

BRAINSTORM CELL THERAPEUTICS INC.

Form 10-Q

November 14, 2016

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2016

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

As of November 7, 2016, the number of shares outstanding of the registrant's Common Stock, \$0.00005 par value per share, was 18,687,987.

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**Item 1. Financial Statements**

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

**INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF SEPTEMBER 30, 2016**

**U.S. DOLLARS IN THOUSANDS**

(Except share data and exercise prices)

(UNAUDITED)

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

**INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF SEPTEMBER 30, 2016**

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)

	September 30, 2016 U.S. \$ in thousands Unaudited	December 31, 2015 U.S. \$ in thousands Audited
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$955	\$ 428
Short-term deposit (Note 4)	10,238	15,527
Account receivable	110	759
Prepaid expenses and other current assets	82	74
Total current assets	11,385	16,788
Long-Term Assets:		
Prepaid expenses and other long-term assets	25	21
Property and Equipment, Net	312	271
Total Long-Term Assets	337	292
Total assets	\$11,722	\$ 17,080
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payables	\$352	\$ 1,169
Accrued expenses	576	1,500
Other accounts payable	267	283
Total current liabilities	1,195	2,952
Stockholders' Equity:		
Stock capital: (Note 5)	11	11
Common stock of \$0.00005 par value - Authorized: 100,000,000 shares at September 30, 2016 and December 31, 2015 respectively; Issued and outstanding: 18,687,987 and 18,643,288 shares at September 30, 2016 and December 31, 2015 respectively.		
Additional paid-in-capital	85,015	84,258

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Accumulated deficit	(74,499)	(70,141	)
Total stockholders' equity	10,527	14,128	
Total liabilities and stockholders' equity	\$11,722	\$ 17,080	

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

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

U.S. dollars in thousands

(Except share data)

	Nine months ended September 30, 2016		Three months ended September 30, 2016	
	2015	2015	2015	2015
	Unaudited		Unaudited	
Operating expenses:				
Research and development, net	\$ 1,927	\$ 4,123	\$ 790	\$ 1,503
General and administrative	2,506	3,016	848	1,068
Operating loss	(4,433 )	(7,139 )	(1,638 )	(2,571 )
Financial (income) expenses, net	(75 )	(35 )	(32 )	32
Net loss	\$(4,358 )	\$(7,104 )	\$(1,606 )	\$(2,603 )
Basic and diluted net profit (loss) per share	\$(0.23 )	\$(0.39 )	\$(0.09 )	\$(0.14 )
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	18,654,826	18,354,580	18,656,615	18,480,957

**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)

	<b>Common stock</b>		<b>Additional</b>		<b>Accumulated</b>	<b>Total</b>
	<b>Number</b>	<b>Amount</b>	<b>paid-in</b>		<b>deficit</b>	<b>stockholders'</b>
			<b>capital</b>			<b>equity</b>
Balance as of January 1, 2015	15,281,497	\$ 11	\$ 68,317		\$ (61,653	) \$ 6,675
Stock-based compensation related to warrants and stock granted to service providers	27,411	-	108		-	108
Stock-based compensation related to stock and options granted to directors and employees	77,332	-	835		-	835
Exercise and reissuance of warrants	2,546,667	(*)	12,409		-	12,409
Exercise of liability classified warrants	29,000	(*)	145		-	145
Exercise of equity classified warrants	536,382	(*)	2,333		-	2,333
Exercise of options	44,999	(*)	109		-	109
Exercise of warrants by Hadasit (Note 7.B.3.(B))	100,000	(*)	2		-	2
Net loss	-	-	-		(8,488	) (8,488 )
Balance as of December 31, 2015	18,643,288	\$ 11	\$ 84,258		\$ (70,141	) \$ 14,128

\* 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	Accumulated	Total
	Number	Amount	paid-in	deficit	stockholders'
			capital		equity
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	-	636	-	636
Net loss	-	-	-	(4,358 )	(4,358 )
Balance as of September 30, 2016	18,687,987	\$ 11	\$ 85,015	\$ (74,499 )	\$ 10,527

\* 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,	
	2016	2015	2016	2015
Cash flows from operating activities:				
Net loss	\$(4,358 )	\$(7,104 )	\$(1,606 )	\$(2,603 )
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	55	73	17	26
Expenses related to shares and options granted to service providers	121	108	90	-
Amortization of deferred stock-based compensation related to options granted to employees and directors	636	955	171	287
Decrease (increase) in accounts receivable and prepaid expenses	641	119	1,140	(552 )
Decrease in trade payables	(817 )	(1,207 )	(3 )	(420 )
Increase (decrease) in other accounts payable and accrued expenses	(940 )	932	(84 )	732
Revaluation of warrants	-	7	-	-
Total net cash used in operating activities	\$(4,662 )	\$(6,117 )	\$(275 )	\$(2,530 )

**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,	
	2016	2015	2016	2015
Cash flows from investing activities:				
Purchase of property and equipment	(96 )	(28 )	(11 )	(12 )
Changes in short-term deposit	5,289	(12,151 )	299	1,953
Investment in lease deposit	(4 )	(2 )	(2 )	(2 )
Total net cash provided by (used in) investing activities	\$5,189	\$(12,181 )	\$ 286	\$ 1,939
Cash flows from financing activities:				
Proceeds from issuances of common stock through equity warrants and options exercises	-	2,348	-	-
Proceeds from issuance of Common stock, net	-	-	-	-
Proceeds from equity offering through issuances of equity warrants and common stock through the exercise of previously issued equity warrants	-	12,409	-	-
Redemption of warrants in cash	-	-	-	-
Total net cash provided by financing activities	\$-	14,757	\$-	-
Increase (decrease) in cash and cash equivalents	527	(3,541 )	11	(591 )
Cash and cash equivalents at the beginning of the period	\$428	4,251	944	1,301
Cash and cash equivalents at end of the period	\$955	\$710	\$ 955	\$ 710
Non-cash financing activities:				
Stock issued for warrants exchange	-	-	-	-
Warrants liability classified as equity	-	130	-	-
Total non-cash financing activities	\$-	\$ 130	-	\$ -

**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; A. 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, B. 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 C. 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 D. 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 any 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. As of September 30, 2016 the Company's liquid resources which include cash, cash equivalents and short term bank deposits amounted to \$11,193. Management believes that, if necessary, the Company's current resources would be sufficient to fund its operations for the next 24 months, however additional financial resources will be needed to conduct our future clinical trials as well as fund other long term operations and there can be no assurance that such additional funds will be available on terms acceptable to the Company, or that the Company will not incur additional unforeseen costs or expenses. Such conditions raise substantial doubts about the Company's long term ability to continue as a going concern. 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, 2015.

Operating results for the three months and the nine months ended September 30, 2016, are not necessarily indicative of the results that may be expected for the year ended December 31, 2016.

**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 does 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 does 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.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to the Interim Condensed Consolidated Financial Statements

NOTE 4 - SHORT TERM INVESTMENTS

Short term investments on September 30, 2016 and December 31, 2015 include bank deposits bearing annual interest rates varying from 0.15% to 1.34%, with maturities of up to 3 and 6 months as of September 30, 2016 and December 31, 2015.

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 served 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.

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 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.

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.

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.):

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 were 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, June 2012 and in June 2016, 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 , 600,000 and 1,600,000 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 (The Plans).

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

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.



**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.):

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 with 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 this director 60,000 shares of restricted Common Stock. The shares will vest in three installments through August 22, 2017.

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. In addition the Company issued to two of its directors and four of its Advisory Board members a total of 59,000 restricted shares of Common Stock. The Options and restricted shares vested over 12 months.

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 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 September 30, the vested portion of the options (to purchase 126,667 shares) were terminated.

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 will cease to vest on November 14, 2016 and the right to exercise the option shall terminate 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. In addition the Company is currently in the process of granting to another director 8,666 restricted shares of Common Stock. The options and restricted shares of Common Stock vest over 12 months until fully vested on June 22, 2017.

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.

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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, 2016		
	Amount of options	Weighted average exercise price \$	Aggregate intrinsic value \$
Outstanding at beginning of period	1,002,451	2.6072	
Granted	70,667	0.75	
Exercised	-	-	
Cancelled	(141,556 )	4.4294	
Outstanding at end of period	931,562	2.1894	205,499
Vested and expected-to-vest at end of period	792,397	2.1812	181,283

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the fair market value of the Company's shares on June 30, 2016 and the exercise price, 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.

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:

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" (EITF 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.

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	-	66,887	113,333	2.25 - 7.05	113,333	Mar 2017 - Oct 2017
Nov 2008	6,667	-	-	6,667	2.25	6,667	Sep-18
Apr-Oct 2009	26,667	6,667	-	20,000	1.005 - 1.5	20,000	Apr 2019 - Oct 2019
Aug 2007- Jan 2011	2,016,667	-	-	2,016,667	3 - 4.35	2,016,667	Nov-17
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	-	-
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	-	-



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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	Jun-17
Jun 2014	84,000	-	-	84,000	4.5	84,000	Jun-17
Jan 2015	3,858,201	-	-	3,858,201	6.5	3,858,201	Jun-18
	14,246,831	4,489,973	3,404,655	6,352,201		6,352,201	

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 granted an aggregate of 27,411 shares of Common Stock to two consultants for services rendered in 2014. The related compensation expense of \$108 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:

	Nine months ended September 30, 2016		Three months ended September 30, 2016	
	2015	2015	2015	2015
	Unaudited		Unaudited	
Research and development	6	19	1	4
General and administrative	661	936	170	283
Total stock-based compensation expense	667	955	171	287

## 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 2016, 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, 2015. 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," "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

We are a biotechnology company developing novel adult stem cell therapies for debilitating neurodegenerative disorders such as Amyotrophic Lateral Sclerosis ("ALS", also known as Lou Gehrig's disease), Multiple Sclerosis ("MS"), and Parkinson's disease ("PD") among others. These diseases for the most part have no or limited treatment options and as such represent unmet medical needs. We believe that NurOwn®, our proprietary process for the propagation of Mesenchymal Stem Cells ("MSC") and their differentiation into neurotrophic factor-("NTF") secreting cells ("MSC-NTF" cells), and their transplantation at, or near, the site of damage, offers the hope of more effectively treating neurodegenerative diseases. Our core technology was developed in collaboration with Prof. Daniel Offen of the

Felsenstein Medical Research Center of Tel Aviv University and the late Prof. Eldad Melamed, who passed away in October 2015, and was 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 exclusive 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 17 employees in Israel and 2 in the United States.

### **Our Proprietary Technology**

Our NurOwn® technology is based on a novel differentiation protocol which induces differentiation of the bone marrow-derived mesenchymal stem cells into neuron-supporting cells, MSC-NTF cells, capable of releasing several neurotrophic factors, including, among others, Glial-derived neurotrophic factor ("GDNF"), Brain-derived neurotrophic factor ("BDNF"), Vascular endothelial growth factor ("VEGF") and Hepatocyte growth factor ("HGF") which are critical for the growth, survival and differentiation of developing neurons. GDNF is one of the most potent survival factors known for peripheral neurons. GDNF, VEGF and HGF have been reported to have important neuro-protective effects in ALS and are currently evaluated separately and independently in other clinical trials for ALS patients.

Our approach to treatment of neurodegenerative diseases with autologous adult stem cells includes a multi-step process beginning with harvesting of undifferentiated mesenchymal stem cells from the patient's own bone marrow, and concluding with transplantation of differentiated, neurotrophic factor-secreting mesenchymal stem cells (MSC-NTF) into the same patient – intrathecally and/or intramuscularly. Intrathecal (injection into the cerebrospinal fluid) transplantation consists of injection by a standard lumbar puncture; there is no need for a laminectomy, which is an invasive, orthopedic spine operation to remove a portion of the vertebral bone, as required by technologies in which cells are implanted directly into the spinal cord. Intramuscular (injection directly into muscle) transplantation is performed via a standard injection procedure as well.

Our proprietary, production process for induction of differentiation of human bone marrow derived mesenchymal stem cells into differentiated cells that produce NTF (MSC-NTF cells, NurOwn®) for clinical use is conducted in full compliance with current Good Manufacturing Practice ("cGMP").

Our proprietary technology is licensed to and developed by our Israeli Subsidiary.

***The NurOwn® Cell Therapy Process***

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

***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 treating neurodegenerative diseases.

The specialized cells secrete neurotrophic factors that may lead to:

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

***Autologous (Self-transplantation)***

The NurOwn® approach is autologous, or self-transplanted, using the patient's own stem cells. In autologous transplantation 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 is free of controversy associated with the use of embryonic stem cells in some countries.

**Cryopreservation**

We have developed a proprietary method for cryopreservation, or freezing, of cells, which enables long-term storage, for the production of repeat patient doses of NurOwn® without the need for additional bone marrow aspirations. Cryopreservation enables us to create a personalized NurOwn® stem cell "bank" for each patient, for, repeated treatments.

### **The ALS Program**

NurOwn® is in clinical development for the treatment of ALS. It has been granted Fast Track designation by the U.S. Food and Drug Administration (the "FDA") and Orphan Drug Designation in both the United States and in Europe for this indication. To date we have completed three clinical trials for ALS patients. Two open label studies were carried out at the Hadassah Medical center ("Hadassah") in Israel and an FDA-approved Phase 2, double blind, placebo controlled study was recently completed at three prestigious U.S. medical centers.

### **Israeli trials**

We have an agreement with Hadasit Medical Research Services and Development Ltd., a subsidiary of the Hadassah Medical Organization, pursuant to which Hadassah provides the Israeli Subsidiary with lab services relating to studies of NurOwn®.

The Principal Investigator (PI) for the Israeli studies was Professor Dimitrios Karussis, MD, PhD, Professor in Neurology head of the MS Center and Unit of Neuroimmunology and Cell Therapies at Hadassah's Department of Neurology.

The first two open label studies, carried out at the Hadassah Medical Center in Jerusalem, Israel (ClinicalTrials.gov Identifier: NCT01051882 and NCT01777646) confirmed the treatment was safe and well tolerated either by the IT or by the IM route of administration as well as by the combined IT and IM administration, and showed some initial indications of efficacy, slowing the slope of disease progression.

The Phase 1/2 first-in-man study was aimed at evaluating the safety of a single initial dose of MSC-NTF cells administered by two different routes. MSC-NTF cells were administered intramuscularly (IM) in a cohort of six early stage ALS patients and intrathecally (IT) in six ALS patients with more progressive disease. This study established safety of administration of MSC-NTF cells via IT and IM at these IM and IT doses.

The Phase 2a trial was a dose-escalating study in three cohorts of 4 early-stage ALS patients aimed at evaluating safety and collecting efficacy data of the combined IT and IM administration. This study established the higher doses



to be safe and showed early signs of change in slope in the ALSFRS-R post treatment compared to the slope pre-treatment. In both these studies, patients were followed for 3 months before and 6 months after transplantation. Additional outcome measures in these studies included change in: muscle strength grading (MVIC) by grip, forced vital capacity (FVC %), muscle bulk estimated by MRI of the upper extremities, upper and lower extremities circumference (cm), electromyography (EMG) parameters.

In January 2016, the Company announced that the results from the Phase 1/2 and Phase 2a studies conducted in Israel were published in the *Journal of the American Medical Association (JAMA) Neurology*. The results of these studies show that intrathecal administration of NurOwn® can slow disease progression in ALS.

### **U.S. Phase 2 Study**

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 (MGH) in Boston, Massachusetts, at the University of Massachusetts Memorial Hospital (UMass) in Worcester, Massachusetts and at the Mayo Clinic in Rochester, Minnesota. The Principal Investigators for the study were Drs. Merit Cudkowicz and James Berry at MGH, Dr. Robert Brown, at UMass and Dr. Anthony Windebank, at the Mayo clinic. 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.

On July 18, 2016 the Company presented top line data from this study in a press release and investor conference call. The Company announced 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.

### **Planned Multi Dose Phase 2 Study at Hadassah**

In January 2016, the Company entered into a collaborative agreement with Hadassah to conduct the planned multi dose Phase 2 trial with NurOwn® in ALS. The agreement was signed with Hadassah, through its technology transfer company Hadasit Medical Research Services and Development Co. Ltd. The Principal Investigator will be Professor Dimitrios Karussis, who served as Principal Investigator in the Company's prior ALS studies.

This planned multi dose study will be the Company's third clinical trial conducted at Hadassah and is designed to provide guidance in preparing a Phase 3 program for NurOwn®. The trial is expected to enroll up to 24 ALS patients who will receive three consecutive stem cell transplantations in order to explore the safety and efficacy of a multi dose treatment. The trial was submitted to the Hadassah's Helsinki Committee and is now awaiting the approval of the Israeli MoH.

The Company is currently considering the possibility of increasing the number of patients and participating clinical sites in this trial in order to increase the statistical power of the study. The advantage of a higher sample size would be that, if NurOwn® shows a clinical benefit in ALS patients, there is a better probability for an efficacy outcome that is statistically significant.

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

In addition the Company is exploring the possible commencement of a program to make NurOwn® available to a limited number of patients with ALS through a regulatory pathway designated for an orphan drug with a good safety profile and strong efficacy signals. This program would potentially provide patients, who today face an unmet need, with access to this investigational treatment before it receives final marketing approval from the regulatory authorities.

### **Future Development Plans**

In addition to its active clinical program in ALS, the Company is reviewing the potential clinical development of NurOwn® in other neurodegenerative disorders, such as Progressive Multiple Sclerosis, Parkinson's disease, and Huntington's disease. The Company has conducted preclinical research in additional neurologic disease areas, including autism. In January 2015, the Company announced positive results from preclinical studies of NurOwn® in the BTBR mouse model of autism. The BTBR mouse exhibits several stereotypical behavioral characteristics that resemble behaviors seen in autism spectrum disorders, including repetitive behaviors, altered social interactions, cognitive rigidity and impaired adaption to environment .

In addition, the Company is engaged in a number of 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.

We are currently developing technology for the long distance shipping of NurOwn®. This technology will enable the Company to transport the NurOwn® from central production facilities to clinics around the world.

We are also engaged in a collaboration with Octane Biotech Inc. ("Octane"), a Canadian firm that focuses on culture systems for cell and tissue therapy, to develop a NurOwn® bioreactor. On June 27, 2014, the Company announced that this collaboration has successfully developed a sophisticated Alpha prototype of the NurOwn® Bioreactor, utilizing a customized disposable cartridge that is dedicated to the intricacies of the Company's NurOwn® process. Based on this first working prototype, the Company and Octane are advancing to the next stage of development with a goal of eventually qualifying a bioreactor for full clinical use. In December 2015, the Company and Octane announced that they have made significant progress toward the development of a novel bioreactor for industrial-scale

manufacture of NurOwn® and had completed key development activities related to the customization of specific features of Octane's Cocoon™ instrumentation platform to enable efficient delivery of NurOwn® stem cell therapy. Additional scale-up/closed system technologies are also under evaluation.

## 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 September 30, 2016, the Company has not earned any revenues from operations. The Company does not expect to earn revenues from operations until at least 2020, if ever. In addition, the Company has incurred operating costs and other expenses of approximately \$1,638,000 during the three months ended September 30, 2016.

### *Research and Development, net:*

Research and development expenses, net for the three months ended September 30, 2016 and 2015 were \$790,000 and \$1,503,000, respectively, representing a decrease of \$713,000. During the three months ended September 30, 2016 we recorded Chief Scientists grants of \$96,000 a decrease of \$503,000 compared to \$599,000 recorded in the three months ended September 30, 2015.

Research and development expenses for the three months ended September 30, 2016 before participation of the Chief Scientist declined by \$1,216,000 compared with the third quarter of 2015. This decrease is due to a decrease of \$1,396,000 for costs of activities related to the U.S. Clinical Trial which were winding down in the third quarter of 2016 including fees to PRC Clinical and regulatory consultants, fees to DFCI and fees to the Mayo Clinic, offset by an increase of \$69,000 in costs associated with the clinical trial, planned to be conducted in Israel and a net increase of \$111,000 of other research and development expenses.

### *General and Administrative:*

General and administrative expenses for the three months ended September 30, 2016 and 2015 were \$848,000 and \$1,068,000, respectively. The decrease in general and administrative expenses of \$220,000 is primarily due to: a decrease of \$113,000 in stock-based compensation expenses and, a decrease of \$110,000 in payroll costs offset by a net increase of \$3,000 of other costs. The decline in payroll expenses was primarily due to the 2015 incurrance of one time severance costs, in connection with the termination of employment of our former Chief Executive Officer.

*Financial Expenses:*

Financial income for the three months ended September 30, 2016 was \$32,000, as compared to financial expenses of \$32,000 for the three months ended September 30, 2015. The main reason for high level of financial income in the three months ended September 30, 2016 was the impact of the 2% strengthening of the New Israeli Shekel vs. the U.S. Dollar on the Company's deposits denominated in New Israeli Shekels.

*Net Loss:*

Net loss for the three months ended on September 30, 2016 was \$1,606,000, as compared to a net loss of \$2,603,000 for the three months ended September 30, 2015. Net loss per share for the three months ended September 30, 2016 and 2015 was \$0.09 and \$0.14, 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, 2016 was 18,656,615, compared to 18,480,957 for the three months ended September 30, 2015.

**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, 2016, the Company had net working capital of \$10,190,000 including cash, cash equivalents and short term bank deposits amounting to \$11,193,000.

Net cash used in operating activities was \$275,000 for the three months ended September 30, 2016. Cash used for operating activities was primarily attributed to cost of clinical trials, 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 \$286,000 for the three months ended September 30, 2016, representing net change in short term interest bearing bank deposits. There were no financing activities during the three months ended September 30, 2016.

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. which are winding down in 2016 (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 will require substantial capital raisings. We expect our current cash position will allow us to meet our obligations 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**



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.

There were no significant changes to our critical accounting policies during the quarter ended September 30, 2016. 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, 2015.

### **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 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 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 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, 2016 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, 2015. 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, 2015, 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, 2015, 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.**

*Departure of Yoram Bibring*

On November 9, 2016, Yoram Bibring 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 to pursue a full-time position with another company. Mr. Bibring's departure is not the result of any disagreement with the Company regarding its operations, policies, practices or related matters.

*Appointment of Alla Patlis*

On November 14, 2016, the Company appointed its Controller, Alla Patlis, as its Interim Chief Financial Officer, effective at the end of business on November 14, 2016. The Company is conducting a search for a new Chief Financial Officer.

Ms. Patlis, 30, has been the Company's Controller since December 23, 2012 and served as Interim Financial Officer of the Company between May 13, 2015 and July 30, 2015. Prior to joining the Company, from 2010 to December 2012, Ms. Patlis was Audit Senior of technology, media and telecommunications industries at Brightman Almagor Zohar & Co. (Certified Public Accountants, A Member of Deloitte Touche Tohmatsu Limited). Ms. Patlis holds an MBA and a Bachelor's degree in Accounting & Economics from Tel Aviv University.

There is no arrangement or understanding between Ms. Patlis and any other person pursuant to which she was appointed as Interim Chief Financial Officer of the Company. There have been no transactions and are no currently proposed transactions to which the Company or any of its subsidiaries was or is a party in which Ms. Patlis has a material interest, which are required to be disclosed under Item 404(a) of Regulation S-K. There are no family relationships between Ms. Patlis and any director or other executive officer of the Company.

During the quarter ended September 30, 2016, 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: November 14, 2016 By: /s/ Yoram Bibring  
Name: Yoram Bibring  
Title: 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*