BRAINSTORM CELL THERAPEUTICS INC.
Form 10-Q
October 29, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

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

For the transition period from _____ to _____

Commission File Number 001-36641

BRAINSTORM CELL THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	20-7273918
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1325 Avenue of Americas, 28th Floor
New York, NY 10019
(Address of principal executive offices) (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 x 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 x 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 x Smaller reporting company x

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 x

As of October 25, 2018, the number of shares outstanding of the registrant's Common Stock, $0.00005 par value per share, was 20,707,237.

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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 September 30, 2018

U.S. DOLLARS IN THOUSANDS

(Except share data and exercise prices)

(UNAUDITED)

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

(Except share data)

	September 30, 2018	December 31, 2017
	U.S. $ in thousands	
	Unaudited	Audited
ASSETS		
Current Assets:		
Cash and cash equivalents	$697	$ 2,483
Short-term deposit (Note 4)	10,194	5,273
Account receivable	492	672
Prepaid expenses and other current assets (Note 5)	1,238	1,195
Total current assets	12,621	9,623
Long-Term Assets:		
Prepaid expenses and other long-term assets (Note 5)	584	1,408
Property and Equipment, Net	564	392
Total long-term assets	1,148	1,800
Total assets	$13,769	$ 11,423
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$2,602	$ 1,424
Accrued expenses	428	817
Deferred grant income (Note 6)	130	2,625
Other accounts payable	631	677
Total current liabilities	3,791	5,543
Total liabilities	$3,791	$ 5,543
Stockholders' Equity:		
Stock capital: (Note 7)	11	11

Common stock of $0.00005 par value - Authorized: 100,000,000 shares at each of September 30, 2018 and December 31, 2017; Issued and outstanding: 20,700,713 and 18,976,169 shares at September 30, 2018 and December 31, 2017, respectively.		
Additional paid-in-capital	94,199	85,944
Receipts on account of shares	4,408	-
Accumulated deficit	(88,640)	(80,075)
Total stockholders' equity	9,978	5,880
Total liabilities and stockholders' equity	$13,769	$ 11,423

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)

U.S. dollars in thousands

(Except share data)

	Nine months ended September 30,		Three months ended September 30,	
	2018	2017	2018	2017
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net	$4,433	$2,544	$1,975	$1,168
General and administrative	4,193	2,693	1,257	1,224
Operating loss	(8,626)	(5,237)	(3,232)	(2,392)
Financial expenses (income), net	(61)	(9)	(56)	11
Net loss	$(8,565)	$(5,228)	$(3,176)	$(2,403)
Basic and diluted net loss per share from continuing operations	$(0.43)	$(0.28)	$(0.15)	$(0.13)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	19,754,159	18,737,307	20,691,900	18,783,997

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

INTERIM CONDENSED STATEMENTS OF CHANGES IN EQUITY (AUDITED)

U.S. dollars in thousands

(Except share data)

	Common Stock		Additional paid-in	Receipts on account of	Accumulated	Total stockholders'
	Number	Amount	capital	shares	deficit	equity
Balance as of January 1, 2017	18,687,987	$ 11	$ 85,014	$ -	$ (75,123)	$ 9,902
Stock-based compensation related to warrants and stock granted to service providers	4,327	(*)	62	-	-	62
Stock-based compensation related to stock and options granted to directors and employees	107,301	(*)	554	-	-	554
Exercise of options	129,887	(*)	209	-	-	209
Exercise of warrants	46,667	(*)	105	-	-	105
Net loss	-	-	-	-	(4,952)	(4,952)
Balance as of December 31, 2017	18,976,169	$ 11	$ 85,944	$ -	$ (80,075)	$ 5,880

* 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 STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Receipts on account of	Accumulated	Total stockholders'
	Number	Amount	capital	shares	deficit	equity
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	11,250	(*)	-	-	-	-
Stock-based compensation related to stock and options granted to directors and employees	121,760	(*)	598	-	-	598
Exercise of options	33,332	(*)	25	-	-	25
Exercise and reissuance of warrants	1,558,202	(*)	7,632	4,408	-	12,040
Net loss	-	-	-	-	(8,565)	(8,565)
Balance as of September 30, 2018	20,700,713	$ 11	$ 94,199	$ 4,408	$ (88,640)	$ 9,978

* 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

	Nine months ended September 30,		Three months ended September 30,	
	2018	2017	2018	2017
Cash flows from operating activities:				
Net loss	$ (8,565)	$ (5,228)	$ (3,176)	$ (2,403)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	89	57	33	23
Expenses related to shares and options granted to service providers	-	18	-	18
Stock-based compensation related to options granted to employees and directors	598	398	235	215
Decrease in accounts receivable and prepaid expenses	965	50	670	561
Increase (decrease) in trade payables	1,178	(70)	(1,580)	48
Increase (decrease) in deferred grant income	(2,495)	5,250	(1,755)	5,250
Increase (decrease) in other accounts payable and accrued expenses	(435)	96	(1,021)	131
Total net cash provided by (used in) operating activities	$ (8,665)	$ 571	$ (6,594)	$ 3,843

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2018	2017	2018	2017
Cash flows from investing activities:				
Purchase of property and equipment	(261)	(118)	(1)	(86)
Net change in short-term deposit	(4,921)	1,360	4,983	(7,150)
Investment in lease deposit	(4)	(1)	1	(2)
Total net cash provided by (used in) investing activities	$ (5,186)	$ 1,241	$ 4,983	$ (7,238)
Cash flows from financing activities:				
Proceeds from exercise of options	25	105	-	75
Exercise and reissuance of warrants	12,040	-	46	-
Total net cash provided by financing activities	$ 12,065	$ 105	$ 46	$ 75
Increase (decrease) in cash and cash equivalents	(1,786)	1,917	(1,565)	(3,320)
Cash and cash equivalents at the beginning of the period	$ 2,483	$ 547	$ 2,262	$ 5,784
Cash and cash equivalents at end of the period	$ 697	$ 2,464	$ 697	$ 2,464

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. Brainstorm Cell Therapeutics Inc. (“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. On February 19, 2013, BCT formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd. in the United Kingdom. Brainstorm UK is currently inactive.

The Company’s Common Stock is publicly traded on the NASDAQ Capital Market under the symbol “BCLI”.

B. The Company, through BCT, holds rights to commercialize certain stem cell technology developed by Ramot of Tel Aviv University Ltd. ("Ramot"), (see Note 3). Using this technology, the Company has been developing novel adult stem cell therapies for debilitating neurodegenerative disorders such as Amyotrophic Lateral Sclerosis (ALS, also known as Lou Gehrig Disease), Multiple Sclerosis (MS) 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 open-label clinical trials of NurOwn in Israel: a Phase 1/2 trial with 12 patients and a Phase 2a trial with 14 additional patients. The results were published in JAMA Neurology a prestigious peer reviewed Neurology journal. Thereafter, Brainstorm performed a single dose double-blind, placebo-controlled, multicenter Phase 2 trial which was conducted at three major US medical centers (MGH, MAYO and UMass). This trial enrolled 48 patients randomized at a 3:1 ratio to receive NurOwn or placebo.

In July 2016 the Company announced the results of its Phase 2 trial that were also presented at AAN, NEALS and MND.

After the successful completion of the Phase 2 study, the Company is currently enrolling a multi-dose double-blind, placebo-controlled, multicenter Phase 3 trial that has been designed to support a Biologic License Application ("BLA") for NurOwn® in ALS. The clinical trial is actively enrolling, at 6 medical centers in the US, an enriched patient population based on superior outcomes observed in the Phase-2 pre-specified sub-group of rapid progressors.

On August 23, 2018 the company announced a positive phase 3 interim safety analysis by the Data Safety Monitoring Board (DSMB). There were no significant safety issues and the DSMB recommended that the trial continue as planned. Confirmation of the safety of repeated injections in the first cohort of 61 active study subjects is an important milestone for the company.

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:

To date the Company has not generated revenues from its 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.

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, 2017.

Operating results for the three months ended September 30, 2018, are not necessarily indicative of the results that may be expected for the year ended December 31, 2018.

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 May 2014, the Financial Accounting Standards Board issued a new standard to achieve a consistent application of revenue recognition within the U.S., resulting in a single revenue model to be applied by reporting companies under U.S. generally accepted accounting principles. Under the new model, recognition of revenue occurs when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the new standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The new standard is effective for us beginning in the first quarter of 2018; early adoption is prohibited. The new standard is required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. The adoption of the standard did 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

In February 2016, the FASB issued ASU 2016-02 “Leases” to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. For operating leases, the ASU requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, on its balance sheet. The ASU retains the current accounting for lessors and does not make significant changes to the recognition, measurement, and presentation of expenses and cash flows by a lessee.

The ASU is effective for the Company in the first quarter of 2019, with early adoption permitted. The Company continues to evaluate the effect of the adoption of this ASU and expects the adoption will result in an increase in the assets and liabilities on the consolidated balance sheets for operating leases and will likely have an insignificant impact on the consolidated statements of comprehensive loss and consolidated statements of cash flows.

In July 2018, the FASB issued ASU No. 2018-11, "Targeted Improvements - Leases (Topic 842)." This update provides an optional transition method that allows entities to elect to apply the standard prospectively at its effective date, versus recasting the prior periods presented. If elected, an entity would recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company have not completed its assessment, including evaluation of transition method and whether to early adopt, but the adoption of ASU 2016-02 will have a material impact on the consolidated balance sheets. However, the Company do not expect the adoption to have a material impact on the recognition, measurement or presentation of lease expenses within the consolidated statements of comprehensive loss or the consolidated statements of cash flows.

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 us 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. Early adoption is permitted. The Company is assessing ASU 2018-07 and does not expect it to have a material impact on its consolidated financial statements.

D. Use of estimates

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

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 with Ramot (as amended and restated, 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 September 30, 2018 and December 31, 2017 include bank deposits bearing annual interest rates varying from 0.05% to 3.15%, with maturities of up to 12 months as of September 30, 2018 and December 31, 2017.

NOTE 5 - PREPAID EXPENSES

In November 2017 the Company has contracted with City of Hope's Center for Biomedicine and Genetics ("COH") to produce clinical supplies of NurOwn® adult stem cells for the Company’s ongoing Phase 3 clinical study. The Company has paid COH $2,665 as advance payment which was recorded as prepaid expense and is amortized over the term of the agreement. As of September 30, 2018, $1,103 and $551 were recorded as current and long-term prepaid expenses, respectively, compared to $1,103 and $1,378 that were recorded as current and long-term prepaid expense, respectively, as of December 31, 2017.

NOTE 6 - 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 $9,050 and $7,050 related to the project was received through September 30, 2018 and December 31, 2017, respectively. The award does not bear a royalty payment commitment nor is the award otherwise refundable. $4,495 and $4,425 was recorded as participation by CIRM in research and development expenses during the nine months ended in September 30, 2018 and during the year ended December 31, 2017, respectively.

NOTE 7 - STOCK CAPITAL

The rights of Common Stock are as follows:

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

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to the Interim Condensed Consolidated Financial Statements

NOTE 7 - STOCK CAPITAL (Cont.):

Private placements and public offerings:

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 ($11,994 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"). Certain Holders of New Warrants also entered into a Share Cap Agreement with the Company, whereby the Holders agreed to a 6-month delay (from the date of issuance) in exercisability of any shares at or in excess of 20% limitation on the size of the entire transaction, pursuant to Nasdaq Listing Rules.

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. Per this requirement, as of September 30 2018, 899,999 of 2,458,201 shares to be issued pursuant to exercise of the 2015 Warrants have not yet been issued and the relating proceeds at an amount of $4,408 were recorded as receipts on account of shares.

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. 333-201704). 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.

Since its inception the Company has raised approximately $59M, 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.

Stock Plans:

As of September 30, 2018, 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 2,200,000 shares of Common Stock available for issuance.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to the Interim Condensed Consolidated Financial Statements

NOTE 7 - STOCK CAPITAL (Cont.):

As of September 30, 2018, 379,329 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:

Pursuant to a September 28, 2015 employment agreement, as amended, 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, and is entitled to receive on each anniversary thereafter (provided he remains Chief Executive Officer), a grant of restricted stock under the 2014 Global Plan (or any successor or other equity plan then maintained by the Company) comprised of a number of shares of Common Stock with a fair market value (determined based on the price of the Common Stock at the end of normal trading hours on the business day immediately preceding the effective date according to Nasdaq) equal to 30% of Mr. Lebovits' Base Salary (31,185 shares on each of July 26, 2017 and July 26, 2018). Each grant shall vest as to twenty-five percent (25%) of the award on each of the first, second, third and fourth anniversary of the date of grant, provided Mr. Lebovits remains continuously employed by the Company from the date of grant through each applicable vesting date. Each grant shall be subject to accelerated vesting upon a Change of Control (as defined in the Lebovits employment agreement) of the Company. In the event of Mr. Lebovits' termination of employment, any portion of a grant that is not yet vested (after taking into account any accelerated vesting) shall automatically be immediately forfeited to the Company, without the payment of any consideration to Mr. Lebovits; and (iii) was granted on July 26, 2017 a fully vested and exercisable option (the "Option") under the 2014 Global Plan 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.

The Lebovits employment agreement contains termination provisions, pursuant to which if the Company terminates the employment agreement or Mr. Lebovits' employment without Cause (as defined in the agreement) or if Mr. Lebovits terminates the employment agreement or his employment thereunder with Good Reason (as defined in the agreement), the Company shall immediately vest such number of equity or equity based awards that would have vested during the six months following the date of termination of employment, conditional upon Mr. Lebovits executing a waiver and release in favor of the Company in a form reasonably acceptable to the Company.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to the Interim Condensed Consolidated Financial Statements

NOTE 7 - STOCK CAPITAL (Cont.):

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

Employees (Cont.):

Pursuant to his February 28, 2017 employment agreement, Dr. Ralph Kern, Chief Operating Officer and Chief Medical Officer of the Company, received on March 6, 2017, and is entitled to receive on each anniversary thereafter (provided he remains employed by the Company), a grant of restricted stock under the 2014 U.S. Plan (or any successor or other equity plan then maintained by the Company) comprised of a number of shares of Common Stock with a fair market value (determined based on the price of the Common Stock at the end of normal trading hours on the business day immediately preceding March 6, 2017 according to Nasdaq) equal to 30% of Dr. Kern's Base Salary (35,885 shares on each of March 6, 2017 and March 6, 2018). Each equity grant shall vest as to twenty-five percent (25%) of the award on each of the first, second, third and fourth anniversary of the date of grant, provided Dr. Kern remains continuously employed by the Company from the date of grant through each applicable vesting date. Each equity grant shall be subject to accelerated vesting upon a Change of Control (as defined in the agreement) of the Company.

In the event of Dr. Kern's termination of employment, any portion of an equity grant that is not yet vested (after taking into account any accelerated vesting) shall automatically be immediately forfeited to the Company, without the payment of any consideration to Dr. Kern.

Pursuant to the agreement, on March 6, 2017, Dr. Kern 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 and shall remain exercisable until the 2nd anniversary of the date of grant, regardless of whether Dr. Kern remains employed by the Company. Uri Yablonka, the Company's Executive Vice President, Chief Business Officer and director was granted a stock option on June 6, 2014 under the Company's Amended and Restated 2004 Global Share Option Plan (the "Global Plan") for the purchase of 33,333 shares of the Company's Common Stock, which was

fully vested and exercisable upon grant. The exercise price for the grant is $2.70 per share. In addition, the Company agreed to grant Mr. Yablonka a stock option under the Global Plan (or the applicable successor option plan) for the purchase of up to 13,333 shares of Common Stock (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like) of the Company on the first business day after each annual meeting of stockholders (or special meeting in lieu thereof) of the Company beginning with the 2014 annual meeting, and provided that Mr. Yablonka remains an employee of the Company on each such date. The exercise price per share of the Common Stock subject to each additional option shall be equal to $0.75 (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like, or changes to the Israeli Annual Option Award under the Company's Director Compensation Plan as amended from time to time). Each additional option vests and becomes exercisable on each monthly anniversary date as to 1/12th the number of shares subject to the option, over a period of twelve months from the date of grant, such that each additional option will be fully vested and exercisable on the first anniversary of the date of grant, provided that Mr. Yablonka remains an employee of the Company on each such vesting date. The Company also granted Mr. Yablonka 5,543 shares of restricted Common Stock on July 13, 2017.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to the Interim Condensed Consolidated Financial Statements

NOTE 7 - STOCK CAPITAL (Cont.):

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

Employees (Cont.):

On November 20, 2017, the Company granted to Eyal Rubin, the Company's Chief Financial Officer, 25,000 shares of restricted Common Stock under 2014 Global Plan, which shall vest as to 100% of the award on April 1, 2018, provided Mr. Rubin remains continuously employed by BCT from the date of grant through the vesting date. In the event of Mr. Rubin's termination of employment prior to April 1, 2018, the restricted stock grant shall automatically be immediately forfeited in its entirety to the Company, without the payment of any consideration to Mr. Rubin. On November 20, 2017 the Company also granted to Mr. Rubin an option to purchase up to 93,686 shares of Common Stock under the 2014 Global Plan, at an exercise price per share equal to $4.30 per share. The Option shall vest and become exercisable as follows: 25% of the shares underlying the Option shall vest and become exercisable on each of the first, second, third and fourth anniversary of the date of grant, until fully vested and exercisable on the fourth anniversary of the date of grant, provided Mr. Rubin remains continuously employed by BCT from the date of grant through each applicable vesting date. The Option shall have a 10 year term and shall be subject to accelerated vesting upon a Change of Control of the Company or Material Secondary Public Offering of the Company (each as defined in Mr. Rubin's employment agreement).

On August 28, 2018, the Company and Arturo Araya entered into an employment agreement, pursuant to which Mr. Araya serves as Chief Commercial Officer of the Company. In accordance with the employment agreement, Mr. Araya receives an annual base compensation of $300,000 and is eligible to receive an annual cash bonus equal to 20% of his base salary, subject to satisfaction of pre-established performance goals. On August 28, 2018 he also received a one-time grant of an option to purchase 200,000 shares of Common Stock under the Company's 2014 Stock Incentive Plan, 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, so that the grant becomes fully vested and exercisable on the fourth anniversary of the grant date. The grant is subject to accelerated vesting upon a Change of Control, as defined in the agreement, and has a 10-year term. Any unvested shares underlying the grant as of the date of the termination of his employment with the Company shall automatically terminate. In connection with the employment agreement

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 7 - 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 director of the Company, except that certain non-employee directors have individualized compensation and are not entitled receive annual director awards under the Director Compensation Plan, but are entitled to committee compensation under the Director Compensation Plan in the event that they qualify for and serve as a member of any committee of the Board. The Director Compensation Plan also determines the annual awards to be granted to qualified directors for their services in future periods, which annual awards have had the same terms since 2014, as further detailed in the Director Compensation Plan. During the 9 months ended September 30, 2018, the following grants were made under the 2014 Plans to eligible directors:

- On February 1, 2018 Dr. Anthony J. Polverino received 3,623 shares of restricted stock for his service as a director.
- On February 26, 2018 and March 26, 2018 Arturo Araya received 5,401 shares of restricted stock for his service as a director and a member of the GNC Committee (2,805 of which were forfeited on August 28, 2018, when Mr. Araya commenced employment with the Company).

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

	For the Nine months ended September 30, 2018		
	Amount of options *	Weighted average exercise price	Aggregate intrinsic value
		$	$
Outstanding at beginning of period	940,954	2.1258	
Granted	550,000	4.0900	
Exercised	(33,332)	0.7500	
Cancelled	-	-	
Outstanding at end of period	1,457,622	3.1193	1,021,285
Vested and expected-to-vest at end of period	807,490	2.3401	1,259,568

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to the Interim Condensed Consolidated Financial Statements

NOTE 7 - STOCK CAPITAL (Cont.):

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

Directors (Cont.):

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the fair market value of the Company's shares on September 30, 2018, 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 nine months ended September 30, 2018 and 2017 amounted to $598 and $398, respectively.

Shares and warrants to investors and service providers:

On January 2, 2018, the Company granted to its legal advisor 11,250 shares of Common Stock for 2017 legal services. The related compensation expense was recorded as general and administrative expense in 2017.

Total Stock-Based Compensation Expense

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

	Nine months ended September 30,	
	2018	2017
Research and development	73	145
General and administrative	525	271
Total stock-based compensation expense	598	416

NOTE 8 - SUBSEQUENT EVENTS

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report contains numerous statements, descriptions, forecasts and projections, regarding Brainstorm Cell Therapeutics Inc. (together with its consolidated subsidiaries, the "Company," "Brainstorm," "we," "us" or "our") and its potential future business operations and performance, including financial results for the most recent fiscal quarter, statements regarding the market potential for treatment of neurodegenerative disorders such as ALS, the sufficiency of our existing capital resources for continuing operations in 2018 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, heath 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, 2017. 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, 2017, 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 engaged in the development of best-in-class autologous cellular therapies derived from a patient's own bone marrow cells for the treatment of neurodegenerative diseases. The Company holds the rights to clinical development and commercialization of the NurOwn® technology platform through an exclusive, worldwide licensing agreement (see details herein). NurOwn® has received Fast Track designation from the U.S. Food and Drug Administration (U.S. FDA) in ALS and has additionally been granted Orphan Status by the U.S. FDA and the European Medicines Agency (EMA). For more information, visit BrainStorm's website at www.brainstorm-cell.com.

Brainstorm Cell Therapeutics Inc. is a biotechnology company committed to bring innovative central nervous system ("CNS") adult stem cell therapies to the market to improve the lives of patients with debilitating neurodegenerative diseases. As a leader in CNS regenerative cellular medicines, Brainstorm is leveraging NurOwn®, its proprietary autologous mesenchymal stem cell platform technology, a strong and expanded intellectual property portfolio, as well as manufacturing and commercialization capabilities, to address growing unmet medical needs across a broad range of neurodegenerative disorders, such as Amyotrophic Lateral Sclerosis ("ALS", also known as Lou Gehrig's disease), Multiple Sclerosis ("MS"), Parkinson's disease ("PD") and Autism Spectrum Disorders ("ASD"). NurOwn® uses proprietary cell culture conditions to induce mesenchymal stem cells (MSCs) to secrete high levels of neurotrophic factors (NTFs) to promote survival of neurons.

Our wholly-owned Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. ("Israeli Subsidiary"), holds rights to commercialize NurOwn® technology through a licensing agreement with Ramot ("Ramot"), the technology transfer company of Tel Aviv University, Israel. We currently employ 31 employees in The United States and in Israel.

In the last 12 months, the Company was awarded a $16 million non-dilutive grant (CIRM CLIN2-0989) from the California Institute for Regenerative Medicine (CIRM) to conduct a U.S. Phase 3 ALS study, launched a 200 participant NurOwn® ALS Phase 3 study that is actively enrolling in 6 leading U.S. centers (NCT03280056), and received GMP approval for NurOwn® manufacturing in Israel. On August 23, 2018, Brainstorm Cell Therapeutics Inc. announced a successful pre-specified interim safety analyses by an independent Data Safety Monitoring Board (DSMB) for the U.S. Phase 3 ALS study. The completion of the NurOwn® ALS Phase 3 study enrollment is anticipated in first half of 2019 and will enable a BLA filing thereafter for FDA approval of NurOwn® in ALS.

The Company also received gross cash proceeds of $12,291,005 in a June 6, 2018 warrant exercise transaction with certain existing Company warrant holders.

The Company continues to expand and strengthen its executive management team and attract key biotechnology industry leaders to the Company. On August 28, 2018, the Company hired Arturo Araya as its Chief Commercial Officer. Mr. Araya has served as a member of the Company's Board of Directors (the "Board") since February 2017. In connection with his employment, Mr. Araya was replaced by Dr. Anthony Polverino on the Governance, Nominating and Compensation Committee of the Board, and Mr. Araya's service on the Board will end at the Company's 2018 Annual Meeting of Stockholders.

The Company's Scientific Advisory Board (SAB), with world leading neuroscientists and experts in the fields of ALS and other neurodegenerative diseases, advises the management team on scientific matters such as research, clinical trials and drug development. The SAB is chaired by Jerold Chun, M.D., Ph.D., an acclaimed neuroscientist and professor at Sanford Burnham Prebys Medical Discovery Institute and has decades of expertise in degenerative disease research and neuroscience drug development.

The (Connell and O'Reilly Families) Cell Manipulation Core Facility (CMCF), at Dana-Farber Cancer Institute (DFCI) in Boston has been recently contracted as a second U.S. manufacturing site to supply NurOwn® for the ongoing randomized, double-blind, multi-dose Phase 3 ALS pivotal trial (ClinicalTrials.gov Identifier: NCT03280056) and to support additional clinical indications. Dana-Farber has commenced manufacturing of NurOwn® for the ALS pivotal trial in October 2018. The addition of Dana Farber as a U.S. manufacturing site will accelerate enrollment of the ALS pivotal trial and support additional clinical indications. This is an important milestone toward U.S. commercialization of NurOwn® in ALS and to support planned IND filings for additional clinical indications. Brainstorm's strategic decision to partner with City of Hope and Dana-Farber was based on their proven track record of excellence in NurOwn® manufacturing in the Company's Phase 2 U.S. trial and their extensive experience with autologous cellular therapy products (i.e., CD19-targeted CAR-T-cell therapies).

Our Proprietary Technology

NurOwn® technology is based on an innovative manufacturing protocol, which induces the differentiation of purified and expanded bone marrow-derived mesenchymal stem cells (“MSC”) into cells that release high levels of multiple neurotrophic factors (“MSC-NTF” cells) for neuroprotection in addition to the intrinsic immunomodulatory effects of MSC cells of origin. These factors are known to be critical for the growth, survival and differentiation of neurons, including: glial-derived neurotrophic factor (“GDNF”); brain-derived neurotrophic factor (“BDNF”); vascular endothelial growth factor (“VEGF”); and hepatocyte growth factor (“HGF”), among others. GDNF is one of the most potent survival factors known for peripheral motorneurons. VEGF and HGF have been demonstrated to have important neuroprotective effects in ALS and other neurodegenerative diseases.

Our approach to the treatment of neurodegenerative diseases with autologous adult stem cells involves a multi-step process that includes: harvesting of undifferentiated stem cells from the patient's own bone marrow; processing of cells at the manufacturing site; cryopreservation to enable multiple treatments from a single bone marrow sample; and intrathecal (“IT”) injection of MSC-NTF cells into the same patient by standard lumbar puncture. This administration procedure does not require hospitalization and has been shown to be safe and well tolerated in multiple CNS clinical trials to date. The ongoing U.S. Phase 3 ALS study is evaluating the therapeutic potential of repeated dosing (2 months dosing interval).

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 differentiation of autologous adult mesenchymal stem cells into MSC-NTF cells *before* transplantation is unique to NurOwn®, making it the first-of-its-kind for the treatment of neurodegenerative diseases.

The specialized MSC-NTF cells secrete multiple neurotrophic factors that may lead to:

- Protection of existing motor neurons;
- Promotion of motor neuron repair; and
- Re-establishment of functional nerve-muscle interactions.

Autologous (Self-transplantation)

The NurOwn® approach 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, 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 ethical controversies 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, which provides the potential for an extended period of exclusivity, within the U.S. and Europe. We have completed two early stage Phase 1 and 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 Open Label Trials

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

In January 2016, the results of the two completed Phase 1/2 study and Phase 2 open label trials were published in JAMA Neurology. This demonstrated a slower rate of disease progression following MSC-NTF cell transplantation as measured by the ALS Functional Rating Score ("ALSFRS-R"), the gold standard for the evaluation of ALS functional status, and Forced Vital Capacity ("FVC"), a measure of pulmonary function, as well as positive trends in the rate of decline of muscle volume and the compound motor axon potential ("CMAPs"). This was the first published clinical data using autologous mesenchymal stem cells, induced under culture conditions to produce NTFs, with the potential to achieve a neuroprotective effect in ALS and modify the course of this disease.

Phase 2 Randomized Trial

The FDA-approved, 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 timepoints in the study over 24 weeks.

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

After the 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 support a Biologic License Application ("BLA") for NurOwn® in ALS. The clinical trial is actively enrolling an enriched patient population based on superior outcomes observed in the Phase-2 pre-specified sub-group of rapid progressors. The primary clinical

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

The independent Data Safety Monitoring Board (DSMB) for the study completed its pre-specified interim analysis of safety outcomes for the first 31 participants treated with NurOwn® in the Phase 3 trial in ALS (NCT03280056). The DSMB indicated there were no significant safety concerns and recommended that the trial continue, as planned without any modifications to the study protocol. The DSMB Chairperson Carlayne Jackson MD, commented “The DSMB appreciates the continued commitment of Brainstorm and the research teams to conducting this trial in such an exemplary manner. We commend them on their outstanding enrollment and the quality of data collection.” Top-line efficacy data is expected in the first half of 2020. The study is registered at www.clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT03280056).

The Company has developed a validated cryopreservation process for the long-term storage of MSC, that allows multiple doses of autologous NurOwn® to be created from a single bone marrow harvest procedure in the multi-dose clinical trial and 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 been also recently contracted to manufacture NurOwn® and placebo for Phase 3 clinical study participants (and has become operational in October 2018).

Patient Access Programs

The Company collaborated with the Tel Aviv Sourasky Medical Center (Ichilov Hospital), and jointly applied by the Israel Hospital Exemption regulatory pathway, which was adopted by the Ministry of Health (MoH) from the European Union regulation, for NurOwn® treatment of ALS. This pathway will enable the Company to make NurOwn® potentially accessible for ALS patients in Israel, for a fee. These treatments will be administered by Advanced Cell Therapies Ltd, a newly formed Israeli company and a wholly owned subsidiary of the Company's Israeli Subsidiary.

In January 2018, the Company announced the receipt of Good Manufacturing Practice (GMP) approval from the Israel MoH for its Israeli contract manufacturing facility. The GMP certificate confirms the Company's manufacturing site compliance with Israeli GMPs which are recognized as equivalent with EU standards. This approval advances the Company's application to the Israel MoH for the treatment of ALS patients under the Hospital Exemption regulation. The GMP certificate was granted after an inspection of the Company's contract manufacturing facilities and has been recently extended up to August 2019.

Non-Dilutive Funding

In July 2017, the Company was awarded a grant in the amount of $15,912,000 from 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 $9,050,000 of the CIRM grant: $7,050,000 was received in 2017 and an additional $2 million was received on April 30, 2018. The grant does not bear a royalty payment commitment nor is the grant otherwise refundable.

In 2017 and 2018, the Company was awarded aggregate grants of approximately $3.2 million from the Israel Innovation Authority ("IIA"). Year to date the Company has received approximately $1.9 million from IIA, made under the 2018 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 7 granted patents and 21 patent applications in the United States, Europe, and Israel, as well as in additional countries worldwide, including countries in the Far East and South America (in calculating the number of granted patents, each

European patent validated in multiple jurisdictions was counted as a single patent).

In July, 2018 the European Patent Office ("EPO") granted a Europe-wide patent for Patent No 2285951, which claims priority from WO 2009/144718. The allowed claims cover methods of treating ALS using mesenchymal stem cells that secrete neurotrophic factors, including brain derived neurotrophic factor (BDNF). This patent will provide protection for MSC-NTF cells (NurOwn®) in the EU validated states until 2029.

The Japanese Patent Office ("JPO") has granted Japanese patent No. 6,362,596, entitled: 'Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors" (sealing date 6 July 2018). This patent will provide protection for MSC-NTF cells (NurOwn®) in Japan until 2033.The allowed claims cover a method of generating cells which secrete brain derived neurotrophic factor (BDNF), glial derived neurotrophic factor (GDNF), hepatocyte growth factor (HGF) and vascular endothelial growth factor (VEGF).

In August 2018 the U.S. Patent and Trademark Office ("USPTO") granted the following two U.S. patents:

1. US Patent No. 10,046,010 titled 'Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors'. Allowed claims cover the method for generating MSC-NTF cells (NurOwn®) in industrial amounts for clinical practice. This patent will provide protection for MSC-NTF cells (NurOwn®) in the US until 2033.
2. US Patent No 10,052,363 relates to methods of treating ALS, Parkinson's disease and Huntington Disease with NurOwn®. This patent will provide protection for MSC-NTF cells (NurOwn®) in the US until 2029.

Scientific presentations

On September 12, 2018, Brainstorm's Chief Medical Officer, Dr. Ralph Kern, presented at the FDA Rare disease workshop in Washington, D.C. Presentation entitled: ALS Case Study: Clinical Trial Designs for Small Patient Populations.

On October 3, 2018, Dr. James Berry (MGH, Boston) presented a clinical poster entitled, “MicroRNA Changes in the NurOwn® Phase 2 ALS Randomized Clinical Trial: Relationship to Neuroprotection and Innate Immunity” at the Annual Northeast Amyotrophic Lateral Sclerosis (NEALS) Conference.

Research and Development

In addition to its active clinical program in ALS, the Company is focusing on further in-depth molecular and functional characterization of NurOwn®. A study profiling NurOwn®'s unique miRNA signature was published in 2017 in *Stem Cell Research & Therapy*. The publication, entitled "miRNA profiling of NurOwn®: mesenchymal stem cells secreting neurotrophic factors" shows that NurOwn® MSC-NTF cells induced to secrete neurotrophic factors have both an enhanced secretion of NTFs as well as a distinct miRNA expression profile that distinguishes them from their MSC of origin. miRNAs have been shown to play critical roles in neuronal and glial cell biological processes. These findings may form the basis for the development of sensitive identity release assays for clinical trials, in vivo cell identification assays, and to elucidate MSC-NTF cells' mechanism of action in ALS and other neurodegenerative diseases. On August 23, 2018 the Company announced a positive Phase 3 interim safety analysis by the Data Safety Monitoring Board (DSMB). There were no significant safety issues and the DSMB recommended that the trial continue as planned. Confirmation of the safety of repeated injections in the first cohort of 61 active study subjects is an important milestone for the Company.

The Company is also reviewing the potential clinical development of NurOwn® in other neurodegenerative disorders, such as progressive multiple sclerosis, Parkinson’s disease, Huntington’s disease and Rett syndrome. Research is currently ongoing to develop additional cell products which might be suitable for multiple neurodegenerative diseases.

For the Phase 3 study in ALS, 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 it 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 September 30, 2018, the Company has not earned any revenue from operations. The Company does not expect to earn revenue from operations until the second half of 2018, if ever. The Company has incurred operating costs and other expenses of approximately $3,232,000 during the three months ended September 30, 2018 compared to $2,392,000 during the three months through September 30, 2017. The increase of $840,000 is due to the ongoing U.S. Phase 3 Clinical Trial.

Research and Development Expenses:

Research and development expenses, net for the three months ended September 30, 2018 and 2017 were $1,975,000 and $1,168,000, respectively, representing an increase of $807,000. This increase is due to (i) an increase of $2,347,000 in connection with the Phase 3 Clinical Trial;(ii) an increase of $126,000 in connection with patents, travel, rent and other activities and (iii) an increase of $48,000 for costs related to payroll and stock-based compensation expenses. The increase was partially offset by an increase of $1,714,000 in participation of the Israel Innovation Authority (“IIA”) and CIRM in 2018, under various awarded grants.

Excluding participation from IIA and CIRM under the grants, research and development expenses increased by $2,522,000 from $1,547,000 in the third quarter of 2017 to $4,069,000 in the third quarter of 2018.

General and Administrative Expenses:

General and administrative expenses for the three months ended September 30, 2018 and 2017 were $1,257,000 and $1,224,000, respectively. The increase in general and administrative expenses of $33,000 is primarily due to an increase of $103,000 in PR and travel partially offset by a decrease of $85,000 in consultants, rent and other costs.

Other Income and Expenses:

Financial income for the three months ended September 30, 2018 was $56,000 as compared to financial expense of $11,000 for the three months ended September 30, 2017.

Net Loss:

Net loss for the three months ended on September 30, 2018 was $3,176,000, as compared to a net loss of $2,403,000 for the three months ended September 30, 2017. Net loss per share for the three months ended September 30, 2018 and 2017 was $0.15 and $0.13, respectively.

The weighted average number of shares of Common Stock used in computing basic and diluted net loss per share for the three months ended September 30, 2018 was 20,691,900, compared to 18,783,997 for the three months ended September 30, 2017.

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. At September 30, 2018, the Company had net working capital of $8,830,000 including cash, cash equivalents and short-term bank deposits amounting to $10,891,000.

Cash, Cash equivalents (including short-term bank deposits) and cash commitments amounted to approximately $11,354,000.

Net cash used in operating activities was $6,594,000 for the three months ended September 30, 2018. 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 $4,983,000 for the three months ended September 30, 2018, representing net decrease in short-term interest-bearing bank deposits. Net cash provided by financing activities was $46,000 for the three months ended September 30, 2018.

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

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

- our ability to obtain funding from third parties, including any future collaborative partners;
- the scope, rate of progress and cost of our clinical trials and other research and development programs;
- the time and costs required to obtain regulatory approvals;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of filing, prosecuting, defending and enforcing patents, patent applications, patent claims, trademarks and other intellectual property rights;
- the effect of competition and market developments; and
- future pre-clinical and clinical trial results.

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 September 30, 2018. 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, 2017.

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 that occurred during the quarter ended September 30, 2018 that 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, 2017. 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, 2017, 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, 2017, 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 September 30, 2018, 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
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: October 29, 2018 *By:/s/ Eyal Rubin*
Name: Eyal Rubin
Title: EVP, Chief Financial Officer

(Principal Financial Officer)