the program to date, we currently intend to utilize the program when we believe the price we can obtain for our Common Stock is attractive.

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 warrants to the Holders to purchase 842,000 shares of Common Stock, at an exercise price of \$7.00, with an expiration date of December 31, 2021, and to amend the 2018 Warrants held by the Holders, to the extent not exercised, to reduce the exercise price to \$7.00 per share and to extend the expiration date to December 31, 2021. 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 to file a registration statement covering the resale of the additional shares of Common Stock underlying the New Warrants.

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 June 30, 2019. 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, 2018.

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 June 30, 2019 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.

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, 2018. 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, 2018, 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, 2018, 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.

Item 5. Other Information.

During the quarter ended June 30, 2019, 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
10.1	Distribution Agreement, dated June 11, 2019, by and between Brainstorm Cell Therapeutics Inc. and Raymond James & Associates, Inc.		8-K	1.1	June 11, 2019
31.1	Certification by the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	*			
31.2	Certification by the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	*			
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	†			
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	†			
101.INS	XBRL Instance Document	*			
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: August 13, 2019

By: /s/ Eyal Rubin
Name: Eyal Rubin
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: August 13, 2019

/s/ Chaim Lebovits

Name: Chaim Lebovits

Title: President and 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, Eyal Rubin, 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: August 13, 2019

/s/ Eyal Rubin

Name: Eyal Rubin
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 June 30, 2019, 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 June 30, 2019 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 June 30, 2019 fairly presents, in all material respects, the financial condition and results of operations.

August 13, 2019

/s/ Chaim Lebovits

Name: Chaim Lebovits

Title: President and 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 June 30, 2019, 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 June 30, 2019 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 June 30, 2019 fairly presents, in all material respects, the financial condition and results of operations.

August 13, 2019

/s/ Eyal Rubin

Name Eyal Rubin

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.
