

**BRAINSTORM CELL THERAPEUTICS INC.**

Form 424B3

March 26, 2015

**Filed Pursuant to Rule 424(b)(3)**

**Registration Statement No. 333-179331**

**Prospectus Supplement No. 12**

**(to Prospectus dated July 19, 2012, as supplemented by Prospectus Supplement No. 1 dated August 16, 2013, Prospectus Supplement No. 2 dated August 16, 2013, Prospectus Supplement No. 3 dated August 16, 2013, Prospectus Supplement No. 4 dated August 16, 2013, Prospectus Supplement No. 5 dated August 16, 2013, Prospectus Supplement No. 6 dated November 14, 2013, Prospectus Supplement No. 7 dated March 27, 2014, Prospectus Supplement No. 8 dated May 13, 2014, Prospectus Supplement No. 9 dated August 12, 2014, Prospectus Supplement No. 10 dated August 27, 2014 and Prospectus Supplement No. 11 dated November 13, 2014)**

**BRAINSTORM CELL THERAPEUTICS INC.**

**19,818,972 Shares of Common Stock**

**Warrants to Purchase 14,864,229 Shares of Common Stock**

**and**

**14,864,229 Shares of Common Stock Underlying Warrants**

This prospectus supplement, together with the prospectus listed above, is to be used by certain holders of the above-referenced securities or by their pledgees, donees, transferees or other successors-in-interest in connection with the offer and sale of such securities.

This prospectus supplement updates and should be read in conjunction with the prospectus dated July 19, 2012 (as supplemented to date), which is to be delivered with this prospectus supplement. Such documents contain information that should be considered when making your investment decision. To the extent there is a discrepancy between the information contained herein and the information in the prospectus, the information contained herein supersedes and replaces such conflicting information.

This prospectus supplement consists of Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 26, 2015.

Our common stock is traded on the Nasdaq Capital Market, under the symbol “BCLI”. On March 25, 2015, the last reported sales price for our common stock was \$4.43 per share. We do not intend to list the warrants on any securities exchange or other trading market and we do not expect that a public trading market will develop for the warrants.

**Investing in the Company’s securities involves risks. See “Risk Factors” beginning on page 4 of the Prospectus, as supplemented or amended by the prospectus supplements filed to date, to read about factors you should consider.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this Prospectus Supplement No. 12 is March 26, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

**x ANNUAL REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2014**

**.. TRANSITION REPORT UNDER 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 Drive, Suite 320

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Hackensack, NJ 07601  
(Address of principal executive offices) (Zip Code)

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

Securities registered under Section 12(b) of the Act:

| <b>Title of each class</b>               | <b>Name of each exchange on which registered</b> |
|--|--|
| <b>Common Stock, \$0.00005 par value</b> | <b>NASDAQ Stock Market LLC</b>                   |

Securities registered under Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.  
Yes  No

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 preceding 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

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. "

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. (Check one):

Large accelerated filer " Accelerated filer " Non-accelerated filer " Smaller reporting company x  
(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 Act).

Yes " No x

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the issuer as of June 30, 2014 (the last business day of the registrant's most recently completed second fiscal quarter), was \$67,525,553.

As of March 23, 2015, the number of shares outstanding of the registrant's common stock, \$0.00005 par value per share, was 18,393,546.

**BRAINSTORM CELL THERAPEUTICS INC.**

**ANNUAL REPORT ON FORM 10-K**

**YEAR ENDED DECEMBER 31, 2014**

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## **PART I**

### **SPECIAL NOTE**

*Unless otherwise specified in this Annual Report on Form 10-K, all references to currency, monetary values and dollars set forth herein shall mean United States (U.S.) dollars.*

### **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

*This Annual 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 2015, 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 Annual Report. 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 (“SEC”).*

### **Item 1. BUSINESS.**

#### **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”), 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. Eldad Melamed, former head of Neurology of the Rabin Medical Center and member of the Scientific Committee of the Michael J. Fox Foundation for Parkinson's Research and Prof. Daniel Offen of the Felsenstein Medical Research Center of Tel Aviv University. 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 16 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 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. VEGF and HGF have been reported to have important neuro-protective effects in ALS.

Our approach to treatment of neurodegenerative diseases with autologous adult stem cells includes a multi-step process beginning with harvesting of undifferentiated 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) 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® Transplantation 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.

**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") 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® in patients with ALS at Hadassah Medical Center ("Hadassah") in collaboration with Professor Dimitrios Karussis, who served as the principal investigator on these studies. We also 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 first study, a Phase 1/2 safety and efficacy study of NurOwn® in ALS patients administered either intramuscularly or intrathecally, was initiated in June 2011 after receiving approval from the Israeli Ministry of Health ("MoH"). In March 2013, Professor Karussis presented some of the data from this trial at the American Academy of Neurology Annual Meeting. The trial results demonstrated the safety of NurOwn® as well as signs of efficacy on both the ALS Functional Rating Score ("ALSFRS-R") and Forced Vital Capacity ("FVC").

In January 2013, the Israeli MoH approved the second study, a Phase 2a combined (intramuscular and intrathecal) treatment, dose-escalating trial, which we also conducted at Hadassah in collaboration with Prof. Karussis. On September 27, 2013, we announced that we had completed treatment of 12 patients in our ALS Phase 2a NurOwn® dose-escalating clinical trial. An interim safety summary for the first 12 patients in the study was submitted to the Hadassah Medical Center Ethical Committee about two month after transplantation of the 12th patient. On December 10, 2013, we announced that Prof. Karussis presented some of his preliminary findings from this trial at the 24<sup>th</sup> International Symposium on ALS/MND in Milan, Italy. In June 2014, Professor Karussis presented interim data from this study 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 vast majority of adverse events being low-grade. 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 3 and 6 months after treatment, compared to the three months prior to treatment. The Company expects to present additional results from this study at one or more medical conferences and to publish the results in a medical journal in 2015.

In December 2013, the Company submitted an Investigational New Drug (“IND”) application to the FDA for NurOwn® in ALS, and on April 28, 2014, the FDA approved commencement of the Company’s randomized, double-blind, placebo controlled multi-center Phase 2 clinical trial of NurOwn® in ALS patients. On June 6, 2014, the Company announced that this clinical trial began, with the enrollment of the first patient at Massachusetts General Hospital in Boston, Massachusetts. The trial is also being conducted at the University of Massachusetts Memorial Hospital in Worcester, Massachusetts and the Mayo Clinic in Rochester, Minnesota. For this study, NurOwn® production occurs 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. This study is designed to enroll 48 patients randomized in a 3:1 ratio to receive NurOwn® or placebo. Results from this trial are not expected until 2016. In February 2015, the Company announced that the Data Safety Monitoring Board (“DSMB”) for the multi-center U.S. Phase 2 clinical trial reviewed the safety data collected through a cutoff date in January 2015, and did not find any lab abnormalities, adverse events or significant protocol deviations that would be cause for concern and therefore approved continuation of the trial as planned.

Future development of NurOwn® in ALS will require additional clinical trials, including the administration of repeated doses to ALS patients enrolled in those trials. The design and timing of subsequent clinical trials in ALS is currently under review by the Company.

### **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 Parkinson’s disease, Huntington’s disease, and multiple sclerosis. The Company is also conducting preclinical research in additional neurologic disease areas, including autism.

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. In January 2013, we announced the development of a proprietary method for cryopreservation, or freezing, of cells, which will enable long-term storage, and production of repeat patient doses of NurOwn® without the need for additional bone marrow aspirations. We believe that cryopreservation will enable us to create a personalized NurOwn® stem cell bank for each patient, for ongoing, repeated treatments. We are planning to use cryopreserved cells in a future clinical trial that will involve administration of multiple doses of NurOwn®.

We are also engaged in 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.

## **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 Annual Report on Form 10-K.

## **History**

The Company was incorporated under the laws of the State of Washington on September 22, 2000, under the name Wizbang Technologies, Inc. and acquired the right to market and sell a digital data recorder product line in certain states in the U.S. Subsequently, the Company changed its name to Golden Hand Resources Inc. On July 12, 2004, the Company entered into a research and license agreement with Ramot to acquire certain stem cell technology and decided to discontinue all activities related to the sales of the digital data recorder product. In November 2004, the Company changed its name from Golden Hand Resources Inc. to Brainstorm Cell Therapeutics Inc. to better reflect its new line of business in development of novel cell therapies for neurodegenerative diseases. In October 2004, the Company formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics Ltd. in Israel. On December 18, 2006, the stockholders of the Company approved a proposal to change the state of incorporation of the Company from the State of Washington to the State of Delaware. The reincorporation was completed on December 21, 2006 through the merger of the Company into a newly formed, wholly-owned Delaware subsidiary of Brainstorm, also named Brainstorm Cell Therapeutics Inc. On February 19, 2013, the Israeli Subsidiary formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd. in the United Kingdom (the “UK Subsidiary”).

## **Recent Developments**

### *Securities Offerings*

On April 25, 2014, the Company entered into agreements with certain holders of warrants originally issued in the Company's August 16, 2013 public offering (the "2013 Warrants") to exchange outstanding 2013 Warrants entitling the holders to purchase an aggregate of 777,470 shares of our common stock, par value \$0.00005 per share (the "Common Stock") for an aggregate of 388,735 unregistered shares of Common Stock.

On May 27, 2014, the Company entered into agreements with certain holders of 2013 Warrants to repurchase outstanding 2013 Warrants entitling the holders to purchase an aggregate of 333,235 shares of Common Stock, for an aggregate of approximately \$600,000. Each share of Common Stock issuable pursuant to the 2013 Warrants was repurchased for a \$1.80 cash payment by the Company per Warrant Share. Warrants participating in the redemption were cancelled and of no further force and effect.

In May 2014, certain holders of 2013 Warrants that did not participate in either the above exchange or redemption and whose 2013 Warrants remain outstanding, waived anti-dilution provisions of their 2013 Warrants.

On June 19, 2014, the Company, pursuant to a June 13, 2014 securities purchase agreement entered into with a group of investors, including several healthcare-focused funds (the "Investors"), effected a private placement of Common Stock and warrants to purchase Common Stock. The Company received gross proceeds of \$10.5 million, resulting from the issuance and sale of 2.8 million shares of Common Stock at a price per share of \$3.75. The Investors received warrants to purchase up to 2.8 million shares of Common Stock at an exercise price of \$5.22 per share (the "2014 Warrants"). The shares of Common Stock issued in the private placement and underlying the 2014 Warrants were registered with the SEC effective July 24, 2014.

On January 8, 2015, holders of 2014 Warrants to purchase an aggregate of approximately 2.5 million shares of our Common Stock exercised their warrants which resulted in approximately \$13 million in proceeds to the Company. As part of this exercise of warrants, we issued new warrants to the holders to purchase up to an aggregate of 3.8 million shares of Common Stock at an exercise price of \$6.50.

#### *Reverse Stock Split and NASDAQ Listing*

A reverse stock split of the Company's shares of Common Stock by a ratio of 1-for-15 was effected on September 15, 2014 at 11:59 p.m. pursuant to an amendment to the Company's Certificate of Incorporation approved by the stockholders of the Company on August 14, 2014. Unless otherwise indicated, all share numbers and exercise prices in this Annual Report on Form 10-K are split-adjusted.

The Company's shares of Common Stock were approved for uplisting to the NASDAQ Capital Market, and commenced trading on the NASDAQ Capital Market when trading began on September 30, 2014. The Company's Common Stock trades under the ticker symbol "BCLI."

#### *Governmental Grants*

In February 2014, we were awarded a \$0.6 million, non-dilutive grant, from the Israeli Office of the Chief Scientist ("OCS") for 2014. In December 2014, we were awarded an additional \$1.7 million, non-dilutive grant, from the OCS for 2015. Since 2007, we have received a total of \$4,200,000 in grants from the OCS.

With regards to any funding received from the OCS, we are obligated to pay royalties to the OCS, amounting to 3% to 3.5% of revenues (subject to the relevant regulations, as amended from time to time) derived from sales of the products funded with the OCS grant, depending on the origin of the products' production. Such royalty payments shall be up to an amount equal to 100% of the grant received. The grant is linked to the exchange rate of the U.S. dollar and bears interest of Libor per annum.

Any plan approved by the OCS research committee for grant funding is subject to Israel's Encouragement of Industrial Research and Development Law, 5744 – 1984 ("R&D Law"), which, among others, restricts the transfer of any know-how (as further defined therein) and the transfer of the manufacture of the outcome product of such Approved Plan outside of Israel.



The OCS research committee may, in special cases, approve the transfer abroad of know-how or any right thereof, derived from research and development conducted under the Approved Plan in Israel, in exchange for receiving know-how from the party abroad; provided, however, that such exchange is towards joint and new research and development.

The OCS research committee may, in special cases and on grounds to be recorded, approve a request to transfer outside of Israel, the manufacturing or the rights to manufacture a product developed within the framework of the Approved Plan; provided, however, that in exchange for such approval, the OCS shall be entitled to, *inter alia*, payment of increased royalties due to the transfer of such manufacturing rights.

*Chief Executive Officer*

The Company appointed Tony Fiorino, M.D., Ph.D. as its Chief Executive Officer, effective June 9, 2014.

## **Company Business Strategy**

Our business strategy is to develop and commercialize NurOwn® as a treatment for one or more neurodegenerative diseases. To this end, our efforts are currently directed to several areas in research, development and manufacturing. The ALS program represents our lead indication and is the most advanced in development, hence much of the Company's focus is on this program. Important tasks include the continued execution of the US randomized, double-blind, placebo controlled Phase 2 study, which we expect to complete enrollment in 2015. We are also preparing our Phase 2a results for presentation and publication in 2015. Finally, we are making preparations to begin a multi-dose study in ALS patients in Israel in 2015. Beyond ALS, we are seeking to move additional programs into clinical development. To that end, we are reviewing our existing preclinical data, initiating research in new areas like autism, and engaging with regulatory and scientific experts to determine the most attractive clinical opportunities. With regard to manufacturing, as noted above, several ongoing research projects and our collaboration with Octane have a goal of increasing the scale and efficiency of NurOwn® production. Our current strategy is designed to allow the Company to be in a position to run larger, registrational studies in the most efficient time frame possible. We may choose to seek a strategic partnership with a pharmaceutical or biotechnology company to support the execution of a registrational clinical program.

Our business model calls for significant investments in research and development. Our research and development expenditures (i) in 2014 (before participation by the OCS) were \$6,116,000, which included \$69,000 in stock-based compensation and (ii) in 2013 (before participation by the OCS) were \$4,030,000, which included \$51,000 in stock-based compensation.

## **Stem Cell Therapy**

Our activities are within the stem cell therapy field. Stem cells are non-specialized cells with a potential for both self-renewal and differentiation into cell types with a specialized function, such as muscle, blood or brain cells. The cells have the ability to undergo asymmetric division such that one of the two daughter cells retains the properties of the stem cell, while the other begins to differentiate into a more specialized cell type. Stem cells are therefore central to normal human growth and development, and also are a potential source of new cells for the regeneration of diseased and damaged tissue. Stem cell therapy aims to restore diseased tissue function by the replacement and/or addition of healthy cells by stem cell transplants.

Mesenchymal stem cells ("MSCs") are a type of stem cell that can be obtained easily from adults and used for both autologous (cells administered back to the same person from whom they were harvested) and allogeneic (cells administered to a person different than the person from whom the cells were harvested) approaches. MSCs are "multipotent" cells that can produce more than one type of specialized cell of the body, such as bone, fat, cartilage, and other types of cells. They secrete factors that promote tissue repair, and decrease inflammatory and immune reactions. The bone marrow is an invaluable source of MSCs and can be accessed through a simple procedure of aspiration. We

believe that human MSCs, which are capable of *in vitro* growth and expansion and multipotent differentiation, are a preferable source of therapeutic stem cells.

## **Neurodegenerative Diseases**

Studies of neurodegenerative diseases suggest that symptoms that arise in afflicted individuals are secondary to defects in neuron cell function and neural circuitry. To date, systemic drug delivery approaches have not been effective in the treatment of these diseases possibly due to the blood-brain-barrier. Consequently, alternative approaches for treating neurodegenerative diseases have been attempted, such as transplantation of cells capable of replacing or supplementing the function of damaged neurons at the site of damage. For such cell replacement therapy to work, implanted cells must survive and integrate, both functionally and structurally, within the damaged tissue.

### **Amyotrophic Lateral Sclerosis (ALS)**

ALS, often referred to as “Lou Gehrig's disease,” is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. The progressive degeneration of the motor neurons in ALS leads to progressive weakness, respiratory failure and eventually, to death, with a median survival for ALS patients is just 3-4 years from the onset of symptoms. Across the world, the prevalence of ALS is approximately 4-7 per 100,000. It is estimated that as many as 30,000 Americans have the disease at any given time, with a similar number afflicted in Europe. Estimated annual treatment costs for advanced stage patients can be as high as \$200,000 (Source: Alliance for Regenerative Medicine).

Treatment decisions are typically determined by the patient's symptoms and the stage of the disease. Some medications used for ALS patients include:

Riluzole – the only medication approved by the FDA to treat ALS. Riluzole extends the time to death or ventilation by several months; however it has not been shown to improve the daily functioning of ALS patients;

Neurodex – approved by the FDA for the treatment of pseudo-bulbar affect, a type of emotional lability that sometimes develops in ALS patients, as well as in patients with other neurological diseases.

Baclofen or diazepam – not FDA-approved for ALS but sometimes used to control muscle spasms, stiffness or tightening (spasticity) that interfere with daily activities; and

Trihexyphenidyl or amitriptyline – not FDA-approved for ALS but sometimes used to treat patients who have excess saliva or secretions, and emotional changes.

Other medications may be prescribed to help reduce such symptoms as fatigue, pain, sleep disturbances, constipation, and excess saliva and phlegm.

## **Multiple Sclerosis (MS)**

MS is a chronic neurodegenerative disorder that affects the brain and spinal cord. Nerve cells are normally insulated with a protective layer called myelin, which allows nerve signals to travel properly. In MS, the myelin is destroyed (demyelination), causing loss of function of the nerve cells and disrupting transmission of brain messages to various parts of the body. While generally thought to be an autoimmune disease, the exact cause of MS is unknown.

MS can cause blurred vision, slurred speech, tremors, numbness, extreme fatigue, and problems with memory and concentration. Most MS patients experience muscle weakness in their extremities and difficulty with coordination and balance. These symptoms may be severe enough to impair walking or even standing. In the worst cases, MS can produce partial or complete paralysis. Most commonly, the course of MS is waxes and wanes (“relapsing-remitting MS”), with progressive forms of the disease somewhat less common.

There are currently over 2.5 million people with MS worldwide, with roughly 800,000 of these in the U.S. and Europe. Over 10,000 new cases are diagnosed annually in the U.S., with the majority of these in women between the ages of 20 and 50. Annual treatment costs for MS can be as much as \$34,000 a year per patient.

Treatment of MS focuses on symptom management, treatment of attacks, and reduction of disease progression. There are a variety of disease-modifying treatments FDA-approved for relapsing-remitting MS; however, patients with progressive forms of MS have limited treatment options.

### **Parkinson's Disease (PD)**

PD is a chronic, progressive disorder in which dopamine-producing neurons residing in the Substantia Nigra region of the brain undergo degeneration and eventually die, resulting in progressive impairment in movement and gait and eventually, leading to dementia. The cause of the disease is unknown.

Over 6.3 million people worldwide suffer from PD, of whom about one million are in the United States. Most people are diagnosed with the disease between the ages of 55 and 65 and about 85% of people with PD are over the age of 65. Prevalence of PD is increasing in line with the general aging of the population. The total economic burden of the disease has been estimated by the National Parkinson Foundation to exceed \$14 billion annually in the U.S. alone.

Treatment of PD primarily comprises dopamine replacement, either directly (levodopa), with dopamine mimetics or by inhibition of its breakdown. These treatments focus on treating the symptoms of the disease and are not a cure for PD. Levodopa has a propensity to cause serious motor response complications with long-term use. Moreover, effective drug dosage often requires gradual increase, leading to more adverse side effects and eventual resistance to its therapeutic action. This greatly limits patient benefit. Therefore, physicians and researchers have sought levodopa-sparing strategies in patients with early-stage disease to delay the need for levodopa.

PD is also treated by Deep Brain Stimulation (“DBS”), which consists of implanting electrodes deep into the brain to provide permanent electrical stimulation to specific areas of the brain and to cause a delay in the activity in those areas. However, DBS is problematic as it can cause uncontrollable and severe side effects such as bleeding in the brain, infection and depression. In addition, like drug therapy, DBS focuses on treating the symptoms of PD and does not provide a cure.

There is a greatly unsatisfied need for novel approaches towards management of PD, primarily to control levodopa-induced adverse side effects and motor dysfunction, as well as to delay the onset of disease-related dementia.

In addition to the symptomatic drug development approaches, there is an intense effort to develop cell and gene therapeutic “curative” approaches to restore the neural function in patients with PD, by (i) replacing the dysfunctional cells with dopamine producing cell transplant, or by (ii) providing growth factors and proteins, such as GDNF, that can maintain or preserve the patient’s remaining dopaminergic cells, protecting them from further degeneration.

## **Intellectual Property**

### *Patents:*

On March 4, 2014, we were granted a U.S. Patent (No. 8,663,987) for our “Mesenchymal Stem Cells for the Treatment of CNS Diseases” (serial number 12/994,761) patent application. This patent relates to our proprietary stem cells induced to secrete large quantities of neurotrophic factors for the treatment of neurodegenerative diseases. A divisional patent application therefrom was issued as US Patent 8,900,574 on December 2, 2014.

On February 11, 2014, the U.S. Patent and Trademark Office (“USPTO”) granted US patent, 8,647,874 for the patent application entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases." This patent relates to the production method of the Company's proprietary stem cells induced to secrete large quantities of neurotrophic factors for the treatment of neurodegenerative diseases. On September 3, 2014, the European Patent Office (“EPO”) issued corresponding patent 1893747, which is currently validated in: CH, CZ, DE, DK, ES, FR, GB,

IE, IT and NL.

On January 22, 2015, we received a Notice of Allowance from Israel's Patent Office for our patent application No. 209604 titled "Isolated Population of Cells, Methods of Generating Same, and Uses Thereof in the Treatment of CNS Diseases."

We have pending patent applications as follows:

A. The Israeli Subsidiary is the sole owner of United States Provisional patent application Serial No. 61/679,822, filed August 6, 2012, entitled "Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors." This application has now been filed as International Application No.: PCT IL2013/050660 and is currently pending as National Phase in the US, EU, Israel, Canada, Brazil and Japan.

This invention is directed to a method of generating MSCs which secrete neurotrophic factors ("NTFs") comprising incubating a population of undifferentiated MSCs in a differentiating medium comprising basic fibroblast growth factor ("bFGF"), platelet derived growth factor ("PDGF"), heregulin and cAMP. The application also covers a method of treating a disease for which administration of neurotrophic factors is beneficial in a subject in need thereof, comprising administering to the subject a therapeutically effective amount of isolated population of MSCs which secrete neurotrophic factors made according to the above method. Also taught is a method of selecting MSCs which secrete NTFs from a mixed population of MSCs, comprising (a) analyzing the cells of said mixed population of cells for at least one of the following parameters: (i) cells which express CD44 below a predetermined threshold, or (ii) cells which express CD73 above a predetermined threshold; and (b) selecting cells which are positive for at least one of said parameters, thereby selecting the MSCs which secrete neurotrophic factors. The application teaches a pharmaceutical composition comprising the isolated population of MSCs as an active agent and a pharmaceutically acceptable carrier.

The Israeli Subsidiary is the sole owner of United States Provisional patent application Serial No. 61/938,172, filed February 11, 2014, entitled "Methods Qualifying Cells." This application has now been filed as International Application No.: PCT/IL2015/050159

B. The Israeli Subsidiary is co-owner, with Ramot, in the invention entitled "Mesenchymal Stem Cells for the Treatment of CNS Diseases", filed as a PCT application on May 26, 2009, currently pending as National Phase patent applications in the following countries:

- Europe: Serial No. 09754337.5
- Europe: Serial No. 13164650.7
- Hong Kong: Serial No. 11107062.5
- Hong Kong: Serial No. 13109415.3

This invention is directed to an isolated human cell comprising at least one mesenchymal stem cell phenotype and secreting brain-derived neurotrophic factor ("BDNF"), wherein a basal secretion of the BDNF is at least five times greater than a basal secretion of the BDNF in a mesenchymal stem cell. Also disclosed in this application is an isolated cell population comprising human mesenchymal stem cells, wherein at least 50% of the cells express glial fibrillary acidic protein ("GFAP") and secrete at least one neurotrophic factor. Also taught is an isolated cell population comprising human cells wherein (i) at least N% of said human cells secreting BDNF, wherein a basal secretion of said BDNF is at least five times greater than a basal secretion of the BDNF in a mesenchymal stem cell; (ii) at least M% of said human cells comprise at least one mesenchymal stem cell phenotype; and (iii) at least one of the human cells secretes the BDNF and the mesenchymal stem cell phenotype; where M and N are each independently selected between 1 and 99. Methods of generating same and uses of same are also disclosed. The method of generating cells useful for treating a CNS disease or disorder comprises (a) incubating mesenchymal stem cells in a culture medium comprising platelet lysate to generate propagated mesenchymal stem cells; and (b) incubating said propagated mesenchymal stem cells in a differentiating medium, thereby generating cells useful for treating the CNS disease or disorder. Another method taught is that of generating cells secreting neurotrophic factors, comprising (i) incubating mesenchymal stem cells in a serum free medium comprising platelet lysate to generate propagated mesenchymal stem cells; and (ii) incubating the propagated mesenchymal stem cells in a differentiating medium comprising at least one differentiating agent, said at least one differentiating agent being selected from the group consisting of platelet derived growth factor ("PDGF"), human neuregulin 1-b1, FGF2, EGF, N2, IBMX and cAMP, thereby generating cells secreting neurotrophic factors. The European applications claim an isolated human cell comprising a cell being non-genetically manipulated, and characterized by: a) expressing tyrosine hydroxylase, nestin and H-NF and b) secreting BDNF, and c) not secreting nerve growth factor ("NGF") wherein a basal secretion of said BDNF is at least five times greater than a basal secretion of said BDNF in a mesenchymal stem cell; an isolated cell population comprising cells generated from human bone marrow derived cells expressing CD73, CD90 and CD105 and not expressing CD14, CD19, CD34, CD45 and HLA-DR, wherein at least 50% of the cells of the cell population express GFAP and secrete BDNF; and a method of generating cells useful for treating a CNS disease or disorder, the method comprising: (1) incubating bone marrow derived cells expressing CD73, CD90 and CD105 and not expressing CD14, CD19, CD34, CD45 and HLA-DR in a culture medium comprising human platelet lysate to generate propagated cells; and (2) incubating said propagated cells in a medium comprising a differentiating agent, thereby generating cells useful for treating the CNS disease or disorder, wherein said differentiating agent is selected from the group consisting of PDGF, human neuregulin 1- 1, FGF2, EGF, N2, IBMX and cAMP.



C. The Israeli Subsidiary is the licensee of the following patent applications owned by Ramot under terms set forth in the Second Ramot Agreement and the Assignment Agreement, as follows:

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1. Invention entitled “Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases”, filed as a PCT application on June 18, 2006, currently pending as National Phase patent application in the US, Serial No.14/173,846.

This invention is directed to an isolated human cell and populations thereof comprising at least one astrocytic phenotype and at least one mesenchymal stem cell phenotype, wherein the mesenchymal stem cell phenotype is not an astrocytic phenotype; an isolated human cell comprising at least one mesenchymal stem cell phenotype and at least one astrocytic structural phenotype, wherein the mesenchymal stem cell phenotype is not an astrocytic structural phenotype; or an isolated human cell comprising at least one mesenchymal stem cell phenotype and at least one astrocytic functional phenotype, wherein the mesenchymal stem cell phenotype is not an astrocytic functional phenotype. Also taught is a method of generating astrocyte-like cells expressing S100 beta, glial fibrillary acidic protein (GFAP), glutamine synthetase, GLAST, GLTI and glial derived neurotrophic factor (GDNF) comprising (a) culturing mesenchymal stem cells in a medium comprising human epidermal growth factor (hEGF) and human basic fibroblast growth factor (hbFGF); and (b) incubating the mesenchymal stem cells in a differentiating medium comprising platelet derived growth factor (PDGF) and human neuregulin 1-b1, thereby generating astrocyte-like cells. Another disclosed method of generating astrocyte-like cells teaches (i) incubating mesenchymal stem cells in a medium comprising hEGF and hbFGF to generate cells predisposed to generate into astrocyte-like cells; and (ii) incubating the predisposed cells in a differentiating medium comprising PDGF and human neuregulin 1-b1, thereby generating astrocyte-like cells.

2. Invention entitled “Methods, nucleic acid constructs and cells for treating neurodegenerative disorders”, filed on May 17, 2005 as United States patent application Serial No. 13/783,607. This invention is directed to a method of treating a neurodegenerative disorder by administering to an individual in need thereof cells capable of exogenously regulatable neurotransmitter synthesis. The cells are produced by incubating bone marrow stromal cells in a differentiating medium comprising docosahexaenoic acid or arachidonic acid and at least one differentiating agent.

*Trademarks:*

We have registered the trademark NUROWN (application no. 85154891, filed October 18, 2010) for use in connection with “compositions of cells derived from stem cells for medical purposes; stem cells for medical purposes.” US Trademark No. 4641441 for NUROWN was registered on November 18, 2014.

The patent applications, as well as relevant know-how and research results are licensed from Ramot. We intend to work with Ramot to protect and enhance our mutual intellectual property rights by filing continuations and divisional patent applications. New discoveries arising in the course of research and development within the Company were and will be patented by us independently.

*Research and License Agreement with Ramot*

On July 12, 2004, we entered into a Research and License Agreement (the “Original Ramot Agreement”) with Ramot, the technology licensing company of Tel Aviv University, which agreement was amended on March 30, 2006 by the Amended Research and License Agreement (described below). Under the terms of the Original Ramot Agreement, Ramot granted to us a license to (i) the inventions, know-how and results made with respect to the above-mentioned stem cell technology developed by the team led by Prof. Melamed and Prof. Offen in the course of the performance of the research, and the patents and pending patent applications owned by Ramot, and (ii) the results of further research to be performed by the same team on the development of the stem cell technology. Simultaneously with the execution of the Original Ramot Agreement, we entered into individual consulting agreements with Prof. Melamed and Prof. Offen pursuant to which all intellectual property developed by Prof. Melamed or Prof. Offen in the performance of services thereunder will be owned by Ramot and licensed to us under the Original Ramot Agreement.

Under the Original Ramot Agreement, we agreed to fund further research relating to the licensed technology in an amount of \$570,000 per year for an initial period of two years, and for an additional two-year period if certain research milestones were met.

In consideration for the license, we originally agreed to pay Ramot:

- An up-front license fee payment of \$100,000;
- An amount equal to 5% of all net sales of products; and
- An amount equal to 30% of all sublicense receipts.

On March 30, 2006 and on May 23, 2006, we entered into an Amended Research and License Agreement and an Amendment Agreement to the Amended Research and License Agreement, respectively (collectively, the “Amended Research and License Agreement”) with Ramot. Under the Amended Research and License Agreement, the funding of further research relating to the licensed technology in an amount of \$570,000 per year was reduced to \$380,000 per year. Moreover, under the Amended Research and License Agreement, the initial period of time that we agreed to fund the research was extended from an initial period of two (2) years to an initial period of three (3) years. The Amended Research and License Agreement also extended the additional two-year period in the Original Ramot Agreement to an additional three-year period, if certain research milestones were met.

We entered into a Second Amended and Restated Research and License Agreement with Ramot on July 26, 2007, effective July 12, 2004 (the “Second Ramot Agreement”), which amended and replaced the Amended Research and License Agreement. The Second Ramot Agreement imposed on us development and commercialization obligations, milestone and other obligations. The license was granted in consideration for (i) royalty payments ranging from three percent (3%) to five percent (5%) of all net sales and (ii) potential payments concerning sublicenses ranging from twenty percent (20%) to twenty-five percent (25%) of sublicense receipts. In addition, in the event that the research period was extended for an additional three year period in accordance with the terms of the Second Ramot Agreement, then we had to make payments to Ramot for each year of the extended research period in the amount of \$380,000. As of June 30, 2007, we owed Ramot an aggregate amount of \$513,249 in overdue payments and patent fees under the Amended Research and License Agreement.

On August 1, 2007, we obtained a waiver and release from Ramot pursuant to which Ramot agreed to an amended payment schedule regarding our payment obligations under the Second Ramot Agreement and waived all claims against us resulting from our previous breaches, defaults and non-payment under the Amended Research and License Agreement.

After our failure to meet the amended payment schedule and subsequent negotiations, on December 24, 2009, we entered into a Letter Agreement and an amended agreement to the Second Ramot Agreement (collectively, the “Letter Agreement”) with Ramot, pursuant to which, among other things, Ramot agreed to: (i) release us from our obligation to fund three years of additional research (which would have totaled \$1,140,000) and (ii) accept conversion of certain research payments due in the amount of \$272,000 into 74,666 shares of our Common Stock. Pursuant to the Letter Agreement, we agreed, among other things, to: (i) reimburse Ramot for outstanding patent-related expenses; and (ii) abandon our rights in certain joint patent rights and patents of Ramot in certain countries.

As of February 2011, Ramot had sold the 74,666 shares of Common Stock of the Company for approximately \$235,000 and we paid the remaining \$5,000 due to Ramot. To date there is no additional debt to Ramot.

On December 20, 2011, we entered into an Assignment Agreement with our Israeli Subsidiary (the “Assignment Agreement”), with the consent of Ramot. Under the Assignment Agreement, we assigned and transferred all of our rights, interests, titles, liabilities and obligations (the “Rights”) under the Second Ramot Agreement to our Israeli Subsidiary, effective as of January 1, 2007 and our Israeli Subsidiary agreed to assume all such Rights. We agreed to be a guarantor of all obligations of our Israeli Subsidiary under the Second Ramot Agreement and Ramot can look to us to demand compliance with the Second Ramot Agreement.

In May 2012, we, the Israeli Subsidiary and Prof. Offen entered into a Consulting Agreement, effective as of January 1, 2012, which replaced the previous consulting agreement, dated July 31, 2004, pursuant to which all work product resulting from the provision of services will vest solely with the Israeli Subsidiary and if any work product resulting from the provision of services results in the creation or development of intellectual property it will be deemed a joint invention, and will be jointly owned by Ramot and the Israeli Subsidiary.

## **Government Regulations and Supervision**

### **Government Regulation and Product Approval**

Once fully developed, we intend to market our bone marrow derived differentiated neurotrophic-factor secreting cell products, NurOwn®, for autologous transplantation in patients by neurosurgeons in medical facilities in the U.S., Europe, Japan and the Pacific Rim. We plan to submit a biologics license application (“BLA”) in the United States from the development of NurOwn® for the treatment of ALS patients. We initiated the regulatory process with a Pre-IND meeting with the FDA in September 2012, and submitted our IND application in December 2013. We have retained expert regulatory consultants to assist us in our approaches to the FDA.

In January 2013, the EMA Committee for Advanced Therapies classified NurOwn® as an Advanced Therapy Medicinal Product.

Government authorities in the United States at the federal, state and local level extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates must receive final approval from the FDA before they may legally be marketed in the United States or by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

### ***U.S. Drug Development Process***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. Biologics are subject to regulation by the FDA under the FDCA, the Public Health Service Act, or the PHSA, and related regulations and other federal, state and local laws and regulations. Biological products are therapies used to treat disease and health conditions. They include a wide variety of products including vaccines, blood and blood components, gene therapies, tissue and proteins. Unlike most prescription products made through chemical processes, biological products generally are made from human and/or animal materials. To be lawfully marketed in interstate commerce, a biologic product must be the subject of a BLA, issued by the FDA on the basis of a demonstration that the product is safe, pure and potent, and that the facility in which the product is manufactured meets standards to assure that it continues to be safe, pure and potent. The FDA has developed and is continuously updating the requirements with respect to cell and gene therapy products and has issued documents concerning the regulation of cellular and tissue-based products. Manufacturers of cell and tissue-based products must comply with the FDA’s current good tissue practices, or cGTP, which are FDA regulations that govern the methods used in, and the facilities

and controls used for, the manufacture of such products. The primary intent of the cGMP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease.

The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, product detention, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a biological product or drug may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other regulations;
- Submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- Performance of adequate and well-controlled clinical trials according to Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed biological product or drug for its intended use;
- Submission to the FDA of a new drug application, or NDA, for a new drug; or a biologics license application for a new biological product;

Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with Good Manufacturing Practices, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity; and FDA review and approval of the BLA or NDA.

The testing and approval process require substantial time, effort and financial resources and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing phase. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. Accordingly, we cannot assure you that submission of an IND will result in the FDA allowing clinical trials to begin or, once begun, issues will not arise that result in the suspension or termination of such trial.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRBs for approval.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1.* The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients having the specific disease.
- Phase 2.* Phase 2 trials involve investigations in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine



dosage tolerance and the optimal dosage and schedule.

*Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Post-approval studies, also called Phase 4 trials, may be conducted after initial marketing approvals. These studies are used to obtain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected side effects. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During the development of a new drug or biologic, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. An SPA is intended to provide assurance that if the agreed upon clinical trial protocol is followed, the clinical trial endpoints are achieved, and there is a favorable risk-benefit profile, the data may serve as the primary basis for an efficacy claim in support of a BLA or an NDA. However, an SPA is not a guarantee of an approval of a product candidate or any permissible claims about the product candidate. In particular, SPAs are not binding on the FDA if previously unrecognized public health concerns arise during the performance of the clinical trial, other new scientific concerns regarding the product candidate's safety or efficacy arise, or if the sponsoring company fails to comply with the agreed upon clinical trial protocol.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the biologic or drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or BLA, requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees which may be waived under certain limited circumstances.

### ***FDA Review of Biologics License Applications and New Drug Applications***

The FDA reviews all BLAs and NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept a BLA or an NDA for filing. In this event, the BLA or NDA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete the initial review of a standard BLA or NDA and respond to the applicant and six months for a priority BLA or NDA. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs or NDAs. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure, and potent and the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and

facilities are in compliance with cGMP requirements, and additionally, in the case of biologics in accordance with cGTP guidelines, and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of independent experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult and the FDA may refuse to approve a BLA or NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information.

Even if such data and information is submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the BLA or NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the BLA or NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to conform the application to a condition suitable for approval. If a complete response letter is issued, the applicant may either resubmit the BLA or NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's or biologic's safety and effectiveness after BLA or NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

### ***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA or BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. However, orphan product designation does provide the potential for a period of exclusivity and we may be eligible for grant funding of up to \$400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven

years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our drug or biological candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in the European Union.

In February 2011, we received Orphan Drug Designation for NurOwn® for the treatment of ALS in the United States. In July 2013, we received Orphan Medicinal Product Designation for NurOwn® for the treatment of ALS from the European Commission. Orphan designation grants a 10-year marketing exclusivity in the EU for the designated indication, as well as several other regulatory incentives.

### ***Patent Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between (a) the effective date of an IND and the submission date of a BLA or an NDA plus (b) the time between the submission date of a BLA or an NDA and the approval of that application. Only one patent applicable to an approved drug or biologic is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of approval of the drug or biologic. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

### ***Biologics Price Competition and Innovation Act of 2009***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to create a new licensure framework for biosimilar products, which could ultimately subject our biological product candidates to competition. Under the BPCIA, a manufacturer may submit an application for licensure of a biological product that is "biosimilar to" or "interchangeable with" a referenced, branded biologic product. Previously, there had been no licensure pathway for such biosimilar or interchangeable products. For purposes of the BPCIA, a reference product is defined as the single biological product licensed under a full BLA against which a biological product is evaluated in an application submitted under a follow-on BLA.

The BPCIA also created a 12-year period of reference product exclusivity, which can be extended to 12.5 years with pediatric exclusivity. The 12-year exclusivity period begins on the date of first licensure of the reference product under the PHSA and during which the licensure of a follow-on application for a biosimilar or interchangeable product cannot be made effective. During the first four years (or four and one-half years with pediatric exclusivity) of the 12-year period, an application for a biosimilar or interchangeable version of the reference product cannot be submitted to the FDA. Under budget proposals submitted by President Obama, the Administration has requested that reference product exclusivity would decrease from twelve to seven years. Congress has not yet enacted such a change in the BPCIA, but could move to enact such a decrease in the reference product exclusivity period.

The BPCIA includes limits on obtaining 12-year reference product exclusivity for certain changes or modifications to the reference product. A separate 12-year reference product exclusivity period does not apply to:

- a BLA supplement for the product that is the reference product;
- a subsequent BLA filed by the same reference product sponsor or manufacturer (or a licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength; or
- a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

In February 2012, the FDA issued three draft guidance documents on biosimilar product development. The FDA is soliciting comments on the draft guidance documents which are described by the FDA as follows: (1) Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, which is intended to assist companies in demonstrating that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting an application, called a "351(k)" application, to the FDA. This draft guidance describes a risk-based "totality-of-the-evidence" approach that the FDA intends to use to evaluate the data and information submitted in support of a determination of biosimilarity of the proposed product to the reference product; (2) Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product, which provides an overview of analytical factors to consider when assessing biosimilarity between a proposed therapeutic protein product and a reference product for the purpose of submitting a 351(k) application; and (3) Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009, which provides answers to common questions from people interested in developing biosimilar products. We cannot predict when or whether these draft guidance documents will ever be finalized or what changes the agency may make in its approach to implementation of the BPCIA.

In addition to creating a 12-year period of reference product exclusivity, the BPCIA clarifies the interaction of that exclusivity with orphan drug exclusivity, such that, if a reference product has been designated for a rare disease or condition the licensure of a biosimilar or interchangeable version of a reference product for such disease or condition may only occur after the later of the expiration of any applicable seven-year orphan drug exclusivity or the 12-year reference product exclusivity (or seven and one-half years and 12.5 years with pediatric exclusivity).

Our biological product candidates, if approved, could be considered reference products entitled to 12-year exclusivity. Even if our products are considered to be reference products eligible for exclusivity, another company could market a competing version of any of our biological products if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

The BPCIA also sets forth a complex mechanism for resolving patent disputes that involves a step-wise exchange of information prior to the initiation of a patent infringement lawsuit against a biosimilar or interchangeable product sponsor. Unlike the Hatch-Waxman Act, the BPCIA provides no automatic stay on approval of a biosimilar product application, except an interchangeable product receives the lesser of one year of exclusivity after the date of first commercial marketing or 18 months of exclusivity after a final court decision or dismissal of a patent challenge or, if the applicant has not been sued, after approval. The BPCIA does not prevent a competitor from conducting its own clinical trials and submitting a full BLA on the same or similar product.

### ***Post-Approval Requirements***

Any drugs for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse effects with the product, reporting of changes in distributed products which would require field alert reports (FARs) for drugs and biological product deviation reports (BPDRs), providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require postmarketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies, or REMS, approved by the FDA. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of drugs and biologics must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.



Drug and biologic manufacturers and other entities involved in the manufacturing and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, GTP applicable to biologics, and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Discovery of previously unknown problems with a product subsequent to its approval may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

### ***Foreign Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to clinically evaluate or sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

### ***Third Party Payor Coverage and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any of our biologic or drug candidates for which we obtain regulatory approval. In both the United States and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the Centers for Medicare and Medicaid Services, or CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payor has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payors.

The U.S. Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our product candidates profitably. For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the associated reconciliation bill, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law.

Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product candidates.

The cost of pharmaceuticals continues to generate substantial governmental and third party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third party payors also require pre-approval of coverage for new or innovative devices, biologics or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug or biological candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs and biologics, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

#### ***Other Healthcare Laws and Compliance Requirements***

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. These regulations include:

the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

the FDCA, which among other things, strictly regulates drug and biologic product marketing, prohibits manufacturers from marketing drug or biologic products for off-label use and regulates the distribution of drug samples; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

## **Compliance with Environmental, Health and Safety Laws**

In addition to FDA regulations, we are also subject to evolving federal, state and local environmental, health and safety laws and regulations. In the past, compliance with environmental, health and safety laws and regulations has not had a material effect on our capital expenditures. We believe that we comply in all material respects with existing environmental, health and safety laws and regulations applicable to us. Compliance with environmental, health and safety laws and regulations in the future may require additional capital expenditures.

## **Sales and Marketing**

We intend to establish and maintain fully-equipped cGMP-certified Cell-Processing Centers in strategic locations to conduct NurOwn® production and distribution over the broadest geographic area. Each Cell-Processing Center would receive an initial bone marrow sample of the patient, harvested at a medical center. The patient's MSC cells would be isolated and expanded, in order to produce an initial dose of NurOwn® cells. A master cell bank for each individual patient would be cryopreserved and maintained for production of subsequent, future NurOwn® doses on a long-term basis for future treatments. These doses would be produced as needed and transported to the medical centers, where they would then be transplanted back into the patient.

We intend to seek partnering opportunities with a strategic partner as we progress towards advanced clinical development and commercialization.

## **Competition**

There are a number of clinical trials underway for potential treatments for ALS, of which only two are stem cell-based trials being conducted by other commercial entities. One is US-based Neuralstem (CUR), which is currently conducting a Phase 2 trial for its allogeneic, human (fetal) spinal cord derived neural stem cells. The other is Corestem, a Korean company, which is currently conducting two Phase 1 stem cell-based clinical trials. One is a recently launched Phase 1 trial with allogeneic bone marrow derived mesenchymal stem cells, and a previous trial, which is not actively recruiting, is with autologous, bone marrow-derived mesenchymal stem cells. There is little public information available about Corestem. Five non-stem cell-based companies are undergoing Phase 1/2, Phase 2 or Phase 3 clinical trials for ALS. A number of academic institutions are also developing treatment candidates for ALS.

## **Employees**

We currently have 18 employees, 16 of whom are full-time. None of our employees is represented by a labor union.

## **Additional Information**

We maintain a website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com). We make available through our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the SEC. We also similarly make available, free of charge through our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act. We are not including the information contained at [www.brainstorm-cell.com](http://www.brainstorm-cell.com) or at any other Internet address as part of, or incorporating it by reference into, this Annual Report on Form 10-K.

## **Item 1A. RISK FACTORS**

*We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. Forward-looking statements in this report and those made from time to time by us through our senior management are made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements concerning the expected future revenues, earnings or financial results or concerning project plans, performance, or development of products and services, as well as other estimates related to future operations are necessarily only estimates of future results and there can be no assurance that actual results will not materially differ from expectations. Forward-looking statements represent management's current expectations and are inherently uncertain. We do not undertake any obligation to update forward-looking statements, except as required by applicable securities laws and regulations. If any of the following risks actually occurs, our financial condition and operating results could be materially adversely affected.*

### **Risks related to our business**

*We need to raise additional capital. If we are unable to raise additional capital on favorable terms and in a timely manner, we will not be able to execute our business plan and we could be forced to restrict or cease our operations.*

We will need to raise additional funds to meet our anticipated expenses so that we can execute our business plan. We expect to incur substantial and increasing net losses for the foreseeable future as we increase our spending to execute our development programs. Our auditors have expressed in their audit report that there is substantial doubt regarding our ability to continue as a going concern.



The amount of financing required will depend on many factors including our financial requirements to fund our research and clinical trials, and our ability to secure partnerships and achieve partnership milestones as well as to fund other working capital requirements. Our ability to access the capital markets or to enlist partners is mainly dependent on the progress of our research and development and regulatory approval of our products.

We expect that the net proceeds from the June 2014 private placement and the exercise of certain June 2014 warrants pursuant to a January 8, 2015 Warrant Exercise Agreement will be sufficient to meet our obligations through the completion of our Phase 2 clinical trial in the United States. However, additional capital may be required or the Company will need to reduce its operating costs in order to finance the Company's operations beyond the current plans or if there are unanticipated significant increases in costs over the next 12 months.

Should we raise additional funds through the issuance of equity, equity-related or debt securities, these securities may have rights, preferences or privileges (including registrations rights) senior to those of the rights of our Common Stock and our stockholders will experience additional dilution.

***Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.***

As described in Note 1 of our 2014 financial statements incorporated herein by reference, our auditors in their audit opinion have expressed concern with respect to our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

***If our NurOwn® treatment candidate does not demonstrate safety and efficacy sufficient to obtain regulatory approval, it will not receive regulatory approval and we will be unable to market it.***

The therapeutic treatment development and regulatory approval process is expensive, uncertain and time-consuming. The timing of any future regulatory approval, if any, for our NurOwn® treatment candidate cannot be accurately predicted. We do not expect to receive regulatory approval for any of our product candidates until at least 2018, if ever. If we fail to obtain regulatory approval for our NurOwn® treatment candidate, we will be unable to market and sell it and we may never be profitable.

As part of the regulatory process, we must conduct clinical trials, including Phase 2 and Phase 3 clinical trials, for our NurOwn® treatment candidate to demonstrate safety and efficacy in humans to the satisfaction of the FDA and regulatory authorities in other countries.

A failure of one or more of our clinical trials can occur at any stage of testing. Previous results obtained in uncontrolled clinical trials may not be predictive of future results obtained in controlled clinical trials. Interim results obtained in clinical trials may not be confirmed upon full analysis of the results of a clinical trial. Results of later stage clinical trials may fail to show the desired safety and efficacy despite acceptable results in earlier clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that have believed their product candidates performed satisfactorily in preclinical and clinical trials have nonetheless failed to obtain marketing approval of their treatments.

Specifically, we are currently comparing our NurOwn® treatment candidate against placebo. There is no other active therapy for ALS. While comparisons of outcomes to results from other reported clinical trials can provide some insight into the efficacy of our NurOwn® treatment candidate, there are many factors that affect the outcome of clinical trials, some of which are not apparent in published reports, and results from two different trials cannot always be reliably compared.

***Part of our business in the foreseeable future will be based on technology licensed from Ramot and if this license were to be terminated upon failure to make required royalty payments in the future, we would need to change our business strategy and we may be forced to cease our operations.***

Agreements we and our Israeli Subsidiary have with Ramot impose on us royalty payment obligations. If we fail to comply with these obligations, Ramot may have the right to terminate the license under certain circumstances. If Ramot elects to terminate our license, we would need to change our business strategy and we may be forced to cease

our operations. We currently do not owe Ramot any overdue payments. Royalties are due upon commencement of revenues by the Company.

***Our Company has a history of losses and we expect to incur losses for the foreseeable future.***

As a development stage company, we are in the early stages of executing our business plan. We had no operational revenues for the fiscal years ended December 31, 2014 or December 31, 2013. Our ability to operate successfully is materially uncertain and our operations are subject to significant risks inherent in a developing business enterprise. We are currently in the process of introducing the Company to strategic partners. In the upcoming three years, the Company will focus on clinical trials. We are unable at this time to foresee when we will generate operational revenues from strategic partnerships or otherwise. Furthermore, we expect to incur substantial and increasing operating losses for the next several years as we increase our spending to execute our development programs. These losses are expected to have an adverse impact on our working capital, total assets and stockholders' equity, and we may never achieve profitability.

***Our product development programs are based on novel technologies and are inherently risky.***

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our stem cell therapy creates significant challenges with regard to product development and optimization, manufacturing, government regulations, and market acceptance. For example, the FDA has relatively limited experience with stem cell therapies. None have been approved by them for commercial sale, and the pathway to regulatory approval for our cell therapy product candidates may accordingly be more complex and lengthy. As a result, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

***We are faced with uncertainties related to our research.***

Our research programs are based on scientific hypotheses and experimental approaches that may not lead to desired results. In addition, the timeframe for obtaining proof of principle and other results may be considerably longer than originally anticipated, or may not be possible given time, resource, financial, strategic and collaborator scientific constraints. Success in one stage of testing is not necessarily an indication that the particular program will succeed in later stages of testing and development. It is not possible to predict, based upon studies in in-vitro models and in animals, whether any of the therapies designed for these programs will prove to be safe, effective, and suitable for human use. Each therapy will require additional research and development, scale-up, formulation and extensive clinical testing in humans. Unsatisfactory results obtained from a particular study relating to a program may cause the Company to abandon its commitment to that program or to the lead therapy or product candidate being tested. The discovery of unexpected toxicities, lack of sufficient efficacy, unacceptable pharmacology, inability to increase scale of manufacture, market attractiveness, regulatory hurdles, competition, as well as other factors, may make our targets, lead therapies or product candidates unattractive or unsuitable for human use, and we may abandon our commitment to that program, target, lead therapy or product candidate. In addition, preliminary results seen in animal and/or limited human testing may not be substantiated in larger controlled clinical trials.

***If serious or unexpected adverse side effects are identified during the development of our NurOwn® treatment candidate, we may need to abandon or limit its development.***

If patients treated with our NurOwn® treatment candidate suffer serious or unexpected adverse effects, we may need to abandon its development or limit development to certain uses or subpopulations in which these effects are less prevalent, less severe or more acceptable from a risk-benefit perspective.

***The field of stem cell therapy is relatively new and our development efforts may not yield an effective treatment of human diseases.***

Our intended cell therapeutic treatment methods for ALS involve a new approach that has not yet been proven to work in humans. We are currently conducting a Phase 2 placebo-controlled clinical trial for ALS, which, together with other stem cell therapies, may ultimately prove ineffective in treatment of human diseases. If we cannot successfully implement our NurOwn® stem cell therapy in human testing, we would need to change our business strategy and we may be forced to cease our operations.

***Our NurOwn® treatment candidate is based on a novel technology, which may raise development issues that we may not be able to resolve, regulatory issues that could delay or prevent approval or personnel issues that may keep us from being able to develop our treatments.***

Regulatory approval of treatment candidates that utilize novel technology such as ours can be more expensive and take longer than for other treatments that are based on more well-known or more extensively studied technology, due to our and the regulatory agencies' lack of experience with them. This may lengthen the regulatory review process, require us to perform additional studies, including clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions. For example, the differentiated cell component of our NurOwn® treatment candidate is a complex biologic product that is manufactured from the patient's own bone marrow that must be appropriately harvested, isolated, expanded and differentiated so that its identity, strength, quality, purity and potency may be characterized prior to release for treatment. No differentiated cell treatment for ALS has yet been approved for marketing by the FDA or any other regulatory agency. The tests that we use to make identity, strength, quality, purity and potency determinations on our NurOwn® treatment candidate may not be sufficient to satisfy the FDA's expectations regarding the criteria required for release of products for patient treatment and the regulatory agency may require us to employ additional testing measures for this purpose, which could require us to undertake additional testing and/or additional clinical trials.

The novel nature of our NurOwn® treatment candidate also means that fewer people are trained in or experienced with treatments of this type, which may make it difficult to recruit, hire and retain capable personnel for the research, development and manufacturing positions that will be required to continue our development and commercialization efforts.

***A significant global market for our services has yet to emerge.***

Very few companies have been successful in their efforts to develop and commercialize a stem cell product. Some stem cell products in general may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their approval or commercial use. The demand for stem cell processing and the number of people who may use cell or tissue-based therapies is difficult to forecast. Physicians, patients, formularies, third party payers or the medical community in general may not accept or utilize any products that the Company or its collaborative partners may develop. Our success is dependent on the establishment of a large global market for our products and services and our ability to capture a share of this market.

***We have limited experience in conducting and managing clinical trials and the application process necessary to obtain regulatory approvals.***

Our limited experience in conducting and managing clinical trials and the application process necessary to obtain regulatory approvals might prevent us from successfully designing or implementing a preclinical study or clinical trial. Many companies in the industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials. If our clinical trials are unsuccessful, or if we do not complete our clinical trials, we may not receive regulatory approval for or be able to commercialize our product candidates.

If we do not succeed in conducting and managing our preclinical development activities or clinical trials, or in obtaining regulatory approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which will materially harm our business.

Our ability to generate revenues from any of our product candidates will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and implement our commercialization strategy. We may, and anticipate that we will need to, transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not succeed in such a transition.

***We may not be able to secure and maintain research institutions to conduct our clinical trials.***

We rely on research institutions to conduct our clinical trials. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreements with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. Furthermore, we may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

***We are subject to a strict regulatory environment. If we fail to obtain and maintain required regulatory approvals for our potential cell therapy products, our ability to commercialize our potential cell therapy products will be severely limited.***

None of our product candidates have received regulatory approval for commercial sale yet. We do not expect to receive regulatory approval for any of our product candidates until at least 2018, if ever.

Numerous statutes and regulations govern human testing and the manufacture and sale of human therapeutic products in the United States and other countries where we intend to market our products. Such legislation and regulation bears upon, among other things, the approval of protocols and human testing, the approval of manufacturing facilities, testing procedures and controlled research, review and approval of manufacturing, preclinical and clinical data prior to marketing approval including adherence to GMP during production and storage as well as regulation of marketing activities including advertising and labeling.

The completion of the clinical testing of our product candidates and the obtaining of required approvals are expected to take several years and require the expenditure of substantial resources. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent regulatory approval and/or commercialization of our product candidates, including the following:

- The FDA or similar foreign regulatory authorities may find that our product candidates are not sufficiently safe or effective or may find our processes or facilities unsatisfactory;

- Officials at the Israeli MoH, the FDA or similar foreign regulatory authorities may interpret data from preclinical studies and clinical trials differently than we do;

- Our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the Israeli MoH, the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and/or clinical trials or to abandon one or more of our development programs;

- The Israeli MoH, the FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations;

- There may be delays or failure in obtaining approval of our clinical trial protocols from the Israeli MoH, the FDA or other regulatory authorities or obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;

- We, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects;

- We may experience difficulties in managing multiple clinical sites;

- Enrollment in our clinical trials for our product candidates may occur more slowly than we anticipate, or we may experience high drop-out rates of subjects in our clinical trials, resulting in significant delays; and

- We may be unable to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates for use in clinical trials.

Investors should be aware of the risks, problems, delays, expenses and difficulties which may be encountered by us in light of the extensive regulatory environment in which our business operates. In particular, our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval may be delayed or denied by the Israeli MoH or the FDA.

Even if a product candidate is approved by the Israeli MoH, the FDA or any other regulatory authority, we may not obtain approval for an indication whose market is large enough to recoup our investment in that product candidate. We may never obtain the required regulatory approvals for any of our product candidates. Later discovery of



previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market.

***Even if regulatory approvals are obtained for our product candidates, we will be subject to ongoing government regulation. If we or one or more of our partners or collaborators fail to comply with applicable current and future laws and government regulations, our business and financial results could be adversely affected.***

The healthcare industry is one of the most highly regulated industries in the United States. The federal government, individual state and local governments and private accreditation organizations all oversee and monitor the activities of individuals and businesses engaged in the delivery of health care products and services. Even if regulatory authorities approve any of our human therapeutic product candidates, current laws, rules and regulations that could directly or indirectly affect our ability and the ability of our strategic partners and customers to operate each of their businesses could include, without limitation, the following:

- State and local licensing, registration and regulation of laboratories, the collection, processing and storage of human cells and tissue, and the development and manufacture of pharmaceuticals and biologics;
- The federal Clinical Laboratory Improvement Act and amendments of 1988;
- Laws and regulations administered by the FDA, including the Federal Food Drug and Cosmetic Act and related laws and regulations;
- The Public Health Service Act and related laws and regulations;
- Laws and regulations administered by the United States Department of Health and Human Services, including the Office for Human Research Protections;
- State laws and regulations governing human subject research;
- Occupational Safety and Health requirements; and
- State and local laws and regulations dealing with the handling and disposal of medical waste.

Compliance with such regulation may be expensive and consume substantial financial and management resources. If we, or any future marketing collaborators or contract manufacturers, fail to comply with applicable regulatory requirements, we may be subject to sanctions including fines, product recalls or seizures, injunctions, total or partial suspension of production, civil penalties, withdrawal of regulatory approvals and criminal prosecution. Any of these sanctions could delay or prevent the promotion, marketing or sale of our products.

***Our NurOwn® treatment candidate, even if approved, may not be accepted in the marketplace; therefore, we may not be able to generate significant revenue, if any.***

Even if our NurOwn® treatment candidate is approved for sale, physicians and the medical community may not ultimately use it or may use it only in applications more restricted than we anticipate. Our NurOwn® treatment candidate, if successfully developed, will compete with a number of traditional products manufactured and marketed by major pharmaceutical and biotechnology companies. Our NurOwn® treatment candidate may also compete with new products currently under development by such companies and others. Physicians will prescribe a treatment only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently available and in use. Physicians also will prescribe a product based on their traditional preferences. Many other factors influence the adoption of new products, including patient perceptions and preferences, marketing and distribution restrictions, adverse publicity, product pricing, views of thought leaders in the medical community and reimbursement by government and private payers. Any of these factors could have a material adverse effect on our business, financial condition, and results of operations.

***Adoption of our NurOwn® treatment candidate for the treatment of patients with ALS, or other neurodegenerative diseases, even if approved, may be slow or limited. If our NurOwn® treatment candidate does not achieve broad acceptance as a treatment option for ALS, or other neurodegenerative diseases, our business would be harmed.***

If approved, the rate of adoption of our NurOwn® treatment candidate as a treatment for ALS, or other neurodegenerative diseases, and the ultimate sales volume for our treatment, will depend on several factors, including educating treating physicians on how to use our NurOwn® treatment candidate. Our NurOwn® treatment candidate utilizes individualized stem cell therapy, which is significantly different from the pharmacological approach currently used to treat neurodegenerative diseases. Acceptance of our NurOwn® treatment candidate by treating physicians may require us to provide them with extensive education regarding the mechanism of action of our treatment, the method of delivery of the treatment, expected side effects and the method of monitoring patients for efficacy and follow-up. In addition, the manufacturing and delivery processes associated with our treatment will require treating physicians to adjust their current treatment of patients, which may delay or prevent market adoption of our NurOwn® treatment candidate as a preferred therapy, even if approved.

***We are subject to environmental, health and safety laws.***

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and humans, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations.

Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

***Our success will depend in part on establishing and maintaining effective strategic partnerships and collaborations, which may impose restrictions on our business and subject us to additional regulation.***

A key aspect of our business strategy is to establish strategic relationships in order to expand or complement our research and development or commercialization capabilities, and to reduce the cost of research and development. There can be no assurance that we will enter into such relationships, that the arrangements will be on favorable terms or that such relationships will be successful. If we are ultimately successful in executing our strategy of securing collaborations with companies that would undertake advanced clinical development and commercialization of our products, we may not have day-to-day control over their activities. Any such collaborator may adhere to criteria for determining whether to proceed with a clinical development program under circumstances where we might have continued such a program. Potential collaborators may have significant discretion in determining the efforts and amount of resources that they dedicate to our collaborations or may be unwilling or unable to fulfill their obligations to us, including their development and commercialization. Potential collaborators may underfund or not commit sufficient resources to the testing, marketing, distribution or other development of our products. They may also not properly maintain or defend our intellectual property rights or they may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability. Potential collaboration partners may have the right to terminate the collaboration on relatively short notice and if they do so or if they fail to perform or satisfy their obligations to us, the development or commercialization of products would be delayed and our ability to realize any potential milestone payments and royalty revenue would be adversely affected.

***We will need to develop or acquire additional capabilities in order to commercialize our NurOwn® treatment candidate, if approved for sale, and we may encounter unexpected costs or difficulties in doing so.***

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and, if our NurOwn® treatment candidate receives regulatory approval, commercialization efforts. Currently, we have no experience in preparing applications for marketing approval, commercial-scale manufacturing, managing of large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. To do this effectively, we must:

- train, manage and motivate a growing employee base;
- accurately forecast demand for our treatment; and
- expand existing operational, financial and management information systems.

We will need to increase our manufacturing capacity prior to seeking approval for the sale of our products. If we are not successful in establishing a regulatory compliant manufacturing process, we may not obtain approval of products or our ability to obtain regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products, if we are even able to generate revenues at all.

***We expect to expand our development, regulatory, manufacturing and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product development, regulatory affairs, manufacturing and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***We have never manufactured our NurOwn® treatment candidate at commercial scale and there can be no assurance that it can be manufactured in compliance with regulations at a cost or in quantities necessary to make it commercially viable.***

We have no experience in commercial-scale manufacturing, the management of large-scale information technology systems or the management of a large-scale distribution system. We may develop our manufacturing capacity in part by expanding our current facilities and/or by setting up additional facilities in other regions of the country. These activities would require substantial additional funds and we would need to hire and train significant numbers of qualified employees to staff these facilities. We may not be able to develop commercial-scale facilities that are sufficient to produce the treatment candidates or their components for later-stage clinical trials or commercial use.

Furthermore, we must supply all necessary documentation, including product characterization and process validation, to regulatory authorities in support of our BLA on a timely basis and must adhere to cGMP regulations and current Good Tissue Practices (“GTP”) enforced by the regulatory authority through its facilities inspection program. We have not fully characterized our NurOwn® treatment candidate and have not validated our manufacturing process. If the FDA determines that the products used in our clinical trials are not sufficiently characterized, we may be required to repeat all or a portion of our clinical trials. If our facilities cannot pass a pre-approval plant inspection, the regulatory approval of the treatment candidates will not be granted.

***We are subject to significant regulation with respect to manufacturing of our NurOwn® treatment candidate.***

All entities involved in the preparation of a therapeutic biological for clinical trials or commercial sale are subject to extensive regulation. Our NurOwn® treatment candidate must be manufactured in accordance with cGMP and GTP

before it can be used in our clinical trials or approved for commercial sale. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational treatment candidates and treatments, including treatment component characterization and process validation, approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party suppliers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our NurOwn® treatment candidate. If any inspection or audit of our manufacturing facilities identifies a failure to comply with applicable regulations, or if a violation of applicable regulations occurs independent of an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed on us or third parties with whom we contract could materially harm our business.

***Lack of coordination internally among our employees and externally with physicians, hospitals and third-party suppliers and carriers, could cause manufacturing difficulties, disruptions or delays and cause us to not meet our expected clinical trial requirements or potential commercial requirements.***

Manufacturing our NurOwn® treatment candidate requires coordination internally among our employees and externally with physicians, hospitals and third-party suppliers and carriers. For example, a patient's physician or clinical site will need to coordinate with us for the shipping of a patient's bone marrow to our manufacturing facility, and we will need to coordinate with them for the shipping of the treatment components to them. Such coordination involves a number of risks that may lead to failures or delays in manufacturing our NurOwn® treatment candidate, including:

- failure to obtain a sufficient supply of key raw materials of suitable quality;
- difficulties in manufacturing our treatment candidates for multiple patients simultaneously;
- difficulties in obtaining adequate patient-specific material, such as bone marrow samples, from physicians;
- difficulties in completing the development and validation of the harvested cells required to ensure the consistency of our NurOwn® treatment candidate;
- failure to ensure adequate quality control and assurances in the manufacturing process as we increase production quantities;
- difficulties in the timely shipping of patient-specific materials to us or in the shipping of the treatment candidates to the treating physicians due to errors by third-party carriers, transportation restrictions or other reasons;
- loss or destruction of, or damage to, patient-specific materials or our NurOwn® treatment candidate during the shipping process due to improper handling by third-party carriers, hospitals, physicians or us;
- loss or destruction of, or damage to, patient-specific materials or our NurOwn® treatment candidate during storage at our facilities; and
- loss or destruction of, or damage to, patient-specific materials or our NurOwn® treatment candidate stored at clinical and future commercial sites due to improper handling or holding by clinicians, hospitals or physicians.

If we are unable to coordinate appropriately, we may encounter delays or additional costs in achieving our clinical and commercialization objectives, including in obtaining regulatory approvals of our treatment candidates and supplying products, which could materially damage our business and financial position.

***We face competition in our efforts to develop cell therapies for ALS and other neurodegenerative diseases.***

We face competition in our efforts to develop cell therapies and other treatment or procedures to cure or slow the effects of ALS and other neurodegenerative diseases. Among our competitors are companies that are involved in the fetal-derived cell transplants or embryonic stem cell derived cell therapy and companies developing adult stem cells. Other companies are developing traditional chemical compounds, new biological drugs, cloned human proteins and other treatments, which are likely to impact the markets that we intend to target. Some of our competitors possess longer operating histories and greater financial, managerial, scientific and technical resources than we do and some possess greater name recognition and established customer bases. Some also have significantly more experience in preclinical testing, human clinical trials, product manufacturing, the regulatory approval process and marketing and distribution than we do.

***The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.***

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies having greater financial resources and discovery technological capabilities, thus intensifying competition in these industries. This trend may also result in fewer potential collaborators or licensees for our therapeutic product candidates. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or collaborators as a result of such consolidation.



*There is a scarcity of experienced professionals in the field of cell therapy and we may not be able to retain key personnel or hire new key personnel needed to implement our business strategy and develop our products and businesses. If we are unable to retain or hire key personnel, we may be unable to continue to grow our business or to implement our business strategy, and our business may be materially and adversely affected.*

Given the specialized nature of cell therapy and the fact that it is a young field, there is an inherent scarcity of experienced personnel in the field. Our success depends on a significant extent to the continued services of certain highly qualified scientific and management personnel. We face competition for qualified personnel from numerous industry sources, and there can be no assurance that we will be able to attract and retain qualified personnel on acceptable terms. The loss of service of any of our key personnel could have a material adverse effect on our operations or financial condition. In the event of the loss of services of such personnel, no assurance can be given that we will be able to obtain the services of adequate replacement personnel. We do not have key person life insurance on our key personnel. The future success of the Company also depends upon our ability to attract and retain additional qualified personnel (including medical, scientific, technical, commercial, business and administrative personnel) necessary to support our anticipated growth, develop our business, and maintain appropriate licensure, on acceptable terms. There can be no assurance that we will be successful in attracting or retaining personnel required by us to continue and grow our operations. The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees, as needed, could result in our inability to continue to grow our business or to implement our business strategy, or may have a material adverse effect on our business, financial condition and results of operations.

***Technological and medical developments or improvements in conventional therapies could render the use of stem cells and our services and planned products obsolete.***

The pharmaceutical industry is characterized by rapidly changing markets, technology, emerging industry standards and frequent introduction of new products. The introduction of new products embodying new technologies, including new manufacturing processes, and the emergence of new industry standards may render our technologies obsolete, less competitive or less marketable. Advances in other treatment methods or in disease prevention techniques could significantly reduce or entirely eliminate the need for our stem cell services, planned products and therapeutic efforts. Additionally, technological or medical developments may materially alter the commercial viability of our technology or services, and require us to incur significant costs to replace or modify equipment in which we have a substantial investment. In either event, we may experience a material adverse effect on our business, results of operations and financial condition.

***We may expend our limited resources to pursue our NurOwn® treatment candidate or a specific indication for its use and fail to capitalize on treatment candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we have focused development of our NurOwn® treatment candidate for use in patients with ALS. As a result, we may forego or delay pursuit of opportunities with other treatment candidates or for other indications that later prove to have greater commercial potential. Our spending on current and future research and development efforts on our NurOwn® treatment candidate for this indication may not yield a commercially viable treatment. Our resource allocation decisions also may cause us to fail to capitalize on a viable commercial treatment, a more viable indication or profitable market opportunities.

We have based our research and development efforts on our NurOwn® treatment candidate. Notwithstanding our large investment to date and anticipated future expenditures in our NurOwn® treatment candidate, we have not yet developed, and may never successfully develop, any marketed treatments using this approach. As a result of pursuing the development of our NurOwn® treatment candidate, we may fail to develop treatment candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success.

Our long-term business plan is to develop our NurOwn® treatment candidate for the treatment of neurodegenerative diseases, such as ALS, MS and PD. Even if we successfully develop our NurOwn® treatment candidate for use in one indication, we may not be successful in our efforts to identify or discover additional indications for it. Clinical programs to develop new indications for our NurOwn® treatment candidate will require substantial technical, financial and human resources. These development programs may initially show promise in identifying potential treatment indications, yet fail to obtain regulatory approval for commercial sale.

If we do not accurately evaluate the commercial potential or target market for our NurOwn® treatment candidate, we may relinquish valuable rights to that treatment through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

***If Ramot is unable to obtain patents on the patent applications and technology licensed to our Israeli Subsidiary or if patents are obtained but do not provide meaningful protection, we may not be able to successfully market our proposed products.***

We rely upon the patent applications filed by Ramot, the technology licensing company of Tel Aviv University, and the license granted to us by Ramot, all in accordance with the Second Ramot Agreement dated as of July 26, 2007. We further agreed under the Second Ramot Agreement that Ramot, in consultation with us, is responsible for obtaining patent protection for technology owned by Ramot and licensed to us. No assurance can be given that any of our pending or future patent applications will be approved, that the scope of any patent protection granted will exclude competitors or provide us with competitive advantages, that any of the patents that may be issued to us will be held valid if subsequently challenged, or that other parties will not claim rights to or ownership of our patents or other proprietary rights that we hold license to. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or products or design around any patents that have been or may be issued to us or any future licensors. Since patent applications in the United States and in Europe are not disclosed until applications are published, there can be no assurance that others did not first file applications for products covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others. Also, we have abandoned our rights to certain patents of Ramot in certain countries in connection with the Letter Agreement by and between us and Ramot dated December 24, 2009, which may limit our ability to fully market our proposed products.

We also rely upon unpatented proprietary technology, know-how and trade secrets and seek to protect them through confidentiality agreements with employees, consultants and advisors. If these confidentiality agreements are breached, we may not have adequate remedies for the breach. In addition, others may independently develop or otherwise acquire substantially the same proprietary technology as our technology and trade secrets.

***We may be unable to protect our intellectual property from infringement by third parties.***

Despite our efforts to protect our intellectual property, third parties may infringe or misappropriate our intellectual property. Our competitors may also independently develop similar technology, duplicate our processes or services or design around our intellectual property rights. We may have to litigate to enforce and protect our intellectual property rights to determine their scope, validity or enforceability. Intellectual property litigation is costly, time-consuming, diverts the attention of management and technical personnel and could result in substantial uncertainty regarding our future viability. The loss of intellectual property protection or the inability to secure or enforce intellectual property protection would limit our ability to develop or market our services in the future. This would also likely have an adverse effect on the revenues generated by any sale or license of such intellectual property. Furthermore, any public announcements related to such litigation or regulatory proceedings could adversely affect the price of our Common Stock.

***Third parties may claim that we infringe on their intellectual property.***

We may be subject to costly litigation in the event our technology is claimed to infringe upon the proprietary rights of others. Third parties may have, or may eventually be issued, patents that would be infringed by our technology. Any of these third parties could make a claim of infringement against us with respect to our technology. We may also be subject to claims by third parties for breach of copyright, trademark or license usage rights. Litigation and patent interference proceedings could result in substantial expense to us and significant diversion of efforts by our technical and management personnel. An adverse determination in any such proceeding or in patent litigation could subject us to significant liabilities to third parties or require us to seek licenses from third parties. Such licenses may not be available on acceptable terms or at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from commercializing our products, which would have a material adverse effect on our business, results of operations and financial condition.

***As a result of our reliance on consultants, we may not be able to protect the confidentiality of our technology, which, if disseminated, could negatively impact our plan of operations.***

We currently have relationships with academic and industry consultants and subcontractors who are not directly employed by us, and we may enter into additional relationships of such nature in the future. We have limited control over the activities of these consultants and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, in connection with every relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results of operations. To the extent that our scientific consultants develop inventions or processes independently that may be applicable to our proposed products, disputes may arise as to the ownership of the proprietary rights to such information, we may expend significant resources in such disputes and we may not win those disputes.

***It is uncertain to what extent the government, private health insurers and third-party payers will approve coverage or provide reimbursement for the therapies and products to which our services relate. Availability for such reimbursement may be further limited by an increasing uninsured population and reductions in Medicare and Medicaid funding in the United States.***

Our ability to successfully commercialize our human therapeutic products will depend significantly on our ability to obtain acceptable prices and the availability of reimbursement to the patient from third-party payers, such as government and private insurance plans. While we have not commenced discussions with any such parties, these third-party payers frequently require companies to provide predetermined discounts from list prices, and they are increasingly challenging the prices charged for pharmaceuticals and other medical products. Our human therapeutic products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us to sell our products on a competitive basis. Further, as cost containment pressures are increasing in the health care industry, government and private payers adopt strategies designed to limit the amount of reimbursement paid to health care providers. Such cost containment measures may include:

- Reducing reimbursement rates;
- Challenging the prices charged for medical products and services;
- Limiting services covered;
- Decreasing utilization of services;
- Negotiating prospective or discounted contract pricing;
- Adopting capitation strategies; and
- Seeking competitive bids.

Similarly, the trend toward managed health care and bundled pricing for health care services in the United States could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our therapies.

We may not be able to negotiate favorable reimbursement rates for our human therapeutic products. If we fail to obtain acceptable prices or an adequate level of reimbursement for our products, the sales of our products would be adversely affected or there may be no commercially viable market for our products.

***Unintended consequences of recently adopted health reform legislation in the U.S. may adversely affect our business.***

The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the U.S., comprehensive programs are under consideration that seek to, among other things, increase access to healthcare for the uninsured and control the escalation of healthcare expenditures within the economy. On March 23, 2010, health reform legislation was approved by Congress and has been signed into law. While we do not believe this legislation will have a direct impact on our business, the legislation has only recently been enacted and requires the adoption of implementing regulations, which may have unintended consequences or indirectly impact our business. For instance, the scope and implications of the recent amendments pursuant to the Fraud Enforcement and Recovery Act of 2009 have yet to be fully determined or adjudicated and as a result it is difficult to predict how future enforcement initiatives may impact our business. Also, in some instances our clients may be health insurers that will be subject to limitations on their administrative expenses and new federal review of “unreasonable” rate increases which could impact the prices they pay for our services. If the legislation causes such unintended consequences or indirect impact, it could have a material adverse effect on our business, financial condition and results of operations.

***Ethical and other concerns surrounding the use of stem cell therapy may negatively impact the public perception of our stem cell services, thereby suppressing demand for our services.***

Although our stem cell business pertains to adult stem cells only, and does not involve the more controversial use of embryonic stem cells, the use of adult human stem cells for therapy could give rise to similar ethical, legal and social issues as those associated with embryonic stem cells, which could adversely affect its acceptance by consumers and medical practitioners. Additionally, it is possible that our business could be negatively impacted by any stigma associated with the use of embryonic stem cells if the public fails to appreciate the distinction between adult and embryonic stem cells. Delays in achieving public acceptance may materially and adversely affect the results of our operations and profitability.

***We are exposed to fluctuations in currency exchange rates.***

A significant portion of our business, particularly our research and development, is conducted outside the United States. Therefore, we are exposed to currency exchange fluctuations in other currencies such as the New Israeli Shekels (“NIS”) and the Euro. Moreover, a portion of our expenses in Israel and Europe are paid in NIS and Euros, respectively, which subjects us to the risks of foreign currency fluctuations. Our primary expenses paid in NIS are employee salaries, fees for consultants and subcontractors and lease payments on our Israeli facilities.

***The dollar cost of our operations in Israel will increase to the extent increases in the rate of inflation in Israel are not offset by a devaluation of the NIS in relation to the dollar, which would harm our results of operations.***

Since a considerable portion of our expenses such as employees' salaries are linked to an extent to the rate of inflation in Israel, the dollar cost of our operations is influenced by the extent to which any increase in the rate of inflation in Israel is or is not offset by the devaluation of the NIS in relation to the dollar. As a result, we are exposed to the risk that the NIS, after adjustment for inflation in Israel, will appreciate in relation to the dollar. In that event, the dollar cost of our operations in Israel will increase and our dollar-measured results of operations will be adversely affected. During the past few years inflation-adjusted NIS appreciated against the dollar, which raised the dollar cost of our Israeli operations. We cannot predict whether the NIS will appreciate against the dollar or vice versa in the future. Any increase in the rate of inflation in Israel, unless the increase is offset on a timely basis by a devaluation of the NIS in relation to the dollar, will increase labor and other costs, which will increase the dollar cost of our operations in Israel and harm our results of operations.

***We may be subject to significant product liability claims and litigation which could adversely affect our future earnings and financial condition.***



Our business exposes us to potential product liability risks inherent in the testing, processing and marketing of stem cell therapy products. Specifically, the conduct of clinical trials in humans involves the potential risk that the use of our stem cell therapy products will result in adverse effects. Such liability claims may be expensive to defend and result in large judgments against us. We currently maintain liability insurance for our clinical trials; however such liability insurance may not be adequate to fully cover any liabilities that arise from clinical trials of our stem cell therapy products. We also maintain errors and omissions, directors and officers, workers' compensation and other insurance appropriate to our business activities. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our own limited resources, which could have a material adverse effect on our financial condition, results of operations and business. Additionally, liability or alleged liability could harm our business by diverting the attention and resources of our management and damaging our reputation and that of our subsidiaries.

***Political, economic and military instability in Israel may impede our ability to execute our plan of operations.***

Our principal operations and the research and development facilities of the scientific team funded by us under the Second Ramot Agreement are located in Israel. Accordingly, political, economic and military conditions in Israel may affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Acts of random terrorism periodically occur which could affect our operations or personnel. Ongoing or revived hostilities or other factors related to Israel could harm our operations and research and development process and could impede our ability to execute our plan of operations.

In addition, Israeli-based companies and companies doing business with Israel have been the subject of an economic boycott by members of the Arab League and certain other predominantly Muslim countries since Israel's establishment. Although Israel has entered into various agreements with certain Arab countries and the Palestinian Authority, and various declarations have been signed in connection with efforts to resolve some of the economic and political problems in the Middle East, we cannot predict whether or in what manner these problems will be resolved. Wars and acts of terrorism have resulted in damage to the Israeli economy, including reducing the level of foreign and local investment.

Furthermore, certain of our officers and employees may be obligated to perform annual reserve duty in the Israel Defense Forces and are subject to being called up for active military duty at any time. Israeli citizens who have served in the army may be subject to an obligation to perform reserve duty until they are between 40 and 49 years old, depending upon the nature of their military service.

#### **Risks related to our Common Stock**

*The price of our stock is expected to be volatile.*

The market price of our Common Stock has fluctuated significantly, and is likely to continue to be highly volatile. To date, the trading volume in our stock has been relatively low and significant price fluctuations can occur as a result. An active public market for our Common Stock may not continue to develop or be sustained. If the low trading volumes experienced to date continue, such price fluctuations could occur in the future and the sale price of our Common Stock could decline significantly. Investors may therefore have difficulty selling their shares.

*Your percentage ownership will be diluted by future issuances of our securities.*

In order to meet our financing needs, we may issue additional significant amounts of our Common Stock and warrants to purchase shares of our Common Stock. The precise terms of any future financings will be determined by us and potential investors and such future financings may also significantly dilute your percentage ownership in the Company.

*ACCBT holds equity participation rights and other rights that could affect our ability to raise funds.*

Pursuant to the Subscription Agreement with ACCBT Corp. (“ACCBT”), a company under the control of Mr. Chaim Lebovits, our President, we granted ACCBT the right to acquire additional shares of our Common Stock whenever we issue additional shares of Common Stock or other securities of the Company, or options or rights to purchase shares of the Company or other securities directly or indirectly convertible into or exercisable for shares of the Company (including shares of any newly created class or series). This participation right could limit our ability to enter into equity financings and to raise funds from third parties. ACCBT is entitled to purchase its pro rata share of any additional securities we offer, so that its percentage ownership of the Company remains the same after any such issuance of additional securities. Such additional securities will be offered to ACCBT at the same price and on the same terms as the other investors in the transaction. ACCBT will have 30 days from the date of our notice to ACCBT of any intended transaction, to decide whether it wishes to exercise its participation rights in the transaction. We also are prohibited from taking certain corporate actions without the consent of ACCBT, including issuing shares, acquiring or divesting assets and making payment of cash compensation over \$60,000 per year. Further, ACCBT also has the right to appoint a majority of our Board of Directors. In connection with the Subscription Agreement, we entered into a registration rights agreement with ACCBT pursuant to which we granted piggyback registration rights to ACCBT. In addition, we issued ACCBT warrants to purchase up to 2,016,666 shares of Common Stock, of which 2,016,666 warrants are presently outstanding. The outstanding warrants contain cashless exercise provisions, which permit the cashless exercise of up to 50% of the underlying shares of Common Stock. 672,222 of such warrants have an exercise price of \$3.00 and the remainder have an exercise price of \$4.35. We registered 1,920,461 shares of Common Stock and 2,016,666 shares of Common Stock underlying the ACCBT Warrants on registration statement No. 333-201705 dated January 26, 2015 pursuant to ACCBT’s registration rights. ACCBT has waived its participation rights and anti-dilution rights with respect to issuances that were made on or prior to January 8, 2015. In March 2014, we entered into an agreement with ACCBT according to which ACCBT waived certain anti-dilution rights. On May 25, 2014, the Company entered into a Warrant Amendment Agreement with ACCBT, pursuant to which the expiration date of each Warrant held by ACCBT was extended until November 5, 2017, in consideration of ACCBT having provided a series of waivers of their rights, including the anti-dilution rights waiver.

***You may experience difficulties in attempting to enforce liabilities based upon U.S. federal securities laws against us and our non-U.S. resident directors and officers.***

Our principal operations are located through our subsidiary in Israel and our principal assets are located outside the U.S. Our Chief Financial Officer and some of our directors are foreign citizens and do not reside in the U.S. It may be difficult for courts in the U.S. to obtain jurisdiction over our foreign assets or these persons and as a result, it may be difficult or impossible for you to enforce judgments rendered against us or our directors or executive officers in U.S. courts. Thus, should any situation arise in the future in which you have a cause of action against these persons or entities, you are at greater risk in investing in our Company rather than a domestic company because of greater potential difficulties in bringing lawsuits or, if successful, collecting judgments against these persons or entities as opposed to domestic persons or entities.

***If we fail to implement and maintain an effective system of internal controls, we may be unable to accurately report our results of operations or prevent fraud, and investor confidence and the market price of our Common Stock may be materially and adversely affected.***

As a public company in the United States, we are subject to the reporting obligations under the U.S. securities laws. The SEC, as required under Section 404 of the Sarbanes-Oxley Act of 2002, has adopted rules requiring every public company to include a report of management on the effectiveness of such company's internal control over financial reporting in its annual report. In prior years, management has identified material weaknesses in our internal control over financial reporting. If any of our prior material weaknesses recurs, or if we identify additional weaknesses or fail to timely and successfully implement new or improved controls, our ability to assure timely and accurate financial reporting may be adversely affected, and we could suffer a loss of investor confidence in the reliability of our financial statements, which in turn could negatively impact the trading price of our shares of Common Stock, result in lawsuits being filed against us by our stockholders, or otherwise harm our reputation. If material weaknesses are identified in the future, it could be costly to remediate such material weaknesses, which may adversely affect our results of operations. In addition, our auditor is not required to attest to the effectiveness of our internal controls over financial reporting due to our status of qualifying as a smaller reporting company. As a result, current and potential investors could lose confidence in our financial reporting, which could harm our business and have an adverse effect on our share price.

***Delaware law could discourage a change in control, or an acquisition of us by a third party, even if the acquisition would be favorable to you, and thereby adversely affect existing stockholders.***

The Delaware General Corporation Law contain provisions that may have the effect of making more difficult or delaying attempts by others to obtain control of our Company, even when these attempts may be in the best interests of stockholders. Delaware law imposes conditions on certain business combination transactions with "interested stockholders." These provisions and others that could be adopted in the future could deter unsolicited takeovers or

delay or prevent changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests.

***We do not expect to pay dividends in the foreseeable future, and accordingly you must rely on stock appreciation for any return on your investment.***

We have paid no cash dividends on our Common Stock to date, and we currently intend to retain our future earnings, if any, to fund the continued development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Further, any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors, including contractual restrictions to which we may be subject, and will be at the discretion of our Board of Directors.

**Item 1B. UNRESOLVED STAFF COMMENTS**

None.

**Item 2. PROPERTIES**

Our executive offices and United States corporate headquarters are located at 3 University Drive, Suite 320, Hackensack, NJ 07601 ("the Headquarters").

In October 2014, we entered into a lease agreement for the Headquarters, according to which we leased approximately 220 square meters of office space for a term of 63 months commencing October 1, 2014. Rent is paid on a monthly basis in the amount of approximately U.S. \$4,300.

On December 1, 2004, our Israeli Subsidiary entered into a lease agreement (the Lease Agreement) for the lease of premises in 12 Basel Street, Petach Tikva, Israel, which include approximately 600 square meters of office and laboratory space. The original term of the lease was 36 months (the Lease Term), commencing on April 1, 2005, with two options to extend: one for an additional 24 months (the First Option); and one for an additional 36 months (the Second Option).

On November 11, 2012, the Israeli Subsidiary entered into an amendment to the Lease Agreement, pursuant to which the Lease Term (including the First Option and the Second Option) was extended by an additional five years, through March 31, 2018. After three years, we will have the right to cancel the agreement with 6 months' notice. Rent is paid on a monthly basis in the amount of NIS 40,000 (approximately U.S. \$10,000).

We expanded our Petach Tikva facility in 2008 to include an animal research facility.

As part of the clinical trials with Hadassah, we pay \$31,250 per month for rental and operation of clean room facilities at Hadassah facilities in Jerusalem.

We believe that the current office and laboratory space is adequate to meet our needs or will be available in the U.S. to meet the needs of U.S. clinical trials.

**Item 3. 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 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 4. MINE SAFETY DISCLOSURES.**

Not applicable.

**PART II**

**Item 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

*Market Information*

Our Common Stock is currently traded on the Nasdaq Capital Market under the symbol “BCLI”. The following table contains information about the range of high and low sales prices for our Common Stock.

| Quarter Ended      | High   | Low    |
|--------------------|--------|--------|
| December 31, 2014  | \$4.94 | \$2.81 |
| September 30, 2014 | \$5.70 | \$3.35 |
| June 30, 2014      | \$5.70 | \$3.45 |
| March 31, 2014     | \$5.55 | \$2.55 |
| December 31, 2013  | \$3.45 | \$1.50 |
| September 30, 2013 | \$3.90 | \$2.25 |
| June 30, 2013      | \$3.75 | \$2.85 |
| March 31, 2013     | \$4.05 | \$3.30 |

The source of these high and low prices was the OTCQB Marketplace for all periods prior to September 24, 2014, and thereafter the Nasdaq Capital Market. The high and low prices listed have been rounded up to the next highest two decimal places. All sales prices are adjusted to reflect our September 15, 2014 one-for-fifteen reverse stock split.

#### *Record Holders*

As of January 30, 2015, there were approximately 51 holders of record of our Common Stock.

#### *Dividends*

We have not paid or declared any cash or other dividends on our Common Stock within the last two fiscal years. Any future determination as to the payment of dividends will depend upon our results of operations, and on our capital requirements, financial condition and other factors relevant at the time.

#### *Equity Compensation Plans*

Information regarding our equity compensation plans and the securities authorized under the plans is included in Item 12 below.



*Recent Sales of Unregistered Securities*

On January 11, 2012, we issued 8,333 shares of our Common Stock to E.H.O. Consulting and Holdings Ltd. in connection with its exercise of a warrant to purchase Common Stock previously issued. The exercise price paid upon exercise of the warrant was \$0.015 per share for a total of \$125, which has been received by us. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On April 13, 2012, pursuant to the April 2010 agreement with Hadasit, we issued a warrant to purchase up to 2,222 shares of our Common Stock at an exercise price of \$0.00075 per share, exercisable for a period of 10 years, to Hadasit Medical Research Services and Development Ltd. The issuance of these securities was effected without registration in reliance upon Regulation D promulgated under the Securities Act. No underwriters were involved with the issuance of such securities and no commissions were paid in connection with such transaction. On October 22, 2014, Hadasit paid the exercise amount and exercised the warrants.

On April 22, 2012, we issued 55,648 shares of our Common Stock to Yossef Levy in connection with his exercise of a warrant to purchase Common Stock previously issued. The exercise price paid upon exercise of the warrant was \$0.15 per share for a total of \$8,347, which has been received by us. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On July 19, 2012, we issued a 2-year warrant to purchase up to 32,931 shares of our Common Stock with an exercise price equal to \$5.22 per share, to Maxim Group LLC, pursuant to our Placement Agency Agreement with Maxim Group LLC dated as of July 19, 2012. These securities were issued without registration pursuant to the exemption afforded by Rule 506 of Regulation D promulgated under the Securities Act. In July 2014, this warrant was cancelled and no longer valid.

On July 19, 2012, we issued a 30-month warrant to purchase up to 15,517 shares of our Common Stock with an exercise price equal to \$4.35 per share, to Leader Underwriters (1993) Ltd, pursuant to our Placement Agency Agreement with Leader Underwriters (1993) Ltd dated as of July 19, 2012. These securities were issued without registration pursuant to the exemption afforded by Rule 506 of Regulation D promulgated under the Securities Act. These warrants were exercised in January 2015. The exercise price of \$67,500 has been received by us.

On January 16, 2013, we issued 4,800 and 9,600 shares of Common Stock to Dani Offen and Eldad Melamed, respectively, for consulting services. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On February 4, 2013, we issued 8,407 shares of Common Stock to Aaron Lasry in accordance with a settlement agreement with Mr. Lasry. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On February 7, 2013, we issued 55,555 shares of Common Stock at a purchase price of \$4.50 per share (for a total purchase price of \$250,000) and a 32-month warrant to purchase up to 55,556 shares of our Common Stock with an exercise price equal to \$7.50 per share to E.E.B Investments and Holdings (2009) Ltd. and pursuant to a Securities Purchase Agreement with E.E.B Investments and Holdings (2009) Ltd. dated February 7, 2013. These securities were issued without registration pursuant to the exemption afforded by Regulation S promulgated under the Securities Act. No underwriters were involved with the issuance of these securities and no commissions were paid in connection with this transaction.

In March 2013, we issued 16,666 shares of Common Stock to Emerging Markets Consulting, LLC for consulting, marketing and public relations services pursuant to our March 2013 Agreement with Emerging Markets Consulting, LLC. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

In March 2013, we issued 10,000 shares of Common Stock to LifeSci Advisors, LLC for consulting, marketing and public relations services pursuant to our March 2013 Agreement with LifeSci Advisors, LLC. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On April 13, 2013, pursuant to the April 2010 agreement with Hadasit, we issued a warrant to purchase up to 2,222 shares of our Common Stock at an exercise price of \$0.00075 per share, exercisable for a period of 10 years, to Hadasit Medical Research Services and Development Ltd. The issuance of these securities was effected without registration in reliance upon Regulation D promulgated under the Securities Act. No underwriters were involved with the issuance of such securities and no commissions were paid in connection with such transaction. On October 22, 2014, Hadasit paid the exercise amount and exercised the warrants.

On March 24, 2014, the Company issued 12,000 and 24,000 shares of Common Stock to Dani Offen and Eldad Melamed, respectively, for consulting services. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On April 13, 2014, pursuant to the April 2010 agreement with Hadasit, the Company issued a warrant to purchase up to 2,222 shares of its Common Stock at an exercise price of \$0.00075 per share, exercisable for a period of 10 years, to Hadasit Medical Research Services and Development Ltd. The issuance of these securities was effected without registration in reliance upon Regulation D promulgated under the Securities Act. No underwriters were involved with the issuance of such securities and no commissions were paid in connection with such transaction. As a result of the April 25, 2014 termination of the Hadasit Agreement, any outstanding and unvested grants made pursuant to the Agreement ceased to vest, and the grant shall be valid until and may be exercised only on or before October 25, 2014.

On April 25, 2014 (the “Effective Date”), the Company entered into agreements with certain holders of 2013 Warrants to exchange outstanding 2013 Warrants entitling the holder to purchase an aggregate of 777,470 shares of Common Stock for an aggregate of 388,735 unregistered shares of Common Stock. On the Effective Date, each share of Common Stock issuable pursuant to the 2013 Warrants (the “Warrant Shares”) was exchanged for shares of unregistered Common Stock equal to one-half (0.5) of the number of Warrant Shares (the “Exchange Shares”), provided that in the event the number of Exchange Shares resulted in a fractional number it was rounded up to the nearest whole share. As of the Effective Date, the 2013 Warrants were cancelled and of no further force and effect. The offer and sale of the Exchange Shares were made in reliance upon the exemption from registration provided for by Rule 506 of Regulation D promulgated under the Securities Act. No form of general solicitation or general advertising was used by the Company, or any representative of the Company, in connection with the offer or sale of the Exchange Shares. No underwriters were involved with the issuance of the Exchange Shares and no commissions were paid in connection with the exchange. Each of the investors represented to the Company that they are an accredited investor.

On June 19, 2014, we issued 2.8 million shares of Common Stock at a price per share of \$3.75 and warrants to purchase up to 2.8 million shares of Common Stock at an exercise price of \$5.22 per share to a group of investors, including several healthcare-focused funds, pursuant to the Securities Purchase Agreement dated June 13, 2014 between the Company and the investors. The Company received gross proceeds of \$10.5 million. The warrants were exercisable immediately upon closing of the private placement and have a term of three (3) years. Maxim Group LLC acted as sole placement agent (the “Placement Agent”) for the private placement. In connection with the private placement, the Company paid the Placement Agent a cash fee equal to 6.9% of the gross proceeds of the private placement, as well as fees and expenses of the Placement Agent of \$35,000. In addition, the Company issued to the Placement Agent a 5-year warrant to purchase up to 84,000 shares of Common Stock, with an exercise price equal to \$4.50. The issuance of the shares, the warrants and the Placement Agent warrant was exempt from the registration requirements of the Securities Act pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act. The Company made this determination based on the representations that each party is an “accredited investor” within the meaning of Rule 501 of Regulation D and has access to information about the Company and its investment.

In June and in July 2014, the Company issued to several investors 150,651 shares of Common Stock pursuant to the exercise of warrants issued in the July 19, 2012 fund raising. The issuance of these securities was effected without registration in reliance upon Regulation D promulgated under the Securities Act. No underwriters were involved with the issuance of such securities and no commissions were paid in connection with such transaction.

On July 9, 2014, the Company issued to Avi Szenberg 6,666 shares of Common Stock pursuant to an agreement with Mr. Szenberg for marketing services provided to the Company. The issuance of these securities was effected without registration in reliance upon Regulation D promulgated under the Securities Act. No underwriters were involved with the issuance of such securities and no commissions were paid in connection with such transaction.

On July 28, 2014, the Company issued to Thomas B. Rosedale 10,752 shares of Common Stock pursuant to an agreement with BRL Law Firm LLC for legal services provided to the Company. The issuance of these securities was effected without registration in reliance upon Regulation D promulgated under the Securities Act. No underwriters were involved with the issuance of such securities and no commissions were paid in connection with such transaction.

On September 3, 2014, the Company issued to Rainbow Biotechnologies Sarl 7,144 shares of Common Stock pursuant to an exercise of warrants issued under the August 2005 Consulting Agreement with Rainbow Biotechnologies Sarl, for an aggregate exercise price of \$16,000. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On October 22, 2014, the Company issued to Hadasit Medical Research Services and Development Ltd., 8,889 shares of Common Stock pursuant to the exercise of warrants issued under the April 2010 Agreement with Hadasit Medical Research Services and Development Ltd. The issuance of these securities was effected without registration in reliance upon Regulation D promulgated under the Securities Act. No underwriters were involved with the issuance of such securities and no commissions were paid in connection with such transaction.

On January 8, 2015, pursuant to a Warrant Exercise Agreement (the “Exercise Agreement”), holders of warrants to purchase an aggregate of approximately 2.5 million shares of the Company’s Common Stock, at an exercise price of \$5.22 per share (the “2014 Warrants”), issued in a private placement to accredited investors that was consummated on June 13, 2014, 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 (the “New Warrants”). The Company received an aggregate of approximately \$13 million in proceeds from the exercises of the 2014 Warrants (the “Exercise Proceeds”). Maxim Group LLC (“Maxim”) acted as solicitation agent for the Exercise Agreement. In connection with the Exercise Agreement, the Company agreed to pay Maxim a cash fee equal to 6.0% of the Exercise Proceeds, as well as fees and expenses of Maxim of \$20,000. In addition, the Company issued Maxim a warrant to purchase up to approximately 38,000 shares of Common Stock (equal to 1.5% of the exercised 2014 Warrants) upon substantially the same terms as the New Warrants (the “Maxim Warrant”). The Company filed a registration statement covering the resale of the additional shares of Common Stock underlying the New Warrants and the Maxim Warrant (together the “Warrants”) on January 26, 2015. The Warrants have not been registered under the Securities Act, or state securities laws. The issuance of the Warrants is exempt from the registration requirements of the Securities Act pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act. The Company made this determination based on the representations that each party is an “accredited investor” within the meaning of Rule 501 of Regulation D.

## **Item 6. SELECTED FINANCIAL DATA**

Not required.

## **Item 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

## **Company Overview**

We are a biotechnology company developing novel adult stem cell therapies for debilitating neurodegenerative disorders such as ALS, MS, and 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 MSC and their differentiation into neurotrophic factor-secreting 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. Eldad Melamed, former head of Neurology of the Rabin Medical Center and member of the Scientific Committee of the Michael J. Fox Foundation for Parkinson's Research and Prof. Daniel Offen of the Felsenstein Medical Research Center of Tel Aviv University. Our wholly-owned Israeli Subsidiary holds rights to commercialize the technology, through a licensing agreement with Ramot. We currently employ 16 employees in Israel and 2 in the United States.

## Results of Operations

For the period from inception (September 22, 2000) until December 31, 2014, the Company did not generate any revenues from operations. The Company does not expect to earn revenues from operations until at least 2018, if ever. In addition, the Company incurred operating costs and expenses of approximately \$7,419,000 during the year ended December 31, 2014.

### *Research and Development, net*

Our business model calls for significant investments in research and development. Our research and development expenditures (i) in 2014 (before participation by the OCS) were \$6,116,000, which included \$69,000 in stock-based compensation and (ii) in 2013 (before participation by the OCS) were \$4,030,000, which included \$51,000 in stock-based compensation. Research and development expenses, net for the year ended December 31, 2014 and 2013 were \$4,772,000 and \$2,917,000, respectively. In addition, our grant from the OCS increased by \$231,000 to \$1,344,000 for the year ended December 31, 2014 from \$1,113,000 for the year ended December 31, 2013.

The increase in research and development expenses is primarily due to (i) an increase of \$2,877,000 to \$3,854,000 for the year ended December 31, 2014, from \$977,000 for the year ended December 31, 2013 for costs of activities related to commencement of the U.S. Clinical Trial including IND submission, fees to PRC Clinical and FDA Consultant, purchase and validation of cleanroom equipment at DFCI and Mayo Clinic, adaptation of cleanroom facility at DFCI, and on-site technology transfer training to DFCI cleanroom personnel; and (ii) an increase in stock-based compensation expenses of \$18,000 in the year ended December 31, 2014 to \$69,000, compared to \$51,000 for the year ended December 31, 2013. This increase was offset by: (i) a decrease of \$538,000 in costs associated with the clinical trials, conducted in accordance with GMP in Hadassah, for an aggregate amount of \$895,000 for the year ended December 31, 2014, compared to \$1,433,000 for the year ended December 31, 2013; (ii) a decrease of \$237,000 in payroll costs; (iii) an increase of \$231,000 in OCS participation from \$1,113,000 in the year ended December 31, 2013 to \$1,344,000 in the year ended December 31, 2014; and (iv) a decrease of \$34,000 for consultants, travel and other from \$590,000 in the year ended December 31, 2013 to \$556,000 in the year ended December 31, 2014.

### *General and Administrative*

General and administrative expenses for the years ended December 31, 2014 and 2013 were \$2,649,000 and \$2,126,000, respectively. The increase in general and administrative expenses for the year ended December 31, 2014, is mainly due to: (i) an increase of \$278,000 in stock-based compensation expenses, from \$767,000 in the year ended December 31, 2013 to \$1,045,000 in the year ended December 31, 2014; (ii) an increase of \$44,000 in payroll costs



due to recruitment of a CEO during 2014; (iii) an increase of \$238,000 for rent, consultants, PR stock costs and others from \$711,000 in the year ended December 31, 2013 to \$949,000 in the year ended December 31, 2014. This increase was partially offset by a decrease of \$37,000 in depreciation and travel costs from \$67,000 in the year ended December 31, 2013 to \$30,000 in the year ended December 31, 2014.

#### *Financial Expenses*

Financial expenses for the year ended December 31, 2014 was \$1,825,000 compared to income of \$144,000 for the year ended December 31, 2013. The financial expenses for year ended December 31, 2014 is mainly due to a financial expense of \$1,743,000 that is due to revaluation of certain warrants issued to investors in the August 2013 public offering ("2013 Warrants"). Certain 2013 Warrants contain anti-dilution provisions. Under generally accepted accounting principles, the anti-dilution provisions require those 2013 Warrants to be valued and classified as a warrant liability on the balance sheet, resulting in a reduction of stockholders' equity. On January 6, 2015, the remaining 2013 Warrants, that did not participate in the redemption and 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 April 25, 2014, the Company exchanged some of the 2013 Warrants, entitling the holders to purchase an aggregate of 777,470 shares of Common Stock, in exchange for 388,735 unregistered shares of Common Stock.

On March 24, 2014, ACCBT and ACC International Holdings Ltd. agreed to irrevocably waive all anti-dilution rights contained in all issued and outstanding warrants to purchase Company Common Stock held by ACCBT Corp. or ACC International Holdings Ltd.

On May 25, 2014, the Company entered into a Warrant Amendment Agreement (the "Amendment") with ACCBT, pursuant to which the expiration date of each Warrant held by ACCBT was extended until November 5, 2017, in consideration of ACCBT having provided a series of waivers of their rights, including anti-dilution rights. ACCBT and the Company are party to a Subscription Agreement, dated as of July 2, 2007, a related Registration Rights Agreement and warrants to purchase up to an aggregate of 2,016,666 shares of Company Common Stock, and related documents (all of the foregoing documents together as amended to date, the "ACCBT Documents"). Pursuant to the Amendment, the ACCBT Documents were amended to reflect the extension of the warrants' expiration date.

On May 27, 2014, the Company entered into agreements with certain holders of 2013 Warrants to repurchase certain then outstanding 2013 Warrants for an aggregate of approximately \$600,000 (the "Redemption"). Each share of Common Stock issuable pursuant to the repurchased 2013 Warrants was repurchased for \$1.80 cash payment by the Company per Warrant Share (the "Redemption Amount") and Warrants participating in the Redemption were cancelled and of no further force and effect. In connection with the Redemption, certain holders of 2013 Warrants which did not participate in the Redemption and whose 2013 Warrants will therefore remain outstanding, have waived anti-dilution provisions of their 2013 Warrants.

The financial income for the year ended December 31, 2013 is mainly due to income from revaluation of warrants of \$174,000 and income from interest receivable from a bank deposit that were offset by conversion exchange rates and bank charges.

#### *Net Loss*

Net loss for the year ended December 31, 2014 was \$9,246,000, as compared to a net loss of \$4,899,000 for the year ended December 31, 2013. Net loss per share for the year ended December 31, 2014 was \$0.68, compared to net loss per share of \$0.46 for the year ended December 31, 2013.

The increase in the net loss for the year ended December 31, 2014 is due to (i) an increase in the progress of clinical trials conducted in GMP facilities in Hadassah and the U.S. Clinical Trial, and (ii) an increase in payroll costs, and (iii) an increase in stock-based compensation expenses. This increase was partially offset by an increase in OCS grants.

The weighted average number of shares of Common Stock used in computing basic and diluted net loss per share for the year ended December 31, 2014 was 13,662,758, compared to 10,738,131 for the year ended December 31, 2013.

The increase in the weighted average number of shares of Common Stock used in computing basic loss per share for the year ended December 31, 2014 was due to: (i) the issuance of shares of Common Stock in a private placement in June 2014, as described in more detail below and in a public offering in August 2013, (ii) the exercise of options and warrants, and (iii) the issuance of shares to service providers.

### **Liquidity and Capital Resources**

We have financed our operations since inception primarily through public and private sales of our Common Stock and warrants and the issuance of convertible promissory notes. As of December 31, 2014, we had \$9,578,000 in total current assets and \$3,113,000 in total current liabilities.

Net cash used in operating activities was \$4,487,000 for the year ended December 31, 2014. Cash used for operating activities in the year ended December 31, 2014 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 used in investing activities was \$4,450,000 for the year ended December 31, 2014.

Net cash provided by financing activities was \$9,685,000 for the year ended December 31, 2014 and is primarily attributable to the 2014 Private Placement, as discussed below.

On June 13, 2014, we entered into a securities purchase agreement with a group of investors, including several healthcare-focused funds (the “Investors”) to effect a private placement (the “2014 Private Placement”) of the Company’s Common Stock and warrants to purchase Common Stock. On June 19, 2014, upon the closing of the 2014 Private Placement, we received gross proceeds of \$10.5 million, resulting from the issuance and sale of 2.8 million shares of Common Stock at a price per share of \$3.75, a 15% discount to the 30 day volume-weighted average price of \$4.41. The Investors also received warrants to purchase up to 2.8 million shares of Common Stock at an exercise price of \$5.22 per share (the “2014 Warrants”). The 2014 Warrants were exercisable immediately upon closing of the 2014 Private Placement and have a term of three (3) years.

On January 8, 2015, the Company signed an agreement according to which the Company issued 2.5 million shares of Common Stock, pursuant to the exercise of the 2014 Warrants for consideration of \$13.3 million dollars. In addition, the Company granted new warrants to the warrant holders to purchase up to an aggregate of approximately 3.8 million unregistered shares of Common Stock at an exercise price of \$6.50.

Maxim Group LLC (“Maxim”) acted as solicitation agent for the exercise of the 2014 Warrants on January 8, 2015, for a cash fee equal to 6.0% of the exercise proceeds, as well as fees and expenses of Maxim of \$20,000. In addition, the Company will issue Maxim a warrant to purchase up to approximately 38,000 shares of Common Stock (equal to 1.5% of the exercised 2014 Warrants) upon substantially the same terms as the new warrants.

Our material cash needs for the next 12 months will include payments of (i) costs of the clinical trial in the U.S., (ii) employee salaries, (iii) payments expected for the upcoming multi-dose clinical trial, (iv) \$31,250 per month 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 that the net proceeds of the 2014 Private Placement and the proceeds from exercise of warrants on January 8, 2015 will be sufficient to meet our obligations in the upcoming 12 months.

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.

**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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

Not required.

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2014**

**U.S. DOLLARS IN THOUSANDS**

(Except share data and exercise prices)

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2014**

U.S. DOLLARS IN THOUSANDS

(Except share data and exercise prices)

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**To the Board of Directors and Stockholders of**

**BRAINSTORM CELL THERAPEUTICS Inc.**

We have audited the accompanying consolidated balance sheet of BRAINSTORM CELL THERAPEUTICS Inc. and its subsidiaries (the "Company") as of December 31, 2014 and 2013, and the related consolidated statement of income, stockholders' deficiency, and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2014 and 2013, and the results of its operations and cash flows for each of the two years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company is engaged in the development of stem cell therapeutic products, and to date has not generated any revenues from such activities. The resulting operating losses raise substantial doubts about its ability to continue as a going concern. Management's plans concerning these matters are described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.



**Brightman Almagor Zohar & Co.**

**Certified Public Accountants**

**A Member of Deloitte Touche Tohmatsu Limited**

**Tel Aviv, Israel**

**March 25, 2015**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**To the Stockholders and Board of Directors of**

**BRAINSTORM CELL THERAPEUTICS INC.**

**(A development stage company)**

We have audited the accompanying consolidated balance sheet of Brainstorm Cell Therapeutics Inc. (a development stage company) ("the Company") and its subsidiary as of December 31, 2007, and the related consolidated statements of operations, statements of changes in stockholders' equity (deficiency) and the consolidated statements of cash flows for the year ended December 31, 2007, for the nine months ended December 31, 2006 and 2005 and for the period from March 31, 2004 through December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits and the report of the other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its subsidiary as of December 31, 2007, and the consolidated results of their operations and cash flows for the year ended December 31, 2007, for the nine months ended December 31, 2006 and 2005 and for the period from March 31, 2004 through December 31, 2007, in conformity with U.S generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, in 2007, the Company adopted Financial Accounting Standard Board Statement No. 123(R), "Share-Based Payment".

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1h, the Company has incurred operating losses and has a negative cash flow from operating activities and has a working capital deficiency. As for the Company research and development license agreement with Ramot, see Note 3. These conditions raise substantial doubt about the Company's ability to continue to operate as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Kost Forer Gabbay & Kasierer

Tel-Aviv, Israel KOST FORER GABBAY & KASIERER

April 13, 2008 A Member of Ernst & Young Global

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESCONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

(Except share data and exercise prices)

|  | December 31,         |              |
|--|----------------------|--------------|
|  | 2014                 | 2013         |
|  | U.S. \$ in thousands |              |
| <b>ASSETS</b>                                  |                      |              |
| Current Assets:                                |                      |              |
| Cash and cash equivalents                      | 4,251                | 3,503        |
| Short-term deposit                             | 4,290                | -            |
| Account receivable (Note 5)                    | 1,005                | 910          |
| Prepaid expenses                               | 32                   | 33           |
| <b>Total current assets</b>                    | <b>9,578</b>         | <b>4,446</b> |
| Long-Term Assets:                              |                      |              |
| Prepaid expenses                               | 20                   | 22           |
| Total long-term investments                    | 20                   | 22           |
| <b>Property and Equipment, Net (Note 6)</b>    | <b>313</b>           | <b>258</b>   |
| Total assets                                   | 9,911                | 4,726        |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>    |                      |              |
| Current Liabilities:                           |                      |              |
| Trade payables                                 | 1,542                | 228          |
| Accrued expenses                               | 1,347                | 877          |
| Other accounts payable                         | 224                  | 227          |
| Total current liabilities                      | 3,113                | 1,332        |
| Long-Term Liabilities:                         |                      |              |
| Warrants issued to investors (Note 8(b)(1)(f)) | 123                  | 655          |
| Total long-term liabilities                    | 123                  | 655          |
| Total liabilities                              | 3,236                | 1,987        |
| Stockholders' Equity:                          |                      |              |

|  |           |           |
|--|-----------|-----------|
| Stock capital: (Note 8)  | 11        | 8         |
| Common stock of \$0.00005 par value - Authorized: 800,000,000 shares at December 31, 2014 and December 31, 2013; Issued and outstanding: 15,281,497 and 11,750,881 shares at December 31, 2014 and December 31, 2013 respectively. |           |           |
| Additional paid-in-capital   | 68,317    | 55,138    |
| Accumulated deficit  | (61,653 ) | (52,407 ) |
| Total stockholders' equity   | 6,675     | 2,739     |
| Total liabilities and stockholders' equity   | 9,911     | 4,726     |

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESCONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands

(Except share data and exercise prices)

|  | Year ended<br>December 31, |            |
|--|----------------------------|------------|
|  | 2014                       | 2013       |
|  | U.S. \$ in thousands       |            |
| Operating costs and expenses:  |                            |            |
| Research and development, net (Note 9)   | \$4,772                    | \$2,917    |
| General and administrative   | 2,649                      | 2,126      |
| Total operating costs and expenses   | 7,421                      | 5,043      |
| Financial expenses (income), net   | 1,825                      | (144 )     |
| Operating loss   | 9,246                      | 4,899      |
| Taxes on income (Note 10)  | -                          | -          |
| Net loss   | \$9,246                    | \$4,899    |
| Basic and diluted net loss per share from continuing operations                                      | 0.68                       | 0.46       |
| Weighted average number of shares outstanding used in computing basic and diluted net loss per share | 13,662,758                 | 10,738,131 |

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

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES****STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**

U.S. dollars in thousands

(Except share data and exercise prices)

|  | Common stock<br>Number | Amount | Additional<br>paid-in<br>capital | Accumulated<br>deficit | Total<br>stockholders'<br>equity |
|--|------------------------|--------|----------------------------------|------------------------|----------------------------------|
| Balance as of December 31, 2012  | 10,005,644             | \$ 7   | \$ 51,483                        | \$ (47,508 )           | \$ 3,982                         |
| Stock-based compensation related to warrants and stock granted to service providers      | 53,980                 |        | 197                              | -                      | 197                              |
| Stock-based compensation related to stock and options granted to directors and employees | 50,666                 |        | 674                              | -                      | 674                              |
| Issuance of shares for public offering   | 1,568,628              | 1      | 2,496                            | -                      | 2,497                            |
| Issuance of shares for private placement   | 55,555                 | (*)    | 250                              | -                      | 250                              |
| Conversion of convertible loans  | 8,408                  | -      | 30                               | -                      | 30                               |
| Exercise of options  | 8,000                  | (*)    | 8                                | -                      | 8                                |
| Net loss   | -                      | -      | -                                | (4,899 )               | (4,899 )                         |
| Balance as of December 31, 2013  | 11,750,881             | \$ 8   | \$ 55,138                        | \$ (52,407 )           | \$ 2,739                         |

\* Represents an amount less than \$1.

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESSTATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

U.S. dollars in thousands

(Except share data and exercise prices)

|  | Common stock<br>Number | Amount | Additional<br>paid-in<br>capital | Accumulated<br>deficit | Total<br>stockholders'<br>equity |
|--|------------------------|--------|----------------------------------|------------------------|----------------------------------|
| Balance as of December 31, 2013  | 11,750,881             | \$ 8   | \$ 55,138                        | \$ (52,407 )           | \$ 2,739                         |
| Stock-based compensation related to warrants and stock granted to service providers      | 53,419                 | -      | 198                              | -                      | 198                              |
| Stock-based compensation related to stock and options granted to directors and employees | 50,667                 | -      | 1,024                            | -                      | 1,024                            |
| Issuance of shares for private placement   | 2,800,000              | 3      | 9,551                            | -                      | 9,554                            |
| Stock issued for warrants exchange   | 388,735                | -      | (*) 1,633                        | -                      | 1,633                            |
| Warrants liability classified as equity  | -                      | -      | 42                               | -                      | 42                               |
| Exercise of warrants   | 180,018                | -      | (*) 701                          | -                      | 701                              |
| Exercise of options  | 57,777                 | -      | (*) 30                           | -                      | 30                               |
| Net loss   | -                      | -      | -                                | (9,246 )               | (9,246 )                         |
| Balance as of December 31, 2014  | 15,281,497             | \$ 11  | \$ 68,317                        | \$ (61,653 )           | \$ 6,675                         |

\* Represents an amount less than \$1.

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



BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF CASH FLOWS**

U.S. dollars in thousands

(Except share data and exercise prices)

|  | Year ended<br>December 31,<br>2014    2013<br>U.S. \$ in<br>thousands |           |
|--|---|-----------|
| Cash flows from operating activities:  |   |           |
| Net loss   | \$(9,246)   | \$(4,899) |
| Adjustments to reconcile net loss to net cash used in operating activities:          |   |           |
| Depreciation and amortization of deferred charges                                    | 106   | 97        |
| Stock based compensation related to shares and warrants granted to service providers | 198   | 227       |
| Stock-based compensation related to options granted to employees                     | 1,024   | 674       |
| Increase in accounts receivable and prepaid expenses                                 | (93 )   | (155 )    |
| Increase (decrease) in trade payables  | 1,314   | (130 )    |
| Increase in other accounts payable and accrued expenses                              | 467   | 306       |
| Revaluation of warrants  | 1,743   | (174 )    |
| Total net cash used in operating activities  | \$(4,487)   | \$(4,054) |

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF CASH FLOWS**

U.S. dollars in thousands

(Except share data and exercise prices)

|   | Year ended<br>December 31, |          |
|---|----------------------------|----------|
|   | 2014                       | 2013     |
|   | U.S. \$ in thousands       |          |
| Cash flows from investing activities:                     |                            |          |
| Purchase of property and equipment                        | (161 )                     | (108 )   |
| Changes in short-term deposit                             | (4,290 )                   | 2,769    |
| Investment in lease deposit                               | 1                          | (5 )     |
| Total net cash provided by (used in) investing activities | \$ (4,450 )                | \$ 2,656 |
| Cash flows from financing activities:                     |                            |          |
| Proceeds from issuance of Common stock, net               | 9,554                      | 3,576    |
| Proceeds from exercise of warrants and options            | 731                        | 8        |
| Redemption of warrants in cash                            | (600 )                     | -        |
| Total net cash provided by financing activities           | 9,685                      | 3,584    |
| Increase (decrease) in cash and cash equivalents          | 748                        | 2,186    |
| Cash and cash equivalents at the beginning of the period  | 3,503                      | 1,317    |
| Cash and cash equivalents at end of the period            | \$ 4,251                   | \$ 3,503 |
| Non-cash financing activities:                            |                            |          |
| Stock issued for warrants exchange                        | 1,633                      | -        |
| Warrants liability classified as equity                   | 42                         | -        |

**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 Consolidated Financial Statements

NOTE 1 - GENERAL

A. Brainstorm Cell Therapeutics Inc. (formerly: Golden Hand Resources Inc. - the "Company") was incorporated in the State of Washington on September 22, 2000.

B. On July 8, 2004, the Company entered into a licensing agreement with Ramot of Tel Aviv University Ltd. ("Ramot"), to acquire certain stem cell technology (see Note 3). Subsequent to this agreement, the Company decided to focus on the development of novel cell therapies for neurodegenerative diseases based on the acquired technology and research to be conducted and funded by the Company.

Following the licensing agreement dated July 8, 2004, the management of the Company decided to abandon all old activities related to the sale of the digital data recorder product.

C. On October 25, 2004, the Company formed a wholly-owned subsidiary in Israel, Brainstorm Cell Therapeutics Ltd. ("BCT").

D. On November 18, 2004, the Company changed its name from Golden Hand Resources Inc. to Brainstorm Cell Therapeutics Inc. to better reflect its new line of business in the development of novel cell therapies for neurodegenerative diseases. BCT, as defined above, owns all operational property and equipment.

The Common Stock is publicly traded on the NASDAQ Capital Market ("Nasdaq") under the symbol "BCLI" (See Note 1(W)).

E. In October 2010, the Israeli Ministry of Health ("MOH") granted clearance for a Phase I/II clinical trial using the Company's autologous NurOwn® stem cell therapy in patients with amyotrophic lateral sclerosis ("ALS"), subject to some additional process specifications as well as completion of the sterility validation study for tests performed.

On February 23, 2011, the Company submitted, to the MOH, all the required documents. Following approval of the MOH, a Phase I/II clinical study for ALS patients using the Company's autologous NurOwn® stem cell therapy (the "Clinical Trial") was initiated in June 2011.

**F.** In February 2011, the U.S. Food and Drug Administration ("FDA") granted orphan drug designation to the Company's NurOwn® autologous adult stem cell product for the treatment of ALS.

**G.** On February 19, 2013, Brainstorm Ltd established a wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd. ("Brainstorm UK"). Brainstorm UK acts on behalf of the parent Company in the EU.

**H.** On February 21, 2013, Brainstorm UK filed a request for Orphan Medicinal Product Designation by the European Medicine Agency (EMA) for its Autologous Bone Marrow derived Mesenchymal Stem cells Secreting Neurotropic factors (MSC-NTF, NurOwn®). On July 17, 2013, the European Commission granted Orphan Drug Designation to the Company's NurOwn® autologous adult stem cell product for the treatment of ALS.

**I.** On March 14, 2013, the Company signed a definitive agreement with the Mayo Clinic in Rochester, Minnesota to conduct its Phase II clinical trial of NurOwn® in ALS pending FDA approval. In addition, Mayo's Human Cell Therapy Laboratory will manufacture the NurOwn® cells for their clinical trial participants.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 1 - GENERAL (Cont.):

Effective April 3, 2013, the Company entered into an agreement with Dana-Farber Cancer Institute (“Dana-Farber”) to provide cGMP-compliant clean room facilities for production of the Company’s NurOwn® stem cell candidate during its Phase II ALS trial in the United States. The Company’s Phase II trial, is conducted at Massachusetts J. General Hospital (“MGH”), the University of Massachusetts (“UMass”) Hospital and the Mayo Clinic. The Connell and O’Reilly Cell Manipulation Core Facility at Dana-Farber will produce NurOwn® for the MGH and UMass Hospital clinical sites.

On September 27, 2013, the Company announced that it recently completed treatment of the 12 patients in its ALS K. Phase IIa dose-escalating clinical trial with the Company’s NurOwn® technology. The Company was informed that one patient in the study expired due to a medical condition unrelated to the Clinical Trial.

The Clinical Trial was being performed at Hadassah Medical Center in Jerusalem, Israel, under the direction of Prof. Dimitrios Karussis, M.D., Ph.D., head of Hadassah’s Multiple Sclerosis Center and a member of the International Steering Committees for Bone Marrow and Mesenchymal Stem Cells Transplantation in Multiple Sclerosis (MS). The study was designed to establish the safety and preliminary efficacy of NurOwn® at increasing dosages.

On December 4, 2013, a Notice of Intention to Grant from the European Patent Office (EPO) was issued for the Company’s patent application entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS L. Diseases" (European serial number EP06766101.7) . This patent relates to the production method for the Company’s proprietary stem cells induced to secrete large quantities of neurotrophic factors for the treatment of neurodegenerative diseases.

M. On February 11, 2014, a Notice of Allowance was issued from the U.S. Patent Office for the same patent application as above, U.S. serial number 11/727,583.

N. On March 4, 2014, a Notice of Allowance was issued from the U.S. Patent Office for the same patent application as above, U.S. serial number 12/994,761.

- O.** On March 24, 2014, BCT signed a definitive agreement with MGH in Boston, MA to conduct a Phase II clinical trial of NurOwn® in ALS, pending FDA approval.

- P.** On April 28, 2014, the Company announced that the FDA has approved commencement of its Phase II clinical trial with NurOwn® in patients with ALS. The trial was launched at MGH in Boston, MA and the UMass Hospital in Worcester, MA after Institutional Review Board (IRB) approvals. Dana-Farber Cancer Institute's Connell O'Reilly Cell Manipulation Core Facility manufactures the NurOwn® cells for these two clinical sites. The trial is also conducted at the Mayo Clinic in Rochester, Minnesota.

- Q.** On June 2, 2014, the Company announced that interim results from the Company's Phase IIa ALS trial conducted at Hadassah Medical Center in Jerusalem, Israel were presented on June 1, 2014 at the Joint Congress of European Neurology by Principal Investigator Professor Dimitrios Karussis. The positive safety and preliminary efficacy results observed in this study are consistent with results observed in the Company's previous Phase I/II trial. Between these two studies, a total of 26 patients have been treated with NurOwn®, the Company's stem cell therapy candidate for ALS.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 1 - GENERAL (Cont.):

On June 6, 2014, the Company announced that its Phase II ALS clinical trial has commenced with the enrollment of the first patient at MGH in Boston, Massachusetts. The Company's Phase II trial is a randomized, double-blind, R. placebo controlled multi-center study designed to evaluate the safety and efficacy of transplantation of NurOwn® in 48 ALS patients. The trial is also being conducted at the UMass Hospital in Worcester, Massachusetts and the Mayo Clinic in Rochester, Minnesota.

On June 10, 2014, the Company announced that it has initiated a study in a mouse model of autism at the Felsenstein Medical Research Center, Sackler Faculty of Medicine, Tel Aviv University, under the direction of S. Professor Daniel Offen. The study explores the effects of the Company's "MSC-NTF" cells on mouse behavior. The study, which is being conducted using the BTBR mouse model for autism, will investigate repetitive behavior, increased cognitive flexibility and improved sociability in mice after administration of a single intracerebroventricular injection of the cells.

On June 24, 2014, the Company signed a definitive agreement with the UMass Hospital in Worcester, MA to T. conduct a Phase II clinical trial of NurOwn® in ALS.

On July 1, 2014, the Company signed a definitive agreement with Professional Research Consulting Clinical Inc., U. CA ("PRC"), to monitor the Phase II clinical trial of NurOwn® in ALS.

A reverse stock split of the Company's shares of Common Stock by a ratio 1-for-15 was effected on September 15, 2014 at 11:59 p.m. pursuant to an amendment to the Company's Certificate of Incorporation approved by the V. stockholders of the Company on August 14, 2014. 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.

The Company's shares of Common Stock were approved for uplisting to the NASDAQ, and commenced trading on W. the NASDAQ on September 30, 2014 under the ticker symbol "BCLI."

**GOING CONCERN:**

As reflected in the accompanying financial statements, the Company's operations for the year ended December 31, 2014, resulted in a net loss of \$9,246. The Company's balance sheet reflects an accumulated deficit of \$61,653. These conditions, together with the fact that the Company has no revenues from operations expected in the near future, raise substantial doubt about the Company's ability to continue to operate as a going concern. The Company's ability to continue operating as a "going concern" is dependent on several factors, among them is its ability to raise sufficient additional working capital.

After the balance sheet date, in January 2015, the Company raised approximately \$16 million, gross, from exercise of warrants issued in July 2012 and from sale of additional warrants in a private offering (See Note 12B). The Company believes that the Company has resources to carry out its operations in the upcoming year. However, there can be no assurance that additional funds will be available on terms acceptable to the Company, or that the Company will not incur additional unforeseen costs or expenses.

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 Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

A. Basis of presentation:

The consolidated financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles ("GAAP") applied on a consistent basis.

B. Use of estimates:

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

C. Financial statements in U.S. dollars:

The functional currency of the Company is the U.S dollar ("dollar") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. Part of the transactions of BCT is recorded in new Israeli shekels ("NIS"); however, a substantial portion of BCT's costs are incurred in dollars or linked to the dollar. Accordingly, management has designated the dollar as the currency of BCT's primary economic environment and thus it is their functional and reporting currency.

Transactions and balances denominated in dollars are presented at their original amounts. Non-dollar transactions and balances have been re-measured to dollars in accordance with the provisions of ASC 830-10 (formerly Statement of Financial Accounting Standard 52), "Foreign Currency Translation". All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statement of operations as financial income or expenses, as appropriate.

D. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, BCT and Brainstorm UK. Intercompany balances and transactions have been eliminated upon consolidation.

E. Cash and cash equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with maturities of three months or less as of the date acquired.

F. Property and equipment:

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated by the straight-line method over the estimated useful lives of the assets.

The annual depreciation rates are as follows:

|  | %  |
|--|--|
| Office furniture and equipment             | 7  |
| Computer software and electronic equipment | 33   |
| Laboratory equipment                       | 15   |
| Leasehold improvements                     | Over the shorter of the lease term (including the option) or useful life |

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

G. Impairment of long-lived assets:

The Company's long-lived assets are reviewed for impairment in accordance with ASC 360-10 (formerly Statement of Financial Accounting Standard 144), "Accounting for the Impairment or Disposal of Long-Lived Assets," whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds their fair value. During 2014 and 2013, no impairment losses were identified.

**H. Accrued post-employment benefit**

The Company entered into an employment agreement with its CEO which contains provisions for severance pay under certain circumstances. If the CEO is terminated by the Company without Cause (as defined in the agreement) or if the CEO terminates employment with Good Reason (as defined in the agreement), the CEO will be entitled to (i) his base salary for between 4 and 9 months (depending on length of employment before termination), (ii) his bonus compensation that he would have been entitled to during this payment period, (iii) the immediate vesting of any options that would have vested within the 6 month period following termination and (iv) health insurance benefits during the payment period. If the CEO's employment is terminated in connection with a Change of Control (as defined in the agreement), the CEO will be entitled to (i) his base salary for 12 months, (ii) his target bonus compensation for the year in which the Change of Control occurred and (iii) immediate vesting of all options granted to the CEO. In accordance with ASC 712, no severance liability has been recorded on the Company's balance sheet with respect to this employment agreement as of December 31, 2014.

The majority of the Company's employees in Israel have agreed to Section 14 of Israel's Severance Pay Law, 5723-1963 ("Section 14"). Pursuant to Section 14, those of the Company's employees that are covered by this section are entitled only to an amount of severance pay equal to monthly deposits, at a rate of 8.33% of their monthly salary, made on their behalf by the Company. Payments in accordance with Section 14 release the Company from any future severance liabilities in respect of those employees. Neither severance pay liability nor severance pay funds under Section 14 for such employees is recorded on the Company's balance sheet.

**I. Fair value of financial instruments:**

The carrying values of cash and cash equivalents, accounts receivable and prepaid expenses, trade payables and other accounts payable approximate their fair value due to the short-term maturity of these instruments.

The Company utilizes the Black Scholes Merton formula to measure the fair value of the warrants issued. The assumptions included in the Black-Scholes model were: (i) the market price of the Company's shares; (ii) the exercise price of the warrant; (iii) risk-free interest; (iv) term available to exercise or redeem the security and (v) the volatility of the shares during the relevant term. The Company determines the volatility of its shares using daily historical quotes of the shares. The risk free interest rate is determined as the interest rate on governmental bonds with maturity commensurate with the term of the warrant.

**J. Accounting for stock-based compensation:**

In accordance with ASC 718-10 (formerly Statement of Financial Accounting Standards 123 (Revised 2004)) the Company estimates the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statement of operations.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

J. Accounting for stock-based compensation (Cont.):

The Company recognizes compensation expense for the value of non-employee awards, which have graded vesting, based on the straight-line method over the requisite service period of each award.

The Company recognizes compensation expense for the value of employee awards that have graded vesting, based on the straight-line method over the requisite service period of each of the awards, net of estimated forfeitures.

The Company estimates the fair value of restricted shares based on the market price of the shares at the grant date and estimates the fair value of stock options granted using a Black-Scholes options pricing model. The option-pricing model requires a number of assumptions, of which the most significant are, expected stock price volatility and the expected option term (the time from the grant date until the options are exercised or expire). Expected volatility was calculated based upon actual historical stock price movements over the period, equal to the expected option term. The Company has historically not paid dividends and has no foreseeable plans to issue dividends. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term.

K. Basic and diluted net loss per share:

Basic net loss per share is computed based on the weighted average number of shares outstanding during each year. Diluted net loss per share is computed based on the weighted average number of shares outstanding during each year, plus the dilutive potential of the Common Stock considered outstanding during the year, in accordance with ASC 260-10 (formerly Statement of Financial Accounting Standard 128), "Earnings per Share".

All outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share for the year ended December 31, 2014 and December 31, 2013, since all such securities have an anti-dilutive effect.

L. Research and development expenses, net:

Research and development expenses, are charged to the statement of operations as incurred.

Royalty-bearing grants from the Government of Israel for funding approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred and applied as a deduction from research and development expenses. Such grants are included as a deduction of research and development costs since at the time received it is not probable the Company will generate sales from these projects and pay the royalties resulting from such sales.

M. Income taxes:

The Company accounts for income taxes in accordance with ASC 740-10 (formerly Statement of Financial Accounting Standard 109), "Accounting for Income Taxes." This Statement requires the use of the liability method of accounting for income taxes, whereby deferred tax asset and liability account balances are determined based on the differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company and BCT provide a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

N. Reverse Stock Split

On September 15, 2014, the Company completed the reverse stock split, whereby each fifteen shares of Common Stock of the Company were combined and were reclassified into one share of Common Stock of the Company, and the number of issued and outstanding shares of Common Stock of the Company was proportionally reduced, in both cases without any change to the authorized number of shares of Common Stock or in the par value of such shares.

Upon implementation of the recapitalization described above, 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.

O. 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 2017; 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 the expected impact of the new standard on its consolidated financial statements.

In June 2014, the Financial Accounting Standards Board issued a new standard which eliminates the concept of a development-stage entity from U.S. GAAP as well as the related requirement to present inception-to-date information. Following the issuance of this standard, inception-to-date information is no longer presented in the Company's financial statements.

In August 2014, the Financial Accounting Standards Board issued a new standard which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements. Further, an entity must provide certain disclosures if there is a substantial doubt about the entity's ability to continue as a going concern. The new standard did not impact the outcome of the Company's assessment with respect to its ability 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 Consolidated Financial Statements

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 - CONSULTING AGREEMENTS

On July 8, 2004, the Company entered into two consulting agreements with Prof. Eldad Melamed and Dr. Daniel Offen (together, the "Consultants"), under which the Consultants provide the Company scientific and medical  
A. consulting services in consideration for a monthly payment of \$6 each. In June 2012, an amendment was signed with Dr. Daniel Offen, according to which the Company pays Daniel Offen a monthly payment of \$6, out of which \$3 is in cash and \$3 is by grant of Company stock.

B.

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On January 16, 2013, the Company granted the Consultants an aggregate of 14,400 shares of Common Stock for their services from January 1, 2012 through December 31, 2012. Related compensation in the amount of \$54 was recorded as research and development expense.

C. On November 13, 2013, the Company approved grants of an aggregate of 30,000 shares of Common Stock to the Consultants, for services rendered during January 1, 2013 through September 30, 2013.

D. 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 2013.

E. As of December 31, 2014, the Company has a total obligation of \$111 for services rendered by the Consultants under the above-mentioned agreements.

NOTE 5 - ACCOUNTS RECEIVABLE

|                                | December<br>31,<br>2014 2013<br>U.S. \$ in<br>thousands |     |
|--------------------------------|---|-----|
| Government institutions        | 43  | 60  |
| Grants receivable from the CSO | 962   | 850 |
|                                | 1,005   | 910 |

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

## NOTE 6 - PROPERTY AND EQUIPMENT

|  | December 31,         |       |
|--|----------------------|-------|
|  | 2014                 | 2013  |
|  | U.S. \$ in thousands |       |
| Cost:                                      |                      |       |
| Office furniture and equipment             | 73                   | 18    |
| Computer software and electronic equipment | 159                  | 149   |
| Laboratory equipment                       | 576                  | 482   |
| Leasehold improvements                     | 716                  | 716   |
|  | 1,524                | 1,365 |
| Accumulated depreciation:                  |                      |       |
| Office furniture and equipment             | 8                    | 5     |
| Computer software and electronic equipment | 132                  | 116   |
| Laboratory equipment                       | 404                  | 350   |
| Leasehold improvements                     | 667                  | 636   |
|  | 1,211                | 1,107 |
| Depreciated cost                           | 313                  | 258   |

Depreciation expenses for the years ended December 31, 2014 and December 31, 2013 were \$106 and \$97, respectively.

## NOTE 7 - COMMITMENTS AND CONTINGENCIES

In November 2012, BCT entered into an amended lease agreement for the lease of its facilities. The term of the A. lease is 60 months, with an option to terminate the agreement with 6 month pre-notice, after 36 months. Rent is paid on a monthly basis in the amount of NIS 40,000 (approximately \$11) per month.

B.

In October 2014, we entered into a lease agreement for our headquarters, according to which we leased approximately 220 square meters of office space for a term of 63 months commencing October 1, 2014. Rent is paid on a monthly basis in the amount of approximately U.S. \$4.

The facilities and vehicles of the Company and BCT are rented under operating leases that expire on various dates. Aggregate minimum rental commitments under non-cancelable leases as of December 31, 2014 are as follows:

| Period ending December 31, 2014 | Facilities | Vehicles | Total |
|---------------------------------|------------|----------|-------|
| 2015                            | 172        | 9        | 181   |
| 2016                            | 103        | -        | 103   |
| 2017                            | 54         | -        | 54    |
| 2018                            | 55         | -        | 55    |
| 2019                            | 57         | -        | 57    |
|                                 | 441        | 9        | 450   |

Total facilities rent expense for the years ended December 31, 2014 and 2013 were \$150 and \$129, respectively.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 7 - COMMITMENTS AND CONTINGENCIES (Cont.):

C. Commitments to pay royalties to the Chief Scientist:

BCT obtained from the Chief Scientist of the State of Israel grants for participation in research and development for the years 2007 through 2014, and, in return, BCT is obligated to pay royalties amounting to 3%-3.5% of its future sales up to the amount of the grant. The grant is linked to the exchange rate of the dollar and bears interest of Libor per annum.

Through the year ended December 31, 2014, total grants obtained amounted to \$1,169. After the balance sheet date, the Company received approximately \$159.

On February 17, 2010, BCT entered into an agreement with Hadasit Medical Research Services and Development Ltd ("Hadasit"), which was revised in June 2011, to conduct clinical trials in ALS patients. According to the agreement, BCT paid to Hadasit \$32 per patient totaling up to \$773 for the conduction of the Clinical Trials. In October 2014, the Company finalized the clinical trial at Hadassah and has no further obligations to Hadasit.

In addition, BCT signed an agreement with Hadasit for rental and operation of one clean room, for the consideration of \$31 monthly. The Company has the right to cease the rental of the clean room at any time upon 30 days' prior notice.

NOTE 8 - 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, according to which for an aggregate subscription price of up to \$5,000, 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 (a) purchase 1,344,444 shares of Common Stock at an exercise price of \$4.35 per share. The warrants may be exercised at any time and expire on November 5, 2013. In May 2012, the warrants were extended by an additional 18 months, through May 5, 2015. In May 2014, the warrants were extended by an additional 18 months, through November 5, 2017.

In January 2011, the Company and the investor signed an agreement to balance the remaining amount due to the investor, totaling \$20, against the remaining balance of the investment and the Company issued the above shares and warrants.

In addition, the Company issued an aggregate of 83,333 shares of Common Stock to a related party as an introduction fee for the investment. As of the balance sheet date, no warrants have been exercised.

(b) In February 2010, the Company issued an aggregate of 399,999 shares of Common Stock to three investors (133,333 to each investor) and warrants to purchase an aggregate of 199,998 shares of Common Stock (66,666 to each investor) with an exercise price of \$7.50 per share for aggregate proceeds of \$1,500 (\$500 from each investor).

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 8 - STOCK CAPITAL (Cont.):

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

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

On July 17, 2012, the Company raised \$5,700 in gross proceeds through a public offering (“2012 Public Offering”) of its Common Stock. The Company issued a total of 1,321,265 shares of Common Stock, (\$4.35 per share) and (c)990,949 warrants to purchase 0.75 shares of Common Stock for every share purchased in the 2012 Public Offering, at an exercise price of \$4.35 per share. The Warrants are exercisable until the 30 month anniversary of the date of issuance.

After deducting closing costs and fees, the Company received net proceeds of approximately \$4,900.

The Company paid to the Placement Agency, Maxim Group LLC (the “Placement Agent”), a cash fee and a corporate finance fee equal to 7% of the gross proceeds of the 2012 Public Offering. In addition, the Company issued to the Placement Agent a two year warrant to purchase up to 32,931 shares of Common Stock (equal to 3% of the number of shares sold in the 2012 Public Offering), with an exercise price equal to \$5.22 (120% of the 2012 Public Offering price). The Warrants are exercisable until the 30 month anniversary of the date of issuance. In addition, the Company issued to Leader Underwriters (1993) Ltd, warrants to purchase 15,517 shares of Common Stock, at an exercise price of \$4.35 per share. The warrants are exercisable until the 30 month anniversary of the date of issuance.

On February 4, 2013, the Company issued 8,408 shares of Common Stock to an investor, according to a settlement (d) 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 February 7, 2013, the Company issued 55,556 units to a private investor for total proceeds of \$250. Each unit (e) consisted of one share of Common Stock and a warrant to purchase one share of Common Stock at \$7.50 per share exercisable for 32 months.

On August 16, 2013, the Company raised \$4,000 (gross) through a registered public offering (“2013 Public Offering”) of its Common Stock. The Company issued a total of 1,568,628 shares of Common Stock, (\$2.55 per share) and 1,176,471 warrants (the “2013 Warrants”) to purchase 0.75 shares of Common Stock for every share purchased in the 2013 Public Offering, at an exercise price of \$3.75 per share. The Warrants are exercisable until the 36 month anniversary of the date of issuance. The Warrants also include, subject to certain exceptions, full (f) 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. In the event of a sale of the Company, each holder of Warrants has the right, exercisable at its option, to require the Company to purchase such holder’s Warrants at a price determined using a Black-Scholes option pricing model as described in 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 Stock of 2,496 were recorded to equity.



BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

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Notes to Consolidated Financial Statements

NOTE 8 - STOCK CAPITAL (Cont.):

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

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

On April 25, 2014, the Company entered into agreements with certain holders of warrants originally issued in the Company's August 16, 2013 public offering (the "2013 Warrants") to exchange outstanding 2013 Warrants entitling the holders to purchase an aggregate of 777,471 shares of Company Common Stock for an aggregate of 388,735 unregistered shares of Common Stock. After the exchange, the 2013 Warrants were cancelled and of no further force and effect.

On May 27, 2014, the Company entered into agreements with certain holders of 2013 Warrants to repurchase outstanding 2013 Warrants entitling the holders to purchase an aggregate of 333,235 shares of Company Common Stock for an aggregate of approximately \$600. Each share of Common Stock issuable pursuant to the 2013 Warrants was repurchased for a \$1.80 cash payment by the Company per Warrant Share. Warrants participating in the Redemption were cancelled and of no further force and effect.

In May 2014, certain holders of 2013 Warrants which did not participate in the Redemption have waived anti-dilution provisions of their 2013 Warrants.

In July 2014, the Company signed an amendment with certain holders of 2013 Warrants that did not participate in the Redemption, to adjust the exercise price of the warrants to \$0.525 per share.

As of December 31, 2014, the fair value of 2013 Warrants that were presented as a liability at its fair value was \$123.

After the balance sheet date, the 2013 Warrants were exercised to Common Stock of the Company and the liability was cancelled. (See Note 12(A)).

On June 19, 2014, the Company, pursuant to the June 13, 2014 securities purchase agreement, entered into with a group of investors, including several healthcare-focused funds, effected a private placement of the Company's Common Stock and warrants to purchase Common Stock. The Company received gross proceeds of \$10.5 million, (g) resulting from the issuance and sale of 2.8 million shares of Common Stock at a price per share of \$3.75, a 15% discount to the 30 day volume-weighted average price of \$4.41. The Investors received warrants to purchase up to 2.8 million shares of Common Stock at an exercise price of \$5.22 per share. The Warrants became exercisable immediately upon closing of the private placement and have a term of three (3) years.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 8 - STOCK CAPITAL (Cont.):

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

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

(a) Options to employees and 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 date of the respective option.

The 2004 and 2005 option plans will expire 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, and the reservation of 600,000 shares of Common Stock for issuance in the aggregate under these stock plans.

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. The options vest primarily over three years. 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 53,333 (in total) 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 after the grant date.

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.

Such options and warrants will vest and become exercisable in twelve (12) consecutive equal monthly amounts.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 8 - STOCK CAPITAL (Cont.):

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

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

(a) Options to employees and directors: (Cont.):

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 Hadasit Agreement 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 Hadasit Agreement ceased to vest, and 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. In October 2014, 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 an option to purchase 26,667 shares of Common Stock at an exercise price of \$2.25 per share. The options are fully vested and are exercisable for a period of 10 years. The compensation related to the option, in the amount of \$78, was recorded as general and administrative expense.

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. The total compensation related to the option was \$105, which is amortized over the vesting period as general and administrative expense.

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. The total compensation expense related to the options of \$95 was recorded as general and administrative expense.

On June 6, 2014, the Company entered into an employment agreement which sets forth the terms of the COO's employment. The COO also was granted a stock option under the Company's Amended and Restated 2004 Global Share Option Plan for the purchase of 33,333 shares of the Company's Common Stock, which was fully vested and exercisable upon grant. The exercise price for the initial grant is \$2.70 per share. The total related compensation expense, in the amount of \$55 was recorded as general and administrative expense.

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U.S. dollars in thousands

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Notes to Consolidated Financial Statements

NOTE 8 - STOCK CAPITAL (Cont.):

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

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

(a) Options to employees and directors: (Cont.):

On June 9, 2014, the Company hired the new CEO. The CEO was granted a stock option for the purchase of 380,000 shares of the Company's Common Stock, which shall vest and become exercisable as to 25% of the shares on the first anniversary of the grant date and the remainder of the shares shall vest and become exercisable in equal monthly installments on each of the 36 monthly anniversaries following the initial vesting date. The exercise price for the CEO Grant is \$4.50 per share. The total related compensation expense, in the amount of \$1,494 will be recorded as general and administrative expense.

On November 1, 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. As of December 31, 2014, the compensation expense related to the options of \$143 was recorded as general and administrative expense.

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

| For the year ended<br>December 31, 2014 |                                 |                                 | For the year ended<br>December 31, 2013 |                                 |                                 |
|---|---------------------------------|---------------------------------|---|---------------------------------|---------------------------------|
| Amount of<br>options                    | Weighted<br>average<br>exercise | Aggregate<br>intrinsic<br>value | Amount of<br>options                    | Weighted<br>average<br>exercise | Aggregate<br>intrinsic<br>value |

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|  |           | price  |           |            | price  |        |
|--|-----------|--------|-----------|------------|--------|--------|
|  |           | \$     | \$        |            | \$     | \$     |
| Outstanding at beginning of period           | 412,388   | 2.5576 |           | 316,777    | 2.7045 |        |
| Granted                                      | 504,000   | 3.6766 |           | 381,777    | 3.7380 |        |
| Exercised                                    | (66,500 ) | 2.1250 |           | (1,333 )   | 1.0050 |        |
| Cancelled                                    | (57,778 ) | 0.5198 |           | (284,833 ) | 4.3095 |        |
| Outstanding at end of period                 | 792,110   | 3.4545 | 1,034,072 | 412,388    | 2.5575 | 58,765 |
| Vested and expected-to-vest at end of period | 331,500   | 2.6994 | 683,088   | 335,795    | 2.5680 | 44,325 |

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 December 31, 2014 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2014.



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Notes to Consolidated Financial Statements

## NOTE 8 - STOCK CAPITAL (Cont.):

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

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

## a) Options to employees and directors: (Cont.)

The options outstanding as of December 31, 2014 and December 31, 2013, have been separated into exercise prices, as follows:

| Exercise price<br>\$ | Options<br>outstanding<br>as of<br>December 31,<br>2013 | Options<br>outstanding as<br>of<br>December 31,<br>2014 | Weighted average<br>remaining<br>contractual<br>Life - Years<br>As of December 31, |      | Options exercisable as of<br>December 31, |         |
|----------------------|---|---|--|------|---|---------|
|                      |   |   | 2013   | 2014 | 2013                                      | 2014    |
| 0.0075               | 44,444  | -   | 7.29   | -    | 40,741                                    | -       |
| 0.7500               | -   | 70,666  | -  | 9.84 | -   | 26,500  |
| 1.005                | 6,445   | 6,445   | 5.50   | 4.50 | 6,445                                     | 6,445   |
| 2.250                | 173,667   | 160,333   | 6.86   | 5.85 | 163,444                                   | 160,333 |
| 2.700                | 105,333   | 130,666   | 8.57   | 7.96 | 42,666                                    | 94,222  |
| 3.000                | 33,833  | -   | 7.51   | -    | 33,833                                    | -       |
| 3.900                | 23,666  | 19,000  | 8.59   | 7.59 | 23,666                                    | 19,000  |
| 4.500                | -   | 380,000   | -  | 9.44 | -   | 0       |
| 4.800                | 2,000   | 2,000   | 6.12   | 5.12 | 2,000                                     | 2,000   |
| 5.850                | 6,000   | 6,000   | 3.5  | 2.50 | 6,000                                     | 6,000   |
| 6.000                | 6,000   | 6,000   | 2.47   | 1.47 | 6,000                                     | 6,000   |
| 7.050                | 6,000   | 6,000   | 3.22   | 2.22 | 6,000                                     | 6,000   |
| 11.25                | 5,000   | 5,000   | 1.16   | 0.16 | 5,000                                     | 5,000   |

|         |         |       |       |         |         |
|---------|---------|-------|-------|---------|---------|
| 412,388 | 792,110 | 7.236 | 8.183 | 335,795 | 331,500 |
|---------|---------|-------|-------|---------|---------|

Compensation expense recorded by the Company in respect of its stock-based employee compensation awards in accordance with ASC 718-10 for the year ended December 31, 2014 and 2013 amounted to \$1,024 and \$674, respectively.

The fair value of the options is estimated at the date of grant using Black-Scholes options pricing model with the following assumptions used in the calculation:

|                                | <b>Year ended December 31,</b> |             |
|--------------------------------|--------------------------------|-------------|
|                                | <b>2014</b>                    | <b>2013</b> |
| Expected volatility            | 122%-123%                      | 121%        |
| Risk-free interest             | 1.49%-1.96%                    | 0.86%       |
| Dividend yield                 | 0%                             | 0%          |
| Expected life of up to (years) | 5.76-6.05                      | 5.4         |

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 8 - STOCK CAPITAL (Cont.):

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

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

(b) Restricted shares to directors:

On August 22, 2011, the Company entered into an agreement with Chen Schor pursuant to which the Company granted to Mr. Schor 61,558 shares of restricted Common Stock of the Company. The shares will vest over 3 years - 1/3 upon each anniversary of the grant date. In addition, the Company will pay \$15 per quarter to Mr. Schor for his services as an Executive Board Member.

On April 19, 2013, 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 will vest in 12 equal monthly portions until fully vested on the anniversary of grant. Related compensation expense in the amount of \$175 was recorded as general and administrative expense.

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 will vest in 12 equal monthly portions until fully vested on the anniversary of grant. Related compensation expense in the amount of \$236 will be recorded as general and administrative expense.

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

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 during 2012, 2013 and 2014 using the Black-Scholes calculation.

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES**

U.S. dollars in thousands

(Except share data and exercise prices)

**Notes to Consolidated Financial Statements**

## NOTE 8 - 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 and investors:(Cont.)**

| <b>Issuance date</b>      | <b>Number of warrants issued</b> | <b>Exercised</b> | <b>Forfeited</b> | <b>Outstanding</b> | <b>Exercise Price \$</b> | <b>Warrants exercisable</b> | <b>Exercisable through</b> |
|---------------------------|----------------------------------|------------------|------------------|--------------------|--------------------------|-----------------------------|----------------------------|
| <b>Nov-Dec 2004</b>       | 973,390                          | 959,734          | 13,656           | -                  | 0.00075 - 0.15           | -                           | -                          |
| <b>Feb-Dec 2005</b>       | 203,898                          | 32,011           | 169,887          | 2,000              | 2.25 - 37.5              | 2,000                       | Jun - Dec 2015             |
| <b>Feb-Dec 2006</b>       | 112,424                          | 48,513           | 31,911           | 32,000             | 0.075 – 22.5             | 32,000                      | Feb - May 2016             |
| <b>Mar-Nov 2007</b>       | 180,220                          | -                | 66,887           | 113,333            | 2.25 - 7.05              | 113,333                     | Mar 2017 – Oct 2017        |
| <b>Nov 2008</b>           | 6,667                            | -                | -                | 6,667              | 2.25                     | 6,667                       | Sep-18                     |
| <b>Apr-Oct 2009</b>       | 26,667                           | 6,667            | -                | 20,000             | 1.005 – 1.5              | 20,000                      | Apr 2019 – Oct 2019        |
| <b>Aug 2007- Jan 2011</b> | 2,016,667                        | -                | -                | 2,016,667          | 3 - 4.35                 | 2,016,667                   | Nov-17                     |
| <b>Jan 2010</b>           | 83,333                           | -                | 83,333           | -                  | 7.5                      | -                           | -                          |
| <b>Feb 2010</b>           | 8,333                            | 8,333            | -                | -                  | 0.15                     | -                           | -                          |
| <b>Feb 2010</b>           | 200,000                          | -                | 200,000          | -                  | 7.5                      | -                           | -                          |
| <b>Feb 2010</b>           | 100,000                          | -                | -                | 100,000            | 0.015                    | 100,000                     | Feb-20                     |
| <b>Feb 2011</b>           | 42,735                           | -                | 42,735           | -                  | 5.85                     | -                           | -                          |
| <b>Feb 2011</b>           | 427,167                          | 63,122           | 364,044          | -                  | 4.2                      | -                           | -                          |
| <b>Feb 2011</b>           | 854,333                          | -                | 854,333          | -                  | 7.5                      | -                           | -                          |
| <b>Jul 2012</b>           | 32,931                           | -                | 32,931           | -                  | 5.22                     | -                           | -                          |
| <b>Jul 2012</b>           | 990,949                          | 150,651          | -                | 840,297            | 4.35                     | 840,297                     | Jan-15                     |
| <b>Feb 2013</b>           | 55,556                           | -                | -                | 55,556             | 7.5                      | 55,556                      | Oct-15                     |

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|                        |            |           |           |           |         |           |        |
|------------------------|------------|-----------|-----------|-----------|---------|-----------|--------|
| <b>April 2010-2014</b> | 12,889     | 8,889     | 4,000     | -         | 0.00075 | 8,889     |        |
| <b>Aug 2013</b>        | 1,147,471  | -         | 1,110,706 | 36,765    | 3.75    | 36,765    | Aug-16 |
| <b>Aug 2013</b>        | 29,000     | -         | -         | 29,000    | 0.525   | 29,000    | Aug-16 |
| <b>Jun 2014</b>        | 2,800,000  | -         | -         | 2,800,000 | 5.22    | 2,800,000 | Jun-17 |
| <b>Jun 2014</b>        | 84,000     | -         | -         | 84,000    | 4.5     | 84,000    | Jun-17 |
|                        | 10,388,628 | 1,277,921 | 2,974,423 | 6,136,284 |         | 6,136,284 |        |

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 8 - 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 shall vest over the course of the trials as follows: 33,333 upon enrollment of 1/3 of the patients; an additional 33,333 upon enrollment of all the patients and the final 33,333 upon completion of the study.

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. As of December 31, 2014, related compensation expense in the amount of \$50 was recorded as general and administrative expense.



BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

## NOTE 8 - STOCK CAPITAL (Cont.):

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

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

(b) Shares: (Cont.):

A summary of the Company's stock awards activity related to shares issued to service providers and related information is as follows:

|                                    | Year ended<br>December 31,<br>2014 | Weighted<br>Amount of average<br>shares issue<br>price<br>\$ | Year ended<br>December 31,<br>2013 | Weighted<br>Amount of average<br>shares issue<br>price<br>\$ |
|------------------------------------|------------------------------------|--|------------------------------------|--|
| Outstanding at beginning of period | 840,367                            | 4.02   | 786,387                            | 4.05   |
| Issued                             | 23,419                             | 4.91   | 53,980                             | 3.60   |
| Outstanding at end of period       | 863,786                            | 4.07   | 840,367                            | 4.02   |

Stock-based compensation and issuance of shares recorded by the Company in respect of shares and warrants granted to service providers amounted to \$198 and \$197 for the years ended December 31, 2014 and 2013, respectively.

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

|  | Year ended<br>December<br>31, |      |
|--|-------------------------------|------|
|  | 2014                          | 2013 |
| Research and development               | 176                           | 105  |
| General and administrative             | 1,046                         | 767  |
| Total stock-based compensation expense | 1,222                         | 872  |

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 9 - RESEARCH AND DEVELOPMENT, NET

|   | Year ended<br>December 31, |         |
|---|----------------------------|---------|
|   | 2014                       | 2013    |
|   | U.S. \$ in<br>thousands    |         |
| Research and development  | 6,116                      | 4,030   |
| Less : Participation by the Israeli Office of the Chief Scientist | (1,344)                    | (1,113) |
|   | 4,772                      | 2,917   |

NOTE 10 - TAXES ON INCOME

A. Tax rates applicable to the income of the Israeli subsidiary:

BCT is subject to a tax rate of 25% in 2013 and 26.5% in 2014 and thereafter, in accordance with the Tax Burden Distribution Law of 2011 as well as subsequent legislation by the Israeli Knesset (Israeli parliament) in August 2013.

Such tax rate changes have no significant impact on the Company's financial statements.

The Company is subject to a blended US tax rate (Federal as well as State Corporate Tax) of 35% in 2013, 2014 and thereafter.

B. Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

|   | December 31,         |         |
|---|----------------------|---------|
|   | 2014                 | 2013    |
|   | U.S. \$ in thousands |         |
| Operating loss carryforward                       | 29,222               | 25,156  |
| Net deferred tax asset before valuation allowance | 10,994               | 8,961   |
| Valuation allowance                               | (10,994)             | (8,961) |
| Net deferred tax asset                            | -                    | -       |

As of December 31, 2014, the Company has provided valuation allowances of \$10,994 in respect of deferred tax assets resulting from tax loss carryforward and other temporary differences. Management currently believes that because the Company has a history of losses, it is more likely than not that the deferred tax regarding the loss carryforward and other temporary differences will not be realized in the foreseeable future.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 10 - TAXES ON INCOME (Cont.):

C. Available carryforward tax losses:

As of December 31, 2014, the Company has an accumulated tax loss carryforward of approximately \$29,222. Carryforward tax losses in Israel are of unlimited duration and carryforward tax losses in the U.S. can be carried forward and offset against taxable income in the future for a period of 20 years. Utilization of U.S. net operating losses may be subject to substantial annual limitations due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

D. Loss from continuing operations, before taxes on income, consists of the following:

|               | Year ended December 31, |          |
|---------------|-------------------------|----------|
|               | 2014                    | 2013     |
|               | U.S. \$ in thousands    |          |
| United States | (3,789 )                | (1,205 ) |
| Israel        | (5,457 )                | (3,694 ) |
|               | (9,246 )                | (4,899 ) |

E. Due to the Company's cumulative losses, the effect of ASC 740 as codified from ASC 740-10 (formerly FIN 48) is not material.

NOTE 11 - TRANSACTIONS WITH RELATED PARTIES

Year ended December  
31,

|   | 2014                 | 2013 |
|---|----------------------|------|
|   | U.S. \$ in thousands |      |
| Fees and related benefits and compensation expenses in respect of options granted to a member of the Board who is a related party | 164                  | 248  |

## NOTE 12 - SUBSEQUENT EVENTS

On January 6, 2015, the remaining 2013 Warrants that did not participate in the redemption and 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.

Pursuant to a Warrant Exercise Agreement, dated January 8, 2015, holders of the Company warrants to purchase an aggregate of approximately 2.5 million shares of the Company's Common Stock at an exercise price of \$5.22 per share, issued in a private placement to accredited investors that was consummated on June 13, 2014, 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 Company received an aggregate of approximately \$13 million in proceeds from the exercises of the 2014 Warrants. 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.

**Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**Item 9A. CONTROLS AND PROCEDURES.**

*Disclosure Controls and Procedures*

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of December 31, 2014 were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that the information 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.

*Management's Report on Internal Control Over Financial Reporting*

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2014. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated 1992 Framework.

Based on our assessment, management concluded that, as of December 31, 2014, the Company's internal control over financial reporting is effective based on those criteria.

#### *Changes in Internal Control Over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



**Item 9B. OTHER INFORMATION.**

None.

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**PART III****Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.****Executive Officers and Directors**

The following table lists our current executive officers and directors. Our executive officers are elected annually by our Board of Directors and serve at the discretion of the Board of Directors. Each current director is serving a term that will expire at our Company's next annual meeting. There are no family relationships among any of our directors or executive officers.

| <b>Name</b>        | <b>Age</b> | <b>Position</b>                      |
|--------------------|------------|--------------------------------------|
| Dr. Tony Fiorino   | 47         | Chief Executive Officer              |
| Chaim Lebovits     | 44         | President                            |
| Liat Sossover      | 46         | Chief Financial Officer              |
| Uri Yablonka       | 38         | Chief Operating Officer and Director |
| Dr. Irit Arbel     | 55         | Chairperson and Director             |
| Mordechai Friedman | 62         | Director                             |
| Alon Pinkas        | 53         | Director                             |
| Chen Schor         | 42         | Director                             |
| Dr. Robert Shorr   | 61         | Director                             |
| Malcolm Taub       | 69         | Director                             |

**Dr. Tony Fiorino** joined the Company on June 9, 2014 as Chief Executive Officer. Dr. Fiorino is an experienced biotechnology executive, entrepreneur and investor with expertise in clinical drug development, biotechnology finance and portfolio management. Dr. Fiorino joined Brainstorm from Greywall Asset Management, where he was a Managing Director and served as a biopharmaceuticals analyst from January 2013, when the fund launched, through May 2014. In March 2008, Dr. Fiorino founded a start-up biotechnology company, EnzymeRx, and served as President and Chief Executive Officer. At EnzymeRx, Dr. Fiorino successfully developed pegylated uricase through Phase 2 studies and led its sale to 3SBio. After closing this transaction in November 2010, Dr. Fiorino served as a consultant to several biotechnology and pharmaceutical companies until joining Greywall. Before founding EnzymeRx, Dr. Fiorino was a biotechnology analyst and portfolio manager for healthcare hedge funds at Pequot Capital and Sands Point Partners and at Citigroup Asset Management, and a sell-side pharmaceuticals equity research analyst at JP Morgan. Dr. Fiorino received his MD and PhD from the Albert Einstein College of Medicine and a BS in Biology from the Massachusetts Institute of Technology, and trained in medicine and dermatology at the Hospital of the University of Pennsylvania.

**Chaim Lebovits** joined the Company in July 2007 as President. On August 1, 2013, the Company appointed Mr. Lebovits as its Principal Executive Officer, and to assume the duties and responsibilities of the Chief Executive Officer on an interim basis until Tony Fiorino was appointed to be Chief Executive Officer in June 2014. Mr. Lebovits controls ACC Holdings International, and its subsidiaries ACC Resources, specializing in the mining, oil and energy industries, and ACC BioTech, which is focused on biotechnology. He has been at the forefront of mining and natural resource management in the African region for over a decade and has spent years leading the exploration and development of resources in West Africa and Israel and served as a member of the board of directors of several companies in the industry. Mr. Lebovits has also held senior positions for the worldwide Chabad Lubavitch organization, the largest Jewish organization in the world today.

**Liat Sossover** joined the Company in June 2010 as our Chief Financial Officer. From 2001 until June 2010, Ms. Sossover served as the Vice President of Finance of ForeScout Technologies, an international high tech company in the network security solutions field. In such role, Ms. Sossover managed all financial and accounting aspects. Prior to that, Ms. Sossover served as VP of Finance and Secretary of Maximal Innovative Intelligence, a high tech company in the field of business intelligence solutions, which was acquired by Microsoft. She has held positions as Chief Financial Officer at Real Time Synthesized Entertainment Technology Ltd (RT-Set), currently known as Vizrt Ltd., a publicly traded company in Norway. Vizrt provides real-time 3D graphics and asset management tools for the broadcast industry. Ms. Sossover served as Financial Controller for BVR Systems (1998), Ltd., currently known as RVB Holdings Ltd., a company that is traded on Nasdaq, which develops, manufactures and markets simulation systems for military applications, which was later acquired by Elbit Systems. Ms. Sossover holds an MBA from Edinburgh University, and a Bachelor's degree in Accounting & Economics from Ben Gurion University.

**Uri Yablonka** joined the Company on June 6, 2014 as Chief Operating Officer and as a member of the Board of Directors. Prior to joining the Company, Mr. Yablonka served since December 2010 as owner and General Manager of Uri Yablonka Ltd., a business consulting firm. He also served since January 2011 as Vice President, Business Development at ACC International Holdings Ltd. (Holdings). Holdings is also an affiliate of ACCBT Corp. Prior to serving with Holdings, Mr. Yablonka served as Senior Partner of PM-PR Media Consulting Ltd. From 2008 to January 2011, Mr. Yablonka was Senior Partner at PM-PR Media Consulting Ltd., where he led public relations and strategy consulting for a wide range of governmental and private organizations. From 2002 to 2008, he served as a correspondent at the Maariv Daily News Paper, including extensive service as a Diplomatic Correspondent. We believe that Mr. Yablonka's skills and experience provide the variety and depth of knowledge, judgment and vision necessary for the effective oversight of the Company. His experience in business consulting and development and media experience are expected to be valuable to the Company in its current stage of growth and beyond, and his governmental experience can provide valuable insight into issues faced by companies in regulated industries such as ours. We believe that these skills and experiences qualify Mr. Yablonka to serve as a director of the Company.

**Dr. Irit Arbel**, one of Brainstorm's co-founders, joined the Company in May 2004 as a director and served as President of the Company for six months. Currently, Dr. Arbel is the Chair of the Governance, Nominating and Compensation Committee. Dr. Arbel serves as Executive Vice President, Research and Development at Savicell Diagnostic Ltd. since July 2012. Savicell Diagnostic Ltd. is a biotechnology company and is a wholly-owned subsidiary of Online Disruptive Technologies, Inc. From 2009 through 2011, Dr. Arbel served as Chairperson of Real Aesthetics Ltd., a company specializing in cellulite ultrasound treatment, and BRH Medical, developer of medical devices for wound healing. She was also Director of M&A at RFB Investment House, a private investment firm focusing on early stage technology related companies. Previously, Dr. Arbel was President and Chief Executive Officer of Pluristem Life Systems, a biotechnology company, and prior to that, Israeli Sales Manager of Merck, Sharp & Dohme, a pharmaceutical company. Dr. Arbel earned her Post Doctorate degree in 1997 in Neurobiology, after performing research in the area of Multiple Sclerosis. Dr. Arbel also holds a Chemical Engineering degree from the Technion, Israel's Institute of Technology. We believe that Dr. Arbel possesses specific attributes that qualify her to serve on our Board of Directors including Dr. Arbel's extensive experience in the biotechnology field and significant leadership skills as a chief executive officer. Dr. Arbel previously served as our President, which service has given her a deep knowledge of the Company and its business and directly relevant management experience.

**Mordechai Friedman** joined the Company on April 4, 2011 as a director and as Chair of the Audit Committee of the Board. Mr. Friedman currently serves as Chairman of IPM Beer Tuvia Ltd. and Vice-Chairman of Triple-M Power Plants Ltd. From 2013 to 2014, Mr. Friedman served as Chief Executive Officer of Israel Financial Levers Ltd, an Israeli real estate company traded on the Tel-Aviv Stock Exchange. From 2007 through 2010, Mr. Friedman served as the Chairman of the Board of The Israel Electric Corp., an electric utility company. From 2005 to 2007, Mr. Friedman served as Deputy Chairman of Brightman Almagor Zohar CPAs, the Israel Member Firm of Deloitte Touché Tohmatsu. Mr. Friedman has been a partner and director in several business ventures and companies in Israel and abroad in the transportation, consumer business, telecommunication and energy industries. Mr. Friedman currently serves as a director in the following public companies: (traded on the Tel-Aviv Stock Exchange): (i) Elco Holdings Ltd. (Chairman of the Board); and (ii) Carmel Olefins Ltd. Mr. Friedman holds a B.A. in Economics and Accounting from Tel Aviv University. We believe that Mr. Friedman possesses specific attributes that qualify him to serve on our Board of Directors including Mr. Friedman's considerable experience in accounting and valuable leadership skills as a chief executive officer.

**Alon Pinkas** joined the Company on December 13, 2010 as a director. Mr. Pinkas served as the Israeli Consul General to New York from 2000 to 2004 and is an internationally respected foreign affairs analyst. Mr. Pinkas currently serves as an Adviser at Tigris Financial Group, a financial services company, and the Rhodium Group, an advisory firm, and as a director for Ormat Industries Limited, B.G.I. Investments (1961) Ltd. and Agri-Invest Ltd. Mr. Pinkas has a B.S. in Political Science from The Hebrew University of Jerusalem and a Masters Degree in Politics from Georgetown University. We believe that Mr. Pinkas possesses specific attributes that qualify him to serve on our Board of Directors including Mr. Pinkas' considerable experience in foreign affairs. Mr. Pinkas also has substantial leadership and government experience from his service as the Consul General of Israel to New York and as chief of staff to Ministers of Foreign Affairs of Israel.

**Chen Schor** joined the Company as a director on August 22, 2011. Mr. Schor is a global industry leader with vast experience in biotechnology, medical devices, business development and private equity. Mr. Schor led multiple licensing and M&A transactions valued at over \$8 billion with companies such as GlaxoSmithKline, Amgen, Pfizer, Bayer, Merck-Serono and OncoGeneX Pharmaceuticals, and raised significant funds from reputable investors. Mr. Schor has a broad range of experience in multiple therapeutic areas including Neurology, Respiratory, Oncology, Auto-Immune, Genetic Diseases, and Women's Health. In addition to leading the global business development at Teva Pharmaceuticals, Mr. Schor played a key role in building early stage companies to regulatory approvals, IPOs and M&As. Since December 2014, Mr. Schor has served as Executive Vice President and Chief Operating Officer of Synta Pharmaceuticals Corp., a NASDAQ listed biopharmaceutical company. From March 2009 until September 2011, Mr. Schor served as Vice President of Business Development, global branded products at Teva Pharmaceuticals. Prior to joining Teva, Mr. Schor was Chief Business Officer at Epix Pharmaceuticals, Inc. (formerly known as Predix Pharmaceuticals, Inc.) from December 2003 until March 2009, leading the formation of more than \$1.5 billion in collaborations with GlaxoSmithKline, Amgen and additional pharmaceutical companies. Prior to joining Epix, Mr. Schor was a Partner at Yozma Venture Capital from September 1998 until December 2003, managing the fund's investments in biotechnology and medical device companies. Mr. Schor previously held positions at Arthur Anderson and BDO Consulting, an advisory firm. Mr. Schor holds an M.B.A., a B.A. in Biology, a B.A. in Economics and is a Certified Public Accountant. We believe that Mr. Schor possesses specific attributes that qualify him to serve on our Board of Directors including Mr. Schor's extensive experience in biotechnology and significant leadership skills from his service as a partner of a venture capital firm.

**Dr. Robert Shorr** joined the Company in March 2005 as a director. Since 1999, Dr. Shorr has served as Chief Executive Officer and Chief Science Officer of Cornerstone Pharmaceuticals, a biotechnology company. He has also been a member of the Department of Biomedical Engineering at SUNY Stony Brook, where he also serves as Director of Business Development for the University's Center for Advanced Technology. He has served as trustee at the Tissue Engineering Charities, Imperial College, London. From 1999 until 2005, Dr. Shorr was Vice-President of Science and Technology (CSO) of United Therapeutics, a NASDAQ listed biotechnology company. Prior to 1998, he was Vice President, Research and Development at Enzon, Inc., a NASDAQ listed pharmaceuticals company, and AT Biochem, a pharmaceuticals company, of which he was also founder. Dr. Shorr also served on the Board of Directors of Biological Delivery Systems Inc., a NASDAQ listed company. Dr. Shorr holds both a Ph.D. and a D.I.C. from the University of London, Imperial College of Science and Technology as well as a B.Sc. from SUNY Buffalo. We believe that Dr. Shorr possesses specific attributes that qualify him to serve on our Board of Directors including Dr. Shorr's extensive experience in biotechnology and valuable leadership skills as a chief executive officer.

**Malcolm Taub** joined the Company in March 2009 as a director. Since October 2010, Mr. Taub has been a Partner at Davidoff Malito & Hatcher LLP, a full service law and government relations firm. From 2001 to September 30, 2010, Mr. Taub was the Managing Member of Malcolm S. Taub LLP, a law firm which practiced in the areas of commercial litigation, among other practice areas. Mr. Taub also works on art transactions, in the capacity as an attorney and a consultant. Mr. Taub has also served as a principal of a firm which provides consulting services to private companies going public in the United States. Mr. Taub has acted as a consultant to the New York Stock Exchange in its Market Surveillance Department. Mr. Taub acts as a Trustee of The Gateway Schools of New York and The Devereux Glenholme School in Washington, Connecticut. Mr. Taub has served as an adjunct professor at Long Island University, Manhattan Marymount College and New York University Real Estate Institute. Mr. Taub holds a B.A. from Brooklyn College and a J.D. from Brooklyn Law School. Mr. Taub formerly served on the Board of Directors of Safer Shot, Inc. (formerly known as Monumental Marketing Inc.). We believe that Mr. Taub possesses specific

attributes that qualify him to serve on our Board of Directors including Mr. Taub's vast law experience and his demonstrated leadership skills as a managing member of a law firm.

## Qualifications of Directors

The Board believes that each director has valuable individual skills and experiences that, taken together, provide the variety and depth of knowledge, judgment and vision necessary for the effective oversight of the Company. As indicated in the foregoing biographies, the directors have extensive experience in a variety of fields, including biotechnology (Drs. Arbel and Shorr and Mr. Schor), accounting (Mr. Friedman), health care and health policy (Dr. Israeli), foreign affairs (Mr. Pinkas), business consulting and development (Mr. Yablonka), media (Mr. Yablonka) and law (Mr. Taub), each of which the Board believes provides valuable knowledge about important elements of our business. Most of our directors have leadership experience at major companies or firms with operations inside and outside the United States and/or experience on other companies' boards, which provides an understanding of ways other companies address various business matters, strategies and issues. As indicated in the foregoing biographies, the directors have each demonstrated significant leadership skills, including as a chief executive officer (Drs. Arbel and Shorr and Mr. Friedman), as the consul general of Israel to New York and as chief of staff to Ministers of Foreign Affairs of Israel (Mr. Pinkas), as the director general of a governmental body (Dr. Israeli), as a managing member of a law firm (Mr. Taub), as general manager of a business consulting firm (Mr. Yablonka) or as a partner of a venture capital firm (Mr. Schor). A number of the directors have extensive public policy, government or regulatory experience, including Consul General of Israel, New York (Mr. Pinkas) and Director General of Israel Ministry of Health (Dr. Israeli), which can provide valuable insight into issues faced by companies in regulated industries such as the Company. One of the directors (Dr. Arbel) has served as the President of the Company and one is currently serving as Chief Operating Officer (Mr. Yablonka), which service has given each a deep knowledge of the Company and its business and directly relevant management experience. The Board believes that these skills and experiences qualify each individual to serve as a director of the Company.

## Certain Arrangements

On August 22, 2011, we entered into an agreement with Chen Schor, which was amended and restated on November 11, 2011 to clarify vesting terms (as amended and restated, the "Executive Director Agreement") pursuant to which we pay \$15,000 per quarter to Mr. Schor for his services as an Executive Board Member. In accordance with the terms of the Executive Director Agreement, the Company and Mr. Schor have also entered into an amended and restated Restricted Stock Agreement on November 11, 2011, pursuant to which Mr. Schor received 61,558 shares of our restricted Common Stock under our 2005 U.S. Stock Option and Incentive Plan. The shares vested over 3 years – 20,519 shares on August 22, 2012, 20,519 shares on August 22, 2013 and 20,519 shares on August 22, 2014. Mr. Schor is not entitled to any other compensation for his services as a director.



## **Involvement in Certain Legal Proceedings**

None of our directors or executive officers has during the past ten years:

· been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

· had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;

· been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;

· been found by a court of competent jurisdiction in a civil action or by the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

· been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

· been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act, any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

## **Committees of the Board of Directors**

### *Audit Committee*

On February 7, 2008, the Board of Directors established a standing Audit Committee in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, which assists the Board of Directors in fulfilling its responsibilities to stockholders concerning our financial reporting and internal controls, and facilitates open communication among the Audit Committee, Board of Directors, outside auditors and management. The Audit Committee discusses with management and our outside auditors the financial information developed by us, our systems of internal controls and our audit process. The Audit Committee is solely and directly responsible for appointing, evaluating, retaining and, when necessary, terminating the engagement of the independent auditor. The

independent auditors meet with the Audit Committee (both with and without the presence of management) to review and discuss various matters pertaining to the audit, including our financial statements, the report of the independent auditors on the results, scope and terms of their work, and their recommendations concerning the financial practices, controls, procedures and policies employed by us. The Audit Committee preapproves all audit services to be provided to us, whether provided by the principal auditor or other firms, and all other services (review, attest and non-audit) to be provided to us by the independent auditor. The Audit Committee coordinates the Board of Directors' oversight of our internal control over financial reporting, disclosure controls and procedures and code of conduct. The Audit Committee is charged with establishing procedures for (i) the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters; and (ii) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters. The Audit Committee reviews all related party transactions on an ongoing basis, and all such transactions must be approved by the Audit Committee. The Audit Committee is authorized, without further action by the Board of Directors, to engage such independent legal, accounting and other advisors as it deems necessary or appropriate to carry out its responsibilities. The Board of Directors has adopted a written charter for the Audit Committee, which is available in the corporate governance section of our website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com). The Audit Committee currently consists of Mr. Friedman (Chair), Dr. Arbel and Mr. Pinkas each of whom is independent within the meaning of The NASDAQ Marketplace Rules and Rule 10A-3 under the Exchange Act. The Board of Directors has determined that Mr. Friedman is an "audit committee financial expert" as defined in Item 407(d)(5) of Regulation S-K. The Audit Committee held five meetings during the fiscal year ended December 31, 2014.

*GNC Committee*

On June 27, 2011, the Board of Directors established a standing Governance, Nominating and Compensation Committee (the “GNC Committee”), which assists the Board in fulfilling its responsibilities relating to (i) compensation of the Company’s executive officers, (ii) the director nomination process and (iii) reviewing the Company’s compliance with SEC corporate governance requirements. The Board has adopted a written charter for the GNC Committee, which is available in the corporate governance section of our website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com). The GNC Committee currently consists of Dr. Arbel (Chair), Dr. Shorr and Mr. Taub, each of whom is independent as defined under applicable Nasdaq listing standards. The GNC Committee held two meetings during the fiscal year ended December 31, 2014.

The GNC Committee determines salaries, incentives and other forms of compensation for the Chief Executive Officer and the executive officers of the Company and reviews and makes recommendations to the Board with respect to director compensation. The GNC Committee meets without the presence of executive officers when approving or deliberating on executive officer compensation, but may invite the Chief Executive Officer to be present during the approval of, or deliberations with respect to, other executive officer compensation. In addition, the GNC Committee administers the Company’s stock incentive compensation and equity-based plans.

The GNC Committee makes recommendations to the Board concerning all facets of the director nominee selection process. Generally, the GNC Committee identifies candidates for director nominees in consultation with management and the independent members of the Board, through the use of search firms or other advisers, through the recommendations submitted by stockholders or through such other methods as the GNC Committee deems to be helpful to identify candidates. Once candidates have been identified, the GNC Committee confirms that the candidates meet the independence requirements and qualifications for director nominees established by the Board. The GNC Committee may gather information about the candidates through interviews, questionnaires, background checks, or any other means that the GNC Committee deems to be helpful in the evaluation process. The GNC Committee meets to discuss and evaluate the qualities and skills of each candidate, both on an individual basis and taking into account the overall composition and needs of the Board. Upon selection of a qualified candidate, the GNC Committee would recommend the candidate for consideration by the full Board.

In considering whether to include any particular candidate in the Board’s slate of recommended director nominees, the Board will consider the candidate’s integrity, education, business acumen, knowledge of the Company’s business and industry, age, experience, diligence, conflicts of interest and the ability to act in the interests of all stockholders. The Board believes that experience as a leader of a business or institution, sound judgment, effective interpersonal and communication skills, strong character and integrity, and expertise in areas relevant to our business are important attributes in maintaining the effectiveness of the Board. As a matter of practice, the Board considers the diversity of the backgrounds and experience of prospective directors as well as their personal characteristics (e.g., gender, ethnicity, age) in evaluating, and making decisions regarding, Board composition, in order to facilitate Board deliberations that reflect a broad range of perspectives. The Board does not assign specific weights to particular criteria and no particular criterion is a prerequisite for each prospective nominee. The Company believes that the

backgrounds and qualifications of its directors, considered as a group, should provide a significant breadth of experience, knowledge and abilities that will allow the Board to fulfill its responsibilities.

## Stockholder Nominations

During the fourth quarter of fiscal year 2014, 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.

## Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act requires our executive officers and directors, and persons who own more than 10% of our Common Stock (collectively, the "Reporting Persons"), to file reports regarding ownership of, and transactions in, our securities with the Securities and Exchange Commission and to provide us with copies of those filings. Based solely on our review of the copies of such forms received by us, or written representations from the Reporting Persons, we believe that during the fiscal year ended December 31, 2014; all Reporting Persons complied with the applicable requirements of Section 16(a) of the Exchange Act, except for the following:

- ACC International Holdings Ltd. filed three late Form 4s, reporting an aggregate of four transactions late.

There are no known failures to file a required Form 3, Form 4 or Form 5.

## Code of Ethics

On May 27, 2005, our Board of Directors adopted a Code of Ethics that applies to, among other persons, members of our Board of Directors, officers and employees. A copy of our Code of Ethics is posted on our website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com). We intend to satisfy the disclosure requirement regarding any amendment to, or waiver of, a provision of the Code of Ethics applicable to our Principal Executive Officer or our senior financial officers (Principal Financial Officer and Controller or Principal Accounting Officer, or persons performing similar functions) by posting such information on our website.

## Item 11. EXECUTIVE COMPENSATION.

### Summary Compensation

The following table sets forth certain summary information with respect to the compensation paid during the fiscal years ended December 31, 2014 and 2013 earned by our Chief Executive Officer, our former Chief Executive Officer, our President, our Chief Financial Officer and our Former Director of Research and Development (the “Named Executive Officers”). In the table below, columns required by the regulations of the SEC have been omitted where no information was required to be disclosed under those columns.

### Summary Compensation Table

| Name and Principal Position                  | Year | Salary  | Bonus | Option Awards |         | All Other Compensation | Total (\$) |
|--|------|---------|-------|---------------|---------|------------------------|------------|
|  |      | (\$)    | (\$)  | (\$)          | (1) (2) | (\$)(3)                |            |
| Tony Fiorino, CEO (4)                        | 2014 | 154,000 | -     | 1,494,000     | (7)     | 35,000                 | 1,683,000  |
| Chaim Lebovits (5)<br>President              | 2014 | -       | -     | -             | -       | -                      | -          |
|  | 2013 | -       | -     | -             | -       | -                      | -          |
| Uri Yablonka (*) Chief Operating Officer (6) | 2014 | 60,000  | -     | 97,411        | (8)     | 27,000                 | 184,411    |
| Liat Sossover (*)<br>Chief Financial Officer | 2014 | 107,000 | -     | -             | -       | 67,000                 | 174,000    |
|  | 2013 | 106,000 | -     | 16,000        | (9)     | 65,000                 | 187,000    |

(\* The Named Executive Officers were paid in NIS; the amounts above are the U.S. dollar equivalent. The conversion rate used was the average of the end of month's rate between the U.S. dollar and the NIS as published by the Bank of Israel, the central bank of Israel.

(1) The amounts shown in the "Option Awards" column represent the aggregate grant date fair value of awards computed in accordance with ASC 718, not the actual amounts paid to or realized by the Named Executive Officer during fiscal 2014 and fiscal 2013. ASC 718 fair value amount as of the grant date for stock options generally is spread over the number of months of service required for the grant to vest.

(2) The fair value of each stock option award is estimated as of the date of grant using the Black-Scholes valuation model. Additional information regarding the assumptions used to estimate the fair value of all stock option awards is included in Note(8)(B)(2)(a) to Consolidated Financial Statements.

(3) Includes management insurance (which includes pension, disability insurance and severance pay), payments towards such employee's education fund, Israeli social security and amounts paid for use of a Company car and cellular phone. Each Named Executive Officer also receives gross-up payments for the taxes on these benefits.

(4) Dr. Fiorino was appointed the Company's CEO effective June 9, 2014.

(5) On August 1, 2013, the Company appointed Chaim Lebovits, the President of the Company, as its Principal Executive Officer, and to assume the duties and responsibilities of the Chief Executive Officer on an interim basis while the Company searched for a new Chief Executive Officer. Mr. Lebovits was not compensated for these services. Mr. Lebovits ceased serving as interim CEO upon the appointment of Dr. Fiorino on June 9, 2014.

(6) Mr. Yablonka joined the Company as its Chief Operating Officer and director on June 6, 2014.

(7) On June 9, 2014, Dr. Fiorino was granted a stock option for purchase of 380,000 shares of the Company's Common Stock at an exercise price of \$4.50, which shall vest and become exercisable as to 25% of the shares on the first anniversary of the grant date and the remainder of the shares shall vest and become exercisable in equal monthly installments on each of the 36 monthly anniversaries following the initial vesting date.

(8) On June 6, 2014, the GNC Committee approved a grant of 33,333 stock options to Mr. Yablonka at an exercise price of \$2.70 per share. Mr. Yablonka also received a grant of 13,333 stock options at an exercise price of \$0.75 per share on August 15, 2014 for his service as a director of the Company.

(9) On December 31, 2013, the GNC Committee approved a grant of 6,666 stock options to Ms. Sossover at an exercise price of \$2.70 per share.

### ***Executive Employment Agreements***

*Tony Fiorino, Chief Executive Officer*

On June 9, 2014, the Company appointed Tony Fiorino, M.D., Ph.D. as its Chief Executive Officer, effective June 9, 2014. On June 9, 2014, the Company and Dr. Fiorino entered into an employment agreement which sets forth the terms of Dr. Fiorino's employment. Pursuant to the agreement, Dr. Fiorino will be paid an annual salary of \$275,000, to be increased annually by no less than \$7,500 per year. Dr. Fiorino will also receive other benefits that are generally made available to the Company's employees. Dr. Fiorino also was granted a stock option on June 9, 2014 for the purchase of 380,000 shares of the Company's Common Stock, which shall vest and become exercisable as to 25% of the shares on the first anniversary of the grant date and the remainder of the shares shall vest and become exercisable in equal monthly installments on each of the 36 monthly anniversaries following the initial vesting date. The exercise price for the grant is \$4.50 per share.



*Chaim Lebovits*

On August 1, 2013, the Company appointed Chaim Lebovits, the President of the Company, as its Principal Executive Officer, and to assume the duties and responsibilities of the Chief Executive Officer on an interim basis until Dr. Tony Fiorino was hired as Chief Executive Officer. Currently, we do not have an employment agreement with Mr. Lebovits and he is not entitled to receive any compensation from us at this time. Mr. Lebovits did not receive compensation for his service as interim CEO.

*Liat Sossover*

Pursuant to her employment agreement dated June 23, 2010, Ms. Sossover is entitled to a monthly salary of 31,900 NIS (approximately \$8,200) per month. Ms. Sossover is also entitled to contributions on her behalf by the Company into a manager's insurance fund, disability insurance and an education fund. Ms. Sossover is provided with a Company car and cellular phone, and a gross-up payment for any taxes relating thereto.

*Uri Yablonka, Chief Operating Officer and Director*

On June 6, 2014, the Company appointed Uri Yablonka as its Chief Operating Officer and director, effective June 6, 2014. On June 6, 2014, the Israeli Subsidiary and Uri Yablonka entered into an employment agreement which sets forth the terms of Mr. Yablonka's employment. Pursuant to the agreement, Uri Yablonka will be paid a monthly salary of 31,900 NIS (approximately \$8,200). Mr. Yablonka will also receive other benefits that are generally made available to the Company's employees, including pension and education fund benefits. The Company will provide Mr. Yablonka with a Company car and cellular phone, and a gross-up payment for any taxes relating thereto. Mr. Yablonka also was granted a stock option on June 6, 2014 under the Company's Amended and Restated 2004 Global Share Option Plan (the "Global Plan") for the purchase of 33,333 shares of the Company's Common Stock, which was fully vested and exercisable upon grant. The exercise price for the grant is \$2.70 per share. In addition, the Company agreed to grant Mr. Yablonka a stock option under the Global Plan (or the applicable successor option plan) for the purchase of up to 13,333 shares of Common Stock (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like) of the Company on the first business day after each annual meeting of stockholders (or special meeting in lieu thereof) of the Company beginning with the 2014 annual meeting, and provided that Mr. Yablonka remains an employee of the Company on each such date. The exercise price per share of the Common Stock subject to each additional option shall be equal to \$0.75 (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like, or changes to the Israeli Annual Option Award under the Company's Director Compensation Plan as amended from time to time). Each additional option will vest and become exercisable on each monthly anniversary date as to 1/12th the number of shares subject to the option over a period of twelve months from the date of grant such that each additional option will be fully vested and exercisable on the first anniversary of the date of grant, provided that Mr. Yablonka remains an employee of the Company on each such vesting date.



***Terms of Option Awards***

All options granted to the Named Executive Officers were granted pursuant to our Global Plan other than grants to Dr. Fiorino, which were made under the 2014 Stock Incentive Plan (the "US Plan"). Each such option expires on the tenth anniversary of the grant date.

On August 1, 2012, Ms. Sossover was granted an option to purchase 4,000 shares of our Common Stock at a price per share of \$3.90. Such option became fully vested and exercisable in 12 equal monthly installments.

On December 31, 2013, Ms. Sossover was granted an option to purchase 6,666 shares of our Common Stock at a price per share of \$2.70. Such option vested and became exercisable as to 1/3 of the shares subject to the option on December 31, 2014 and the remainder of the shares subject to the option vest and become exercisable over the following 24 months in equal installments.

Grants to Dr. Fiorino and Mr. Yablonka are described in the summaries of their executive employment agreements above and incorporated herein.

**Outstanding Equity Awards**

The following table sets forth information regarding equity awards granted to the Named Executive Officers that are outstanding as of December 31, 2014. In the table below, columns required by the regulations of the SEC have been omitted where no information was required to be disclosed under those columns.

**Outstanding Equity Awards at December 31, 2014**

| Name | Option Awards   |   | Option Exercise Price (\$) | Option Expiration Date |
|------|---|---|----------------------------|------------------------|
|      | Number of Securities Underlying Unexercised Options (#) | Number of Securities Underlying Exercised Options (#) |                            |                        |
|      |   |   |                            |                        |

|               | Exercisable | Unexercisable |     |      |            |
|---------------|-------------|---------------|-----|------|------------|
| Tony Fiorino  | -           | 380,000       | (1) | 4.50 | 6/9/2024   |
| Uri Yablonka  | 33,333      | -             |     | 2.70 | 6/6/2024   |
|               | 4,444       | 8,889         | (2) | 0.75 | 8/15/2024  |
| Liat Sossover | 26,666      | -             |     | 0.18 | 6/23/2020  |
|               | 4,000       | -             |     | 0.26 | 8/1/2022   |
|               | 2,222       | 4,444         | (3) | 2.70 | 12/31/2023 |

- (1) Options for the purchase of 95,000 shall vest and become exercisable on June 9, 2015. Options for the purchase of 7,916 shares will vest and become exercisable monthly after the initial vesting date until the option is fully vested. Options for the purchase of 4,444 shares were vested and exercisable as of December 31, 2014. Options for the
- (2) purchase of 1,111 shares will vest monthly until the option is fully vested and exercisable on the first anniversary of the date of grant. Options for the purchase of 2,222 shares were vested and exercisable as of December 31, 2014. Options for the
- (3) purchase of 185 shares will vest and become exercisable on the last day of each month until the option is fully vested.

### *Stock Incentive Plans*

In November 2004 and February 2005, the Board of Directors adopted and ratified the 2004 Global Share Option Plan (as amended, the “Prior Global Plan”) and the 2005 U.S. Stock Option and Incentive Plan (as amended, the “Prior U.S. Plan” and together with the Prior Global Plan, the “Prior Plans”), respectively, and further approved the reservation of 609,564 shares of our Common Stock for issuance thereunder. Our stockholders approved the Prior Plans and the shares reserved for issuance thereunder at a special meeting of stockholders that was held on March 28, 2005.

On April 28, 2008, the Board approved the amendment and restatement of the Prior Plans to increase the number of shares available for issuance under the Prior Plans by an additional 333,333 shares. Our stockholders approved the amendment and restatement of the Prior Plans on June 5, 2008.

On April 21, 2011, the Board approved another amendment and restatement of the Prior Plans to increase the number of shares available for issuance under the Prior Plans by an additional 333,333 shares. Our stockholders approved the amendment and restatement of the Prior Plans on June 10, 2011.

On May 6, 2012, the Board approved another amendment and restatement of the Prior Plans to increase the number of shares available for issuance under the Prior Plans by an additional 600,000 shares. Our stockholders approved the amendment and restatement of the Prior Plans on June 12, 2012.

At the 2014 Annual Meeting of Stockholders of the Company on August 14, 2014, the Company’s stockholders approved the Company’s 2014 Stock Incentive Plan and the Company’s 2014 Global Share Option Plan (together, the “Plans”). The Plans were approved by the Company’s Board of Directors on July 9, 2014, subject to the approval of the Company’s stockholders, and became effective upon the stockholders’ approval on August 14, 2014. On October 30, 2014, the Governance, Nominating and Compensation Committee of the Board of Directors of the Company approved (i) forms of Incentive Stock Option Agreement, Nonstatutory Stock Option Agreement and Restricted Stock Agreement, each under the Company’s 2014 Stock Incentive Plan, and (ii) a form of Option Agreement under the Company’s 2014 Global Share Option Plan.

The Company may issue up to 600,000 shares (subject to adjustment for certain changes in the Company's capitalization) of Common Stock, which pool shall be shared between the Plans, and, accordingly, shares issued pursuant to awards issued under either Plan shall reduce the number of shares available for issuance under the other Plan.

Starting August 14, 2014, we no longer issue awards under each of the Prior Plans; however, grants that were made prior to August 14, 2014 under the Prior Plans will remain outstanding pursuant to their terms.

Under the 2014 Global Share Option Plan, we granted a total of 70,666 options with \$0.75 exercise prices to directors of the Company. Under the 2014 Stock Incentive Plan (the "U.S. Plan"), we issued an additional 50,666 shares of restricted stock and options to directors and Advisory Board members. As of December 31, 2014, there were 478,668 shares available for issuance under the Plans.

**Compensation of Directors**

The following table sets forth certain summary information with respect to the compensation paid during the fiscal year ended December 31, 2014 earned by each of the directors of the Company. In the table below, columns required by the regulations of the SEC have been omitted where no information was required to be disclosed under those columns.

**Director Compensation Table for Fiscal 2014**

| Name                   | Fees<br>Earned or<br>Paid in<br>Cash (\$) | Stock<br>Awards<br>(\$)(1) | Option<br>Awards<br>(\$)<br>(1)(2) | Total<br>(\$) |
|------------------------|---|----------------------------|------------------------------------|---------------|
| Dr. Irit Arbel         | —   | —                          | 80,581 (3)                         | 80,581        |
| Mr. Mordechai Friedman | —   | —                          | 53,013 (4)                         | 53,013        |
| Mr. Alon Pinkas        | —   | —                          | 48,772 (5)                         | 48,772        |
| Mr. Chen Schor         | 60,000 (6)                                | —                          | —                                  | 60,000        |
| Dr. Robert Shorr       | —   | 40,300 (7)                 | —                                  | 40,300        |
| Mr. Malcolm Taub       | —   | 40,300 (8)                 | —                                  | 40,300        |

(1) The amounts shown in the “Stock Awards” and “Option Awards” columns represent the aggregate grant date fair value of awards computed in accordance with ASC 718, not the actual amounts paid to or realized by the directors during fiscal 2014.

(2) The fair value of each stock option award is estimated as of the date of grant using the Black-Scholes valuation model. Additional information regarding the assumptions used to estimate the fair value of all stock option awards is included in Note(8)(B)(2)(a) to Consolidated Financial Statements.

(3) At December 31, 2014, Dr. Arbel had options (vested and unvested) to purchase 115,218 shares of Common Stock.

(4) At December 31, 2014, Mr. Friedman had options (vested and unvested) to purchase 47,777 shares of Common Stock.

(5) At December 31, 2014, Mr. Pinkas had options (vested and unvested) to purchase 44,665 shares of Common Stock.

(6) Represents the amount paid to Mr. Schor pursuant to the Executive Director Agreement for his services as a director and consultant.

(7) At December 31, 2014, Mr. Shorr had 5,778 shares of unvested restricted Common Stock.

(8) At December 31, 2014, Mr. Taub had 5,778 shares of unvested restricted Common Stock.



On July 9, 2014, the Board voted to amend and restate the Company's non-employee director compensation plan (the "Amended Director Compensation Plan") to increase the annual award to non-U.S. directors to a nonqualified stock option to purchase 13,333 shares of Common Stock with an exercise price of \$0.75 per share and to clarify the terms of committee member grants. Pursuant to the Amended Director Compensation Plan, every non-employee director of the Company, other than Chen Schor, is eligible to participate in the Amended Director Compensation Plan. Each eligible director is granted an annual award immediately following each annual meeting of stockholders beginning with the 2014 annual meeting. For non-U.S. directors, this annual award consists of a nonqualified stock option to purchase 13,333 shares of Common Stock. For U.S. directors, at their option, this annual award is either (i) a nonqualified stock option to purchase 6,666 shares of Common Stock or (ii) 6,666 shares of restricted stock. Additionally, each member of the GNC Committee or Audit Committee of the Board receives (i) a nonqualified stock option to purchase 2,000 shares of Common Stock or (ii) in the case of U.S. directors and at their option, 2,000 shares of restricted stock. The chair of the GNC Committee or Audit Committee will instead of the above committee award receive (i) a nonqualified stock option to purchase 3,333 shares of Common Stock or (ii) in the case of U.S. directors and at their option, 3,333 shares of restricted stock. Any eligible participant who is serving as chairperson of the Board shall also receive (i) a nonqualified stock option to purchase 6,666 shares of Common Stock or (ii) in the case of U.S. directors and at their option, 6,666 shares of restricted stock. Awards are granted on a pro rata basis for directors serving less than a year at the time of grant. The exercise price for options for U.S. directors will be equal to the closing price per share of the Common Stock on the grant date as reported on the Over-the-Counter Bulletin Board or the national securities exchange on which the Common Stock is then traded. The exercise price for options for non-U.S. directors is \$0.75. Every option and restricted stock award will vest monthly as to 1/12 the number of shares subject to the award over a period of twelve months from the date of grant, provided that the recipient remains a member of the Board on each such vesting date, or, in the case of a committee award, remains a member of the committee on each such vesting date.

On August 15, 2014, the following grants were made under the Amended Director Compensation Plan to the eligible directors: Dr. Arbel received a stock option to purchase 25,333 shares of Common Stock for her service as a director, chairperson of the Board, chair of the GNC Committee and a member of the Audit Committee; Mr. Friedman received a stock option to purchase 16,666 shares of Common Stock for his service as a director and chair of the Audit Committee; Mr. Pinkas received a stock option to purchase 15,333 shares of Common Stock for his service as a director and a member of the Audit Committee; Mr. Shorr received 8,666 shares of restricted stock for his service as a director and a member of the GNC Committee; and Mr. Taub received 8,666 shares of restricted stock for his service as a director and a member of the GNC Committee. On August 15, 2014, the Company also granted to Mr. Yablonka a stock option to purchase 13,333 shares of Common Stock for his service as a director.

On August 22, 2011, Mr. Schor received a grant of 61,558 shares of restricted stock and receives \$15,000 per quarter for his services as a director and advisor of the Company pursuant to the terms of the Executive Director Agreement, as described in detail in “Certain Arrangements” under Item 10.

## **Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

### **Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth certain information as of January 30, 2015 with respect to the beneficial ownership of our Common Stock by the following: (i) each of our current directors; (ii) the Named Executive Officers; (iii) all of the current executive officers and directors as a group; and (iv) each person known by the Company to own beneficially more than five percent (5%) of the outstanding shares of our Common Stock.

For purposes of the following table, beneficial ownership is determined in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as otherwise noted in the footnotes to the table, we believe that each person or entity named in the table has sole voting and investment power with respect to all shares of our Common Stock shown as beneficially owned by that person or entity (or shares such power with his or her spouse). Under the SEC’s rules, shares of our Common Stock issuable under options that are exercisable on or within 60 days after January 30, 2015 (“Presently Exercisable Options”) or under warrants that are exercisable on or within 60 days after January 30, 2015 (“Presently Exercisable Warrants”) are deemed outstanding and therefore included in the number of shares reported as beneficially owned by a person or entity named in the table and are used to compute the percentage of the Common Stock beneficially owned by that person or entity. These shares are not, however, deemed outstanding for computing the percentage of the Common Stock beneficially owned by any other person or entity. Unless otherwise indicated, the address of each person listed in the table is c/o Brainstorm Cell Therapeutics Inc., 3 University Drive, Suite 320, Hackensack, NJ 07601.



The percentage of the Common Stock beneficially owned by each person or entity named in the following table is based on 18,393,546 shares of Common Stock outstanding as of January 30, 2015 plus any shares issuable upon exercise of Presently Exercisable Options and Presently Exercisable Warrants held by such person or entity.

| Name of Beneficial Owner   | Shares Beneficially Owned |     |                     |   |
|--|---------------------------|-----|---------------------|---|
|  | Number of Shares          |     | Percentage of Class |   |
| Directors and Named Executive Officers   |                           |     |                     |   |
| Chaim Lebovits   | 4,078,066                 | (1) | 20.0                | % |
| Tony Fiorino   | 2,500                     |     | *                   |   |
| Liat Sossover  | 33,443                    | (2) | *                   |   |
| Uri Yablonka   | 41,110                    | (2) | *                   |   |
| Irit Arbel   | 257,995                   | (3) | 1.4                 | % |
| Mordechai Friedman   | 40,833                    | (2) | *                   |   |
| Alon Pinkas  | 38,276                    | (2) | *                   |   |
| Chen Schor   | 61,558                    |     | *                   |   |
| Robert Shorr   | 41,333                    |     | *                   |   |
| Malcolm Taub   | 48,554                    | (4) | *                   |   |
| All current directors and officers as a group (10 persons)                               | 4,643,668                 | (5) | 22.5                | % |
| 5% Shareholders  |                           |     |                     |   |
| ACCBT Corp.  | 4,078,066                 | (1) | 20.0                | % |
| Morgan & Morgan Building<br>Pasea Estate, Road Town<br>Tortola<br>British Virgin Islands |                           |     |                     |   |
| Sabby Management, LLC<br>10 Mountainview Road, Suite 205<br>Upper Saddle River, NJ 07458 | 1,466,666                 | (6) | 9.6                 | % |

\*Less than 1%.

(1) Consists of (i) 1,933,794 shares of Common Stock owned by ACCBT Corp., (ii) 2,016,666 shares of Common Stock issuable to ACCBT Corp. upon the exercise of Presently Exercisable Warrants and (iii) 127,606 shares of Common Stock owned by ACC International Holdings Ltd. ACC International Holdings Ltd. and Chaim Lebovits, our President, may each be deemed the beneficial owners of these shares.

(2) Consists of shares of Common Stock issuable upon the exercise of Presently Exercisable Options.

(3) Includes 104,662 shares of Common Stock issuable upon the exercise of Presently Exercisable Options. Dr. Arbel's address is 6 Hadishon Street, Jerusalem, Israel.

(4) Includes 6,666 shares of Common Stock issuable upon the exercise of Presently Exercisable Options.

(5) Includes (i) 1,933,794 shares of Common Stock owned by ACCBT Corp. (Chaim Lebovits, our President, may be deemed to be the beneficial owner of these shares), (ii) 2,016,666 shares of Common Stock issuable to ACCBT Corp. upon the exercise of Presently Exercisable Warrants, (iii) 127,606 shares of Common Stock owned by ACC International Holdings Ltd. (Chaim Lebovits, our President, may be deemed to be the beneficial owner of these shares) and (iv) 264,990 shares of Common Stock issuable upon the exercise of Presently Exercisable Options.

(6) Based solely on information provided in the Schedule 13G filed by Sabby Healthcare Master Fund, Ltd., Sabby Volatility Warrant Master Fund, Ltd., Sabby Management, LLC and Hal Mintz with the SEC on February 2, 2015. As calculated in accordance with Rule 13d-3 of the Exchange Act, (i) Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Master Fund, Ltd. beneficially own 800,000 and 666,666 shares of Common Stock, respectively, representing approximately 5.2% and 4.4% of the Common Stock, respectively, and (ii) Sabby Management, LLC and Hal Mintz each beneficially own 1,466,666 shares of the Common Stock, representing approximately 9.6% of the Common Stock. Sabby Management, LLC and Hal Mintz do not directly own any shares of Common Stock, but each indirectly owns 1,466,666 shares of Common Stock. Sabby Management, LLC, a Delaware limited liability company, indirectly owns 1,466,666 shares of Common Stock because it serves as the investment manager of Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd., Cayman Islands companies. Mr. Mintz indirectly owns 1,466,666 shares of Common Stock in his capacity as manager of Sabby Management, LLC. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over these shares except to the extent of its or his pecuniary interest therein.

**Equity Compensation Plan Information**

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2014:

| Plan Category  | Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted-average price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans |     |
|--|---|--|--|-----|
| Equity compensation plans approved by security holders     | 1,810,335   | \$ 2.33456   | 665,896  | (1) |
| Equity compensation plans not approved by security holders | —   | —  | —  |     |
| Total  | 1,810,335   | 2.33456  | 665,896  | (1) |

A total of 2,476,231 shares of our Common Stock are reserved for issuance in aggregate under the Plans. Any (1) awards granted under either the Global Plan or the U.S. Plan will reduce the total number of shares available for future issuance under the other plan.

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.**

**Certain Relationships and Related Transactions**

The Audit Committee of our Board reviews and approves all related-party transactions. A “related-party transaction” is a transaction that meets the minimum threshold for disclosure under the relevant SEC rules (transactions involving amounts exceeding the lesser of \$120,000 or one (1) percent of the average of the smaller reporting company's total assets at year end for the last two fiscal years in which a “related person” or entity has a direct or indirect material interest). “Related persons” include our executive officers, directors, 5% or more beneficial owners of our Common Stock, immediate family members of these persons and entities in which one of these persons has a direct or indirect material interest. When a potential related-party transaction is identified, management presents it to the Audit Committee to determine whether to approve or ratify it.

The Audit Committee reviews the material facts of any related-party transaction and either approves or disapproves of the entry into the transaction. If advance approval of a related-party transaction is not feasible, then the transaction will be considered and, if the Audit Committee determines it to be appropriate, ratified by the Audit Committee. No director may participate in the approval of a transaction for which he or she is a related party.

***Research and License Agreement with Ramot***

On July 12, 2004, we entered into the Original License Agreement with Ramot, a former 5% stockholder of the Company, which agreement was amended on March 30, 2006 by the Amended Research and License Agreement (described below). Under the terms of the Original Ramot Agreement, Ramot granted to us an exclusive license to (i) the inventions, know-how and results made with respect to the stem cell technology developed by the team led by Prof. Melamed and Prof. Offen in the course of the performance of the research, and the patents and pending patent applications owned by Ramot, and (ii) the results of further research to be performed by the same team on the development of the stem cell technology. Simultaneously with the execution of the Original Ramot Agreement, we entered into individual consulting agreements with Prof. Melamed and Prof. Offen pursuant to which all intellectual property developed by Prof. Melamed or Prof. Offen in the performance of services thereunder will be owned by Ramot and licensed to us under the Original Ramot Agreement.

Under the Original Ramot Agreement, we agreed to fund further research relating to the licensed technology in an amount of \$570,000 per year for an initial period of two years, and for an additional two-year period if certain research milestones were met.

In consideration for the license, we originally agreed to pay Ramot:

- An up-front license fee payment of \$100,000;
- An amount equal to 5% of all net sales of products; and
- An amount equal to 30% of all sublicense receipts.

On March 30, 2006 and on May 23, 2006, we entered into an Amended Research and License Agreement and an Amendment Agreement to the Amended Research and License Agreement, respectively (collectively, the “Amended Research and License Agreement”) with Ramot. Under the Amended Research and License Agreement, the funding of further research relating to the licensed technology in an amount of \$570,000 per year was reduced to \$380,000 per year. Moreover, under the Amended Research and License Agreement, the initial period of time that we agreed to fund the research was extended from an initial period of two (2) years to an initial period of three (3) years. The Amended Research and License Agreement also extended the additional two-year period in the Original Ramot Agreement to an additional three-year period, if certain research milestones were met.

We entered into a Second Amended and Restated Research and License Agreement with Ramot on July 26, 2007, effective July 12, 2004 (the “Second Ramot Agreement”), which amended and replaced the Amended Research and License Agreement. The Second Ramot Agreement imposed on us development and commercialization obligations, milestone and other obligations. The license was granted in consideration for (i) royalty payments ranging from three percent (3%) to five percent (5%) of all net sales and (ii) potential payments concerning sublicenses ranging from



twenty percent (20%) to twenty-five percent (25%) of sublicense receipts. In addition, in the event that the research period was extended for an additional three year period in accordance with the terms of the Second Ramot Agreement, then we had to make payments to Ramot for each year of the extended research period in the amount of \$380,000. As of June 30, 2007, we owed Ramot an aggregate amount of \$513,249 in overdue payments and patent fees under the Amended Research and License Agreement.

On August 1, 2007, we obtained a waiver and release from Ramot pursuant to which Ramot agreed to an amended payment schedule regarding our payment obligations under the Second Ramot Agreement and waived all claims against us resulting from our previous breaches, defaults and non-payment under the Amended Research and License Agreement.

After our failure to meet the amended payment schedule and subsequent negotiations, on December 24, 2009, we entered into a Letter Agreement and an amended agreement to the Second Ramot Agreement (collectively, the "Letter Agreement") with Ramot, pursuant to which, among other things, Ramot agreed to: (i) release us from our obligation to fund three years of additional research (which would have totaled \$1,140,000) and (ii) accept conversion of certain research payments due in the amount of \$272,000 into 74,666 shares of our Common Stock. Pursuant to the Letter Agreement, we agreed, among other things, to: (i) reimburse Ramot for outstanding patent-related expenses; and (ii) abandon our rights in certain joint patent rights and patents of Ramot in certain countries.

As of February 2011, Ramot had sold the 74,666 shares of Common Stock of the Company for \$235,000 and the Company paid the remaining approximately \$5,000 due to Ramot. There is no additional debt to Ramot.

On December 20, 2011, we entered into an Assignment Agreement with our Israeli Subsidiary (the "Assignment Agreement"), with the consent of Ramot. Under the Assignment Agreement, we assigned and transferred all of our rights, interests, titles, liabilities and obligations (the "Rights") under the Second Ramot Agreement to our Israeli Subsidiary, effective as of January 1, 2007 and our Israeli Subsidiary agreed to assume all such Rights. We agreed to be a guarantor of all obligations of our Israeli Subsidiary under the Second Ramot Agreement and Ramot can look to us to demand compliance with the Second Ramot Agreement.

In May 2012, we, the Israeli Subsidiary and Prof. Offen entered into a Consulting Agreement, effective as of January 1, 2012, which replaced the previous consulting agreement, dated July 31, 2004, pursuant to which all work product resulting from the provision of services will vest solely with the Israeli Subsidiary and if any work product resulting from the provision of services results in the creation or development of intellectual property it will be deemed a joint invention, and will be jointly owned by Ramot and the Israeli Subsidiary.

#### ***Investment Agreement with ACCBT Corp.***

On July 2, 2007, we entered into a Subscription Agreement (the "Subscription Agreement") with ACCBT, a company under the control of Mr. Chaim Lebovits, our President, pursuant to which we agreed to sell (i) up to 1,833,333 shares of our Common Stock for an aggregate subscription price of up to \$5.0 million (the "Subscription Shares"), and (ii) for no additional consideration, warrants to purchase up to 2,016,666 shares of our Common Stock (the "ACCBT Warrants"). Subject to certain closing conditions, separate closings of the purchase and sale of the shares and the warrants were scheduled to take place from August 30, 2007 through November 15, 2008. The warrants originally had the following exercise prices: (i) warrants for the first 672,222 shares of our Common Stock had an exercise price of \$3.00; (ii) warrants for the next 672,222 shares of our Common Stock had an exercise price of \$4.35; and (iii) warrants for the final 672,223 shares of our Common Stock had an exercise price of \$5.40. Each warrant issued pursuant to the Subscription Agreement was to expire on November 5, 2011.

Pursuant to the terms of the Subscription Agreement, as amended, and a related registration rights agreement, ACCBT has the following rights for so long as ACCBT or its affiliates hold at least 5% of our issued and outstanding share capital:

**Board Appointment Right :** ACCBT has the right to appoint 50.1% (any fractions to be rounded up to the nearest whole number) of the members of our Board of Directors and any of our committees and the Board of Directors of our subsidiary.

**Preemptive Right :** ACCBT has the right to receive thirty days' notice of, and to purchase a pro rata portion (or greater under certain circumstances where offered shares are not purchased by other subscribers) of, securities issued by us, including options and rights to purchase shares. This preemptive right does not include issuances under our equity incentive plans.

**Consent Right :** ACCBT's written consent is required for certain corporate actions, including issuance of shares (other than existing warrants and issuances under our incentive plans), amendment of our charter or bylaws, repurchase of shares, declaration or payment of dividends or distributions, related party transactions, non-ordinary course transactions involving \$25,000 or more, liquidation or dissolution, the creation, acquisition or disposition of a subsidiary or entry into a joint venture or strategic alliance, a material change to our business, merger, change of control, sale of the Company, any acquisition, and any payment of cash compensation over \$60,000 per year.

In addition, ACCBT is entitled to demand and piggyback registration rights, whereby ACCBT may request, upon 15 days' written notice, that we file, or include within a registration statement to be filed, with the Securities and Exchange Commission for ACCBT's resale of the Subscription Shares, as adjusted, and the shares of our Common Stock issuable upon exercise of the ACCBT Warrants.

On August 18, 2009, we entered into an amendment to the Subscription Agreement (the “Amendment”), dated as of July 31, 2009, with ACCBT. Under the terms of the Subscription Agreement, ACCBT was no longer obligated to invest any further amounts in the Company. Pursuant to the Amendment, ACCBT agreed to invest the remaining amount outstanding under the Subscription Agreement up to \$5.0 million in the Company, and, in return, we agreed to amend the Subscription Agreement to, among other things: (i) decrease the purchase price per share of the Subscription Shares that ACCBT previously purchased or will purchase pursuant to the terms of the Subscription Agreement, as amended, from \$2.73 to \$1.80 (the “Repricing”); (ii) adjust the number of shares of Common Stock issuable under the Subscription Agreement in accordance with the Repricing; (iii) extend the expiration date of all warrants; (iv) amend the exercise price of certain of the warrants from \$5.40 to \$4.35; and (v) revise the investment schedule of the purchase and sale of the Subscription Shares. Pursuant to the Amendment, the Repricing retroactively applied to all Subscription Shares purchased by ACCBT prior to the Amendment.

As of the date of this Annual Report on Form 10-K, ACCBT has purchased all of the Subscription Shares.

Warrants to purchase up to 2,016,666 shares of Common Stock were issued to ACCBT, all of which are presently outstanding. The outstanding ACCBT Warrants contain cashless exercise provisions, which permit the cashless exercise of up to 50% of the underlying shares of Common Stock, and 672,222 of such ACCBT Warrants have an exercise price of \$3.00 and the remainder have an exercise price of \$4.35.

On May 25, 2014, the Company entered into a Warrant Amendment Agreement with ACCBT, pursuant to which the expiration date of each ACCBT Warrant was extended until November 5, 2017, in consideration of ACCBT having provided a series of waivers of their rights, including anti-dilution rights. Pursuant to the amendment, the ACCBT documents were amended to reflect the extension of the warrants’ expiration date.

We registered 1,920,461 shares of Common Stock and 2,016,666 shares of Common Stock underlying the ACCBT Warrants on registration statement No. 333-201705 dated January 26, 2015 pursuant to ACCBT’s registration rights.

#### ***Agreement with Abraham Israeli***

On April 13, 2010, the Company, Dr. Israeli, then a member of the Board of Directors, and Hadasit entered into an Agreement, which was amended to clarify certain terms on December 31, 2011 (as amended, the “Hadasit Agreement”), pursuant to which Dr. Israeli agreed, during the term of the Hadasit Agreement, to serve as (i) our Clinical Trials Advisor and (ii) a member of our Board of Directors. Any party may terminate the Hadasit Agreement upon 30 days’ prior written notice to the other parties. In consideration of the services to be provided by Dr. Israeli to us under the Hadasit Agreement, we agreed to grant options and warrants annually during the term of the Hadasit Agreement for the purchase of our Common Stock, as follows:

an option for the purchase of 11,111 shares of Common Stock at an exercise price equal to \$0.00075 per share to Dr. Israeli; and warrants for the purchase of 2,222 shares of Common Stock at an exercise price equal to \$0.00075 per share to Hadasit.

Such options vested and became exercisable in twelve (12) consecutive equal monthly amounts.

In December 2013, the Board of Directors agreed to grant to Prof. Israeli additional options in connection with the yearly grant under the Hadasit Agreement.

The Hadasit Agreement was terminated effective April 25, 2014 when Dr. Israeli resigned from the Board of Directors. The Hadasit Agreement provided terms for Prof. Israeli's service as the Company's Clinical Trials Advisor and a member of the Company's Board of Directors, both of which ceased on April 25, 2014. As a result of the termination of the Hadasit Agreement, 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 Hadasit Agreement ceased to vest, and the grants were valid until and may be exercised only on or before October 25, 2014. All such grants were exercised.

## Independence of the Board of Directors

The Board of Directors has determined that each of Dr. Arbel, Mr. Friedman, Mr. Pinkas, Dr. Shorr and Mr. Taub satisfies the criteria for being an “independent director” under the standards of the Nasdaq Stock Market, Inc. (“Nasdaq”) and has no material relationship with the Company other than by virtue of service on the Board of Directors. Mr. Schor and Mr. Yablonka are not considered “independent directors.” The Board of Directors also determined that Dr. Israeli, a former director, satisfied the criteria for being an “independent director” under the Nasdaq standards and had no material relationship with the Company other than by virtue of his service on the Board of Directors. During the course of determining the independence of Dr. Israeli, the Board of Directors considered the Hadasit Agreement described in “Certain Relationships and Related Transactions” above. Dr. Israeli resigned from the Board as of April 25, 2014.

The Board of Directors is comprised of a majority of independent directors and the Audit and GNC Committees are comprised entirely of independent directors.

## Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

### Independent Registered Public Accounting Firm

#### *Principal Accountant Fees and Services*

The following table presents fees for professional audit services rendered by Brightman Almagor Zohar & Co., a member of Deloitte Touche Tohmatsu (“Deloitte”) for the audit of our financial statements for the fiscal years ended December 31, 2014 and 2013 and fees billed for other services rendered by Deloitte during those periods.

|                           | December<br>31,<br>2014 | December<br>31,<br>2013 |
|---------------------------|-------------------------|-------------------------|
| Audit Fees (1)            | \$ 51,000               | \$ 51,000               |
| Audit-Related Fees (XBRL) | \$ 6,000                | \$ 6,000                |
| Tax Fees                  | \$ 4,000                | \$ 4,000                |
| Public Offering Fees      | \$ 7,000                | \$ 43,000               |
| All Other Fees (2)        | \$ 34,000               | \$ 20,000               |
| Total Fees                | \$ 102,000              | \$ 124,000              |

Audit fees are comprised of fees for professional services performed by Deloitte for the audit of our annual (1) financial statements and the review of our quarterly financial statements, as well as other services provided by Deloitte in connection with statutory and regulatory filings or engagements.

In the year ended December 31, 2013, the services performed by Deloitte were for the 2013 Public Offering, (2) Inter-Company agreement and Sarbanes-Oxley Act. The services performed in the year ended December 31, 2014 were with respect to the Inter-Company agreement and Sarbanes-Oxley Act.

We did not use Deloitte for financial information system design and implementation. These services, which include designing or implementing a system that aggregates source data underlying the financial statements and generates information that is significant to our financial statements, are provided internally or by other service providers. We did not engage Deloitte to provide compliance outsourcing services.

### **Pre-approval Policies**

Our Audit Committee is responsible for pre-approving all services provided by our independent auditors. All of the above services and fees were reviewed and approved by the Audit Committee before the services were rendered.

The Board of Directors has considered the nature and amount of fees billed by Deloitte and believes that the provision of services for activities unrelated to the audit is compatible with maintaining Deloitte's independence.

## **PART IV**

### **Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.**

Financial Statements.

The financial statements listed in the Index to Consolidated Financial Statements are filed as part of this report.

Financial Statement Schedules.

All financial statement schedules have been omitted as they are either not required, not applicable, or the information is otherwise included.

Exhibits.

The exhibits listed in the Exhibit Index are filed with or incorporated by reference in this report.

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**SIGNATURES**

In accordance with Section 13 or 15(d) 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: March 24, 2015 By: /s/ Dr. Tony Fiorino  
Name: Dr. Tony Fiorino  
Title: Chief Executive Officer*

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| <i>Signature</i>                                     | <i>Title</i>  | <i>Date</i>             |
|--|---|-------------------------|
| <i>/s/ Dr. Tony Fiorino<br/>Dr. Tony Fiorino</i>     | <i>Chief Executive Officer<br/>(Principal Executive Officer)</i>                | <i>March 24, 2015</i>   |
| <i>/s/ Liat Sossover<br/>Liat Sossover</i>           | <i>Chief Financial Officer<br/>(Principal Financial and Accounting Officer)</i> | <i>March 26, 2015</i>   |
| <i>/s/ Irit Arbel<br/>Irit Arbel</i>                 | <i>Director</i>   | <i>March 26, 2015</i>   |
| <i>/s/ Mordechai Friedman<br/>Mordechai Friedman</i> | <i>Director</i>   | <i>March 26, 2015</i>   |
| <i>Alon Pinkas</i>                                   | <i>Director</i>   | <i>March ____, 2015</i> |
| <i>/s/ Chen Schor<br/>Chen Schor</i>                 | <i>Director</i>   | <i>March 24, 2015</i>   |
| <i>/s/ Robert Shorr<br/>Robert Shorr</i>             | <i>Director</i>   | <i>March 25, 2015</i>   |
| <i>/s/ Malcolm Taub<br/>Malcolm Taub</i>             | <i>Director</i>   | <i>March 24, 2015</i>   |

*/s/ Uri Yablonka*  
*Uri Yablonka*

*Director*

*March 26, 2015*

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## EXHIBIT INDEX

### Exhibit

#### No. Description

- 2.1 Agreement and Plan of Merger, dated as of November 28, 2006, by and between Brainstorm Cell Therapeutics Inc., a Washington corporation, and Brainstorm Cell Therapeutics Inc., a Delaware corporation, is incorporated herein by reference to Appendix A of the Company's Definitive Schedule 14A dated November 20, 2006 (File No. 333-61610).
- 3.1 Certificate of Incorporation of Brainstorm Cell Therapeutics Inc. is incorporated herein by reference to Appendix B of the Company's Definitive Schedule 14A dated November 20, 2006 (File No. 333-61610).
- 3.2 Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc. dated September 15, 2014, incorporated herein by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K dated September 15, 2014 (File No. 000-54365).
- 3.3 ByLaws of Brainstorm Cell Therapeutics Inc. is incorporated herein by reference to Appendix C of the Company's Definitive Schedule 14A dated November 20, 2006 (File No. 333-61610).
- 3.4 Amendment No. 1 to ByLaws of Brainstorm Cell Therapeutics Inc., dated as of March 21, 2007, is incorporated herein by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K dated March 27, 2007 (File No. 333-61610).
- 4.1 Specimen Certificate of Common Stock of Brainstorm Cell Therapeutics Inc., incorporated herein by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K dated September 15, 2014 (File No. 000-54365).
- 10.1 Research and License Agreement, dated as of July 8, 2004, by and between the Company and Ramot at Tel Aviv University Ltd. is incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K dated July 8, 2004 (File No. 333-61610).
- 10.2 Research and License Agreement, dated as of March 30, 2006, by and between the Company and Ramot at Tel Aviv University Ltd. is incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K dated March 30, 2006 (File No. 333-61610).
- 10.3 Amendment Agreement, dated as of May 23, 2006, to Research and License Agreement, by and between the Company and Ramot at Tel Aviv University Ltd. is incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K/A dated March 30, 2006 (File No. 333-61610).
- 10.4 Amendment Agreement, dated as of March 31, 2006, among the Company, Ramot at Tel Aviv University Ltd. and certain warrant holders is incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K dated March 30, 2006 (File No. 333-61610).
- 10.5 Second Amended and Restated Research and License Agreement, dated July 26, 2007, by and between the Company and Ramot at Tel Aviv University Ltd. is incorporated herein by reference to Exhibit 10.4 of the



- 10.6 Second Amended and Restated Registration Rights Agreement, dated August 1, 2007, by and between the Company and Ramot at Tel Aviv University Ltd. is incorporated herein by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-QSB dated June 30, 2007 (File No. 333-61610).
- 10.7 Waiver and Release, dated August 1, 2007, executed by Ramot at Tel Aviv University Ltd. in favor of the Company is incorporated herein by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-QSB dated June 30, 2007 (File No. 333-61610).
- 10.8 Letter Agreement, dated December 24, 2009, by and between the Company and Ramot at Tel Aviv University Ltd. is incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed December 31, 2009 (File No. 333-61610).
- 10.9 Amendment No. 1 to Second Amended and Restated Research and License Agreement, by and between the Company and Ramot at Tel Aviv University Ltd. is incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed December 31, 2009 (File No. 333-61610).
- 10.10 Assignment Agreement, dated December 20, 2011, by and between the Company and Brainstorm Cell Therapeutics Ltd. is incorporated herein by reference to Exhibit 10.12 of the Company's Registration Statement on Form S-1, as filed with the SEC on February 3, 2012 (File No. 333-179331).
- 10.11 Consulting Agreement, dated as of July 8, 2004, by and between the Company and Prof. Eldad Melamed is incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K dated July 8, 2004 (File No. 333-61610).
- 10.12 Consulting Agreement, dated as of May 31, 2012, by and between the Company and Dr. Daniel Offen, incorporated herein by reference to Exhibit 10.15 of the Company's Registration Statement filed June 29, 2012 (File No. 333-179331).
- 10.13 Lease Agreement, dated as of December 1, 2004, among the Company, Petah Tikvah Science and Technology District 'A' Ltd., Petah Tikvah Science and Technology District 'B' Ltd. and Atzma and Partners Maccabim Investments Ltd. is incorporated herein by reference to Exhibit 10.10 of the Company's Quarterly Report on Form 10-QSB dated December 31, 2004 (File No. 333-61610).
- 10.14\* Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K dated August 14, 2014 (File No. 000-54365).
- 10.15\* Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan, incorporated herein by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K dated August 14, 2014 (File No. 000-54365).
- 10.16\* Form of Incentive Stock Option Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K dated October 30, 2014 (File No. 001-36641).
- 10.17\* Form of Nonstatutory Stock Option Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K dated October 30, 2014 (File No. 001-36641).
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Form of Restricted Stock Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K dated October 30, 2014 (File No. 001-36641).

10.19\* Form of Option Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan, incorporated herein by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K dated October 30, 2014 (File No. 001-36641).

- 10.20 Subscription Agreement, dated July 2, 2007, by and between the Company and ACCBT Corp. is incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on July 5, 2007 (File No. 333-61610).
- 10.21 Amendment to Subscription Agreement, dated as of July 31, 2009, by and between the Company and ACCBT Corp. is incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on August 24, 2009 (File No. 333-61610).
- 10.22 Form of Common Stock Purchase Warrant issued by the Company to ACCBT Corp. is incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on July 5, 2007 (File No. 333-61610).
- 10.23 Form of Registration Rights Agreement by and between the Company and ACCBT Corp. is incorporated herein by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed on July 5, 2007 (File No. 333-61610).
- 10.24 Form of Security Holders Agreement, by and between ACCBT Corp. and certain security holders of the Registrant is incorporated herein by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed on July 5, 2007 (File No. 333-61610).
- 10.25\* Employment Agreement, dated June 23, 2010, by and between the Brainstorm Cell Therapeutics Ltd. and Liat Sossover is incorporated herein by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 16, 2010 (File No. 333-61610).
- 10.26 Clinical Trial Agreement, entered into as of February 17, 2010, among BrainStorm Cell Therapeutics Ltd., Prof. Dimitrios Karussis and Hadasit Medical Research Services and Development Ltd. is incorporated herein by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 15, 2011 (File No. 000-54365).
- 10.27 Amendment to the Clinical Trial Agreement, entered into as of June 27, 2011, among BrainStorm Cell Therapeutics Ltd., Prof. Dimitrios Karousis and Hadasit Medical Research Services and Development Ltd. is incorporated herein by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on August 15, 2011 (File No. 000-54365).
- 10.28\* BrainStorm Cell Therapeutics Inc. Director Compensation Plan is incorporated herein by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on August 15, 2011 (File No. 000-54365).
- 10.29\* Amended and Restated Executive Director Agreement, dated November 11, 2011, by and between the Company and Chen Schor is incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed November 16, 2011 (File No. 333-61610).
- 10.30 Warrant Amendment Agreement, dated as of May 10, 2012, by and between BrainStorm Cell Therapeutics Inc. and ACCBT Corp. is incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2012 (File No. 000-54365)
- 10.31 Form of Common Stock Purchase Warrant issued by Brainstorm Cell Therapeutics Inc. to Placement Agent, incorporated herein by reference to Exhibit A of Exhibit 10.58 of the Company's Registration Statement filed June 29, 2012 (File No. 333-179331).

10.32 Form of Warrant is incorporated herein by reference to Annex B of the Company's Rule 424(b)(1) Prospectus filed July 19, 2012 (File No. 333-179331).

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- 10.33 Form of Warrant is incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 13, 2013 (File No. 000-54365).
- 10.34 Form of Securities Exchange Agreement, dated as of April 25, 2014 by and between Brainstorm Cell Therapeutics Inc. and the Holder (defined therein) is incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 12, 2014 (File No. 000-54365).
- 10.35 Form of May 27, 2014 Brainstorm Cell Therapeutics Inc. Warrant Redemption Agreement is incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 12, 2014 (File No. 000-54365).
- 10.36 Form of May 27, 2014 Brainstorm Cell Therapeutics Inc. Waiver Regarding Anti-Dilution is incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 12, 2014 (File No. 000-54365).
- 10.37 Amendment of Warrants dated May 19, 2014 by and among Brainstorm Cell Therapeutics Inc., ACCBT Corp. and ACC International Holdings Ltd. is incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 12, 2014 (File No. 000-54365).
- 10.38\* Employment Agreement dated June 6, 2014 between BrainStorm Cell Therapeutics Ltd. and Uri Yablonka, incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated June 6, 2014 (File No. 000-54365).
- 10.39\* Employment Agreement dated June 9, 2014 between Brainstorm Cell Therapeutics Inc. and Anthony Fiorino, M.D., Ph.D., incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated June 9, 2014 (File No. 000-54365).
- 10.40 Common Stock Purchase Warrant issued by Brainstorm Cell Therapeutics Inc. to Placement Agent, incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K dated June 19, 2014 (File No. 000-54365).
- 10.41 Form of Securities Purchase Agreement, incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated June 13, 2014 (File No. 000-54365).
- 10.42 Form of Warrant is incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated June 13, 2014 (File No. 000-54365).
- 10.43 Form of Registration Rights Agreement, incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K dated June 13, 2014 (File No. 000-54365).
- 10.44\* Brainstorm Cell Therapeutics Inc. Second Amended and Restated Director Compensation Plan, incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K dated July 9, 2014 (File No. 000-54365).
- 10.45 Form of Warrant is incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated January 8, 2015 (File No. 001-36641).
- 10.46

Maxim Engagement Letter, dated January 6, 2015, is incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated January 8, 2015 (File No. 001-36641).

- 10.47 Warrant Exercise Agreement, dated as of January 8, 2015, is incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated January 8, 2015 (File No. 001-36641).

21 Subsidiaries of the Company.

23.1 Consent of Brightman Almagor & Co., a member of Deloitte Touche Tohmatsu.

23.2 Consent of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global.

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.

The following financial information from the Annual Report on Form 10-K of Brainstorm Cell Therapeutics Inc. for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (1) Consolidated Balance Sheets as of December 31, 2014, and 2013; (2) Consolidated Statements of Operations for the years ended December 31, 2014 and 2013 and from September 22, 2000 (Inception) to December 31, 2014; (3) Statements of Changes in Stockholders' Equity (Deficit) from September 22, 2000 (Inception) through December 31, 2014; (4) Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013 and from September 22, 2000 (Inception) to December 31, 2014; and (5) Notes to Financial Statements.

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\*Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of Form 10-K.