

BRAINSTORM CELL THERAPEUTICS INC.  
Form 10-Q  
May 15, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2017

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 (I.R.S. Employer  
incorporation or organization) Identification No.)

3 University Plaza Drive, Suite 320

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Hackensack, NJ 07601  
(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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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  (Do not check if a smaller reporting company) Smaller reporting company

Emerging growth company

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

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

As of May 5, 2017, the number of shares outstanding of the registrant's Common Stock, \$0.00005 par value per share, was 18,735,550.

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**Item 1. Financial Statements**

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

**INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF MARCH 31, 2017**

**U.S. DOLLARS IN THOUSANDS**

(Except share data and exercise prices)

(UNAUDITED)

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

**INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF MARCH 31, 2017**

U.S. DOLLARS IN THOUSANDS

(Except share data and exercise prices)

(UNAUDITED)

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESINTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

(Except share data)

	March 31, 2017 U.S. \$ in thousands Unaudited	December 31, 2016 U.S. \$ in thousands Audited
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$604	\$ 547
Short-term deposit (Note 4)	7,743	9,443
Account receivable	202	306
Prepaid expenses and other current assets	176	148
Total current assets	8,725	10,444
Long-Term Assets:		
Prepaid expenses and other long-term assets	26	25
Property and Equipment, Net	281	297
Total Long-Term Assets	307	322
Total assets	\$9,032	\$ 10,766
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payables	\$362	\$ 345
Accrued expenses	90	152
Other accounts payable	337	367
Total current liabilities	789	864
Stockholders' Equity:		
Stock capital: (Note 5)	11	11
Common stock of \$0.00005 par value - Authorized: 100,000,000 shares at March 31, 2017 and December 31, 2016 respectively; Issued and outstanding: 18,699,665 and 18,687,987 shares at March 31, 2017 and December 31, 2016 respectively.		

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Additional paid-in-capital	85,140	85,014
Accumulated deficit	(76,908)	(75,123 )
Total stockholders' equity	8,243	9,902
Total liabilities and stockholders' equity	\$9,032	\$ 10,766

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



BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

U.S. dollars in thousands

(Except share data)

	Three months ended March 31,	
	2017	2016
	U.S. \$ in thousands	
Operating expenses:		
Research and development, net	\$941	\$986
General and administrative	829	826
Operating loss	(1,770 )	(1,812 )
Financial expenses (income), net	15	(22 )
Net loss	\$(1,785 )	\$(1,790 )
Basic and diluted net loss per share from continuing operations	\$(0.10 )	\$(0.10 )
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	18,688,377	18,653,804

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESINTERIM CONDENSED STATEMENTS OF CHANGES IN EQUITY (AUDITED)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	<b>Accumulated</b>	Total
	Number	Amount	capital	<b>deficit</b>	stockholders' <b>equity</b>
Balance as of January 1, 2016	18,643,288	\$ 11	\$ 84,258	\$ (70,141	) \$ 14,128
Stock-based compensation related to warrants and stock granted to service providers	36,033	(*)	121	-	121
Stock-based compensation related to stock and options granted to directors and employees	8,666	-	635	-	635
Net loss	-	-	-	(4,982	) (4,982 )
Balance as of December 31, 2016	18,687,987	\$ 11	\$ 85,014	\$ (75,123	) \$ 9,902

\* Represents an amount less than \$1.

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESINTERIM CONDENSED STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	<b>Accumulated</b>	Total stockholders'
	Number	Amount	capital	<b>deficit</b>	<b>equity</b>
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	11,678	(*)	-	-	-
Stock-based compensation related to stock and options granted to directors and employees	-	-	126	-	126
Net loss	-	-	-	(1,785	) (1,785 )
Balance as of March 31, 2017	18,699,665	\$ 11	\$ 85,140	\$ (76,908	) \$ 8,243

\* 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

	Three months ended March 31, 2017      2016 U.S. \$ in thousands	
Cash flows from operating activities:		
Net loss	\$ (1,785 )	\$ (1,790 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	16	16
Expenses related to shares and options granted to service providers	-	31
Amortization of deferred Stock-based compensation related to options granted to employees and directors	126	203
Decrease in accounts receivable and prepaid expenses	76	269
Increase (decrease) in trade payables	17	(888 )
Decrease in other accounts payable and accrued expenses	(92 )	(822 )
Total net cash used in operating activities	\$ (1,642 )	\$ (2,981 )

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESINTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. dollars in thousands

	Three months ended March 31,	
	2017	2016
	U.S. \$ in thousands	
Cash flows from investing activities:		
Purchase of property and equipment	-	(26 )
Changes in short-term deposit	1,700	4,794
Investment in lease deposit	(1 )	(2 )
Total net cash provided by (used in) investing activities	\$ 1,699	\$ 4,766
Cash flows from financing activities:		
Total net cash provided by financing activities	\$ -	\$ -
Increase in cash and cash equivalents	57	1,785
Cash and cash equivalents at the beginning of the period	\$ 547	\$ 428
Cash and cash equivalents at end of the period	\$ 604	\$ 2,213

**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

Brainstorm Cell Therapeutics Inc. (formerly: Golden Hand Resources Inc. - the “Company”) was incorporated in the State of Washington on September 22, 2000. The Company currently holds two wholly owned subsidiaries; Brainstorm Cell Therapeutics Ltd. (“BCT”), an Israeli Company which currently conducts all of the research and development activities of the Company, and Brainstorm Cell Therapeutics UK Ltd. (“Brainstorm UK”). Brainstorm UK acts on behalf of the parent Company in the EU. Brainstorm UK is currently inactive. The Common Stock is publicly traded on the NASDAQ Capital Market under the symbol “BCLI”.

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), 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.

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 NuOwn or placebo. Future development of NurOwn for ALS will require additional clinical trials typically required to provide an adequate basis for regulatory approval and product labeling. These additional trials will include the administration of repeated doses to ALS patients enrolled in these trials.

On September 15, 2014 the Company completed a reverse stock split of the Company’s shares of Common Stock by a ratio 1-for-15. The Company adjusted all ordinary shares, options, warrants, per share data and exercise prices included in these financial statements for all periods presented to reflect the reverse stock split. On August 26, 2015 the shareholders of the Company approved a reduction of the number of authorized shares of Common Stock of the Company from 800,000,000 to 100,000,000.

**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.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to the Interim Condensed Consolidated Financial Statements

NOTE 2 - BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

A. Unaudited Interim Financial Statements

The accompanying unaudited interim condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of U.S. Securities and Exchange Commission Regulation S-X. Accordingly, they do not include all the information and footnotes required by 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, 2016.

Operating results for the three months ended March 31, 2017, are not necessarily indicative of the results that may be expected for the year ended December 31, 2017.

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. As the Company has not incurred revenues to date, it is unable to determine to expected impact of the new standard on its consolidated financial statements.

In January 2016, the FASB issued an amended standard requiring changes to recognition and measurement of certain financial assets and liabilities. The standard primarily affects equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. This standard is effective beginning in the first quarter of 2018. Certain provisions allow for early adoption. The Company do not expect that the adoption of this standard will have a significant impact on the financial position or results of operations.

In February 2016, the FASB issued a new lease accounting standard requiring that we recognize lease assets and liabilities on the balance sheet. This standard is effective beginning in the first quarter of 2019; early adoption is permitted. The Company have not yet determined the impact of the new standard on its 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.):

In March 2016, the FASB issued an accounting standard update aimed at simplifying the accounting for share-based payment transactions. Included in the update are modifications to the accounting for income taxes upon vesting or settlement of awards, employer tax withholding on shared-based compensation, forfeitures, and financial statement presentation of excess tax benefits. This standard is effective beginning in the first quarter of 2017; early adoption is permitted. The Company do not expect that the adoption of this standard will have a significant impact on the financial position or results of operations.

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 and we are evaluating whether we will early adopt. 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.

D. Use of estimates

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

NOTE 3 - RESEARCH AND LICENSE AGREEMENT

The Company has a Research and License Agreement, as amended and restated, with Ramot. The Company obtained a waiver and release from Ramot pursuant to which Ramot agreed to an amended payment schedule regarding the Company's payment obligations under the Research and License Agreement and waived all claims against the Company resulting from the Company's previous defaults and non-payment under the Research and License Agreement. The waiver and release amended and restated the original payment schedule under the original agreement providing for payments during the initial research period and additional payments for any extended research period.

The Company is to pay Ramot royalties on Net Sales on a Licensed Product by Licensed Product and jurisdiction by jurisdiction basis as follows:

So long as the making, producing, manufacturing, using, marketing, selling, importing or exporting of such  
a) Licensed Product is covered by a Valid Claim or is covered by Orphan Drug Status in such jurisdiction – 5% of all Net Sales.

In the event the making, producing, manufacturing, using, marketing, selling, importing or exporting of such  
b) Licensed Product is not covered by a Valid Claim and not covered by Orphan Drug status in such jurisdiction – 3% of all Net Sales until the expiration of 15 years from the date of the First Commercial Sale of such Licensed Product in such jurisdiction.

#### NOTE 4 - SHORT TERM INVESTMENTS

Short term investments on March 31, 2017 and December 31, 2016 include bank deposits bearing annual interest rates varying from 0.15% to 1.48%, with maturities of up to 1 and 6 months as of March 31, 2017 and December 31, 2016.

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 5 - STOCK CAPITAL

A. 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.

B. Issuance of shares, warrants and options:

1. Private placements and public offering:

In July 2007, the Company entered into an investment agreement, that was amended in August 2009 with ACCBT Corp. a company under the control of the Company's current Chief Executive Officer, according to which for an aggregate consideration of approximately \$5 million the Company issued 2,777,777 shares of Common Stock and a warrant to purchase 672,222 shares of Common Stock at an exercise price of \$3 per share and a warrant to purchase 1,344,444 shares of common stock at an exercise price of \$4.35 per share. The warrants are exercisable, through November 5, 2017.

Our current Chief Executive Officer has served as the President of the Company since July 2007 and in addition has as Chief Executive Officer from August 2013 until June 2014. On September 28, 2015 he was reappointed and currently serves as Chief Executive Officer of the Company.

On September 28, 2015 the Company granted to its Chief Executive Officer an option to purchase 369,619 shares of Common Stock at an exercise price of \$2.45 per share. The option vested over 12 months until fully vested on August 28, 2016.

In February 2010, the Company issued an aggregate 399,999 shares of Common Stock and warrants to purchase an aggregate of 199,998 shares of Common Stock with an exercise price of \$7.50 per share for aggregate proceeds of \$1.5 million.

On July 17, 2012, the Company raised a \$5.7 million of gross proceeds through a public offering (“2012 Public Offering”) of its common stock and warrants to purchase common stock. The Company issued a total of 1,321,265 shares of common stock (\$4.35 per share), and thirty month warrants to purchase 990,949 shares of Common Stock at an exercise price of \$4.35 per share. After deducting closing costs and fees, the Company received net proceeds of approximately \$4.9 million. The Company paid to the placement agent, a cash fee and a corporate finance fee equal to 7% of the gross proceeds of the offering. In addition, the Company issued to the placement agent a two year warrant to purchase up to 32,931 shares of Common Stock, with an exercise price equal to \$5.22.

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 5 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

1. Private placements and public offering: (Cont.):

On February 7, 2013, the Company issued 55,556 units to a private investor for total proceeds of \$250. Each unit consisted of one share of Common Stock and a warrant to purchase one share of Common Stock at \$7.5 per share exercisable for 32 months. On October 7, 2015 the warrants were cancelled.

On August 16, 2013, the Company raised \$4 million, gross, through a registered public offering (“2013 Public Offering”) of its Common Stock and the issuance of warrants to purchase Common Stock. The Company issued a total of 1,568,628 Common Stock, (\$2.55 per share) and three year warrants to purchase 1,176,471 shares of Common Stock, at an exercise price of \$3.75 per share (the “2013 Warrants”). The Warrants also included, subject to certain exceptions, full ratchet anti-dilution protection in the event of the issuance of any Common Stock, securities convertible into common stock, or certain other issuances at a price below the then-current exercise price of the Warrants, which would result in an adjustment to the exercise price of the Warrants. After deducting closing costs and fees, the Company received net proceeds of approximately \$3.3 million. In accordance with the provisions of ASC 815 (formerly FAS 133) the proceeds related to the warrants at the amount of \$829 were recorded to liabilities at the fair value of such warrants as of the date of issuance, and the proceeds related to common stocks of 2,496 were recorded to equity.

On April 25, 2014, the Company entered into agreements with some of holders of the 2013 Warrants to exchange warrants to purchase an aggregate of 777,471 shares of Company common stock for an aggregate of 388,735 unregistered shares of Common Stock.

On May 27, 2014 the Company entered into agreements with certain warrant holders to redeem “2013 warrants” to purchase 333,235 shares of Company common stock, in consideration for approximately \$600 payable in cash (\$1.80 per Warrant).

In May 2014, certain holders of 2013 Warrants which did not participate in the redemption and whose 2013 Warrants will therefore remained outstanding waived the anti-dilution provisions of their 2013 Warrants.

In July 2014, the Company agreed to adjust the exercise price of the remaining “2013 Warrants” to \$0.525 per share.

On January 6, 2015, the remaining “2013 Warrants” holders that did not provide a waiver of their anti-dilution rights, exercised their warrants. Therefore, the liability related to the 2013 Warrants has been cancelled.

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 5 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

1. Private placements and public offering: (Cont.):

On June 13, 2014, the Company raised gross proceeds of \$10.5 million through a private placement of the Company's Common Stock and warrants purchase Common Stock. The Company issued 2.8 million shares of Common Stock at a price per share of \$3.75 and three year warrants to purchase up to 2.8 million shares of Common Stock at an exercise price of \$5.22 per share.

Pursuant to a Warrant Exercise Agreement, dated January 8, 2015, holders of the Company's warrants (issued in June 2014) to purchase an aggregate of 2,546,667 shares of the Company's Common Stock at an exercise price of \$5.22 per share, agreed to exercise their 2014 Warrants in full and the Company agreed to issue new warrants to the holders to purchase up to an aggregate of approximately 3.8 million unregistered shares of Common Stock at an exercise price of \$6.50 per share. The \$6.50 warrants expire in June 2018. Gross proceeds from the exercise of the warrants was approximately \$13.3 million. In connection with the Exercise Agreement, the Company agreed to pay to the Placement Agency a cash fee equal to 6.0% of the Exercise Proceeds, as well as fees and expenses of the Placement Agency of \$20. In addition, the Company issued the Placement Agency a warrant to purchase 38,000 shares of Common Stock upon substantially the same terms as the New Warrants. Net of fees and related expenses the proceeds from the warrant exercise amounted to approximately \$12.4 million.

Since its inception the Company has raised approximately \$46.6M, 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.

2. Share-based compensation to employees and to directors:



On November 25, 2004, the Company's stockholders approved the 2004 Global Stock Option Plan and the Israeli Appendix thereto (which applies solely to participants who are residents of Israel) and on March 28, 2005, the Company's stockholders approved the 2005 U.S. Stock Option and Incentive Plan, and the reservation of 609,564 shares of Common Stock for issuance in the aggregate under these stock plans.

In June 2008, June 2011 and in June 2012, the Company's stockholders approved increases in the number of shares of common stock available for issuance under these stock option plans by 333,333, 333,333 and 600,000 shares, respectively

Each option granted under the plans is exercisable until the earlier of ten years from the date of grant of the option or the expiration dates of the respective option plans. The 2004 and 2005 options plans expired on November 25, 2014 and March 28, 2015, respectively.

On August 14, 2014, the Company's stockholders approved the 2014 Global Share Option Plan and the Israeli Appendix thereto (which applies solely to participants who are residents of Israel) and the 2014 Stock Incentive Plan.

A total 600,000 shares of Common Stock were reserved for issuance in the aggregate under these stock plans.

On June 21, 2016 the Company's stockholders approved an amendment to the Plans which increased the shared pool of shares of common stock available for issuance under the Plans by 1,600,000, from 600,000 to 2,200,000.

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 5 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

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

The exercise price of the options granted under the plans may not be less than the nominal value of the shares into which such options are exercised. Any options that are canceled or forfeited before expiration become available for future grants.

From 2005 through 2009, the Company granted its directors options to purchase an aggregate of 53,333 shares of Common Stock of the Company at an exercise price of \$2.25 per share. The options are fully vested and will expire 10 years from the date of issuance.

On April 13, 2010, the Company, Abraham Israeli and Hadasit Medical Research Services and Development Ltd. ("Hadasit") entered into an Agreement (as amended, the "Hadasit Agreement") pursuant to which Prof. Israeli agreed, during the term of the Hadasit Agreement, to serve as (i) the Company's Clinical Trials Advisor and (ii) a member of the Company's Board of Directors.

Accordingly, the Company granted to Prof. Israeli in each of April 2010, June 2011, April 2012 and April 2013, an option to purchase 11,111 shares of Common Stock at an exercise price equal to \$0.00075 per share.

In addition, the Company granted Hadasit, in each of April 2010, June 2011, April 2012, and April 2013, a warrant to purchase 2,222 shares of Common Stock at an exercise price equal to \$0.00075 per share.

In addition, on April 13, 2014, pursuant to the Hadasit Agreement, and pursuant to the December 2013 letter from the Company to Prof. Israeli, the Company issued to Prof. Israeli, an option to purchase 20,000 shares of its Common Stock at an exercise price of \$0.00075 per share.

On April 25, 2014 the Agreement among the Company, Prof. Abraham Israeli and Hadasit was terminated. As a result of the termination, Prof. Israeli and Hadasit will no longer receive annual grants to purchase shares of Common Stock, and any outstanding and unvested grants made pursuant to the Agreement ceased to vest. The grants were valid until and exercisable only on or before October 25, 2014.

In October 2014, Prof Israeli exercised his option to purchase 44,444 shares of Common Stock of the Company, and Hadasit exercised its warrants to purchase 8,889 shares of Common Stock of the Company.

On December 16, 2010, the Company granted to two of its directors fully vested options to purchase an aggregate of 26,667 shares of Common Stock at an exercise price of \$2.25 per share.

On August 22, 2011, the Company entered into an agreement one of its directors pursuant to which the Company granted the director 61,558 restricted shares of

Common Stock of the Company. The shares vested through August 22, 2014. In addition, the Company is paying the director \$15 per quarter his services.

On May 3, 2015 the Company granted to a director 60,000 shares of restricted Common Stock. The shares will vest in three installments through August 22, 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 5 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

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

On August 1, 2012, the Company granted to three of its directors options to purchase an aggregate of 30,667 shares of Common Stock of the Company at \$2.25 per share.

On April 19, 2013, the Company granted to three of its directors options to purchase an aggregate of 30,667 shares of Common Stock of the Company at \$2.25 per share. In addition the Company issued to two of its directors and four of its Advisory Board members a total of 50,667 restricted shares of Common Stock. The Options and restricted shares vested over 12 months.

On June 6, 2014, the Company granted its Chief Operating Officer a fully vested option to purchase 33,333 shares of the Company's common stock. The exercise price of the grant was \$2.70 per share.

On June 9, 2014, the Company's former Chief Executive Officer was granted a stock option for the purchase of 380,000 shares of the Company's common stock, vesting over four years, with an exercise price of \$4.5 per share. On November 10, 2015 the Company and the former CEO agreed that the unvested portion of the option as of October 30, 2015 (to purchase 253,333 shares) will be forfeited and that the vested portion of the option (to purchase 126,667 shares) will terminate on September 30, 2016.

On August 15, 2014, the Company issued to two of its directors and four of its Advisory Board members a total of 50,667 restricted shares of Common Stock. The shares vested over 12 months.

On October 31, 2014, the Company granted to four of its directors options to purchase an aggregate of 70,666 shares of Common Stock of the Company at \$0.75 per share. The options vest over 12 months.

On June 1, 2015, the Company granted to a director fully vested options to purchase an aggregate of 6,667 shares of Common Stock of the Company at \$0.75 per share.

On July 30, 2015 the Company's newly appointed Chief Financial Officer was granted an option to purchase 165,000 shares of Common Stock at an exercise price of \$3.17 per share. The option will vest over 3 years. Effective December 1, 2015 the Company and the Chief Financial Officer agreed to amend the option agreement. Pursuant to the amendment, 82,500 shares were cancelled. The 82,500 remaining shares continued to vest and become exercisable in accordance with the terms of the grant: 20,625 shares vested and became exercisable on July 30, 2016 and 2.08333% of the 82,500 shares were scheduled to vest and become exercisable on each monthly anniversary date starting on August 30, 2016 through the fourth anniversary of the grant, so that the 82,500 shares would become fully vested and exercisable on July 30, 2019. On November 9, 2016, the Company's Chief Financial Officer notified the Company that he is terminating his part time employment with the Company effective at the end of business on November 14, 2016. The option ceased to vest on November 14, 2016 and the right to exercise the option was terminated February 14, 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 5 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

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

On August 27, 2015 the Company granted to four of its seven directors options to purchase an aggregate of 70,665 shares of Common Stock at an exercise price of \$0.75 per share, and granted to two of its directors an aggregate of 17,332 restricted shares of Common Stock. The options and restricted shares of Common Stock vest over 12 months until fully vested on August 27, 2016.

On September 28, 2015 the Company granted to its newly appointed Chief Executive Officer an option to purchase 369,619 shares of Common Stock at an exercise price of \$2.45 per share. The option vested over 12 months until fully vested on August 28, 2016.

On July 14, 2016 the Company granted to four of its seven directors options to purchase an aggregate of 70,665 shares of Common Stock at an exercise price of \$0.75 per share, and on September 26, 2016 granted 8,666 restricted share of Common Stock to one director and on March 28, 2017 granted 8,666 restricted shares of Common Stock to another director. The options and restricted shares of Common Stock vest over 12 months until fully vested on June 22, 2017.

On February 26, 2017 the Company granted a stock option to a director to purchase up to 6,667 shares of Common Stock at an exercise price of \$0.75 per share. The option was fully vested and exercisable on the date of grant.

On February 26, 2017 the Company granted a director 3,012 shares of restricted common stock. The grant will vest in 12 consecutive, equal monthly installments commencing on the one month anniversary of the date of grant, until fully

vested on the first anniversary of the date of grant, provided grantee remains a director of the Company on each such vesting date.

On March 6, 2017, the Company granted to its newly appointed Chief Operating Officer 35,885 shares of restricted common stock, which vests 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 grantee remains continuously employed by the Company from the date of grant through each applicable vesting date, and is subject to accelerated vesting upon a Change of Control (as defined in an agreement with grantee) of the Company. In the event of grantee's termination of employment, any portion of the 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 grantee.

On March 6, 2017, the Company granted to its newly appointed Chief Operating Officer an option to purchase up to 47,847 shares of Common Stock at an exercise price per share of \$4.18. The option is fully vested and exercisable as of the date of grant and shall remain exercisable until the 2nd anniversary of the date of grant, regardless of whether grantee remains employed by 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 5 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.)

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

The Company accounts for shares and warrant grants issued to non-employees using the guidance of ASC 505-50, “Equity-Based Payments to Non-Employees” (EITTF 96-18, “Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services”), whereby the fair value of such option and warrant grants is determined using a Black-Scholes options pricing model at the earlier of the date at which the non-employee’s performance is completed or a performance commitment is reached.

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

	For the three months ended March 31, 2017		
	Amount of options	Weighted average exercise price \$	Aggregate intrinsic value \$
Outstanding at beginning of period	874,841	2.1258	
Granted	54,514	3.7605	
Exercised	-	-	
Cancelled	(38,446 )	3.6160	
Outstanding at end of period	890,909	2.1615	1,860,623





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 5 - STOCK CAPITAL (Cont.):

## B. Issuance of shares, warrants and options: (Cont.)

## 3. Shares and warrants to investors and service providers: (Cont.)

(a) **Warrants to investors and service providers:**

The fair value for the warrants to service providers was estimated on the measurement date determined using a Black-Scholes option pricing model, with the following weighted-average assumptions for the year ended December 31, 2010; weighted average volatility of 140%, risk free interest rates of 2.39%-3.14%, dividend yields of 0% and a weighted average life of the options of 5-5.5 and 1-9 years. There were no grants to service providers since 2010.

Issuance date	Number of warrants issued	Exercised	Forfeited	Outstanding	Exercise Price \$	Warrants exercisable	Exercisable through
Nov-Dec 2004	973,390	959,734	13,656	-	0.00075 - 0.15	-	-
Feb-Dec 2005	203,898	32,011	171,887	-	2.25 - 37.5	-	-
Feb-Dec 2006	112,424	48,513	63,911	-	0.075 - 22.5	-	-
Mar-Nov 2007	180,220	-	100,220	80,000	2.25 - 7.05	80,000	<b>Oct 2017</b>
Nov 2008	6,667	-	-	6,667	2.25	6,667	<b>Sep-18</b>
Apr-Oct 2009	26,667	6,667	-	20,000	1.005 - 1.5	20,000	<b>Apr 2019- Oct 2019</b>
Aug 2007- Jan 2011	2,016,667	-	-	2,016,667	3 - 4.35	2,016,667	<b>Nov-17</b>
Jan 2010	83,333	-	83,333	-	7.5	-	-
Feb 2010	8,333	8,333	-	-	0.15	-	-
Feb 2010	200,000	-	200,000	-	7.5	-	-
Feb 2010	100,000	100,000	-	-	0.015	-	-

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Feb 2011	42,735	-	42,735	-	5.85	-	-
Feb 2011	427,167	63,122	364,044	-	4.2	-	-
Feb 2011	854,333	-	854,333	-	7.5	-	-
Jul 2012	32,931	-	32,931	-	5.22	-	-
Jul 2012	990,949	687,037	303,911	-	4.35	-	-
Feb 2013	55,556	-	55,556	-	7.5	-	-
April 2010-2014	12,889	8,889	4,000	-	0.00075	-	-
Aug 2013	1,147,471	-	1,147,471	-	3.75	-	-
Aug 2013	29,000	29,000	-	-	0.525	-	-
Jun 2014	2,800,000	2,546,667	-	253,333	5.22	253,333	<b>Jun-17</b>
Jun 2014	84,000	-	-	84,000	4.5	84,000	<b>Jun-17</b>
Jan 2015	3,858,201	-	-	3,858,201	6.5	3,858,201	<b>Jun-18</b>
	14,246,831	4,489,973	3,437,988	6,318,868		6,318,868	

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 5 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

3. Shares and warrants to service providers: (Cont.):

(b) Shares:

On December 30, 2009, the Company issued to Ramot 74,667 shares of Common Stock (See Note 3).

On December 31, 2011, the Company issued to Hadasit warrants to purchase up to 100,000 restricted shares of Common Stock at an exercise price of \$0.015 per share, exercisable for a period of 5 years. The warrants vested over the course of the trials and were exercised in 2015.

On January 16, 2013, the Company granted an aggregate of 14,400 shares of Common Stock of the Company to two consultants, for services rendered through December 31, 2012. Related compensation expense in the amount of \$54 was recorded as research and development expense.

On February 4, 2013, the Company issued 8,408 shares of Common Stock to an investor, according to a settlement agreement, for the correction of the conversion rate of a \$200 convertible loan. The convertible loan was issued in 2006 and converted in 2010.

On March 11, 2013, the Company granted to its legal advisor 12,913 shares of Common Stock for 2013 legal services. The related compensation expense in the amount of \$44.5 was recorded as general and administrative expense.

On November 13, 2013, the Company approved a grant of 30,000 shares of Common Stock to the Consultants, for services rendered during January 1, 2013 through September 30, 2013 (the "2013 Shares"). On March 24, 2014, the Company approved grants of an aggregate of 6,000 shares of Common Stock to the Consultants for services rendered in 2014, and issued such shares together with the 2013 Shares.

On March 11, 2013, the Company granted to two of its service providers an aggregate of 26,667 shares of Common Stock. The shares were issued as compensation for public relations services. The related compensation expense in the amount of \$92 was recorded as general and administrative expense.

On July 28, 2014, the Company granted to its legal advisor 10,752 shares of Common Stock for 2014 legal services. The related compensation expense in the amount of \$50 was recorded as general and administrative expense.

On April 29, 2015, the Company approved grants of an aggregate of 27,411 shares of Common Stock to the Consultants for services rendered in 2014. The related compensation expense was recorded as research and development expense.

On January 2, 2016, the Company granted to its legal advisor 10,752 shares of Common Stock for 2015 legal services. The related compensation expense of \$31 was recorded as general and administrative expense.

On September 22, 2016, the Company granted of an aggregate of 25,281 shares of Common Stock to two consultants for services rendered in 2015. The related compensation expense was recorded as research and development 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 5 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

4. 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:

	Three months ended	
	March 31,	
	2017	2016
Research and development	\$ 55	\$ 3
General and administrative	71	231
Total stock-based compensation expense	\$ 126	\$ 234

## 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. and its potential future business operations and performance, including statements regarding the market potential for treatment of neurodegenerative disorders such as ALS, the sufficiency of our existing capital resources for continuing operations in 2017 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. 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.” Some of these are described under “Risk Factors” in this report and in our annual report on Form 10-K for the fiscal year ended December 31, 2016. 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 “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 addition to the other information set forth herein and elsewhere in our other public filings with the Securities and Exchange Commission.*

### Company Overview

Brainstorm Cell Therapeutics Inc. is an integrated biotechnology company actively engaged in the development and commercialization of innovative adult stem cell therapies for the treatment of debilitating neurodegenerative disorders that have no or limited treatment options, thus representing a unique opportunity to address unmet medical needs. These include Amyotrophic Lateral Sclerosis (“ALS”, also known as Lou Gehrig’s disease), Multiple Sclerosis (“MS”), and Parkinson’s disease (“PD”) among others. NurOwn® is our proprietary process for the propagation of adult bone marrow-derived Mesenchymal Stem Cells (“MSC”), their differentiation into neurotrophic factor- (“NTF”) secreting cells

(“MSC-NTF”), and transplantation at, or close to, the site of damage.

Evidence to date from published animal and human studies suggest that NurOwn® offers the potential for more effective treatment of neurodegenerative diseases relative to existing therapies through unique neuroprotective and immunomodulatory effects. Groundbreaking ALS CSF biomarker work has demonstrated a strongly correlated increase in neurotrophic factors and a reduction in inflammatory biomarkers (MCP-1 and SDF-1) in NurOwn®-treated and not in placebo treated participants. This is a clear indicator of the mechanism by which this technology acts in ALS, and in related neurodegenerative diseases.

Our core technology was developed in collaboration with Professor (Prof.) Daniel Offen (Felsenstein Medical Research Center, Tel Aviv University), and the late Prof. Eldad Melamed, former head of Neurology of the Rabin Medical Center and former member of the Scientific Committee of the Michael J. Fox Foundation for Parkinson’s Research. Our wholly-owned Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. (the “Israeli Subsidiary”), holds rights to commercialize the technology, through a licensing agreement with Ramot at Tel Aviv University Ltd. (“Ramot”), the technology transfer company of Tel Aviv University, Israel. We currently employ 21 employees in Israel and 2 in the United States.

### **Our Proprietary Technology**

Facilitated by NurOwn® technology, the differentiated MSC-NTF cells are capable of releasing several highly disease relevant neurotrophic factors, including Glial-derived neurotrophic factor (“GDNF”), Brain-derived neurotrophic factor (“BDNF”), Vascular endothelial growth factor (“VEGF”) and Hepatocyte growth factor (“HGF”), all critical for the growth, survival and differentiation of developing neurons. GDNF is one of the most potent factors involved in the protection and survival of peripheral neurons. VEGF and HGF have been reported to have important protective effects on neurons and other non-neuronal glial cells in ALS as well as other neurodegenerative diseases. The effects of neurotrophic factors on neurons may include:

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



In addition to the consistent and important release of neurotrophic factors, NurOwn<sup>®</sup> demonstrates consistent *in vitro* modification of the immune response (immunomodulation) and *in vivo* modulation of CSF biomarkers. Neuroinflammation is an important cause of disease progression in neurodegenerative diseases, including ALS. The proprietary NurOwn<sup>®</sup> process results in significant measurable differences from undifferentiated MSCs, including: enhanced release of neurotrophic factors; release of neurotrophic factors that are very low or not expressed by MSCs; and a unique micro-RNA profile that may regulate growth and development of neurons (neurogenesis), VEGF and neuroinflammation. In preclinical studies, NurOwn<sup>®</sup> was found to be more effective than MSC in treating Autism, Parkinson's disease, Huntington's disease and multiple sclerosis. The combination of enhanced NTF release and neuromodulation may be an optimal approach to restore function and reduce ongoing CNS tissue damage in neurodegenerative disease.

NurOwn<sup>®</sup> treatment is a multi-step process (see table below) beginning with harvesting of undifferentiated stem cells from the patient's own bone marrow, and concluding with transplantation of the resulting differentiated, neurotrophic factor-secreting mesenchymal stem cells (MSC-NTF) back into the patient – intrathecally (injection into the cerebrospinal fluid) by standard lumbar puncture and/or intramuscularly. This unique technology is the first-of-its-kind for the treatment of neurodegenerative diseases.

### **The NurOwn<sup>®</sup> Transplantation Process**

- Bone marrow aspiration from patient;
- Isolation and propagation of the patient's mesenchymal stem cells;
- Differentiation of the mesenchymal stem cells into neurotrophic-factor secreting (MSC-NTF) cells; and
- Autologous transplantation into the same patient's spinal cord and/or muscle tissue.

Our proprietary technology process is conducted in full compliance with current Good Manufacturing Practice ("cGMP"). It is licensed to and developed by our Israeli Subsidiary.

### ***Advances of NurOwn<sup>®</sup> Beyond Current Therapies - Patient Benefits***

Given that NurOwn<sup>®</sup>'s approach involves transplantation of the stem cells derived from the same patient (autologous), there is 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 precludes the controversy associated with the use of embryonic stem cells in some countries.

Patients received NurOwn<sup>®</sup> in a single administration in the Phase 2 study. The Phase 3 program will involve multiple doses (3) that may be repeated 6 months later, whereas other therapies require multiple daily oral or intravenous administration.

MSC can be cryopreserved and, as required, can be subsequently differentiated into NurOwn<sup>®</sup>, and demonstrate product characteristics like NurOwn<sup>®</sup> cells derived from fresh MSC of the same patient/donor. This will allow the Company to provide repeated doses of autologous NurOwn<sup>®</sup> from a single bone marrow aspirate in its upcoming multi-dose clinical trial and will avoid the need for patients to undergo repeated bone marrow aspiration for a 2-year period.

## **The ALS Program**

### **Phase 1/2 and Phase 2a clinical studies for ALS patients**

The clinical development program for NurOwn<sup>®</sup> in ALS has been granted Fast Track designation by the U.S. Food and Drug Administration (the “FDA”) for this indication, and has been granted Orphan Status in both the United States and in Europe. We have completed two clinical trials of NurOwn<sup>®</sup> in patients with ALS at Hadassah Medical Center (“Hadassah”) (Principal Investigator (PI)- Professor (Prof.) Dimitrios Karussis). Laboratory services for of NurOwn<sup>®</sup> studies for the Israeli Subsidiary have been provided by Hadassah through an agreement with Hadasit Medical Research Services and Development Ltd., a subsidiary of the Hadassah Medical Organization.

A Phase 1/2 safety and efficacy study of NurOwn<sup>®</sup> in ALS patients administered either intramuscularly or intrathecally, was initiated in June 2011 after receiving approval from the Israeli Ministry of Health (“MoH”). The trial results, which were presented by Prof. Karussis at the American Academy of Neurology Annual Meeting on March 2013, demonstrated the safety of NurOwn<sup>®</sup> as well as signs of ALS patient functional improvement, as measured by the ALS Functional Rating Score (“ALSFRS-R”) and improved breathing, as measured by the Forced Vital Capacity (“FVC”).

A Phase 2a combined (intramuscular and intrathecal) treatment, dose-escalating trial, approved by the Israeli MoH in January 2013, was also conducted at Hadassah (PI- Prof. Dimitrios Karussis) and by September 27, 2013, we announced that 12 patients had successfully completed treatment. On December 10, 2013 Prof. Karussis presented some of the preliminary findings from this trial at the 24<sup>th</sup> International Symposium on ALS/MND in Milan, Italy, followed in June 2014 by the interim data of the trial, at the Joint Congress of European Neurology in Istanbul, Turkey. The last follow-up visits in this study occurred in September 2014. On January 5, 2015, the Company presented final top line data from this study in a press release and investor conference call. The results of this study confirmed the safety profile observed in the earlier Phase 1/2 trial, with the clear majority of adverse events being low-grade and transient. There were two deaths and two serious adverse events, all of which were deemed by the investigators to be unrelated to treatment. Subjects in this study showed a meaningful reduction in the rate of disease progression for the three and six months after treatment, compared to the three months prior to treatment. This

confirmed the safety of intrathecal administration of NurOwn® in ALS.

In January 2016, the Company announced the publication of a paper in the January 2016 edition of JAMA Neurology based on the results of the first in man Phase 1/2 study and Phase 2 dose escalation study with NurOwn® in ALS. The data provide indication of clinically meaningful benefit as reflected by a slower rate of ALS disease progression following NurOwn® treatment, a positive trend on two ALS disease biomarkers, including rate of decline of muscle volume and electrical muscle function. This was the first published clinical data with NurOwn®, or any treatment, to achieve a neuroprotective effect in ALS and potentially modify the course of disease.

In April 2016, the Company presented the combined results of the Phase 1/2 and Phase 2a NurOwn® clinical studies in ALS at the ISRASTEM 2016 and 6th Israel Stem Cell Society (ISCS) joint annual meeting which took place in Tel Aviv, Israel.

### **US Multicenter Double Blind Placebo Controlled Clinical Study for ALS Patients**

In December 2013, the Company submitted an Investigational New Drug (“IND”) application to the FDA for NurOwn® in ALS, and on April 28, 2014, we initiated an FDA-approved randomized, double-blind, placebo controlled multi-center U.S. Phase 2 clinical trial evaluating NurOwn® in ALS patients. The trial was conducted at the Massachusetts General Hospital (PIs- Drs. Merit Cudkowicz and James Berry) in Boston, Massachusetts, at the University of Massachusetts Memorial Hospital (PI- Dr. Robert Brown) in Worcester, Massachusetts and at the Mayo Clinic (Drs. Anthony Windebank and Nathan Staff) in Rochester, Minnesota. For this study, NurOwn® was manufactured at the Connell and O’Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute in Boston, Massachusetts and at the Human Cellular Therapy Lab at the Mayo Clinic. In the study 48 patients were randomized 3:1 to receive NurOwn® or placebo.

In February 2015, the Company announced that the Data Safety Monitoring Board (“DSMB”) for the multi-center U.S. Phase 2 clinical trial had reviewed the safety data collected through a cutoff date in January 2015, and did not find any significant lab abnormalities, adverse events or significant protocol deviations that would be cause for concern and therefore approved continuation of the trial as planned.

On August 11, 2015, the Company announced that it had completed enrollment achieving the target of 48 subjects to be enrolled in its ongoing randomized, double-blind placebo-controlled Phase 2 clinical trial of NurOwn® in ALS. The Company further announced, in November 2015, that the DSMB review of the safety data collected through a cutoff date in October 2015 for the multi-center U.S. Phase 2 clinical trial indicated that 47 of the 48 patients enrolled in the study confirmed that they experienced no treatment-related serious adverse events (SAEs). Furthermore, the DSMB did not identify any significant adverse events, lab abnormalities or significant protocol deviations that would be cause for concern.

In July 2016, the Company announced topline data from the recently completed U.S. randomized, double-blind, placebo-controlled Phase 2 Study of NurOwn® in ALS which confirmed that the study achieved its primary objective, demonstrating that NurOwn® was safe and well tolerated. NurOwn® also achieved multiple secondary efficacy endpoints, showing clear evidence of a clinically meaningful benefit. Notably, response rates were higher for NurOwn®-treated subjects compared to placebo at all time points in the study out to 24 weeks.

In October 2016, some of the Company’s topline phase 2 ALS clinical trial results were presented by Dr. Robert Brown and Dr. James Berry, at the 15th Annual Meeting of the Northeast ALS Consortium (NEALS).

In December 2016, the Company announced that data from the Company's Phase 2 study of NurOwn® in ALS, would be highlighted in presentations at the 27th International Symposium on ALS/MND, being held December 7-9, 2016 in Dublin, Ireland. Lead investigator, Dr. James Berry, presented new data from the Phase 2 study demonstrating that in ALS patients treated with NurOwn®, CSF neurotrophic factors (VEGF, HGF and LIF) showed a statistically significant increase and correlated with a statistically significant decrease in CSF inflammatory markers (MCP-1 and SDF-1) two weeks post-transplantation compared to pre-transplantation. In addition, reductions in CSF inflammatory markers at two weeks post-transplantation correlated with improvements in ALSFRS-R slope at 12 weeks post-transplantation, consistent with the proposed mechanism of action of NurOwn® in ALS. Dr. Berry also presented the pre-specified responder analyses from the Phase 2 trial which examined percentage improvements in post treatment of Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) slope compared to pre-treatment slope. These analyses showed that, in the NurOwn® treated group, a greater number of patients achieved the high threshold of 100% or greater improvement in the post-treatment vs. pre-treatment slope, compared with the placebo group. Responders were defined as those in whom disease symptoms were essentially halted for the period of the treatment effect or those who achieved a positive improvement on their ALSFRS-R score. Moreover, in the pre-specified subgroup that excluded subjects whose disease was progressing slowly, this effect was even more pronounced. Dr. Berry's presentation was posted on the Company website.

### **Phase 3 Clinical Study for ALS Patients**

In December 2016, the Company announced that it had recently completed a successful End-of-Phase 2 Meeting with the United States Food and Drug Administration (FDA). The Company reached general agreement with the FDA to proceed to a Phase 3 trial. Importantly, the FDA accepted the key elements of the Phase 3 program to support a Biologic License Application (BLA) for NurOwn® in ALS. The planned Phase 3 clinical trial will be a randomized, double-blind, placebo-controlled multi-dose trial that will be conducted at multiple sites in the U.S. and in Israel. The trial is expected to begin enrolling patients in the second quarter of 2017.

In January 2017, the Company announced that it had validated its cryopreservation process for NurOwn® in preparation for the upcoming Phase 3 clinical study in ALS. The validation involved a comparison of NurOwn® (MSC-NTF cells) derived from fresh mesenchymal stem cells (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. The cryopreserved MSC can differentiate into NurOwn®, similar to the NurOwn® derived from fresh MSC of the same patient/donor, prior to cryopreservation. This will allow the Company to provide repeated doses of autologous NurOwn® from a single bone marrow aspirate in its upcoming multi-dose clinical trial. Cryopreservation will avoid the need for patients to undergo repeated bone marrow aspirations.

In February 2017, the Company announced that it plans to contract with City of Hope's Center for Biomedicine and Genetics to produce clinical supplies of NurOwn® adult stem cells for the company's planned randomized, double-blind, multi-dose Phase 3 clinical study in patients with ALS. City of Hope is expected to support all U.S. medical centers that will be participating in the Phase 3 trial.

Future development of NurOwn® in ALS will require additional clinical trials, including a Phase 3 FDA-approved multi dose trial.

### **Patient Access Programs**

In December 2016, the Company announced that it plans to apply for Hospital Exemption for NurOwn® in Israel that will allow patient access to NurOwn® as a treatment that has been granted Hospital Exemption. This recently approved pathway would permit the Company to partner with a medical center in Israel and be allowed to treat patients with NurOwn® for a fee. Hospital Exemption allows for advanced therapy medicinal products to be made available to a group of patients to be agreed upon by the Israeli Ministry of Health. It is intended to provide patients with the possibility to benefit from a custom-made, innovative, individual treatment where there is a critical unmet need and an absence of valid therapeutic alternatives. The treatment is usually a custom-made product, such as NurOwn®, manufactured using a patient's own cells that are prepared on a non-routine basis. To qualify for a Hospital Exemption, several important criteria must be met including preparation according to specific quality standards (equivalent to those for a licensed product), use in a hospital and use under the exclusive responsibility of a medical practitioner.

In March 2017, the Company announced that it has signed a Memorandum of Understanding (MOU) with The Medical Research, Infrastructure, and Health Services Fund of the Tel Aviv Sourasky Medical Center (Ichilov Hospital) to explore the possibility of making NurOwn® available to Amyotrophic Lateral Sclerosis (ALS) patients under the provisions of Hospital Exemption regulation. The MOU also covers the participation of Tel Aviv Sourasky Medical Center in the planned Phase 3 trial that will investigate NurOwn® in ALS. The MOU sets forth the basic terms under which the Company and Tel Aviv Sourasky Medical Center would work together to submit an application to the Israeli Ministry of Health that will allow patient access to NurOwn® and is subject to a definitive agreement. The agreement is expected to be formalized in the first half of 2017.

In February 2017, the Company announced that it has signed an agreement with CCRM, a Toronto-based leader in developing and commercializing regenerative medicine technologies, and cell and gene therapies, to support the market authorization request for NurOwn®. At this time, CCRM is assisting the Company as it explores the opportunity to access Health Canada's early access pathway for treatment of patients with ALS. If NurOwn® qualifies for Health Canada's "Notice of Compliance with Conditions" pathway it could be authorized in Canada for distribution in early 2018.

## **Funding**

In May 2016, the Company announced that for the ninth consecutive year its wholly-owned subsidiary, Brainstorm Cell Therapeutics Ltd., was awarded a new grant of approximately \$1,470,000 from Israel's Office of the Chief Scientist (OCS). The Office of the Chief Scientist, is part of the Ministry of Economy Program to support innovative technologies in Israel. The funds supported the development of NurOwn® Phase 2 clinical program in ALS.

## **Intellectual Property**

In October 2016, the Company announced that it has been granted United States Patent No. 9,474,787 titled "Mesenchymal Stem Cells for the Treatment of CNS Diseases. The allowed claims cover mesenchymal stem cells that secrete neurotrophic factors, including brain-derived neurotrophic factor (BDNF) and glial derived neurotrophic factor (GDNF), as well as a pharmaceutical composition comprising these factors.

## **Future Development Plans**

In addition to its active clinical program in ALS, the Company is focusing on further in-depth molecular characterization of NurOwn® and its adaptation to additional indications. The Company is reviewing the potential clinical development of NurOwn® in other neurodegenerative disorders, such as Parkinson's disease, Huntington's disease, and multiple sclerosis. More research is currently being done on developing an additional product which might be suitable for many neurodegenerative diseases.

Brainstorm is pursuing studies to explore the potential benefit of NurOwn® in autism, a poorly understood disorder of brain development that affects 1% of the worldwide population and for which there are no approved drug treatments. In April 2017, the Company announced the Publication of the NurOwn® Autism Research Study, entitled "Long Term Beneficial Effect of Neurotrophic Factors-Secreting Mesenchymal Stem Cells Transplantation in the BTBR Mouse Model of Autism," (Perets N. et al. Behav Brain Res. 2017 Apr 6. [Epub ahead of print] PMID: 28392323) showing that transplantation of NurOwn® in the BTBR mice demonstrated significant long-term improvements in autistic behavior in the BTBR mice compared to MSC treated and to untreated BTBR mice.

In addition, the Company is engaged in several research initiatives to improve the scale and efficiency of NurOwn® production and to improve the stability of NurOwn®, which is currently produced in clean room facilities close to the clinical trial sites, where the cells are administered to patients.

## **Management**

In March 2016, the Company announced the appointment of Ralph Z. Kern, MD, MHSc to the positions of Chief Operating Officer and Chief Medical Officer, effective March 6, 2017. Dr. Kern joins Brainstorm Cell Therapeutics from Biogen, where he was Senior Vice President and Head of Worldwide Medical. His previous industry appointments include Head of Neuroscience Medical Unit at Novartis and Global Medical Director of Personalized Genetic Health at Genzyme Corporation.



## **Corporate Information**

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 3 University Plaza Drive, Suite 320, Hackensack, NJ 07601, 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) until March 31, 2017, the Company has not earned any revenues from operations. The Company does not expect to earn revenues from operations until 2018, if ever. The Company has incurred operating costs and other expenses of approximately \$1,770,000 during the three months ended March 31, 2017 compared to 1,812,000 during the three months through March 31, 2016.

### *Research and Development Expenses:*

Research and development expenses, net for the three months ended March 31, 2017 and 2016 were \$941,000 and \$986,000, respectively, representing a decrease of \$45,000. This decrease is due to a decrease of \$222,000 for costs of activities related to the U.S. Clinical Trial, offset by an increase of \$177,000 for costs associated with the clinical trial, planned to be conducted in Israel, payroll and a net increase of other research and development expenses.

### *General and Administrative Expenses:*

General and administrative expenses for the three months ended March 31, 2017 and 2016 were \$829,000 and \$826,000, respectively. The increase in general and administrative expenses of \$3,000 is primarily due to: a decrease of \$ 160,000 in stock-based compensation expenses offset by a net increase of \$163,000 of other costs.

### *Other Income and Expenses:*

Financial expenses for the three months ended March 31, 2017 was \$15,000 as compared to financial income of \$22,000 for the three months ended March 31, 2016.

*Net Loss:*

Net loss for the three months ended on March 31, 2017 was \$1,785,000, as compared to a net loss of \$1,790,000 for the three months ended March 31, 2016. Net loss per share for the three months ended March 31, 2017 and 2016 was \$0.10.

The weighted average number of shares of Common Stock used in computing basic and diluted net loss per share for the three months ended March 31, 2017 was 18,688,377, compared to 18,653,804 for the three months ended March 31, 2016.

### **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 March 31, 2017, the Company had net working capital of \$7,936,000 including cash, cash equivalents and short term bank deposits amounting to \$8,347,000.

Net cash used in operating activities was \$1,642,000 for the three months ended March 31, 2017. Cash used for operating activities was primarily attributed to cost of rent of clean rooms and materials for clinical trials, payroll costs, rent, outside legal fee expenses and public relations expenses. Net cash provided by investing activities was \$1,699,000 for the three months ended March 31, 2017, representing net change in short term interest bearing bank deposits. There were no financing activities during the three months ended March 31, 2017.

On June 4, 2015, we filed a shelf registration statement, effective June 10, 2015, relating to Common Stock, warrants and units that we may sell from time to time in one or more offerings, up to a total dollar amount of \$100,000,000. We have not filed any supplemental prospectus defining particular terms of securities to be offered under the shelf registration statement.

Our material cash needs for the next 24 months, assuming we do not expand our clinical trials beyond the upcoming multi dose clinical trial in Israel, will include (i) costs of the clinical trial in the U.S. (ii) employee salaries, (iii) costs expected for the upcoming multi-dose clinical trial in Israel, (iv) payments to Hadassah for rent and operation of the GMP facilities, and (v) fees to our consultants and legal advisors, patents, and fees for facilities to be used in our research and development.

Future operations are expected to be highly capital intensive and may require substantial capital raisings. We expect our current cash position will allow us to meet our obligations throughout second quarter of 2018 including the initiation of a Phase 3 trial that will include 200 patients in the upcoming 24 months (assuming the multi dose clinical trial will include 24 patients and will not be expanded into a power trial).

Over the longer term if we are not able to raise substantial 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 pursue larger clinical trials in ALS and 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 gain regulatory approvals;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of filing, prosecuting, defending and enforcing patents, patent applications, patent claims, trademarks and other intellectual property rights;
- 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 March 31, 2017. 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, 2016.

#### **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, revenues 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 Interim 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 Interim 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 Securities and Exchange Commission'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 Interim 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 March 31, 2017 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, 2016. 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, 2016, 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, 2016, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 5. Other Information.**

During the quarter ended March 31, 2017, 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 Exhibits listed in the Exhibit Index immediately preceding such Exhibits are filed with or incorporated by reference in this report.

SIGNATURES

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

**BRAINSTORM CELL  
THERAPEUTICS INC.**

*Date: May 12, 2017 By: /s/ Alla Patlis*

*Name: Alla Patlis*

*Title: Interim Chief Financial Officer*

*(Principal Financial Officer)*



EXHIBIT INDEX

**Exhibit**

**No. Description**

- 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*