

BRAINSTORM CELL THERAPEUTICS INC.

Form 10-K

March 08, 2018

**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, 2017**

**“ 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.)

1745 Broadway, 17<sup>th</sup> Floor  
New York, NY 10019  
(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 (Nasdaq Capital Market)</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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of 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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer "

Accelerated filer "

Non-accelerated filer " (Do not check if a smaller reporting company) Smaller reporting company x

Emerging growth company "

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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, 2017 (the last business day of the registrant's most recently completed second fiscal quarter), was \$67,672,149.

As of March 6, 2018, the number of shares outstanding of the registrant's Common Stock, \$0.00005 par value per share, was 19,070,040.

**BRAINSTORM CELL THERAPEUTICS INC.**

**ANNUAL REPORT ON FORM 10-K**

**YEAR ENDED DECEMBER 31, 2017**

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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. (together with its consolidated subsidiaries, the “Company,” “Brainstorm,” “we,” “us” or “our”) 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 2018, 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,” “proceeds” 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**

Brainstorm Cell Therapeutics Inc. is a biotechnology company focused on the development and commercialization of innovative Central Nervous System (“CNS”) adult stem cell therapies designed to address the significant unmet medical needs of patients with debilitating neurodegenerative diseases. Utilizing our proprietary mesenchymal stem cell platform technology, NurOwn®, Brainstorm is advancing therapies to treat a broad range of neurodegenerative disorders, such as Amyotrophic Lateral Sclerosis (“ALS”), also known as Lou Gehrig’s disease), Multiple Sclerosis (“MS”), and Parkinson’s disease (“PD”), which currently have limited or no treatment options.

## **2017 and Recent Highlights**

The Company made significant progress in 2017, advancing NurOwn®, our late stage differentiated mesenchymal stem cell therapy, into a Phase 3 trial for the treatment of ALS. Enrollment in this randomized, double-blind, placebo-controlled, multi-dose clinical trial of NurOwn® for ALS is now ongoing. This Phase 3 trial builds upon the promising efficacy seen in prior trials including our randomized Phase 2 trial conducted in the U.S.

We received a non-dilutive \$16 million grant from the California Institute for Regenerative Medicine (“CIRM”) and a grant of approximately \$2.1 million from the Israel Innovation Authority (“IIA”) in support of NurOwn® and the Phase 3 study of NurOwn® in ALS.

We enhanced our manufacturing capabilities in 2017 by completing a validation of the cryopreservation process for the long-term storage of mesenchymal stem cells (“MSC”). Cryopreservation allows us to provide repeated doses of NurOwn® from a single bone marrow aspirate, avoiding the need for patients to undergo repeated bone marrow aspirations, and moving us closer to our goal of providing best-in-class therapies designed to extend and improve the quality of life in patients with neurodegenerative disorders.

We strengthened our executive team in 2017 with the appointment of three senior officers: Ralph Z. Kern, MD, MHSc in the dual role as Chief Operating Officer and Chief Medical Officer; Mary Kay Turner as Vice President of Patient Advocacy and Government Affairs; and Eyal Rubin as Chief Financial Officer, responsible for corporate finance and accounting. These individuals were chosen for their deep neuroscience experience, significant industry expertise and long track record of industry achievements.

Our Board of Directors was also strengthened in 2017 with the addition of June S. Almenoff, M.D., Ph.D., FACP, and Arturo O. Araya, M.A., M.B.A., whose extensive experience in drug development and commercialization, and cell and gene therapy are valuable assets to Brainstorm. Dr. Almenoff served as President and CMO of Furiex Pharmaceuticals and served GlaxoSmithKline (GSK) as a Vice President in the Clinical Safety organization and chaired a PhRMA-FDA working group. Mr. Araya served as the Vice President and Head of Global Commercial for the Cell and Gene Therapies Unit for Novartis Pharmaceutical Corporation, where he led a cross-functional team to globally commercialize a portfolio of cell and gene therapies, prior to which he served as Novartis' Global Brand Leader for CTL019, a CAR-T therapy and served as Associate Director of Marketing Intelligence, Business Development & Licensing at Bristol-Myers Squibb Company.

In February 2018, we announced the appointment of Anthony Polverino, Ph.D., to our board of directors. Dr. Polverino, who is currently interim chief scientific officer of Kite (formerly Kite Pharma and now a wholly-owned subsidiary of Gilead Sciences). Dr. Polverino is a highly accomplished senior biopharmaceutical executive with more than 25 years' industry experience in drug research and development. Dr. Polverino replaced Dr. Robert Shorr who left the board of directors.

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

## **Our Proprietary Technology**

Our NurOwn® technology is based on a novel differentiation protocol, which induces the differentiation of bone marrow-derived mesenchymal stem cells, into neuro-protective and immunomodulatory, cells ("MSC-NTF" cells) capable of releasing multiple neurotrophic factors. These factors are known to be critical for the growth, survival and differentiation of neurons, they include: glial-derived neurotrophic factor ("GDNF"); brain-derived neurotrophic factor ("BDNF"); vascular endothelial growth factor ("VEGF"); and hepatocyte growth factor ("HGF"). GDNF is one of the most potent survival factors known for peripheral neurons. VEGF and HGF have been demonstrated to have important neuro-protective effects in ALS and in other neurodegenerative diseases.



Our approach to the 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 includes an Intrathecal (“IT”) injection of differentiated, neurotrophic factor-secreting mesenchymal stem cells into the same patient. The MSC-NTF cells are transplanted by intrathecal transplantation; into the cerebrospinal fluid by standard lumbar puncture. This procedure does not require hospitalization and has been shown to be safe and well tolerated in multiple CNS clinical trials to date.

Our proprietary technology and manufacturing processing of MSC-NTF cells for clinical use is conducted in full compliance with current Good Manufacturing Practice (“cGMP”).

Our proprietary technology is fully licensed to and developed by Brainstorm Cell Therapeutics Ltd., our wholly-owned subsidiary (the “Israeli Subsidiary”).

### ***The NurOwn® Transplantation Process***

- Bone marrow aspiration from patient;
- Isolation and propagation of the mesenchymal stem cells (MSC);
- Cryopreservation of MSC;
- Thawing and differentiation of the MSC into neurotrophic-factor secreting (MSC-NTF; NurOwn®) cells; and
- Autologous transplantation into the patient's cerebrospinal fluid by IT injection (lumbar puncture).

### ***Differentiation before Transplantation***

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

The specialized cells secrete neurotrophic factors that may lead to:

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

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

The NurOwn® approach is autologous, or self-transplanted, using the patient's own bone-marrow derived 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 ethical controversies associated with the use of embryonic stem cells in some countries.

### **The ALS Program**

NurOwn® is currently in late stage clinical development for the treatment of ALS. It has been granted Fast Track designation by the U.S. Food and Drug Administration ("FDA") for this indication, and has been granted Orphan Status

in both the United States and in Europe. We have completed two early stage clinical trials of NurOwn® in patients with ALS at the Hadassah Medical Center (“Hadassah”) in Jerusalem as well as a Phase 2 double-blind, placebo-controlled, clinical study at three prestigious US Medical centers, all highly experienced in the management and investigation of ALS.

### *Phase 1/2 open label trials*

The first two open-label studies were approved by the Israeli Ministry of Health (“MoH”) and the U.S. study was conducted under an FDA Investigational New Drug (“IND”) application. The first-in-human study, a Phase 1/2 safety and efficacy study of NurOwn® administered either intramuscularly or intrathecally in 12 ALS patients, was initiated in June 2011. This study demonstrated the safety of NurOwn® by both routes of administration, as well as signs of efficacy on both the ALS Functional Rating Score (“ALSFRS-R”), the industry gold standard, and a well-established measure, for evaluating the functional status of patients with a ALS, and Forced Vital Capacity (“FVC”), a measure of pulmonary function.

In January 2016, results of the two completed open label studies were published in JAMA Neurology. The publication presented the outcome of the Phase 1/2 study and Phase 2 dose escalation study with NurOwn® in ALS patients. The data provided indication of clinically meaningful benefit as reflected by a slower rate of disease progression in the period post treatment, as well as a positive trend on the rate of decline of muscle volume and on the compound motor axon potential (“CMAPs”). These were the first published clinical data using autologous mesenchymal stem cells, induced under culture conditions, to produce NTFs, with the potential to achieve a neuroprotective effect in ALS and modify the course of this disease.

### *Phase 2 Randomized Trial*

The FDA-approved, randomized, double-blind, placebo controlled multi-center U.S. Phase 2 clinical trial evaluating NurOwn® in ALS patients was conducted at three leading medical centers (i) Massachusetts General Hospital (Harvard Medical School) in Boston, Massachusetts, (ii) University of Massachusetts Memorial Hospital in Worcester, Massachusetts, and (iii) Mayo Clinic in Rochester, Minnesota. For this study, NurOwn® was manufactured at the Connell and O’Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute in Boston and at the Human Cellular Therapy Lab at the Mayo Clinic. In this study 48 patients were randomized 3:1 to receive NurOwn® or placebo.

Topline data from this Phase 2 Study were announced by the Company in July 2016. Further details were presented by investigators Dr. Robert Brown and Dr. James Berry, at the 15th Annual Meeting of the Northeast ALS Consortium (NEALS) in October 2016 and by Dr. Berry at the 27th International Symposium on ALS/MND, in Dublin, Ireland, in December 2016. Key findings from the trial were as follows:

The study achieved its primary objective, demonstrating that NurOwn® transplantation was safe and well tolerated. There were no discontinuations from the trial due to AEs and there were no deaths in the study. The most common adverse events (of mild or moderate severity), were transient procedure-related such as headache, back pain, pyrexia arthralgia and injection-site discomfort, these were more commonly seen in the NurOwn-Treated participant compared to placebo.

NurOwn® also achieved multiple secondary efficacy endpoints, showing evidence of a clinically meaningful benefit. Notably, response rates were higher in NurOwn®-treated subjects, compared to placebo, at all time points in the study out to 24 weeks.

Pre-specified responder analyses examined percentage improvements in post treatment of ALSFRS-R slope compared to pre-treatment slope. These analyses showed that, in the NurOwn® treated group, a greater proportion of treated patients achieved 100% improvement in the post-treatment vs. pre-treatment slope, compared with the placebo group. In addition, a greater proportion of NurOwn® treated patients achieved a 1.5 point/month improvement in the post-treatment vs. pre-treatment ALSFRS-R slope, compared with the placebo group.

In summary, NurOwn® responders experienced a halt in disease progression or improvement, as measured by the post-treatment vs. pre-treatment ALSFRS-R slope change. Moreover, in the pre-specified subgroup that was defined to exclude subjects whose disease was progressing more slowly, this effect was even more pronounced. These are novel observations, that have not been seen in prior ALS clinical studies.

As an important confirmation of the biology of NurOwn®, levels of neurotrophic factors and inflammatory markers were measured in the cerebral-spinal fluid (“CSF”) samples collected from patients. In the samples of those patients treated with NurOwn®, statistically significant increases in levels of neurotrophic factors VEGF, HGF and LIF and a statistically significant reduction in inflammatory markers MCP-1, SDF-1 and CHIT-1 was observed post-transplantation. Furthermore, the observed reduction in inflammatory markers correlated with clinical outcomes. These results were not seen in placebo treated patients, consistent with the biological action of NurOwn.

The Phase 2 study strongly suggests that repeat dosing and evaluation of ALS rapid progressors would optimize the probability of success in a phase 3 program.

### ***Phase 3 Trial***

The Company completed a successful End-of-Phase 2 Meeting with the United States Food and Drug Administration (FDA) and reached a general agreement to proceed to a Phase 3 trial. Importantly, the FDA accepted the key elements of the Phase 3 program (a multi-dose double-blind, placebo-controlled, multicenter trial protocol) to support a Biologic License Application (“BLA”) for NurOwn® in ALS. The trial is enrolling a patient population based on a Phase-II pre-specified sub-group of rapid progressors, which demonstrated superior outcomes. The primary clinical efficacy outcome measure is the ALSFR-S score responder analysis, a score that measures a patient's ability to perform tasks that are directly affected by ALS. The Phase 3 trial will also expand upon Phase 2 biomarker evaluations to further understand their potential to predict ALS disease progression and treatment response as well as confirm the biology of NurOwn® in a larger study population. The study will be conducted at six leading US Medical centers, three of which participated in the prior Phase 2 study. Patient enrollment commenced in October 2017 at Massachusetts General Hospital followed by the other 5 study sites, including University of California Irvine Medical Center, University of Massachusetts Medical Center, Mayo Clinic in Rochester, Minnesota, the California Pacific Medical Center in San Francisco, and Cedar Sinai Medical Center in Los Angeles. Interim safety data are expected in mid-2018 and top-line data in late 2019. The study is registered [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier NCT03280056).

The Company has developed a cryopreservation process for the long-term storage of MSC, that will allow multiple doses of autologous NurOwn® to be created from a single bone marrow aspirate in the multi-dose clinical trial and avoid the need for patients to undergo repeated bone marrow aspirations. A validation study was conducted in 2017 comparing NurOwn®, MSC-NTF cells, derived from fresh mesenchymal stem cells to those derived from cryopreserved MSC. Company scientists were successful in showing that the MSC can be stored in the vapor phase of liquid nitrogen for prolonged periods of time, while maintaining their characteristics. The cryopreserved MSC are capable of differentiating into NurOwn®, similar to the NurOwn® derived from fresh MSC of the same patient/donor, prior to cryopreservation.

The Company has contracted with City of Hope's Center for Biomedicine and Genetics to produce clinical supplies of NurOwn® adult stem cells for the ongoing Phase 3 clinical study. City of Hope is currently supporting the production for the patients treated in the Phase 3 trial.

The Company collaborated with the Tel Aviv Sourasky Medical Center (Ichilov Hospital), and jointly applied in the Israel Hospital Exemption regulatory pathway, which was adopted by the MoH from the European Union regulation, for NurOwn® treatment of ALS. This pathway will enable the Company to make NurOwn® potentially accessible for ALS patients for a fee.

### **Non-Dilutive Funding**

In June 2017, the Company announced that for the tenth consecutive year its Israeli Subsidiary, was awarded a new grant from Israel Innovative Authority in the amount of \$2,100,000. The Israel Innovative Authority is part of the Ministry of Economy Program to support innovative technologies in Israel. The funds supported the initial development of the NurOwn® Phase 3 clinical program in ALS.

In July 2017, the Company was granted an award in the amount of \$15,912,000 from the California Institute of Regenerative Medicine (CIRM) to support the pivotal Phase 3 study of NurOwn®, for the treatment of ALS. The award provided for a \$5,250,000 project initial payment, which was received during the third quarter of 2017, and up to \$15,912,000 in future milestone payments (inclusive of the project initial payment). The award does not bear a royalty payment commitment, nor is the award otherwise refundable.

### **Research and Development**

In addition to advancing its lead clinical program in ALS, the Company is leveraging th biology and clinical experience to explore additional indication including Parkinson's disease and progressive multiple sclerosis. A study profiling NurOwn®'s unique miRNA signature was recently published in Stem Cell Research & Therapy. The publication entitled "miRNA profiling of NurOwn®: mesenchymal stem cells secreting neurotrophic factors" shows that NurOwn® MSC-NTF cells induced to secrete neurotrophic factors have both an enhanced secretion of NTFs as well as a distinct miRNA expression profile that distinguishes them from their MSCs of origin. miRNAs have shown to play critical roles in neuronal and glial cell biological processes. These findings may form the basis for the development of sensitive identity release assays for clinical trials, in vivo cell identification assays, and to elucidate MSC-NTF cells' mechanism of action in ALS and other neurodegenerative diseases.

In addition, the Company is engaged in several research initiatives to improve and upscale NurOwn®'s manufacturing capabilities and capacity.

We have developed a cryopreservation process that enables the preservation of expended MSCs prior to the final differentiation process. This enables a single bone marrow aspiration to provide sufficient cell quantities for multiple dosing up to 3 years. We are using this process in our Phase 3 clinical trial. In addition, we are further developing a proprietary method to cryopreserve the final differentiated cell product, which will enable us to provide ready-for-injection therapeutic cell doses of NurOwn® that will create a stem cell bank for each patient, for ongoing, repeated treatments.

## **Corporate Information**

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 1745 Broadway, 17<sup>th</sup> Floor, New York, NY 10019, and our telephone number is (201) 488-0460. We maintain an Internet website at <http://www.brainstorm-cell.com>. The information on our website is not incorporated into this Annual Report on Form 10-K.

## **History**

In 2004, the Company entered into a research and license agreement with Ramot to acquire certain stem cell technology, commenced development of novel cell therapies for neurodegenerative diseases, and discontinued its previous business selling digital data recorders. The Company was incorporated in the State of Delaware on November 15, 2006, and previously was incorporated in the State of Washington. In October 2004, the Company formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics Ltd., in Israel. On February 19, 2013, the Israeli Subsidiary formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd., in the United Kingdom. A reverse stock split of the Company's shares of Common Stock by a ratio of 1-for-15 was effected after market close on September 15, 2014, in connection with the September 30, 2014 listing of the Company's Shares of Common Stock on the NASDAQ Capital Market. Unless otherwise indicated, all share numbers and exercise prices in this Annual Report on Form 10-K are split-adjusted.

The Company's Common Stock trades on the NASDAQ Capital Market under the ticker symbol "BCLI."

## **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 last stage development phase of our lead indication, hence much of the Company's resources are focused on this program. We are leveraging our strong existing pre-clinical data, initiating to advance new pre-clinical programs and engaging with scientific and regulatory experts to pursue the most attractive clinical and business opportunities. Important tasks include the execution of the ongoing US randomized, double-blind, placebo controlled Phase 3 study. The Company is actively engaged in several ongoing development projects with the goal of increasing the scale and efficiency of NurOwn® manufacturing. Our current strategy is to fully execute the Phase 3 Clinical Trial and if successful submit a BLA for NurOwn® in ALS. We may also choose to seek a strategic partnership with a pharmaceutical or biotechnology company for the global commercialization of NurOwn® for ALS, or to support the execution of additional registration-enabling clinical programs in other neurodegenerative disease.

## **NurOwn Stem Cell Therapy in CNS Diseases**

We are strategically focused on fully executing the late stage development of NurOwn® in ALS and actively exploring its application in other CNS disorders based on a broad preclinical experience in ALS, Parkinson's Disease, Huntington's Disease, MS and Autism. NurOwn® cells are derived from non-specialized mesenchymal stem cells which have a potential for both self-renewal and differentiation into cell types with a specialized function, such as muscle, blood or brain cells. The cells can undergo asymmetric division, such that one of the two daughter cells retain 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 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 can be easily obtained from adult tissues 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 aspiration procedure. 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. Furthermore, the differentiation of MSC into neuronal lineage is a critically important attribute in the application of MSC-based cell therapies in neurodegenerative disease for both safety and efficacy reasons.



Studies of neurodegenerative diseases suggest that symptoms and functional impairments that arise in afflicted individuals are secondary to defects in neuron cell function and the associated 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 (“BBB”) limiting access and the ensuing lack of effective central nervous system (CNS) target engagement. 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. The application of NurOwn® in neurodegenerative disease is based on the capacity of the cells to deliver disease-relevant biologically active molecules, such as neurotrophic factors, at or near to the site of tissue injury, following intrathecal administration.

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

ALS, often referred to as “Lou Gehrig's disease,” is a progressive neurodegenerative disease that primarily affects motor 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 patients lead to progressive weakness, respiratory failure and eventually, death. The median survival for ALS patients is between 2 and 5 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 about 51,000 afflicted in the territory of the European Single Market. Estimated annual treatment costs for advanced stage patients can be as high as \$100,000-\$200,000 per annum.

Treatment decisions are typically determined by the patient's symptoms, preferences and the stage of the disease. Approved disease modifying medications include:

Riluzole –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.

Radicava (Edaravone) – a free radical scavenger- recently approved by FDA (May 2017) based on a single Phase 3 study carried out in Japan.

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

### **Multiple Sclerosis (MS)**

MS is a chronic neuroinflammatory and neurodegenerative disorder that affects the brain, optic nerves and spinal cord. Nerve cells are normally insulated with a protective layer called myelin, which enables 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 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 patients located in the U.S. and Europe. Over 10,000 new cases are diagnosed annually in the U.S., mostly affecting women between the ages of 20 and 50. Annual drug treatment costs for MS can be as much as \$80,000 a year per patient.

Treatment of MS focuses on symptom management, treatment of attacks, and prevention of future attacks. There are few treatments that modify disease progression in the absence of ongoing inflammatory activity. There are a variety of disease-modifying treatments FDA-approved for relapsing-remitting MS; however, patients with progressive forms of MS have an unmet need that remains to be addressed by currently available DMTs.

### **Parkinson’s Disease (PD)**

PD is a chronic, progressive neurodegenerative 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 may be associated with dementia. The cause of the disease is presently unknown.

Over 7 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 such as on-off phenomenon, motor fluctuations and involuntary movements. 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 may be associated with significant treatment morbidity such as bleeding in the brain, infection and depression. In addition, similar to drug therapy, DBS focuses on treating the symptoms of PD and does not provide a cure.

There is a great unmet need for novel approaches towards management of PD, primarily to control Levodopa-induced adverse side effects and motor fluctuations, and potentially 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**

We are committed to the protection of our technology and intellectual property with patents and other methods described below.

We are the sole licensee or assignee of 7 granted patents and 21 patent applications in the United States, Europe, and Israel, as well as in additional countries worldwide, including countries in the Far East and South America (in calculating the number of granted patents, each European patent validated in multiple jurisdictions was counted as a single patent).

On June 18, 2006, an International Patent Application (Publication No. WO 2006/134602) was filed entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases." National phase applications were filed in many jurisdictions including US and Europe. On February 11, 2014, the U.S. Patent and Trademark Office (“USPTO”) granted US patent, 8,647,874 which claims priority from this PCT application. This patent relates to the production method of the Company's proprietary stem cells induced to secrete large quantities of neurotrophic factors.

On January 30, 2018, the U.S. Patent and Trademark Office (“USPTO”) granted US patent, No. 9,879,225 which claims priority from this same PCT application" This patent relates to methods of treating amyotrophic lateral sclerosis (ALS) and Parkinson's disease using mesenchymal stem cells that secrete neurotrophic factors, specifically glial

derived neurotrophic factor (GDNF).

On September 3, 2014, a European patent was granted by the European Patent Office ("EPO") which claims priority from WO 2006/134602. This patent (Pat. No. 1893747), has been validated in the following European countries: CH, CZ, DE, DK, ES, FR, GB, IE, IT and NL. The granted claims relate to the method of generating the cells.

On May 26, 2009, an International Patent Application (Publication No. WO 2009/144718) was filed entitled "Mesenchymal stem cells for the treatment of CNS diseases". National phase applications were filed in US, Europe and Israel.

On March 4, 2014, we were granted U.S. Patent (No. 8,663,987) which claims priority from WO 2009/144718. The claims of this granted patent relate to the composition of cells.

A divisional patent application therefrom was granted as US Patent No. 8,900,574 on December 2, 2014. The claims of this granted patent relate to a method of treating neurodegenerative disorders by administering MSC-derived cells which secrete BDNF and do not secrete bNGF. The neurodegenerative diseases include Parkinson's disease, amyotrophic lateral sclerosis (ALS) and Huntingdon's disease. A subsequent divisional patent application therefrom was granted as United States Patent No. 9,474,787 titled "Mesenchymal Stem Cells for the Treatment of CNS Diseases. The granted claims cover mesenchymal stem derived-cells that secrete neurotrophic factors, including brain-derived neurotrophic factor (BDNF) and glial derived neurotrophic factor (GDNF), as well as pharmaceutical compositions comprising these factors.

In September 2015, we were granted a patent by Israel's Patent Office for our application No. 209604 titled "Isolated Population of Cells, Methods of Generating Same, and Uses Thereof in the Treatment of CNS Diseases" which claims priority from WO 2009/144718. The claims cover the cell composition itself, the method of generating and the use of the cells for treating any CNS disease or disorder.

In January 2018 the European Patent Office ("EPO") issued a Notice of Intention to Grant an European-wide patent for Patent Application No. 09754337.5 which claims priority from WO 2009/144718. The allowed claims cover methods of treating amyotrophic lateral sclerosis (ALS) using mesenchymal stem cells that secrete neurotrophic factors, including Brain derived neurotrophic factor (BDNF).

Additional PCT patent applications have been filed and National phase applications are currently under examination in several jurisdictions worldwide. Specifically, International Patent Application WO2014/024183 was filed on August 4, 2013, WO2015/121859 was filed on February 11, 2015, and WO 2018/015945 was filed on July 13, 2017.

The following table provides a description of our key patents and patent applications and is not intended to represent an assessment of claims, limitations or scope. In some cases, a jurisdiction is listed as both pending and granted for a single patent family. This is due to pending continuation or divisional applications of the granted case.

<b>Patent Name/ Int. App. No.</b>	<b>Pending Jurisdictions</b>	<b>Allowed Jurisdictions</b>	<b>Granted Jurisdictions</b>	<b>Expiry Date</b>
<b>ISOLATED CELLS AND POPULATIONS COMPRISING SAME FOR THE TREATMENT OF CNS DISEASES/PCT/IL2006/000699</b>	<b>US</b>		<b>Europe, US</b>	<b>2030</b>
<b>MESENCHYMAL STEM CELLS FOR THE TREATMENT OF CNS DISEASES PCT/IL2009/000525</b>	<b>Hong Kong</b>	<b>Europe</b>	<b>US, Israel,</b>	<b>2032</b>
<b>METHODS OF GENERATING MESENCHYMAL STEM CELLS WHICH SECRETE NEUROTROPHIC FACTORS / PCT/IL2013/050660</b>	<b>US, Europe, Hong Kong, Israel, Canada, Brazil, Japan</b>			<b>2038</b>
<b>METHOD OF QUALIFYING CELLS /PCT IL2015/050159</b>	<b>US, Europe, Hong Kong, Israel, Canada, Brazil, Japan</b>			<b>2040</b>
<b>Methods of treating ALS PCT/IL2017/050801</b>	<b>PCT</b>			<b>2042</b>

*Trademarks:*

NurOwn® is a registered trademark (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*

The Company has maintained a commercial relationship with Ramot, the technology transfer group within Tel Aviv University, since July 2004, when the Company and Ramot entered into a Research and License Agreement (the “Original Agreement”). The Original Agreement was amended in both March and May of 2006, when the parties signed, respectively, an Amended and Restated Research and License Agreement (the “Amended and Restated Agreement”) and Amendment Number 1 to the Amended and Restated Agreement. Thereafter, the Company and Ramot entered into a Letter Agreement in December 2009 which further amended the Amended and Restated Agreement by releasing the Company from various duties and obligations (including the Company’s commitment to fund three (3) years of additional Ramot research - a financial commitment of \$1,140,000), while converting other payments due and owing to Ramot by the Company into shares of Common Stock. In December 2011, the Company assigned the Amended and Restated Agreement (as amended) to its Israeli Subsidiary with the consent of Ramot, provided the Company agreed to guaranty the performance obligations of its Israeli Subsidiary thereunder. The Amended and Restated Agreement was amended in both April 2014 (Amendment Number 2) and March 2016 (Amendment Number 3).

In addition to the foregoing, on April 30, 2014, the Israeli Subsidiary executed a consulting agreement (the “Offen Consulting Agreement”) with Professor Offen of Tel Aviv University, which expressly replaced their previous agreement (signed in July 2004). Pursuant to the Offen Consulting Agreement, Professor Offen granted our Israeli Subsidiary exclusive rights, title and interest in and to all work product and deliverables resulting from the provision of his services thereunder, except that any new intellectual property arising from this agreement would be deemed a joint invention that is jointly owned by both our Israeli Subsidiary and Ramot. To date, no such joint inventions have resulted from this consulting agreement. The Offen Consulting Agreement was terminated on January 18, 2018.

The primary focus of our agreements (and subsequent amendments) with Ramot has and continues to be the commissioning of a group of scientists within Tel Aviv University to carry out research in the area of the stem-cell technology referenced above, and the granting of rights to the Company (and later our Israeli Subsidiary, after the assignment referenced above) in the inventions, know-how and results procured from such research (the “Ramot IP”).

In consideration for the rights granted to our Israeli Subsidiary in and to the Ramot IP, our Israeli Subsidiary is required to pay Ramot royalties ranging between three percent (3%) and five percent (5%) of all net sales realized from the exploitation of the Ramot IP, as well as remittances of between twenty percent (20%) and twenty-five percent (25%) on revenues received from the sub-licensing of the Ramot IP.

Pursuant to the third amendment of the Amended and Restated Agreement referenced above, Ramot agreed to convert the exclusive licenses then-existing, to outright transfers and assignments of the Ramot IP, thereby granting our Israeli Subsidiary ownership thereof.

### **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.

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

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

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 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 Biological License Application (“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 cGTP 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 biologic 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 stem cell therapies will be granted on a timely basis, if at all.

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 stem cell therapy 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 stem cell therapy 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 stem cell therapy does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the stem cell therapy, 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.

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.

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 stem cell therapy 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 stem cell therapy 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 stem cell therapy 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 stem cell therapy as defined by the FDA or if our stem cell therapy is determined to be contained within the competitor's product for the same indication or disease. If a stem cell therapy 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 stem cell therapies, 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 stem cell therapy 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 stem cell therapy. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

### ***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 post marketing 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 stem cell therapies. 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 stem cell therapies 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***

Coverage and reimbursement status of any approved therapy carries uncertainty and risk. In both the United States and foreign markets, our ability to commercialize our stem cell therapies successfully, and to attract commercialization partners for our stem cell therapies, 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 stem cell therapies can be subject to challenge, reduction or denial by the government and other payors.

Possible legislation at the Federal and State levels in the United States focused on cost containment and price transparency may impact our ability to sell our stem cell therapies for maximum profitably. It appears likely that the pressure on pharmaceutical pricing will continue, especially under the Medicare program, which may also increase our regulatory burdens and operating costs. Moreover, additional changes could be made to governmental healthcare programs that could significantly impact the success of our stem cell therapies.

The 21st Century Cures Act and its regenerative medicine provisions may be beneficial to the development of our stem cell therapy. The 21st Century Cures Act was signed into law on Dec. 13, 2016. The goal of this landmark legislation is to accelerate the discovery, development, and delivery of new treatments. It includes regenerative medicines provisions aimed at bringing new innovations and advances to patients quicker and more efficiently. On Nov. 16, 2017, the US Food and Drug Administration (FDA) issued a comprehensive regenerative medicine policy framework. The draft guidance issued by the FDA defines the regenerative medicine provisions in the 21st Century Cures Act by providing additional information to further the development and access to innovative regenerative medicine therapies.

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 stem cell therapies 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 stem cell therapy 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 stem cell therapies 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 several clinical trials underway evaluating experimental treatments for ALS, of which only two are stem cell-based trials being conducted by other commercial entities. US-based Neuralstem (CUR) completed a Phase 2 intraspinal transplantation trial for its allogeneic, human (fetal) spinal cord derived neural stem cells. Data presented in 2015 this product to be safe and well-tolerated with no acceleration in disease progression due to the therapeutic intervention. Neuralstem has discussed plans for a for a larger, controlled, registration directed clinical trial but it is not clear if it will proceed with this trial. Q Therapeutics has gained FDA approval for a Phase 1/2 intraspinal transplantation study with its Q-Cells®, purified human glial progenitor cells isolated from brain tissue. Corestem, a Korean company, recently completed a Phase 1 trial in ALS showing that repeated intrathecal administration of autologous, bone marrow-derived mesenchymal stem cells was safe. No details about clinical benefit was reported and there is little public information available about Corestem.

Several experimental ALS therapies such as Masitinib (AB Science), NP-001 (Neuraltus), and Actemra (Tocilizimab, Genentech) are selectively targeting neuroinflammation. AB Science completed a Phase 3 trial for masitinib in ALS. However, a regulatory filing for masitinib in another indication, indolent systemic mastocytosis, was rejected by the EU's Committee for Medicinal Products for Human Use (CHMP) because of concerns about its adherence to good clinical practices. Neuraltus Pharma is developing NP001, is a small molecule that modulates macrophages to promote an anti-inflammatory state in order to reduce the rate of motoneuron loss. NP001 is currently being tested in a Phase 2 trial that was launched in September 2016, and topline results are expected in 2018. A previous Phase 2 study failed to show statistically significant benefit. Cytokinetics is a late stage biopharmaceutical company that recently completed a Phase 3 clinical trial with tirasemtiv, a muscle troponin sensitizer. This study failed to demonstrate an improvement in slow vital capacity, a measure of breathing strength or other functional improvement, and as a consequence, Cytokinetics has suspended the development of tirasemtiv. Amylyx Pharmaceuticals is developing AMX0035, a combination of two compounds, sodium phenylbutyrate and tauroursodeoxycholic acid, that are proposed to have a synergistic effect when administered together. Amylyx recently initiated a Phase 2 trial in ALS patients and topline results are expected in 2019. Therapies specifically targeting genetic mutations in a small subset of ALS patents, such as SOD1 and C9ORF72, are being evaluated using antisense oligonucleotide technology (Biogen, IONIS, and WAVE Therapeutics). In addition, academic institutions are also developing treatment candidates for ALS, including mesenchymal stem cells genetically modified to increase GDNF expression.

Currently, there are two approved ALS therapies, Riluzole and Radicava, that have demonstrated mild improvements in survival and ALS function, respectively. Riluzole, approved by the FDA in 1995, extends the time to death or ventilation by several months; however, it has not been shown to improve the daily functioning of ALS patients. Radicava (Edaravone) is a free radical scavenger recently approved by FDA (May 2017) based on a single Phase 3 study carried out in Japan

## **Employees**

We currently have 24 employees, all 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*. 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* 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**

### **Risks Related to our Financial Condition and Capital Requirements**

*We need to raise additional capital. If we are unable to raise additional capital in favorable terms and 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.

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.

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

Management's plan includes raising funds from outside potential investors. However, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. 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 2017 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 Brainstorm.

***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, 2016 or December 31, 2017. 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.

*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.

### **Risks Related to our Cell Therapy Product Development Efforts**

*If our NurOwn® stem cell therapy does not demonstrate safety and efficacy sufficient to obtain regulatory approval, it may 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® stem cell therapy cannot be accurately predicted. We do not expect to receive regulatory approval for any of our stem cell therapies until March 2018, if ever. If we fail to obtain regulatory approval for our NurOwn® stem cell therapy, we will be unable to market and sell it and we may never be profitable.

As part of the regulatory process, we are conducting Phase 3 clinical trials, for our NurOwn® stem cell therapy to demonstrate safety and efficacy in humans to meet the requirements of the FDA and regulatory authorities in other countries. If successful, this could be the basis for market authorization by the FDA and other jurisdictions.

A failure of one or more of our clinical trials can occur at any stage of testing. 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 NurOwn® stem cell therapy against placebo. Comparisons of outcomes of other reported clinical trials may provide some insight into the efficacy of NurOwn® stem cell therapy, however, these studies may be of limited comparative value due to the many factors that affect the outcome of clinical trials, some of which are not apparent in published reports.

***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 stem cell therapies 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 stem cell therapies 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 or stem cell therapies unattractive or unsuitable for human use, and we may abandon our commitment to that program, target or stem cell therapy. 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® stem cell therapy, we may need to abandon or limit its development.***

If patients treated with our NurOwn® stem cell therapy 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.

***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 stem cell therapies.

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 stem cell therapies, or might be



significantly delayed in doing so, which will materially harm our business.

Our ability to generate revenues from any of our stem cell therapies 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.

### **Risks Related to Our Business Operations and Commercialization of Stem Cell Therapies**

*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 for ALS involve a new approach that is yet to be proven in a Phase 3 powered for efficacy trial. We are currently conducting a Phase 3 placebo-controlled clinical trial for ALS, which, together with other stem cell therapies, may ultimately prove ineffective. 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® stem cell therapy, 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® stem cell therapy 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® stem cell therapy, if successfully developed, will compete with a number of traditional products manufactured and marketed by major pharmaceutical and biotechnology companies. Our NurOwn® stem cell therapy 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® stem cell therapy for the treatment of patients with ALS, or other neurodegenerative diseases, even if approved, may be slow or limited. If our NurOwn® stem cell therapy does not achieve broad acceptance as a treatment option for ALS, or other neurodegenerative diseases, our business would be negatively impact our revenue forecast.***

If approved, the rate of adoption of our NurOwn® stem cell therapy 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® stem cell therapy. Our NurOwn® stem cell therapy utilizes individualized stem cell therapy, which is significantly different from the pharmacological approach currently used to treat neurodegenerative diseases. Acceptance of our NurOwn® stem cell therapy 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® stem cell therapy as a preferred therapy, even if approved.

***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® stem cell therapy, 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® stem cell therapy 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® stem cell therapy 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 stem cell therapies 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® stem cell therapy 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 stem cell therapies will not be granted.

*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® stem cell therapy 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® stem cell therapy, including:

- failure to obtain a sufficient supply of key raw materials of suitable quality;
- difficulties in manufacturing our stem cell therapies 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® stem cell therapy;
- 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 stem cell therapies 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® stem cell therapy 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® stem cell therapy during storage at our facilities; and
- loss or destruction of, or damage to, patient-specific materials or our NurOwn® stem cell therapy 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 stem cell therapies 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 stem cell therapies. 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® stem cell therapy or a specific indication for its use and fail to capitalize on stem cell therapies 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® stem cell therapy for use in patients with ALS. As a result, we may forego or delay pursuit of opportunities with other stem cell therapies 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® stem cell therapy 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® stem cell therapy. Notwithstanding our large investment to date and anticipated future expenditures in our NurOwn® stem cell therapy, 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® stem cell therapy, we may fail to develop stem cell therapies 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 NurOwn® stem cell therapy 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 stem cell therapies 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 stem cell therapies or lead to significant post-approval limitations or restrictions. For example, the differentiated cell component of our NurOwn® stem cell therapy 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® stem cell therapy 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® stem cell therapy 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.

***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 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.

***Man-Made Problems Such as Computer Viruses or Terrorism May Disrupt Our Operations and Harm Our Operating Results***

Despite our implementation of network security measures our servers are vulnerable to computer viruses, break-ins, and similar disruptions from unauthorized tampering with our computer systems. Any such event could have a material adverse effect on our business, operating results, and financial condition. Efforts to limit the ability of malicious third parties to disrupt the operations of the internet or undermine our own security efforts may meet with resistance. In addition, the continued threat of terrorism and heightened security and military action in response to this threat, or any future acts of terrorism, may cause further disruptions to the economies of the United States, Israel and other countries and create further uncertainties or otherwise materially harm our business, operating results, and financial condition. Likewise, events such as widespread blackouts could have similar negative impacts. To the extent that such disruptions or uncertainties result in delays or access to data or personal information, our business, operating results, and financial condition could be materially and adversely affected.

**Risks Related to Government Regulation**

***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 stem cell therapies have received regulatory approval for commercial sale yet. We do not expect to receive regulatory approval for any of our stem cell therapies until at least March 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 stem cell therapies 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 stem cell therapies, including the following:

The FDA or similar foreign regulatory authorities may find that our stem cell therapies 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 stem cell therapies 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 stem cell therapies 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 stem cell therapy 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 stem cell therapy. We may never obtain the required regulatory approvals for any of our stem cell therapies. 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 stem cell therapies, 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 stem cell therapies, 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.

*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.

*We are subject to significant regulation with respect to manufacturing of our NurOwn® stem cell therapy.*

All entities involved in the preparation of a therapeutic biological for clinical trials or commercial sale are subject to extensive regulation. Our NurOwn® stem cell therapy 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 stem cell therapies 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® stem cell therapy. 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.

Our long-term business plan is to develop our NurOwn® stem cell therapy for the treatment of neurodegenerative diseases, such as ALS, MS and PD. Even if we successfully develop our NurOwn® stem cell therapy 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® stem cell therapy 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® stem cell therapy, 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.

### **Risks Related to Our Intellectual Property**

*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.

***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.

*We received grants from the Israel Innovation Authority, or IIA, we are subject to on-going restrictions.*

We have received royalty-bearing grants from the IIA, for research and development programs that meet specified criteria. The terms of the IIA's grants may limit various technology transfer know-how developed under an approved research and development program outside of Israel.

### **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 and Chief Executive Officer, 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 entering into transactions greater than \$500,000. Further, ACCBT also has the right to appoint 30% 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 November 2, 2017. In March 2014, we entered into an agreement with ACCBT according to which ACCBT waived certain anti-dilution rights. On November 2, 2017, 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, 2022, in consideration of ACCBT having provided a series of waivers of their rights and reduction of rights.

***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 Chief Business 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**

### **Corporate Headquarters and other office space**

Our United States corporate headquarters are located at 1745 Broadway, 17<sup>th</sup> Floor, New York, NY 10019. The Company is party to an office service agreement for the license of this space.

Our Israeli Subsidiary is party to 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, including an

animal research facility. The lease term is from December 1, 2004 through March 31, 2018, with an option to extend for an additional 45 months and a right to terminate the extension option on December 31, 2019 with 4 months' notice. Rent is paid on a monthly basis in the amount of NIS 40,000 (approximately U.S. \$11,500).

As part of the clinical trials with Hadassah, we pay approximately \$33,000 per month per clean room for rental and operation of 2 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 required.

**PART II**

**Item MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND  
5. 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, 2017	\$4.49	\$2.95
September 30, 2017	\$5.18	\$3.84
June 30, 2017	\$5.10	\$3.50
March 31, 2017	\$4.70	\$2.48
December 31, 2016	\$3.08	\$2.06
September 30, 2016	\$3.87	\$2.27
June 30, 2016	\$2.78	\$2.09
March 31, 2016	\$3.25	\$1.90

The source of these high and low prices is the Nasdaq Capital Market. The high and low prices listed have been rounded up to the next highest two decimal places.

*Record Holders*

As of March 6, 2018, there were approximately 45 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 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.

On November 19, 2015, the Company issued to Hadasit Medical Research Services and Development Ltd., 100,000 shares of Common Stock pursuant to the exercise of warrants issued under the February 17, 2010 Clinical Trial Agreement, as amended May 30, 2011, 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.

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

Not required.

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

### **Company Overview**

Brainstorm is a biotechnology company focused on development and commercialization of novel adult stem cell therapies designed to address the significant unmet medical needs of patients with debilitating neurodegenerative disorders. Utilizing our proprietary mesenchymal platform technology, NurOwn®, Brainstorm is advancing therapies to treat a broad range of neurodegenerative diseases, such as Amyotrophic Lateral Sclerosis (“ALS”), also known as Lou Gehrig’s disease), Multiple Sclerosis (“MS”), and Parkinson’s disease (“PD”), which currently have limited or no treatment options.

### **Results of Operations**

For the period from inception (September 22, 2000) until December 31, 2017, the Company did not generate any revenues from operations. In addition, the Company incurred operating costs and expenses of approximately \$4,999,000 during the year ended December 31, 2017.

### ***Research and Development, net***

Our business model calls for significant investments in research and development. Our research and development expenditures, net in the year ended December 31, 2017 were \$977,000, a decrease of \$1,273,000 compared to \$2,250,000 for the year ended December 31, 2016. Included in these amounts were OCS research and development grants that are recorded as an offset to expenses as well as CIRM grant. OCS grants included as an offset were \$1,393,000 in 2017 and \$1,185,000 in 2016 while CIRM grant included in research and development expenses were \$4,425,000 in 2017 only. Excluding OCS grant and CIRM grants, research and development expenses increased by \$3,360,000 from \$3,435,000 in 2016 to \$6,795,000 in 2017.

This increase is primarily due to an increase of \$1,976,000 to \$2,969,000 for the year ended December 31, 2017, from \$993,000 for the year ended December 31, 2016 for costs of activities related to the U.S. Clinical Trial, primarily due to expenses in connection with the Phase 3 Clinical Trial. In addition, there was an increase of \$817,000 in payroll and stock-based compensation expenses, (ii) an increase of \$378,000 in the costs of activities related to the Israeli clinical trials and costs of materials and (iii) an increase of \$283,000 in travel, rent and various other expenses. This increase was partially offset by a decrease of \$94,000 in the costs of patents and other.

### ***General and Administrative***

General and administrative expenses for the years ended December 31, 2017 and 2016 were \$4,022,000 and \$2,833,000, respectively. The increase of \$1,189,000 in general and administrative expenses is mainly due to: (i) an increase of \$235,000 in payroll and stock-based compensation expenses; (ii) an increase of \$309,000 in the cost of our investor relations and public relations activities and consultants, and (iii) an increase of \$645,000 in travel, rent and various other expenses.

### ***Financial Expenses***

The financial income of \$47,000 for the year ended December 31, 2017 is mainly due to interest earned on our cash, cash equivalents and short-term deposits. Financial income for the year ended December 31, 2016 was \$101,000.

### ***Net Loss***

Net loss for the year ended December 31, 2017 was \$4,952,000, as compared to a net loss of \$4,982,000 for the year ended December 31, 2016. Net loss per share for the year ended December 31, 2017 and December 31, 2016 was \$0.26 and \$0.27, respectively.

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, 2017 was 18,777,348 compared to 18,663,162 for the year ended December 31, 2016.

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, 2017 was due to: (i) the issuance of shares to service providers and directors and (ii) the exercise of options and warrants.

### **Going Concern**

To date the Company has not generated any revenues from its activities and has incurred substantial operating losses. Management expects the Company to continue to generate substantial operating losses and to continue to fund its operations primarily through utilization of its current financial resources and through additional raises of capital. Management believes that the Company's current resources are sufficient to fund its operations for the next 12 months, however there can be no assurance that additional funds necessary for the Company's long-term operations will be available on terms acceptable to the Company, or that the Company will not incur additional unforeseen costs or expenses. Such conditions raise substantial doubts about the Company's long term ability to continue as a going concern. The Company's 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.

### **Liquidity and Capital Resources**

The Company has financed its operations since inception primarily through public and private sales of its Common Stock and warrants and the issuance of convertible promissory notes. At December 31, 2017, the Company had net working capital of \$4,080,000 including cash, cash equivalents and short-term bank deposits amounting to \$7,756,000.

Net cash used in operating activities for the year ended December 31, 2017 was \$2,364,000. Cash used for operating activities was primarily attributed to cost of clinical trials, rent of clean rooms and materials for clinical trials, payroll costs, rent, outside legal fee expenses and public relations expenses.

Net cash provided by investing activities for the year ended December 31, 2017 was \$3,986,000 representing primarily a net decrease in short-term deposits.

Net cash provided by financing activities for the year ended December 31, 2017 was \$314,000 from the exercises of warrants and options during the year.

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 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.

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

Our material cash needs for the next 12 months will include (i) costs of the Phase 3 clinical trial in the U.S. (ii) employee salaries, , (iii) payments to Hadassah for rent and operation of the GMP facilities, and (iv) fees to our consultants and legal advisors, patents, and fees for facilities to be used in our research and development.

Future operations are expected to be highly capital intensive and will require substantial capital raisings. We expect our current cash position will allow us to meet our obligations in the upcoming 12 months.

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

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

### **Critical Accounting Policies**

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing in this Annual Report. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

**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 the Company are recorded in new Israeli shekels ("NIS"); however, a substantial portion of the Company's costs are incurred in dollars or linked to the dollar. Accordingly, management has designated the dollar as the currency of the Company'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.

**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.

**Accounting for stock-based compensation:**

In accordance with ASC 718-10 the Company estimates the fair value of equity-based payment.

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.

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.

**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 and California Institute of Regenerative Medicine (CIRM) 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.

### **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, 2017**

**U.S. DOLLARS IN THOUSANDS**

(Except share data and exercise prices)

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2017**

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.**

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Brainstorm Cell Therapeutics Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016 and the related consolidated statements comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

**Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's lack of revenues and substantial operating losses raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material

misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting 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.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Brightman Almagor Zohar & Co.  
Certified Public Accountants  
Member of Deloitte Touche Tohmatsu Limited

Tel Aviv, Israel

March 8, 2018

We have served as the Company's auditor since 2008.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESCONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

(Except share data)

	December 31,	
	2017	2016
	U.S. \$ in thousands	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$2,483	\$547
Short-term deposit (Note 8)	5,273	9,443
Account receivable (Note 4)	672	306
Prepaid expenses and other current assets	1,195	148
Total current assets	9,623	10,444
Long-Term Assets:		
Prepaid expenses and other long-term assets (Note 5)	1,408	25
Property and Equipment, Net (Note 6)	392	297
Total Long-Term Assets	1,800	322
Total assets	\$11,423	\$10,766
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payables	\$1,424	\$345
Accrued expenses	817	152
Deferred grant income (Note 9)	2,625	-
Other accounts payable	677	367
Total current liabilities	5,543	864
Total liabilities	\$5,543	\$864
Stockholders' Equity:		
Stock capital: (Note 10)	11	11
Common Stock of \$0.00005 par value - Authorized: 100,000,000 shares at December 31, 2017 and December 31, 2016 respectively; Issued and outstanding: 18,976,169 and 18,687,987 shares at December 31, 2017 and December 31, 2016 respectively.		

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Additional paid-in-capital	85,944	85,014
Accumulated deficit	(80,075)	(75,123)
Total stockholders' equity	5,880	9,902
Total liabilities and stockholders' equity	\$11,423	\$10,766

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIESSTATEMENTS OF COMPREHENSIVE LOSS

U.S. dollars in thousands

(Except share data)

	Year ended December 31,	
	2017	2016
	U.S. \$ in thousands	
Operating expenses:		
Research and development, net (Note 11)	\$977	\$2,250
General and administrative	4,022	2,833
Operating loss	(4,999 )	(5,083 )
Financial expenses (income), net	(47 )	(101 )
Taxes on income (Note 12)	-	-
Net loss	\$(4,952 )	\$(4,982 )
Basic and diluted net loss per share from continuing operations	\$(0.26 )	\$(0.27 )
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	18,777,348	18,663,162

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

**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)

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

\* Represents an amount less than \$1.

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

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

U.S. dollars in thousands

	Year ended December 31, 2017 U.S. \$ in thousands	2016
Cash flows from operating activities:		
Net loss	\$ (4,952 )	\$ (4,982 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	85	77
Shares and options granted to service providers	62	121
Deferred Stock-based compensation related to options granted to employees and directors	554	635
Decrease (increase) in accounts receivable and prepaid expenses	(2,792 )	379
Increase (decrease) in trade payables	1,079	(824 )
Deferred grant income	2,625	-
Increase (decrease) in other accounts payable and accrued expenses	975	(1,264 )
Total net cash used in operating activities	\$ (2,364 )	\$ (5,858 )

**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

	Year ended	
	December 31,	
	2017	2016
	U.S. \$ in thousands	
Cash flows from investing activities:		
Purchase of property and equipment	(180 )	(103 )
Changes in short-term deposit	4,170	6,084
Investment in lease deposit	(4 )	(4 )
Total net cash provided by investing activities	\$ 3,986	\$ 5,977
Cash flows from financing activities:		
Proceeds from exercise of warrants and options	314	-
Total net cash provided by financing activities	\$ 314	\$ -
Increase in cash and cash equivalents	1,936	119
Cash and cash equivalents at the beginning of the period	\$ 547	\$ 428
Cash and cash equivalents at end of the period	\$ 2,483	\$ 547

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 1 - GENERAL

The Company was incorporated in the State of Delaware on November 15, 2006, and previously was incorporated in the State of Washington. In October 2004, the Company formed its wholly-owned subsidiary, Brainstorm Cell A. Therapeutics Ltd. ("BCT") in Israel, which currently conducts all of the research and development activities of the Company. On February 19, 2013, the Israeli Subsidiary formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd. in the United Kingdom. Brainstorm UK is currently inactive.

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

The Company, through BCT, holds rights to commercialize certain stem cell technology developed by Ramot of Tel Aviv University Ltd. ("Ramot"), (see Note 3). Using this technology, the Company has been developing novel adult stem cell therapies for debilitating neurodegenerative disorders such as Amyotrophic Lateral Sclerosis (ALS, B. also known as Lou Gherig Disease), Multiple Sclerosis (MS) and Parkinson's disease. The Company developed a proprietary process, called NurOwn, for the propagation of Mesenchymal Stem Cells and their differentiation into neurotrophic factor secreting cells. These cells are then transplanted at or near the site of damage, offering the hope of more effectively treating neurodegenerative diseases.

The process is currently autologous, or self-transplanted.

NurOwn is in clinical development for the treatment of ALS. The Company has completed two single dose clinical trials of NurOwn in Israel, a phase 1/2 trial with 12 patients and a phase 2a trial with additional 12 patients. In July C. 2016 the Company announced the results of its phase 2 trial which was conducted in three major medical centers in the US. This single dose trial included 48 patients randomized in a 3:1 ratio to receive NuOwn or placebo.

The Company made significant progress in 2017, advancing NurOwn®, its late stage differentiated mesenchymal stem cell therapy, into a Phase 3 trial for the treatment of ALS. Enrollment in this randomized, double-blind, D. placebo-controlled, multi-dose clinical trial of NurOwn® for ALS is now ongoing. This Phase 3 trial builds upon the promising efficacy seen in prior trials including the randomized Phase 2 trial conducted in the U.S.

**E.** On August 26, 2015 the shareholders of the Company approved a reduction of the number of authorized shares of Common Stock of the Company from 800,000,000 to 100,000,000.

**GOING CONCERN:**

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

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

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY**

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 "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 SUBSIDIARY**

U.S. dollars in thousands

(Except share data and exercise prices)

**Notes to Consolidated Financial Statements**

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):**

**G. Accrued post-employment benefit**

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.

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

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

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

In accordance with ASC 718-10 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.

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.

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.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

J. 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 "Earnings per Share".

All outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share for the years ended December 31, 2017 and December 31, 2016, since all such securities have an anti-dilutive effect.

K. Research and development expenses, net:

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

Royalty-bearing grants from the Israel Innovation Authorities ("IIA") and a non-dilutive, non-royalty-bearing grant from the California Institute of Regenerative Medicine ("CIRM") 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

L. Income taxes:

The Company accounts for income taxes in accordance with ASC 740-10 "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 SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

M. Recent Accounting Standards

In May 2014, the Financial Accounting Standards Board issued a new standard to achieve a consistent application of revenue recognition within the U.S., resulting in a single revenue model to be applied by reporting companies under U.S. generally accepted accounting principles. Under the new model, recognition of revenue occurs when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the new standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The new standard is effective for us beginning in the first quarter of 2018; early adoption is prohibited. The new standard is required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. As the Company has not incurred revenues to date, it is unable to determine to expected impact of the new standard on its consolidated financial statements.

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

The ASU is effective for the Company in the first quarter of 2019, with early adoption permitted. The Company continues to evaluate the effect of the adoption of this ASU and expects the adoption will result in an increase in the assets and liabilities on the consolidated balance sheets for operating leases (see Note 7) and will likely have an insignificant impact on the consolidated statements of earnings.

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

In May 2017, the FASB issued ASU 2017-09 “Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting,” which clarifies when a change to terms or conditions of a share-based payment award must be accounted for as a modification. The new guidance requires modification accounting if the vesting condition, fair value or the award classification is not the same both before and after a change to the terms and conditions of the award. The new guidance is effective on a prospective basis beginning on January 1, 2018 and early adoption is permitted. The Company does not expect the adoption of this standard to have an impact on its consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 3 - RESEARCH AND LICENSE AGREEMENT

The Company entered into a Research and License Agreement, as amended and restated, with Ramot (the “License Agreement”). Pursuant to the remuneration terms of the License Agreement, the Company has agreed to pay Ramot royalties on Net Sales of the Licensed Product as follows:

a) So long as the making, producing, manufacturing, using, marketing, selling, importing or exporting (collectively, the “Commercialization”) of such Licensed Product is covered by a Valid Claim or is covered by Orphan Drug Status, the Company shall pay Ramot a royalty of 5% of the Net Sales received by the Company and resulting from such Commercialization; and

b) In the event the Commercialization of the Licensed Product is neither covered by a Valid Claim nor by Orphan Drug status, the Company shall pay Ramot a royalty of 3% of the Net Sales received by the Company resulting from such Commercialization. This royalty shall be paid from the First Commercial Sale of the Licensed Product and for a period of fifteen (15) years thereafter.

Capitalized terms set forth above which are not defined shall have the meanings attributed to them under the License Agreement.

NOTE 4 - ACCOUNTS RECEIVABLE

	December 31,	
	2017	2016
Grants receivable from IIA	\$ 574	\$ 154
Government institutions and other	98	152
	\$ 672	\$ 306



## NOTE 5 - PREPAID EXPENSES

In November 2017 the Company has contracted with City of Hope's Center for Biomedicine and Genetics ("COH") to produce clinical supplies of NurOwn® adult stem cells for the Company's ongoing Phase 3 clinical study. As of December 31, 2017, the Company has paid COH \$3,222, which includes \$2,665 advance payment. The advance was recorded as prepaid expense and is amortized over the term of the agreement. As of December 31, 2017, \$1,103 and \$1,378 were recorded as current and long-term prepaid expense, respectively.

## NOTE 6 - PROPERTY AND EQUIPMENT

	December 31,	
	2017	2016
Cost:		
Office furniture and equipment	\$73	\$73
Computer software and electronic equipment	189	182
Laboratory equipment	875	702
Leasehold improvements	716	716
	1,853	1,673
Accumulated depreciation:		
Office furniture and equipment	23	18
Computer software and electronic equipment	176	166
Laboratory equipment	552	492
Leasehold improvements	710	700
	1,461	1,376
Depreciated cost	\$392	\$297

Depreciation expenses for the years ended December 31, 2017 and December 31, 2016 were \$85 and \$77, respectively.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

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Notes to Consolidated Financial Statements

NOTE 7 - COMMITMENTS AND CONTINGENCIES

In October 2014, the Company entered into a lease agreement for its US offices, according to which BCT leased A. 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. \$5.

In October 2017, BCT entered into an amended lease agreement for the lease of its facilities. The term of the lease B. is 45 months, with an option to terminate the agreement with 4 month pre-notice, before December 31, 2019. Rent is paid on a monthly basis in the amount of NIS 40,000 (approximately \$11) per month.

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, 2017 are as follows:

Period ending December 31,	Facilities	Vehicles	Total
2018	\$ 196	\$ 10	\$206
2019	199	-	199
2020	43	-	43
	\$ 438	\$ 10	\$448

Total facilities rent expense for the years ended December 31, 2017 and 2016 were \$198 and \$182, respectively.

C. Commitments to pay royalties to the IIA:

BCT obtained from the Chief Scientist of the State of Israel grants for participation in research and development for the years 2007 through 2016, 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, 2017, total grants obtained amounted to \$988.

In addition to the royalties which the Company is required to pay to Ramot on its Commercialization of the Licensed Product as described in Note 3 hereof, the Company has other financial obligations under the License Agreement, including without limitation, certain research funding commitments as well as a commitment to reimburse Ramot for all of its documented Licensed Product patent-related expenses. Pursuant to the License Agreement, in the event the Company elects not to reimburse Ramot for any specific patent expenses, the Company's corresponding Commercialization rights will be terminated by Ramot. By way of example, if the Company elects, in its sole discretion, not to reimburse Ramot's patent expenses which are incurred in a particular jurisdiction, the Company's right to Commercialize the Licensed Product in the same jurisdiction may be terminated by Ramot. As of December 31, 2017, there are no outstanding obligations owed to Ramot in connection with the above.

#### NOTE 8 - SHORT TERM DEPOSITS

Short term investments on December 31, 2017 and December 31, 2016 include bank deposits bearing annual interest rates varying from 0.05% to 1.90%, with maturities of up to 5 months as of December 31, 2017 and 2016.

#### NOTE 9 - DEFERRED GRANT INCOME

In July 2017 the Company received an award in the amount of \$15,912 from CIRM to support the pivotal Phase 3 study of NurOwn®, for the treatment of ALS. \$7,050 related to the project was received during the third and fourth quarters of 2017.

The award does not bear a royalty payment commitment nor is the award otherwise refundable.

\$4,425 was recorded as participation by CIRM in research and development expenses (see Note 11).

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 10 - STOCK CAPITAL

The rights of Common Stock:

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.

Private placements and public offerings:

The Company is party to a July 2, 2007 subscription agreement and related registration rights agreement and warrants, amended July 31, 2009, May 10, 2012, May 19, 2014 and November 2, 2017 (together as amended, the “ACCBT Documents”) with ACCBT Corp. (“ACCBT”), a company under the control of Mr. Chaim Lebovits, the Company’s President and Chief Executive Officer, pursuant to which, for an aggregate purchase price of approximately \$5.0 million, the Company sold to ACCBT 1,920,461 shares of its Common Stock (the “Subscription Shares”) and warrants to purchase up to 2,016,666 shares of its Common Stock (the “ACCBT Warrants”). The ACCBT Warrants contain cashless exercise provisions, which permit the cashless exercise of up to 50% of the underlying shares of Common Stock. 672,222 of the ACCBT Warrants have an exercise price of \$3.00 and the remainder has an exercise price of \$4.35. All of the ACCBT Warrants are presently outstanding. The Company 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 registration rights in the ACCBT Documents.

ACCBT has Board appointment rights, preemptive rights and consents rights pursuant to the ACCBT Documents. The foregoing description reflects the November 2, 2017 Warrant Amendment Agreement between the Company and

ACCBT, pursuant to which the rights and privileges of the ACCBT Entities relating to the management of the Company were reduced, in exchange for a five (5) year extension of the expiration of the Company warrants held by the ACCBT Entities. Pursuant to the amendment, the ACCBT Documents were amended as follows: (i) the ACCBT Entities existing right to appoint 50.1% of the Board of Directors of the Company and its subsidiaries was reduced to 30%; (ii) the ACCBT Entities' consent rights regarding Company matters pursuant to the ACCBT Documents were limited to transactions greater than \$500,000 (previous to the amendment the consent right was for transactions of \$25,000 or more); and (iii) the expiration date of each of the ACCBT Warrants was extended until November 5, 2022 (the previous expiration date was November 5, 2017).

On June 13, 2014, the Company raised gross proceeds of \$10.5 million through a private placement of the Company's Common Stock and warrants purchase Common Stock. The Company issued 2.8 million shares of Common Stock at a price per share of \$3.75 and three-year warrants to purchase up to 2.8 million shares of Common Stock at an exercise price of \$5.22 per share of which 2,546,667 were exercised in January 8, 2015 as detailed below and the remaining 337,333 Warrants at an exercise price of \$5.22 per share weren't exercised and expired in June 19, 2017.

Pursuant to a Warrant Exercise Agreement, dated January 8, 2015, holders of Company warrants, issued in June 2014 to purchase an aggregate of 2,546,667 shares of the Company's Common Stock at an exercise price of \$5.22 per share, exercised their 2014 Warrants in full, and the Company issued 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.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

## NOTE 10 - STOCK CAPITAL (Cont.):

The \$6.50 warrants expire in June 2018. Gross proceeds from the exercise of the warrants were approximately \$13.3 million. In connection with the Exercise Agreement, the Company issued the Placement Agency a warrant to purchase 38,200 shares of Common Stock upon substantially the same terms as the \$6.50 warrants. Net of fees and related expenses the proceeds from the warrant exercise amounted to approximately \$12.4 million. All \$6.50 warrants remain outstanding and unexercised as of December 31, 2017.

Since its inception the Company has raised approximately \$46.6M, net in cash in consideration for issuances of Common Stock and warrants in private placements and public offerings as well as proceeds from warrants exercises.

The following table sets forth the number, exercise price and expiration date of the warrants outstanding as of December 31, 2017:

Issuance Date	Outstanding As Of December 31, 2017	Exercise price	Exercisable Through
Nov-08	6,666	2.25	Sep-18
Apr-Oct 2009	20,000	1.005 - 1.5	Apr-Oct 2019
Aug 2007- Jan 2011	2,016,666	3 - 4.35	Nov-22
Jan-15	3,858,201	6.5	Jun-18
	5,901,533		

**Stock Plans:**

During the fiscal year ended December 31, 2017, the Company had outstanding awards for stock options under four stockholder approved plans: (i) the 2004 Global Stock Option Plan and the Israeli Appendix thereto (the "2004 Global

Plan”) (ii) the 2005 U.S. Stock Option and Incentive Plan (the “2005 U.S. Plan,” and together with the 2004 Global Plan, the “Prior Plans”); (iii) the 2014 Global Share Option Plan and the Israeli Appendix thereto (which applies solely to participants who are residents of Israel) (the “2014 Global Plan”); and (iv) the 2014 Stock Incentive Plan (the “2014 U.S. Plan” and together with the 2014 Global Plan, the “2014 Plans”).

The 2004 Global Plan and 2005 U.S. Plan expired on November 25, 2014 and March 28, 2015, respectively. Grants that were made under the Prior Plans remain outstanding pursuant to their terms. The 2014 Plans were approved by the stockholders on August 14, 2014 (at which time the Company ceased to issue awards under each of the 2005 U.S. Plan and 2004 Global Plan) and amended on June 21, 2016. Unless otherwise stated, option grants prior to August 14, 2014 were made pursuant to the Company’s Prior Plans, and grants issued on or after August 14, 2014 were made pursuant to the Company’s 2014 Plans, and expire on the tenth anniversary of the grant date.

The 2014 Plans have a shared pool of 2,200,000 shares of Common Stock available for issuance. As of December 31, 2017, 1,013,868 shares were available for future issuances under the 2014 Plans. The exercise price of the options granted under the 2014 Plans may not be less than the nominal value of the shares into which such options are exercised. Any options under the 2014 Plans that are canceled or forfeited before expiration become available for future grants. The Governance, Nominating and Compensation Committee (the “GNC Committee”) of the Board of Directors of the Company administers the Company’s stock incentive compensation and equity-based plans.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 10 - STOCK CAPITAL (Cont.):

**Share-based compensation to employees and to directors:**

*Employees:*

Pursuant to a September 28, 2015 employment agreement, as amended, Chaim Lebovits, the Company's Chief Executive Officer and President (i) was granted a stock option under the 2014 Global Plan on September 28, 2015 for the purchase of up to 369,619 shares of the Company's Common Stock at a per share exercise price of \$2.45, which grant is fully vested and exercisable and shall be exercisable for a period of two years after termination of employment; (ii) received on July 26, 2017, and is entitled to receive on each anniversary thereafter (provided he remains Chief Executive Officer), a grant of restricted stock under the 2014 Global Plan (or any successor or other equity plan then maintained by the Company) comprised of a number of shares of Common Stock with a fair market value (determined based on the price of the Common Stock at the end of normal trading hours on the business day immediately preceding the effective date according to Nasdaq) equal to 30% of Mr. Lebovits' Base Salary (31,185 shares on July 26, 2017). Each grant shall vest as to twenty-five percent (25%) of the award on each of the first, second, third and fourth anniversary of the date of grant, provided Mr. Lebovits remains continuously employed by the Company from the date of grant through each applicable vesting date. Each grant shall be subject to accelerated vesting upon a Change of Control (as defined in the Lebovits employment agreement) of the Company. In the event of Mr. Lebovits' termination of employment, any portion of a grant that is not yet vested (after taking into account any accelerated vesting) shall automatically be immediately forfeited to the Company, without the payment of any consideration to Mr. Lebovits; and (iii) was granted on July 26, 2017 a fully vested and exercisable option (the "Option") under the 2014 Global Plan to purchase up to 41,580 shares of Common Stock, which shall remain exercisable until the 2nd anniversary of the date of grant, regardless of whether Mr. Lebovits remains employed by the Company, with an exercise price per share of \$4.81.

The Lebovits employment agreement contains termination provisions, pursuant to which if the Company terminates the employment agreement or Mr. Lebovits' employment without Cause (as defined in the agreement) or if Mr. Lebovits terminates the employment agreement or his employment thereunder with Good Reason (as defined in the agreement), the Company shall immediately vest such number of equity or equity based awards that would have



vested during the six (6) months following the date of termination of employment, conditional upon Mr. Lebovits executing a waiver and release in favor of the Company in a form reasonably acceptable to the Company.

Pursuant to his February 28, 2017 employment agreement, Dr. Ralph Kern, Chief Operating Officer and Chief Medical Officer of the Company, received on March 6, 2017, and is entitled to receive on each anniversary thereafter (provided he remains employed by the Company), a grant of restricted stock under the 2014 U.S. Plan (or any successor or other equity plan then maintained by the Company) comprised of a number of shares of Common Stock with a fair market value (determined based on the price of the Common Stock at the end of normal trading hours on the business day immediately preceding March 6, 2017 according to Nasdaq) equal to 30% of Dr. Kern's Base Salary (35,885 shares on March 6, 2017). Each equity grant shall vest as to twenty-five percent (25%) of the award on each of the first, second, third and fourth anniversary of the date of grant, provided Dr. Kern remains continuously employed by the Company from the date of grant through each applicable vesting date. Each equity grant shall be subject to accelerated vesting upon a Change of Control (as defined in the agreement) of the Company. In the event of Dr. Kern's termination of employment, any portion of an equity grant that is not yet vested (after taking into account any accelerated vesting) shall automatically be immediately forfeited to the Company, without the payment of any consideration to Dr. Kern.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 10 - STOCK CAPITAL (Cont.):

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

*Employees (Cont.):*

Pursuant to the agreement, on March 6, 2017, Dr. Kern also received an option under the 2014 U.S. Plan to purchase up to 47,847 shares of Common Stock with an exercise price per share of \$4.18. The option was fully vested and exercisable and shall remain exercisable until the 2nd anniversary of the date of grant, regardless of whether Dr. Kern remains employed by the Company.

Uri Yablonka, the Company's Executive Vice President, Chief Business Officer and director was granted a stock option on June 6, 2014 under the Company's Amended and Restated 2004 Global Share Option Plan (the "Global Plan") for the purchase of 33,333 shares of the Company's Common Stock, which was fully vested and exercisable upon grant. The exercise price for the grant is \$2.70 per share. In addition, the Company agreed to grant Mr. Yablonka a stock option under the Global Plan (or the applicable successor option plan) for the purchase of up to 13,333 shares of Common Stock (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like) of the Company on the first business day after each annual meeting of stockholders (or special meeting in lieu thereof) of the Company beginning with the 2014 annual meeting, and provided that Mr. Yablonka remains an employee of the Company on each such date. The exercise price per share of the Common Stock subject to each additional option shall be equal to \$0.75 (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like, or changes to the Israeli Annual Option Award under the Company's Director Compensation Plan as amended from time to time). Each additional option vests and becomes exercisable on each monthly anniversary date as to 1/12th the number of shares subject to the option, over a period of twelve months from the date of grant, such that each additional option will be fully vested and exercisable on the first anniversary of the date of grant, provided that Mr. Yablonka remains an employee of the Company on each such vesting date. The Company also granted Mr. Yablonka 5,543 shares of restricted Common Stock on July 13, 2017

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

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 10 - STOCK CAPITAL (Cont.):

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

*Employees (Cont.):*

On August 17, 2017, the Company granted Mary Kay Turner VP, Patient Advocacy and Government Affairs of the Company, 9,924 shares of restricted Common Stock under the 2014 U.S. Plan which vests as to 25% of the grant on each of August 1, 2018, August 1, 2019, August 1, 2020 and August 1, 2021, provided that Ms. Turner is employed by the Company on each such vesting date; in the event of the termination of her employment, any portion of the Initial Equity Grant that has not yet vested as of the effective date of termination shall be automatically and immediately forfeited to the Company without payment of any consideration to her.

On July 13, 2017, the Company granted 5,543 shares of restricted Common Stock under the 2014 Global Plan to each of Yael Gothelf VP, Scientific & Regulatory Affairs and Yossef Levi VP, Cell Production.

*Directors:*

From 2005 through 2015, the Company granted its directors options to purchase an aggregate of 402,778 shares of Common Stock at an average exercise price of \$1.34 per share.

The Company's Second Amended and Restated Director Compensation Plan was approved in July 9, 2014 and amended on April 29, 2015, February 26, 2017 and July 13, 2017 (as amended, the "Director Compensation Plan"). The Director Compensation Plan governs Company compensation of eligible non-employee director of the Company,

except that certain non-employee directors have individualized compensation and are not entitled receive annual director awards under the Director Compensation Plan, but are entitled to committee compensation under the Director Compensation Plan in the event that they qualify for and serve as a member of any committee of the Board. The Director Compensation Plan also determines the annual awards to be granted to qualified directors for their services in future periods, which annual awards have had the same terms since 2014, as further detailed in the Director Compensation Plan. On November 10, 2017, the following grants were made under the 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. Schor received 2,000 shares of restricted stock for his service as a member of the Audit Committee; Dr. 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 12,000 shares of restricted stock for his service as a director, chair of the Audit Committee and a member of the GNC Committee.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 10 - STOCK CAPITAL (Cont.):

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

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

	For the year ended December 31, 2017			For the year ended December 31, 2016		
	Amount of options	Weighted average exercise price \$	Aggregate intrinsic value \$	Amount of options	Weighted average exercise price \$	Aggregate intrinsic value \$
Outstanding at beginning of period	874,841	2.1258		1,002,451	2.6072	
Granted	240,446	3.5178		70,667	0.75	
Exercised	(129,888)	3.9175		-	-	
Cancelled	(44,445 )	1.6104		(198,277 )	4.0691	
Outstanding at end of period	940,954	2.4681	1,366,213	874,841	2.1258	362,336
Vested and expected-to-vest at end of period	811,824	2.3317	1,289,457	839,509	2.1837	299,088

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, 2017 and December 31, 2016 and the exercise price, multiplied by the number of in-the-money options on those dates) that would have been received by the option holders had all option holders exercised their options on those dates.



BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 10 - STOCK CAPITAL (Cont.):

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

The options outstanding as of December 31, 2017 and December 31, 2016, have been separated into exercise prices, as follows:

Exercise price \$	Options outstanding		Weighted average remaining contractual Life - Years		Options exercisable as of	
	As of December 31, 2017	2016	As of December 31, 2017	2016	As of December 31, 2017	2016
0.75	213,333	213,665	6.99	8.67	177,889	178,333
1.005	5,333	6,445	1.50	2.50	5,333	6,445
2.25	69,889	137,000	3.57	4.72	69,889	137,000
2.45	369,619	369,619	7.75	8.75	369,619	369,619
2.70	82,667	93,333	5.65	6.54	82,667	93,333
3.17	-	25,779	-	0.12	-	25,779
3.90	15,000	15,000	4.59	5.59	15,000	15,000
4.18	47,847	-	1.18	-	47,847	-
4.3	93,686	-	9.89	-	-	-
4.80	2,000	2,000	2.11	3.11	2,000	2,000
4.81	41,580	-	1.56	-	41,580	-
5.85	-	6,000	-	0.5	-	6,000
7.05	-	6,000	-	0.22	-	6,000



940,954    874,841    6.59    7.38    811,824    839,509

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, 2017 and 2016 amounted to \$554 and \$635, 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:

	Year ended December 31,	
	2017	2016
Expected volatility	67%-70%	75%-77%
Risk-free interest	0.97%-2.13%	1.20% - 1.27%
Dividend yield	0%	0%
Expected life of up to (years)	5.5	5.25

#### **Shares and warrants issued to 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", whereby the fair value of such warrant grants is determined using a Black-Scholes options pricing model at the earlier of the date at which the non-employee's performance is completed or a performance commitment is reached.

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY**

U.S. dollars in thousands

(Except share data and exercise prices)

**Notes to Consolidated Financial Statements**

NOTE 10 - STOCK CAPITAL (Cont.):

**Shares and warrants issued to service providers (Cont.):**

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

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

On August 17, 2017 the Company issued to Anthony Fiorino, the former CEO of the Company, for consulting services rendered, a grant of 4,327 shares of restricted stock under the 2014 U.S. Plan, which vests in eight equal quarterly installments (starting November 17, 2017) until fully vested on the second anniversary of the date of grant.

Compensation expense recorded by the Company in respect of its stock-based service provider compensation awards in accordance with ASC 718-10 for the year ended December 31, 2017 and 2016 amounted to \$62 and \$121, respectively.

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

**Total Stock-Based Compensation Expense**

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

	Year ended December 31,	
	2017	2016
Research and development	\$ 164	\$ 96
General and administrative	452	660
Total stock-based compensation expense	\$ 616	\$ 756

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 11 - RESEARCH AND DEVELOPMENT, NET

	Year ended December 31,	
	2017	2016
	U.S. \$ in thousands	
Research and development	\$ 6,795	\$ 3,435
Less : Participation by the Israel Innovation Authorities	(1,393 )	(1,185 )
Less : Participation by CIRM	(4,425 )	-
	\$ 977	\$ 2,250

NOTE 12 - TAXES ON INCOME

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

BCT is subject to a tax rate of 24% in 2017. In 2018 the tax rate is expected to decrease to 23%.

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

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,  
2017      2016  
U.S. \$ in thousands

Operating loss carryforward	\$51,107	\$39,967
Net deferred tax asset before valuation allowance	14,090	13,333
Valuation allowance	(14,090)	(13,333)
Net deferred tax asset	\$-	\$-

As of December 31, 2017, the Company has provided valuation allowances of \$14,090 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 SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 12 - TAXES ON INCOME (Cont.):

C. Available carryforward tax losses:

As of December 31, 2017, the Company has an accumulated tax loss carryforward of approximately \$51,107. 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,	
	2017	2016
	U.S. \$ in thousands	
United States	\$ (2,532 )	\$ (1,451 )
Israel	(2,420 )	(3,531 )
	\$ (4,952 )	\$ (4,982 )

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

On December 22, 2017, the Tax Cuts and Jobs Act (the "Tax Act") was signed into law in the United States. The Tax Act, among other provisions, introduces changes in the U.S corporate tax rate, business related exclusions and deductions and credits, and has internationally tax consequences for companies that operate international. Most of the changes introduced in the Tax Act are effective beginning on January 1, 2018.

G.

As a result of the tax act the Company is subject to a reduced blended U.S. tax rate of 34% starting on January 1, 2018. The other effects of the Tax Act provisions are still being identified and evaluated by Management.

NOTE 13 - TRANSACTIONS WITH RELATED PARTIES

Other than transactions and balances related to cash and share based compensation to officers and directors, the Company did not have any transactions and balances with related parties and executive officers during 2017 and 2016.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

NOTE 14 -SUBSEQUENT EVENTS

On January 3, 2018, the Company received a Good Manufacturing Practice (GMP) approval from the Israel Ministry of Health (MoH) for its Israeli contract manufacturing facility. The GMP certificate confirms the Company's manufacturing site compliance with Israeli GMPs which are recognized as equivalent with EU standards.

On February 5, 2018, the Company appointed Anthony Polverino, Ph.D., as a board member. Dr. Polverino, is currently interim chief scientific officer of Kite (formerly Kite Pharma and now a wholly-owned subsidiary of Gilead Sciences) and a highly accomplished senior biopharmaceutical executive with more than 25 years' industry experience in drug research and development.

On February 5, 2018 Dr. Robert Shorr left the Company's board of directors.

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



**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, 2017 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, 2017. 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, 2017, 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.

**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>
Chaim Lebovits	47	President and Chief Executive Officer
Dr. Ralph Kern	60	Chief Operating Officer and Chief Medical Officer
Eyal Rubin	42	Chief Financial Officer
Uri Yablonka	41	Executive Vice President, Chief Business Officer and Director
Dr. Irit Arbel	58	Chairperson and Director
Dr. June S. Almenoff	61	Director
Arturo O. Araya	47	Director
Chen Schor	45	Director
Dr. Anthony Polverino	55	Director
Malcolm Taub	72	Director

**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 June 2014. On September 22, 2015, the Company appointed Chaim Lebovits as its Chief Executive Officer. 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.

**Dr. Ralph Kern** joined the Company on March 6, 2017 as Chief Operating Officer and Chief Medical Officer. Prior to joining the Company, Dr. Kern was Senior Vice President, Head Worldwide Medical at Biogen Inc. since 2016. Prior positions at Biogen Inc. include Vice President, Head of Global Therapeutic Areas from 2015 to 2016 and Vice President, Head of Global Medical Neurology in 2015. Dr. Kern has also served Novartis Pharmaceuticals

Corporation as Vice President, Head Neuroscience Medical Unit from 2014 to 2015 and as Vice President, Head MS Medical Unit from 2011 to 2014. He also worked for Genzyme Corporation from 2006 to 2011 where he served as Global Medical Director, Personalized Genetic Health (2010-2011), Head of Medical Affairs, Canada (2006-2008), General Manager, Fabry Disease (2008-2010) and Head of Medical Affairs, Canada (2006-2008). He also served as University Neurology Program Director at the University of Toronto (2003-2006), Consultant Neurologist at Mount Sinai Hospital (2001-2006) and Director, EMG, EEG and Evoked Potential Laboratory at The Credit Valley Hospital (1988-2001).

**Eyal Rubin** joined the Company on November 20, 2017 as Chief Financial Officer and Treasurer. Prior to joining the Company, Eyal Rubin served since January, 2015 as Vice President, Head of Corporate Treasury for Teva Pharmaceutical Industries Ltd. (symbol: TEVA), a multinational pharmaceutical company. From March, 2013 to January, 2015, Mr. Rubin worked as Teva Pharmaceutical Industries Ltd.'s Regional Treasurer for ASIA and EMIA. From January, 2010 to March, 2013, he served as Head of the Finance & Banking department at Cellcom Israel LTD (NASDAQ:CEL), an Israeli telecommunications company.

**Uri Yablonka** joined the Company on June 6, 2014 as Chief Operating Officer and as a member of the Board. On March 6, 2017 he was appointed Executive Vice President, Chief Business Officer and ceased to serve as the Company's Chief Operating Officer. 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 the Company'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 Chairperson of the Board and 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 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.

**Dr. Anthony Polverino** joined the Company on February 5, 2018 as a director. Dr. Polverino is currently the interim chief scientific officer of Kite (now a wholly-owned subsidiary of Gilead Sciences), which he joined in 2015, and where he is currently responsible for establishing Kite's strategic non-clinical R&D roadmap to support its current and future portfolio. Prior to this, he was the vice president of research at Kite, where his responsibilities included corporate goal setting, budget allocation, scientific and investor interactions, business development in-licensing and partnership deals. Dr. Polverino spent 20 years in positions of increasing responsibilities at Amgen, Inc., most recently as executive director of its Therapeutic Innovation Unit, where he managed research programs in oncology, metabolic disease, inflammatory disease and schizophrenia. Prior to Amgen, he was a postdoctoral scientist at Cold Spring Harbor Laboratory, where he worked primarily on oncology research. Dr. Polverino is an author of several patents, and has been published in nearly 40 scientific and peer-reviewed journals. He earned a B.Sc. in Biochemistry/Physiology and a B.Sc. (Honors) in Pharmacology, both from Adelaide University in Adelaide, Australia and a Ph.D. in Biochemistry from Flinders University, also in Adelaide.

**Dr. June S. Almenoff** joined the Company on February 26, 2017 as a director. Dr. Almenoff is an accomplished executive with 20 years of experience in the pharmaceutical industry. She recently served as President and CMO of Furiex Pharmaceuticals (from 2010 to 2014). During her 4-year tenure, the company's valuation increased approximately ten-fold, culminating in its acquisition by Actavis plc for approximately \$1.2 billion in 2014. Furiex's lead product, eluxadoline (Viberzi TM), a novel gastrointestinal drug, has recently been approved in both the US and EU. Prior to joining Furiex, Dr. Almenoff was at GlaxoSmithKline (GSK) from 1997-2010, where she held various positions of increasing responsibility. During her time at GSK, she was a Vice President in the Clinical Safety organization, chaired a PhRMA-FDA working group and worked in the area of scientific licensing. Dr. Almenoff also led the development of pioneering systems for minimizing risk in drug development which have been widely adapted by industry and regulators. Dr. Almenoff is currently an independent biopharma consultant and Board Director. Her areas of expertise include translational medicine, clinical development and commercial strategy. She is Executive Chair of RDD Pharma, a private, clinical-stage biopharma company (since 2015) and an Independent Director of Tigenix NV (Nasdaq: TIG) since 2016, and Ohr Pharmaceuticals (Nasdaq: OHRP) since 2013. She serves on the

Scientific Advisory Board of Redhill Biopharma (Nasdaq: RDHL). She is on the advisory boards of several private life-sciences companies and the investment advisory board of the Harrington Discovery Institute. Dr. Almenoff received her B.A. cum laude from Smith College and graduated with AOA honors from the M.D.-Ph.D. program at the Icahn (Mt. Sinai) School of Medicine. She completed post-graduate medical training at Stanford University Medical Center (Internal Medicine, Infectious Diseases) and served on the faculty of Duke University School of Medicine. She is a Consulting Professor at Duke and a Fellow of the American College of Physicians. We believe that Dr. Almenoff possesses specific attributes that qualify her to serve on our Board including her valuable leadership skills and her deep knowledge of pharmaceutical product development.

**Arturo O. Araya** joined the Company on February 26, 2017 as a director. From 2002 to 2016, Mr. Araya worked for Novartis Pharmaceutical Corporation, where he served as the Vice President and Head of Global Commercial for Novartis' Cell and Gene Therapies Unit (June 2014 to July 2016), where he led a cross-functional team to globally commercialize a portfolio of cell and gene therapies. In his prior role as Novartis' Global Brand Leader for CTL019 (September 2012-May 2014), a CAR-T therapy, he was responsible for developing early launch plans, including worldwide and multiple indication forecasts and resource modeling. He has lead the Oncology Unit for Novartis in seven countries (March 2002-August 2012). Prior to his tenure at Novartis, Mr. Araya was with Bristol-Myers Squibb Company (1999-2002), most recently as Associate Director of Marketing Intelligence, Business Development & Licensing. He earned an M.B.A. from the University of Michigan, and an M.A. and B.S. in Engineering from the University of Connecticut. We believe that Mr. Araya possesses specific attributes that qualify him to serve on our Board including his extensive experience in biotechnology and valuable leadership skills.

**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. In July 2016, Mr. Schor joined resTORbio, Inc and is currently serving as Co-Founder, President, and CEO. From December 2014 to July 2016, Mr. Schor was an officer with Synta Pharmaceuticals Corp., a NASDAQ listed biopharmaceutical company. From October 2012 to December 2014, Mr. Schor served as President and CEO of Novalere, Inc. 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 including Mr. Schor's extensive experience in biotechnology and significant leadership skills from his service as a partner of a venture capital firm.

**Malcolm Taub** joined the Company in March 2009 as a director. Since October 2010, Mr. Taub has been a Partner at Davidoff Malito & Hutcher 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 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, Almenoff and Polverino and Messrs. Araya and Schor), accounting (Mr. Schor), 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 an executive officer (Drs. Arbel, Almenoff and Polverino and Messrs. Schor, Araya and Yablonka), 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, 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 Business 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 paid \$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. On May 3, 2015, we entered into a Restricted Stock Agreement with Mr. Schor, pursuant to which Mr. Schor received a grant of 60,000 shares of our restricted Common Stock under our 2014 Stock Incentive Plan in consideration for Mr. Schor's ongoing services as an Executive Director of the Company. The shares of restricted stock vested as follows: 20,000 on August 22, 2015, 20,000 on August 22, 2016 and 20,000 on August 22, 2017. On February 26, 2017 the Executive Director Agreement was terminated by mutual agreement of Chen Schor and the Company, and the Board approved that Chen Schor will receive the following compensation for his service on the Board: an annual cash award in the amount of \$30,000, paid in biannual installments, that Mr. Schor will not receive annual director awards under the Director Compensation Plan, but in the event that Mr. Schor serves as a member of any committee of the Board he will be entitled to committee compensation under the Director Compensation Plan.



On June 1, 2015 pursuant to the Company's First Amendment to the Second Amended and Restated Director Compensation Plan, we granted a stock option to Irit Arbel, the Company's Chair of the Board of Directors, to purchase up to 6,667 shares of Common Stock at a purchase price of \$0.75 per share. On February 26, 2017 pursuant to the Company's Second Amendment to the Second Amended and Restated Director Compensation Plan, we granted a stock option to Dr. Arbel to purchase up to 6,667 shares of Common Stock at a purchase price of \$0.75 per share. On July 13, 2017 pursuant to the Company's Third Amendment to the Second Amended and Restated Director Compensation Plan, we granted a stock option to Dr. Arbel to purchase up to 12,000 shares of Common Stock at a purchase price of \$0.75 per share. Each option was fully vested and exercisable on the date of grant.

Pursuant to a February 26, 2017 resolution of the Board, Dr. Almenoff receives the following compensation for her service on the Board: an annual cash award in the amount of \$30,000, paid in biannual installments. Dr. Almenoff will not receive annual director awards under the Director Compensation Plan, but in the event that Dr. Almenoff serves as a member of any committee of the Board she will be entitled to committee compensation under the Director Compensation Plan. Dr. Almenoff has not been appointed to any Board committee at this time.

Pursuant to a February 26, 2017 resolution of the Board, Mr. Araya receives the following compensation for his service on the Board: an annual cash award in the amount of \$12,500, paid in biannual installments, and an annual restricted stock award (each, an "Araya Grant") valued at \$12,500 on the date of grant, as determined based on the closing price of the Company's common stock at the end of normal trading hours on the date of grant, or the previous closing price in the event the grant date does not fall on a business day. The Araya Grant will vest in 12 consecutive, equal monthly installments commencing on the one month anniversary of the date of grant, until fully vested on the first anniversary of the date of grant, provided Mr. Araya remains a director of the Company on each such vesting date. Each Araya Grant will be issued under the Company's 2014 Stock Incentive Plan (or successor plan thereto, the "Plan") and be subject to the limitations of the Plan and any SEC or Nasdaq listing requirements and any required stockholder approvals. In no event shall the number of shares issuable in any Araya Grant exceed (i) the limits imposed under NASDAQ or other applicable rules without the receipt of stockholder approval thereof or (ii) the number of available shares available for issuance under the Plan. In the event the number of shares issuable under an Araya Grant is capped as a result thereof, the Company shall use commercially reasonable efforts to seek the requisite stockholder and/or other approvals in connection with the Company's next annual meeting of stockholders to allow the Company to issue the additional shares. If the Company seeks stockholder approval and fails to receive the requisite approval, then the Company shall have no additional liability to Mr. Araya with respect to the Company's inability to issue additional shares or options to Mr. Araya. Mr. Araya will not receive annual director awards under the Director Compensation Plan, but in the event that Mr. Araya serves as a member of any committee of the Board he will be entitled to committee compensation under the Director Compensation Plan. Mr. Araya has not been appointed to any Board committee at this time. Mr. Araya will not receive annual director awards under the Director Compensation Plan, but in the event that Mr. Araya serves as a member of any committee of the Board he will be entitled to committee compensation under the Director Compensation Plan. Mr. Araya has not been appointed to any Board committee at this time.

Uri Yablonka serves as the Company's EVP & Chief Business Officer and is compensated for all services as an officer and director of the Company pursuant to an employment agreement with the Company and related compensation

described under “Executive Employment Agreements” in the Executive Compensation section below.

### **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. Taub (Chair), Dr. Arbel and Mr. Schor 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. Schor is an “audit committee financial expert” as defined in Item 407(d)(5) of Regulation S-K. The Audit Committee held four meetings during the fiscal year ended December 31, 2017.

### *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) and Mr. Taub, each of whom is independent as defined under applicable NASDAQ listing standards. The GNC Committee held six (6) meetings during the fiscal year ended December 31, 2017.

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 2017, we made no material changes to the procedures by which stockholders may recommend nominees to our Board of Directors, as described in our most recent proxy statement.

### **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, 2017 all Reporting Persons complied

with the applicable requirements of Section 16(a) of the Exchange Act other than one late Form 4 filed by Arturo Araya, reporting one transaction 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, 2017 and 2016 earned by our President and Chief Executive Officer, our Chief Operating Officer and our Chief Business Officer (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 and Stock Awards		All Other Compensation (\$)(3)	Total (\$)
				(1)	(2)		
Chaim Lebovits (*) President and CEO (6)	2017	391,250	250,000(4)	193,500	(5)	170,600	1,005,350
	2016	282,500	141,250(7)	-		130,000	553,750
Ralph Kern, Chief Operating Officer (8)	2017	417,000	-	200,000	(9)	59,000	676,000
	2016	-	-	-		-	-
Uri Yablonka (*), Executive Vice President, Chief Business Officer (10)	2017	122,000	-	73,500	(11)	62,000	257,500
	2016	100,000	-	27,000	(12)	53,000	180,000

(\*) These 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 2017 daily rates 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 and Stock 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 2017 and fiscal 2016. 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 10 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. Each Named Executive Officer also receives gross-up payments for the taxes on these benefits.

(4) In July 2017, the Company paid Mr. Lebovits a discretionary cash bonus payment of \$250,000 in recognition of his contributions to the Company’s performance in fiscal year 2017.

(5) On July 26, 2017 Mr. Lebovits received a grant of an option to purchase up to 41,580 shares of Common Stock at an exercise price of \$4.81 per share, and a grant of 31,185 shares of restricted Common Stock.

(6) On September 22, 2015, the Company appointed Chaim Lebovits as its Chief Executive Officer.

(7) On December 5, 2016, the Company paid Mr. Lebovits a discretionary cash bonus payment of \$141,250 in recognition of his contributions to the Company's performance in fiscal year 2016.

(8) Dr. Kern's employment with the Company began on March 6, 2017.

(9) On March 6, 2017 Dr. Kern received a grant of an option to purchase up to 47,847 shares of Common Stock at an exercise price of \$4.18 per share, and a grant of 35,885 shares of restricted Common Stock.

(10) Mr. Yablonka's employment with the Company began on June 6, 2014.

(11) On November 10, 2017, Mr. Yablonka received a grant of 13,333 stock options at an exercise price of \$0.75 per share. On July 13, 2017 he received a grant of 5,543 shares of Common Stock.

(12) On June 22, 2016, Mr. Yablonka received a grant of 13,333 stock options at an exercise price of \$0.75 per share.

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

#### *Chaim Lebovits*

On September 28, 2015, Chaim Lebovits, the Company's Chief Executive Officer and President, and the Company's wholly owned subsidiary Brainstorm Cell Therapeutics Ltd. (the "Subsidiary"), entered into an employment agreement, which was amended July 26, 2017 (as amended, the "Lebovits Employment Agreement"). Pursuant to the Lebovits Employment Agreement, Chaim Lebovits is paid a salary at the annual rate of \$500,000 (the "Base Salary"). Mr. Lebovits also receives other benefits that are generally made available to the Subsidiary's employees. In addition, he is provided with a cellular phone and a company car, with all costs including taxes borne by the Subsidiary.



Pursuant to the Lebovits Employment Agreement, Mr. Lebovits was granted a stock option under the Company's 2014 Global Share Option Plan on September 28, 2015 for the purchase of up to 369,619 shares of the Company's Common Stock at a per share exercise price of \$2.45, which grant is fully vested and exercisable and shall be exercisable for a period of two years after termination of employment. Pursuant to the Lebovits Employment Agreement, Mr. Lebovits was granted on July 26, 2017, and will also be eligible to receive in the future, an annual cash bonus equal to 50% of his base salary, subject to his satisfaction of pre-established performance goals to be mutually agreed upon by the Board of Directors of the Company and Mr. Lebovits. Performance shall be evaluated through a performance management framework and a bonus range based on the target bonus.

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

Pursuant to the Lebovits Employment Agreement, on July 26, 2017, Mr. Lebovits also received a fully vested and exercisable option (the "Option") under the Company's 2014 Global Share Option Plan to purchase up to 41,580 shares of Common Stock, which shall remain exercisable until the 2<sup>nd</sup> anniversary of the date of grant, regardless of whether Mr. Lebovits remains employed by the Company. The exercise price per share is \$4.81.

The Lebovits Employment Agreement contains termination provisions, pursuant to which if the Company terminates the Employment Agreement or Mr. Lebovits' employment without Cause (as defined in the agreement) or if Mr. Lebovits terminates the employment agreement or his employment thereunder with Good Reason (as defined in the agreement), the Company shall: (i) within 90 days pay Mr. Lebovits, as severance pay, a lump sum equal to six (6) months of Base Salary (which shall increase to nine (9) months after July 26, 2019 and twelve (12) months after July 26, 2020) (provided Mr. Lebovits is actively employed by the Company on such dates) (the "Payment Period"); (ii) pay Mr. Lebovits within 30 days of his termination of employment any bonus compensation that Mr. Lebovits would be entitled to receive during the Payment Period in the absence of his termination without Cause or for Good Reason; (iii) immediately vest such number of equity or equity based awards that would have vested during the six (6) months following the date of termination of employment; and (iv) shall continue to provide to Mr. Lebovits health insurance benefits during the Payment Period, unless otherwise provided by a subsequent employer. The foregoing severance payments are conditional upon Mr. Lebovits executing a waiver and release in favor of the Company in a form reasonably acceptable to the Company.

*Dr. Ralph Kern*

On February 28, 2017, the Company and Dr. Ralph Kern entered into an employment agreement, effective March 6, 2017, which sets forth the terms of Dr. Kern's employment (as amended by Amendment No. 1 dated March 3, 2017, the "Agreement"). Pursuant to the Agreement, Dr. Kern is paid an annual salary of \$500,000 (the "Base Salary"), which may be increased (but not decreased) at the sole discretion of the Board of Directors of the Company. Dr. Kern will also be eligible to receive an annual cash bonus equal to 30% of his base salary, subject to his satisfaction of pre-established performance goals to be mutually agreed upon by the Board and Dr. Kern. Performance shall be evaluated through a performance management framework and a bonus range based on the target bonus. Dr. Kern will also receive other benefits that are generally made available to the Company's employees.

Pursuant to the Agreement, Dr. Kern received on March 6, 2017, and is entitled to receive on each anniversary thereafter (provided he remains employed by the Company), a grant of restricted stock under the Company's 2014 Stock Incentive Plan (or any successor or other equity plan then maintained by the Company) comprised of a number of shares of common stock of the Company, \$0.00005 par value ("Common Stock") with a fair market value (determined based on the price of the Common Stock at the end of normal trading hours on the business day immediately preceding March 6, 2017 according to Nasdaq) equal to 30% of Dr. Kern's Base Salary. Each equity grant shall vest as to twenty-five percent (25%) of the award on each of the first, second, third and fourth anniversary of the date of grant, provided Dr. Kern remains continuously employed by the Company from the date of grant through each applicable vesting date. Each equity grant shall be subject to accelerated vesting upon a Change of Control (as defined in the Agreement) of the Company. In the event of Dr. Kern's termination of employment, any portion of an equity grant that is not yet vested (after taking into account any accelerated vesting) shall automatically be immediately forfeited to the Company, without the payment of any consideration to Dr. Kern.

Pursuant to the Agreement, on March 6, 2017, Dr. Kern also received an option under the Company's 2014 Stock Incentive Plan to purchase up to 47,847 shares of Common Stock with an exercise price per share of \$4.18. The option was fully vested and exercisable and shall remain exercisable until the 2<sup>nd</sup> anniversary of the date of grant, regardless of whether Dr. Kern remains employed by the Company.

The Agreement contains termination provisions, pursuant to which if the Company terminates the Agreement or Dr. Kern's employment without Cause (as defined in the Agreement) or if Dr. Kern terminates the Agreement or his employment thereunder with Good Reason (as defined in the Agreement), the Company shall: (i) within 90 days pay Dr. Kern, as severance pay, a lump sum equal to six (6) months of Base Salary (which shall increase to nine (9) months after the second anniversary of March 6, 2017 and twelve (12) months after the third anniversary of March 6, 2017) (provided Dr. Kern is actively employed by the Company on such dates) (the "Payment Period"); (ii) pay Dr. Kern within 30 days of his termination of employment any bonus compensation that Dr. Kern would be entitled to receive during the Payment Period in the absence of his termination without Cause or for Good Reason; (iii) immediately vest such number of equity or equity based awards that would have vested during the six (6) months following the date of termination of employment; and (iv) shall continue to provide to Dr. Kern health insurance benefits during the Payment Period, unless otherwise provided by a subsequent employer. The foregoing severance payments are conditional upon Dr. Kern executing a waiver and release in favor of the Company in a form reasonably acceptable to the Company.

#### *Eyal Rubin*

On October 31, 2017, the Subsidiary and Eyal Rubin, the Company's EVP and Chief Financial Officer, entered into an employment agreement which sets forth the terms of Mr. Rubin's employment, starting on November 20, 2017 (the "Commencement Date"). Pursuant to the employment agreement, Eyal Rubin is paid a gross monthly salary of NIS 59,000 (approximately \$17,000 per month), and is entitled to an annual cash bonus equal to 25% of his annual base salary, paid pro-rata on a quarterly basis. Mr. Rubin also receives other benefits that are generally made available to the Subsidiary's employees. The employment agreement provides that if the Subsidiary terminates the employment agreement or Mr. Rubin's employment without Cause (as defined in the employment agreement), the Subsidiary shall pay Mr. Rubin, as a special severance pay, an amount equal to six (6) months of his then-current salary, as well as any portion of the bonus compensation that Mr. Rubin would otherwise be entitled to receive during the six (6) month period following the termination if his employment would not have been terminated, subject to execution of a full and general waiver and release.

On November 20, 2017, the Company granted to Mr. Rubin 25,000 shares of restricted Common Stock under the Company's 2014 Global Share Option Plan, which shall vest as to 100% of the award on April 1, 2018, provided Mr. Rubin remains continuously employed by the Subsidiary from the date of grant through the vesting date. In the event of Mr. Rubin's termination of employment prior to April 1, 2018, the restricted stock grant shall automatically be immediately forfeited in its entirety to the Company, without the payment of any consideration to Mr. Rubin.

*Uri Yablonka*

Uri Yablonka, the Company's Executive Vice President, Chief Business Officer and director, is party to a June 6, 2014 employment agreement with the Subsidiary, which was amended July 26, 2017. Pursuant to the agreement, Uri Yablonka is paid a monthly salary of 41,000 NIS (approximately \$11,800 per month). Mr. Yablonka also receives other benefits that are generally made available to the Company's employees, including pension and education fund benefits. The Company provides Mr. Yablonka with a Company car and cellular phone, and a gross-up payment for any taxes relating thereto. Pursuant to the agreement, 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 vests and becomes exercisable on each monthly anniversary date as to 1/12th the number of shares subject to the option, over a period of twelve months from the date of grant, such that each additional option will be fully vested and exercisable on the first anniversary of the date of grant, provided that Mr. Yablonka remains an employee of the Company on each such vesting date. In addition, Mr. Yablonka was granted 5,543 shares of Common Stock under the 2014 Global Plan on July 13, 2017.

*Terms of Option Awards*

Stock option grants to the Named Executive Officers are described in the summaries of their executive employment agreements above and incorporated herein. Unless otherwise stated, option grants issued to Named Executive Officers prior to August 14, 2014 were made pursuant to the Company's 2004 Global Share Option Plan and grants issued to Named Executive Officers on or after August 14, 2014 were made pursuant to the Company's 2014 Global Share Option Plan, and expire on the tenth anniversary of the grant date.

**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, 2017. 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, 2017**

Name	Option Awards		Option Exercise Price (\$)	Option Expiration Date	Stock Awards	
	Number of Underlying Unexercised Options (#) Exercisable	Number of Underlying Unexercised Options (#) Unexercisable			Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)
Chaim Lebovits	369,619	-	2.45	9/28/2025	31,185(2)	122,245
	41,580	-	4.81	7/26/2019		

Uri Yablonka	33,333	-		2.70	6/6/2024		
	13,333	-		0.75	8/15/2024		
	13,333	-		0.75	8/27/2025		
	13,333			0.75	6/22/2026		
	1,111	12,222	(3)	0.75	11/10/2027		
Ralph Kern	47,847	-		4.18	3/6/2019	35,885(4)	140,670

(1)Based on the fair market value of our Common Stock on December 29, 2017 (\$3.92 per share).

Restricted stock award vests 25% on each of the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> anniversary of date of grant (July 26, 2017),  
 (2)provided that Chaim Lebovits remains continuously employed by the Company from the date of grant through each applicable vesting date.

Options for the purchase of 1,111 shares were vested and exercisable on December 31, 2017. Options for the  
 (3)purchase of 1,111 shares will vest and become exercisable monthly until the option is fully vested and exercisable on the first anniversary of the date of grant.

Restricted stock award vests 25% on each of the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> anniversary of date of grant (March 6, 2017),  
 (4)provided that Ralph Kern remains continuously employed by the Company from the date of grant through each applicable vesting date.

### Stock Incentive Plans

During the fiscal year ended December 31, 2017, the Company had outstanding awards for stock options under four plans: (i) the 2004 Global Stock Option Plan and the Israeli Appendix thereto (the “2004 Global Plan”) (ii) the 2005 U.S. Stock Option and Incentive Plan (the “2005 U.S. Plan,” and together with the 2004 Global Plan, the “Prior Plans”); (iii) the 2014 Global Share Option Plan and the Israeli Appendix thereto (which applies solely to participants who are residents of Israel) (the “2014 Global Plan”); and (iv) the 2014 Stock Incentive Plan (the “2014 U.S. Plan” and together with the 2014 Global Plan, the 2014 Plans).

The 2004 Global Plan and 2005 U.S. Plan expired on November 25, 2014 and March 28, 2015, respectively. Grants that were made under the Prior Plans remain outstanding pursuant to their terms. The 2014 Plans were approved by the stockholders on August 14, 2014 (at which time the Company ceased to issue awards under each of the 2005 U.S. Plan and 2004 Global Plan) and amended on June 21, 2016. Unless otherwise stated, option grants prior to August 14, 2014 were made pursuant to the Company’s Prior Plans, and grants issued on or after August 14, 2014 were made pursuant to the Company’s 2014 Plans, and expire on the tenth anniversary of the grant date.

The 2014 Plans have a shared pool of 2,200,000 shares of common stock available for issuance. The exercise price of the options granted under the 2014 Plans may not be less than the nominal value of the shares into which such options are exercised. Any options under the 2014 Plans that are canceled or forfeited before expiration become available for future grants.

## Compensation of Directors

The following table sets forth certain summary information with respect to the compensation paid during the fiscal year ended December 31, 2017 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 2017

Name	Fees		Option		Total
	Earned or Paid in Cash (\$)	Stock Awards (\$)(1)	Awards (\$)(1)(2)		
Dr. Irit Arbel	—	—	163,880(3)		163,880
Dr. June S. Almenoff	25,000 (4)	—			25,000
Arturo O. Araya	10,417 (5)	12,500(6)			22,917
Mordechai Friedman	—	—	—	(7)	—
Alon Pinkas	—	—	—	(8)	—
Mr. Chen Schor	32,500 (9)	8,180 (10)	—		40,680
Dr. Robert Shorr	—	35,444(11)	—		35,444
Mr. Malcolm Taub	—	49,080(12)	—		49,080

(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 2017.

(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 10 – Share-based compensation to employees and to directors to Consolidated Financial Statements.

(3) At December 31, 2017, Dr. Arbel had options (vested and unvested) to purchase 196,553 shares of Common Stock.

- (4) Represents amounts paid to Dr. Almenoff for services as a director.
- (5) Represents amounts paid to Mr. Araya for services as a director.
- (6) At December 31, 2017, Mr. Araya had 502 shares of unvested restricted Common Stock.
- (7) At December 31, 2017, Mr. Friedman had options (vested and unvested) to purchase 33,332 shares of Common Stock.
- (8) At December 31, 2017, Mr. Pinkas had no options (vested or unvested) to purchase shares of Common Stock.
- (9) Represents the amount paid to Mr. Schor pursuant to the Executive Director Agreement for his services as a director and consultant.
- (10) At December 31, 2017, Mr. Schor had 1,834 shares of unvested restricted Common Stock.
- (11) At December 31, 2017, Dr. Shorr had 7,944 shares of unvested restricted Common Stock.
- (12) At December 31, 2017, Mr. Taub had 11,000 shares of unvested restricted Common Stock.

#### *Director Compensation Plan*

We review the level of compensation of our non-employee directors on a periodic basis. To determine how appropriate the current level of compensation for our non-employee directors is, we have historically obtained data from a number of different sources, including publicly available data describing director compensation in peer companies and survey data collected by an independent compensation consultant. Those of our directors who are not employees of Brainstorm receive compensation for their services as directors as follows:



The Company's Second Amended and Restated Director Compensation Plan was approved July 9, 2014 and amended on April 29, 2015, February 26, 2017 and July 13, 2017 (as amended, the "Director Compensation Plan"). Under the 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. Every non-employee director of the Company is eligible to participate in the Director Compensation Plan, except that Chen Schor, Dr. June S. Almenoff, Arturo O. Araya and Dr. Anthony Polverino are not entitled receive annual director awards under the Director Compensation Plan, but are entitled to committee compensation under the Director Compensation Plan in the event that they qualify for and serve as a member of any committee of the Board. Chen Schor, Dr. Almenoff, Mr. Araya and Dr. Polverino's director compensation is further discussed below.

Pursuant to a February 26, 2017 resolution of the Board, Dr. Almenoff receives the following compensation for her service on the Board: an annual cash award in the amount of \$30,000, paid in biannual installments. Dr. Almenoff will not receive annual director awards under the Director Compensation Plan, but in the event that Dr. Almenoff serves as a member of any committee of the Board she will be entitled to committee compensation under the Director Compensation Plan. Dr. Almenoff has not been appointed to any Board committee at this time.

Pursuant to resolutions of the Board, Mr. Araya and Dr. Polverino each receives the following compensation for his service on the Board: an annual cash award in the amount of \$12,500, paid in biannual installments, and an annual restricted stock award (each, a "Grant") valued at \$12,500 on the date of grant, as determined based on the closing price of the Company's common stock at the end of normal trading hours on the date of grant, or the previous closing price in the event the grant date does not fall on a business day. The Grant will vest in 12 consecutive, equal monthly installments commencing on the one month anniversary of the date of grant, until fully vested on the first anniversary of the date of grant, provided the recipient remains a director of the Company on each such vesting date. Each Grant will be issued under the Company's 2014 Stock Incentive Plan (or successor plan thereto, the "Plan") and be subject to the limitations of the Plan and any SEC or NASDAQ listing requirements and any required stockholder approvals. In no event shall the number of shares issuable in any Grant exceed (i) the limits imposed under NASDAQ or other applicable rules without the receipt of stockholder approval thereof or (ii) the number of available shares available for

issuance under the Plan. In the event the number of shares issuable under a Grant is capped as a result thereof, the Company shall use commercially reasonable efforts to seek the requisite stockholder and/or other approvals in connection with the Company's next annual meeting of stockholders to allow the Company to issue the additional shares. If the Company seeks stockholder approval and fails to receive the requisite approval, then the Company shall have no additional liability to recipient with respect to the Company's inability to issue additional shares or options to recipient. Mr. Araya and Dr. Polverino will not receive annual director awards under the Director Compensation Plan, but in the event that they serve as a member of any committee of the Board they will be entitled to committee compensation under the Director Compensation Plan. Mr. Araya and Dr. Polverino have not been appointed to any Board committee at this time.

On February 26, 2017 the Amended and Restated Executive Director Agreement between the Company and Chen Schor dated November 11, 2011 was terminated by mutual agreement of Chen Schor and the Company, and the Board approved that Chen Schor will receive the following compensation for his service on the Board: an annual cash award in the amount of \$30,000, paid in biannual installments; that Mr. Schor will not receive annual director awards under the Director Compensation Plan, but in the event that Mr. Schor serves as a member of any committee of the Board he will be entitled to committee compensation under the Director Compensation Plan; and that the restricted stock grant (the "Schor Grant") of 60,000 shares of restricted Common Stock previously granted to Mr. Schor under the Company's 2014 Stock Incentive Plan will continue to vest as previously agreed: 20,000 on: (a) August 22, 2015 (b) 20,000 on August 22, 2016 and (c) 20,000 on August 22, 2017 (at which time the Grant was fully vested). Mr. Schor has served as a member of the audit committee since November 9, 2017.

On July 13, 2017 pursuant to the Company's Third Amendment to the Second Amended and Restated Director Compensation Plan, we granted a stock option to Dr. Arbel to purchase up to 12,000 shares of Common Stock at a purchase price of \$0.75 per share, which was fully vested and exercisable on the date of grant.

On November 10, 2017, the following grants were made under the 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. Schor received 2,000 shares of restricted stock for his service as a member of the Audit Committee; Dr. 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 12,000 shares of restricted stock for his service as a director, chair of the Audit Committee and a member of the GNC Committee.

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

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

The following table sets forth certain information as of February 25, 2018 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 February 25, 2018 ("Presently Exercisable Options") or under warrants that are exercisable on or within 60 days after February 25, 2018 ("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., 1745 Broadway, 17th Floor, New York, NY 10019.

The percentage of the Common Stock beneficially owned by each person or entity named in the following table is based on 19,070,040 shares of Common Stock outstanding as of February 25, 2018, 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	4,531,650	(1)	21.1	%
Ralph Kern	83,732	(2)	*	
Uri Yablonka	86,430	(3)	*	
June Almenoff	0		*	
Arturo Araya	3,012	(4)	*	
Irit Arbel	337,608	(5)	1.8	%
Chen Schor	123,558	(6)	*	

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Anthony Polverino	3,623	(7)	*	
Malcolm Taub	29,332	(8)	*	
All current directors and officers as a group (9 persons)	5,198,945	(9)	23.8	%
5% Shareholders				
ACCBT Corp.	4,089,266	(10)	19.4	%
Morgan & Morgan Building				
Pasea Estate, Road Town				
Tortola				
British Virgin Islands				

\*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, (iii) 138,806 shares of Common Stock owned by ACC International Holdings Ltd., (iv) 411,199 shares of Common Stock issuable upon the exercise of Presently Exercisable Options and (v) 31,185 shares of restricted stock (7,796 of which will vest on each of July 26, 2018, July 26, 2019 and July 26, 2020, and the remaining 7,797 of which will vest on July 26, 2021). Chaim Lebovits, our Chief Executive Officer, may be deemed the beneficial owner of these shares.

(2) Consists of 47,847 shares of Common Stock issuable upon the exercise of Presently Exercisable Options and 35,885 shares of restricted Common Stock, 8,971 of which will vest on each of March 6, 2018, March 6, 2019 and March 6, 2020, and the remaining 8,972 will vest on March 6, 2021.

- (3) Includes 78,887 of shares of Common Stock issuable upon the exercise of Presently Exercisable Options.
- (4) Includes 251 shares of restricted Common Stock that vest on February 26, 2018.
- (5) Includes 181,775 shares of Common Stock issuable upon the exercise of Presently Exercisable Options. Dr. Arbel's address is 6 Hadishon Street, Jerusalem, Israel.
- (6) Includes 1,502 shares of restricted Common Stock that vest in equal monthly installments from March 10, 2018 to November 10, 2018.
- (7) Consists of shares of restricted stock which vest in 12 consecutive, equal monthly installments commencing on March 1, 2018 until fully vested February 1, 2019.
- (8) Includes 9,000 shares of restricted Common Stock that vest monthly from March 10, 2018 to November 10, 2018.

Includes (i) 1,933,794 shares of Common Stock owned by ACCBT Corp. (Chaim Lebovits, our Chief Executive Officer, 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 (Chaim Lebovits, our Chief Executive Officer, may be deemed to be the beneficial owner of these shares), (iii) 138,806 shares of Common Stock owned by ACC International Holdings Ltd. (Chaim Lebovits, our Chief Executive Officer, may be deemed to be the beneficial owner of these shares) and (iv) 1,109,679 shares of Common Stock issuable upon the exercise of Presently Exercisable Options.

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) 138,806 shares of Common Stock owned by ACC International Holdings Ltd.

### Equity Compensation Plan Information

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2017:

Number of securities to be issued upon exercise of	Weighted-average price of exercise	Number of securities remaining available for future
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Plan Category	outstanding options, warrants and rights	outstanding options, warrants and rights	issuance under equity compensation plans	
Equity compensation plans approved by security holders	940,954	\$ 2.4681	1,013,868	(1)
Equity compensation plans not approved by security holders	—	—	—	
Total	940,954	\$ 2.4681	1,013,868	(1)

A total of 1,954,822 shares of our Common Stock are reserved for issuance in aggregate under the Plans and the (1) Prior Plans. Any 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***

The Company has maintained a commercial relationship with Ramot, the technology transfer group within Tel Aviv University, since July 2004, when the Company and Ramot entered into a Research and License Agreement (the “Original Agreement”). The Original Agreement was amended in both March and May of 2006, when the parties signed, respectively, an Amended and Restated Research and License Agreement (the “Amended and Restated Agreement”) and Amendment Number 1 to the Amended and Restated Agreement. Thereafter, the Company and Ramot entered into a Letter Agreement in December 2009 which further amended the Amended and Restated Agreement by releasing the Company from various duties and obligations (including the Company’s commitment to fund three (3) years of additional Ramot research - a financial commitment of \$1,140,000), while converting other payments due and owing to Ramot by the Company into shares of Common Stock. In December 2011, the Company assigned the Amended and Restated Agreement (as amended) to its Israeli Subsidiary with the consent of Ramot, provided the Company agreed to guaranty the performance obligations of its Israeli Subsidiary thereunder. The Amended and Restated Agreement was amended in both April 2014 (Amendment Number 2) and March 2016 (Amendment Number 3).

In addition to the foregoing, on April 30, 2014, the Israeli Subsidiary executed a consulting agreement (the “Offen Consulting Agreement”) with Professor Offen of Tel Aviv University, which expressly replaced their previous agreement (signed in July 2004). Pursuant to the Offen Consulting Agreement, Professor Offen granted our Israeli Subsidiary exclusive rights, title and interest in and to all work product and deliverables resulting from the provision of his services thereunder, except that any new intellectual property arising from this agreement would be deemed a joint invention that is jointly owned by both our Israeli Subsidiary and Ramot. To date, no such joint inventions have resulted from this consulting agreement. The Offen Consulting Agreement was terminated on January 18, 2018.

The primary focus of our agreements (and subsequent amendments) with Ramot has and continues to be the commissioning of a group of scientists within Tel Aviv University to carry out research in the area of the stem-cell technology referenced above, and the granting of rights to the Company (and later our Israeli Subsidiary, after the assignment referenced above) in the inventions, know-how and results procured from such research (the “Ramot IP”).

In consideration for the rights granted to our Israeli Subsidiary in and to the Ramot IP, our Israeli Subsidiary is required to pay Ramot royalties ranging between three percent (3%) and five percent (5%) of all net sales realized from the exploitation of the Ramot IP, as well as remittances of between twenty percent (20%) and twenty-five

percent (25%) on revenues received from the sub-licensing of the Ramot IP.

Pursuant to the third amendment of the Amended and Restated Agreement referenced above, Ramot agreed to convert the exclusive licenses then-existing, to outright transfers and assignments of the Ramot IP, thereby granting our Israeli Subsidiary ownership thereof.

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

We are party to a July 2, 2007 subscription agreement and related registration rights agreement and warrants, amended July 31, 2009, May 10, 2012, May 19, 2014 and November 2, 2017 (together as amended, the “ACCBT Documents”) with ACCBT, a company under the control of Mr. Chaim Lebovits, our President and Chief Executive Officer, pursuant to which, for an aggregate purchase price of approximately \$5.0 million, we sold to ACCBT 1,920,461 shares of our Common Stock (the “Subscription Shares”) and warrants to purchase up to 2,016,666 shares of our Common Stock (the “ACCBT Warrants”). The ACCBT Warrants contain cashless exercise provisions, which permit the cashless exercise of up to 50% of the underlying shares of Common Stock. 672,222 of the ACCBT Warrants have an exercise price of \$3.00 and the remainder have an exercise price of \$4.35. All of the ACCBT Warrants are presently outstanding.

Pursuant to the terms of the ACCBT Documents, 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 30% 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 Brainstorm transactions greater than \$500,000.

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. 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.

The foregoing description reflects the November 2, 2017 Warrant Amendment Agreement between the Company and ACCBT, pursuant to which the rights and privileges of the ACCBT Entities relating to the management of the Company were reduced, in exchange for a five (5) year extension of the expiration of the Company warrants held by the ACCBT Entities. Pursuant to the amendment, the ACCBT Documents were amended as follows: (i) the ACCBT Entities existing right to appoint 50.1% of the Board of Directors of the Company and its subsidiaries was reduced to 30%; (ii) the ACCBT Entities' consent rights regarding Company matters pursuant to the ACCBT Documents were limited to transactions greater than \$500,000 (previous to the amendment the consent right was for transactions of \$25,000 or more); and (iii) the expiration date of each of the ACCBT Warrants was extended until November 5, 2022 (the previous expiration date was November 5, 2017).

Mr. Lebovits, the Company's President and Chief Executive Officer, is deemed to control ACCBT. Mr. Lebovits employment agreement with the Company and related employee compensation are described under "Executive Employment Agreements" in the Executive Compensation section above.

### **Independence of the Board of Directors**

The Board of Directors of the Company (the "Board") has determined that each of Dr. Arbel, Dr. Almenoff, Mr. Araya, Dr. Polverino 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 is comprised of a majority of independent directors and the Governance, Nominating and Compensation Committee (the “GNC Committee”) is comprised entirely of independent directors. A majority of the Audit Committee is comprised of independent directors. Since November 9, 2017 Chen Schor has served as the “audit committee financial expert” in accordance with Nasdaq Rule 5605(c)(2)(B). Mr. Schor is not currently independent under Nasdaq Rule 5605(a)(2) due to his previous executive director service to the Company provided pursuant to the Executive Director Agreement (described under “Executive Employment Agreements” in the Executive Compensation section above) which terminated February 26, 2017. However, the Board has determined that due to his financial expertise, Mr. Schor’s membership on the Audit Committee is in the best interests of the Company and its stockholders.

**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, 2017 and 2016 and fees billed for other services rendered by Deloitte during those periods.

	December 31,	
	2017	2016
Audit Fees (1)	\$51,000	\$51,000
Audit-Related Fees (XBRL)	\$-	\$6,000
Tax Fees	\$4,000	\$4,000
All Other Fees (2) (3)	\$31,000	\$26,000
Total Fees	\$86,000	\$87,000

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.

(2) In the year ended December 31, 2017 the services performed by BDO Israel in connection with Sarbanes-Oxley Act and Cyber Security Report.

(3) In the year ended December 31, 2016. \$7,000 out of the \$26,000 were paid to Deloitte in connection with 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.

See the Exhibit Index immediately following the signature page of this Annual Report on Form 10-K.

### **Item 16. FORM 10-K SUMMARY.**

Not required.

**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 7<sup>th</sup>, 2018 By: /s/ Chaim Lebovits  
Name: Chaim Lebovits  
Title: President and 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/ Chaim Lebovits Chaim Lebovits</i>	<i>President and Chief Executive Officer (Principal Executive Officer)</i>	<i>March 7<sup>th</sup>, 2018</i>
<i>/s/ Eyal Rubin Eyal Rubin</i>	<i>Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)</i>	<i>March 7<sup>th</sup>, 2018</i>
<i>/s/ Irit Arbel Irit Arbel</i>	<i>Director</i>	<i>March 6<sup>th</sup>, 2018</i>
<i>/s/ June S. Almenoff June S. Almenoff</i>	<i>Director</i>	<i>March 6<sup>th</sup>, 2018</i>
<i>/s/ Arturo O. Araya Arturo O. Araya</i>	<i>Director</i>	<i>March 6<sup>th</sup>, 2018</i>
<i>/s/ Chen Schor Chen Schor</i>	<i>Director</i>	<i>March 6<sup>th</sup>, 2018</i>
<i>/s/ Anthony Polverino Anthony Polverino</i>	<i>Director</i>	<i>March 6<sup>th</sup>, 2018</i>
<i>/s/ Malcolm Taub Malcolm Taub</i>	<i>Director</i>	<i>March 6<sup>th</sup>, 2018</i>

*/s/ Uri Yablonka*  
*Uri Yablonka*

*Director*

*March 6<sup>th</sup>, 2018*

## EXHIBIT INDEX

Exhibit Number	Description	Filed (or Furnished) with this Form 10-K	Incorporated by Reference Herein		
			Form	Exhibit & File No.	Date Filed
<u>2.1</u>	<u>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.</u>		<u>Definitive Schedule 14A</u>	<u>Appendix A File No. 333-61610</u>	<u>November 20, 2006</u>
<u>3.1</u>	<u>Certificate of Incorporation of Brainstorm Cell Therapeutics Inc.</u>		<u>Definitive Schedule 14A</u>	<u>Appendix B File No. 333-61610</u>	<u>November 20, 2006</u>
<u>3.2</u>	<u>Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc. dated September 15, 2014.</u>		<u>Form 8-K</u>	<u>Exhibit 3.1 File No. 000-54365</u>	<u>September 16, 2014</u>
<u>3.3</u>	<u>Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc. dated August 31, 2015.</u>		<u>Form 8-K</u>	<u>Exhibit 3.1 File No. 001-366641</u>	<u>September 4, 2015</u>
<u>3.4</u>	<u>ByLaws of Brainstorm Cell Therapeutics Inc.</u>		<u>Definitive Schedule 14A</u>	<u>Appendix C File No. 333-61610</u>	<u>November 20, 2006</u>
<u>3.5</u>	<u>Amendment No. 1 to ByLaws of Brainstorm Cell Therapeutics Inc., dated as of March 21, 2007.</u>		<u>Form 8-K</u>	<u>Exhibit 3.1 File No. 333-61610</u>	<u>March 27, 2007</u>
<u>4.1</u>	<u>Specimen Certificate of Common Stock of Brainstorm Cell Therapeutics Inc.</u>		<u>Form 8-K</u>	<u>Exhibit 4.1 File No. 000-54365</u>	<u>September 16, 2014</u>
<u>10.1</u>	<u>Research and License Agreement, dated as of July 8, 2004, by and between the Company and Ramot at Tel Aviv University Ltd.</u>		<u>Form 8-K</u>	<u>Exhibit 10.1 File No. 333-61610</u>	<u>July 16, 2004</u>





<p><u>10.2</u> <u>Research and License Agreement, dated as of March 30, 2006, by and between the Company and Ramot at Tel Aviv University Ltd.</u></p>	<p><u>Form 8-K</u></p>	<p><u>Exhibit 10.1</u> <u>File No.</u> <u>333-61610</u></p>	<p><u>April 4, 2006</u></p>
<p><u>10.3</u> <u>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.</u></p>	<p><u>Form 8-K/A</u></p>	<p><u>Exhibit 10.1</u> <u>File No.</u> <u>333-61610</u></p>	<p><u>May 30, 2006</u></p>
<p><u>10.4</u> <u>Amendment Agreement, dated as of March 31, 2006, among the Company, Ramot at Tel Aviv University Ltd. and certain warrant holders.</u></p>	<p><u>Form 8-K</u></p>	<p><u>Exhibit 10.2</u> <u>File No.</u> <u>333-61610</u></p>	<p><u>April 4, 2006</u></p>
<p><u>10.5</u> <u>Second Amended and Restated Research and License Agreement, dated July 26, 2007, by and between the Company and Ramot at Tel Aviv University Ltd.</u></p>	<p><u>Form 10-QSB</u></p>	<p><u>Exhibit 10.4</u> <u>File No.</u> <u>333-61610</u></p>	<p><u>August 20, 2007</u></p>
<p><u>10.6</u> <u>Second Amended and Restated Registration Rights Agreement, dated August 1, 2007, by and between the Company and Ramot at Tel Aviv University Ltd.</u></p>	<p><u>Form 10-QSB</u></p>	<p><u>Exhibit 10.5</u> <u>File No.</u> <u>333-61610</u></p>	<p><u>August 20, 2007</u></p>
<p><u>10.7</u> <u>Waiver and Release, dated August 1, 2007, executed by Ramot at Tel Aviv University Ltd. in favor of the Company.</u></p>	<p><u>Form 10-QSB</u></p>	<p><u>Exhibit 10.6</u> <u>File No.</u> <u>333-61610</u></p>	<p><u>August 20, 2007</u></p>
<p><u>10.8</u> <u>Letter Agreement, dated December 24, 2009, by and between the Company and Ramot at Tel Aviv University Ltd.</u></p>	<p><u>Form 8-K</u></p>	<p><u>Exhibit 10.1</u> <u>File No.</u> <u>333-61610</u></p>	<p><u>December 31, 2009</u></p>
<p><u>10.9</u> <u>Amendment No. 1, dated December 24, 2009, to the Second Amended and Restated Research and License Agreement dated July 26, 2007 by and between Brainstorm Cell Therapeutics Ltd. and Ramot at Tel Aviv University Ltd.</u></p>	<p><u>Form 8-K</u></p>	<p><u>Exhibit 10.2</u> <u>File No.</u> <u>333-61610</u></p>	<p><u>December 31, 2009</u></p>

<u>10.10</u>	<u>Assignment Agreement, dated December 20, 2011, by and between the Company and Brainstorm Cell Therapeutics Ltd.</u>	<u>Form S-1/A</u>	<u>Exhibit 10.12</u> <u>File No.</u> <u>333-179331</u>	<u>February 3, 2012</u>
<u>10.11</u>	<u>Amendment No. 2, dated April 30, 2014, to the Second Amended and Restated Research and License Agreement dated July 26, 2007 by and between Brainstorm Cell Therapeutics Ltd. and Ramot at Tel Aviv University Ltd.</u>	<u>Form 10-K</u>	<u>Exhibit 10.11</u> <u>File No.</u> <u>001-36641</u>	<u>March 9, 2016</u>
<u>10.12</u>	<u>Amendment No. 3, effective February 18, 2016, to the Second Amended and Restated Research and License Agreement dated July 26, 2007 by and between Brainstorm Cell Therapeutics Ltd. and Ramot at Tel Aviv University Ltd.</u>	<u>Form 10-K</u>	<u>Exhibit 10.12</u> <u>File No.</u> <u>001-36641</u>	<u>March 9, 2016</u>
<u>10.13</u>	<u>Consulting Agreement, dated as of April 30, 2014, by and between Brainstorm Cell Therapeutics Ltd. and Dr. Daniel Offen.</u>	<u>Form S-1</u>	<u>Exhibit 10.15</u> <u>File No.</u> <u>333-179331</u>	<u>June 29, 2012</u>
<u>10.14*</u>	<u>Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1 File</u> <u>No. 000-54365</u>	<u>August 15, 2014</u>
<u>10.15*</u>	<u>Amendment No. 1 to the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.</u>	<u>Schedule 14A</u>	<u>Appendix A File</u> <u>No. 000-36641</u>	<u>May 11, 2016</u>
<u>10.16*</u>	<u>Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.</u>	<u>Form 8-K</u>	<u>Exhibit 10.2 File</u> <u>No. 000-54365</u>	<u>August 15, 2014</u>
<u>10.17*</u>	<u>Amendment No. 1 to the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.</u>	<u>Schedule 14A</u>	<u>Appendix B File</u> <u>No. 000-36641</u>	<u>May 11, 2016</u>
<u>10.18*</u>	<u>Form of Incentive Stock Option Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1 File</u> <u>No. 001-36641</u>	<u>November 4, 2014</u>

<u>10.19*</u>	<u>Form of Nonstatutory Stock Option Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.</u>	<u>Form 8-K</u>	<u>Exhibit 10.2 File No. 001-36641</u>	<u>November 4, 2014</u>
<u>10.20*</u>	<u>Form of Restricted Stock Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.</u>	<u>Form 8-K</u>	<u>Exhibit 10.3 File No. 001-36641</u>	<u>November 4, 2014</u>
<u>10.21*</u>	<u>Form of Option Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.</u>	<u>Form 8-K</u>	<u>Exhibit 10.4 File No. 001-36641</u>	<u>November 4, 2014</u>
<u>10.22</u>	<u>Subscription Agreement, dated July 2, 2007, by and between the Company and ACCBT Corp.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1 File No. 333-61610</u>	<u>July 5, 2007</u>
<u>10.23</u>	<u>Amendment to Subscription Agreement, dated as of July 31, 2009, by and between the Company and ACCBT Corp.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1 File No. 333-61610</u>	<u>August 24, 2009</u>
<u>10.24</u>	<u>Form of Common Stock Purchase Warrant issued by the Company to ACCBT Corp.</u>	<u>Form 8-K</u>	<u>Exhibit 10.2 File No. 333-61610</u>	<u>July 5, 2007</u>
<u>10.25</u>	<u>Form of Registration Rights Agreement by and between the Company and ACCBT Corp.</u>	<u>Form 8-K</u>	<u>Exhibit 10.3 File No. 333-61610</u>	<u>July 5, 2007</u>
<u>10.26</u>	<u>Form of Security Holders Agreement, by and between ACCBT Corp. and certain security holders of the Company.</u>	<u>Form 8-K</u>	<u>Exhibit 10.4 File No. 333-61610</u>	<u>July 5, 2007</u>
<u>10.27</u>	<u>Warrant Amendment Agreement, dated as of May 10, 2012, by and between Brainstorm Cell Therapeutics Inc. and ACCBT Corp.</u>	<u>Form 10-Q</u>	<u>Exhibit 10.1 File No. 000-54365</u>	<u>May 11, 2012</u>

<u>10.28</u>	<u>Amendment of Warrants dated May 19, 2014 by and among Brainstorm Cell Therapeutics Inc., ACCBT Corp. and ACC International Holdings Ltd.</u>	<u>Form 10-Q</u>	<u>Exhibit 10.4</u> <u>File No.</u> <u>000-54365</u>	<u>August 12, 2014</u>
<u>10.29</u>	<u>2017 Amendment of Warrants and Subscription Agreement dated November 2, 2017 by and among Brainstorm Cell Therapeutics Inc., ACCBT Corp. and ACC International Holdings Ltd.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1</u> <u>File No.</u> <u>001-36641</u>	<u>November 3, 2017</u>
<u>10.30</u>	<u>Clinical Trial Agreement, entered into as of February 17, 2010, among Brainstorm Cell Therapeutics Ltd., Prof. Dimitrios Karousis and Hadasit Medical Research Services and Development Ltd.</u>	<u>Form 10-Q</u>	<u>Exhibit 10.1</u> <u>File No.</u> <u>000-54365</u>	<u>August 15, 2011</u>
<u>10.31</u>	<u>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.</u>	<u>Form 10-Q</u>	<u>Exhibit 10.2</u> <u>File No.</u> <u>000-54365</u>	<u>August 15, 2011</u>
<u>10.32*</u>	<u>Amended and Restated Executive Director Agreement, dated November 11, 2011, by and between the Company and Chen Schor.</u>	<u>Form 8-K/A</u>	<u>Exhibit 10.1</u> <u>File No.</u> <u>333-61610</u>	<u>November 16, 2011</u>
<u>10.33*</u>	<u>Employment Agreement dated June 6, 2014 between Brainstorm Cell Therapeutics Ltd. and Uri Yablonka.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1</u> <u>File No.</u> <u>000-54365</u>	<u>June 9, 2014</u>
<u>10.34*</u>	<u>Restricted Stock Award Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan, regarding July 26, 2017 grant to Chaim Lebovits.</u>	<u>Form 10-Q</u>	<u>Exhibit 10.2</u> <u>File No.</u> <u>001-36641</u>	<u>October 17, 2017</u>
<u>10.35</u>	<u>Form of Securities Purchase Agreement.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1</u> <u>File No.</u> <u>000-54365</u>	<u>June 13, 2014</u>
<u>10.36</u>	<u>Form of Warrant.</u>	<u>Form 8-K</u>	<u>Exhibit 10.2</u> <u>File No.</u> <u>000-54365</u>	<u>June 13, 2014</u>

<u>10.37</u>	<u>Form of Registration Rights Agreement.</u>	<u>Form 8-K</u>	<u>Exhibit 10.3 File No. 000-54365</u>	<u>June 13, 2014</u>
<u>10.38</u>	<u>Form of Warrant.</u>	<u>Form 8-K</u>	<u>Exhibit 4.1 File No. 001-36641</u>	<u>January 8, 2015</u>
<u>10.39</u>	<u>Warrant Exercise Agreement, dated as of January 8, 2015.</u>	<u>Form 8-K</u>	<u>Exhibit 10.2 File No. 001-36641</u>	<u>January 8, 2015</u>
<u>10.40*</u>	<u>Employment Agreement dated September 28, 2015 between Brainstorm Cell Therapeutics Inc. and Chaim Lebovits.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1 File No. 001-36641</u>	<u>September 28, 2015</u>
<u>10.41*</u>	<u>First Amendment to Employment Agreement dated March 7, 2016 between Brainstorm Cell Therapeutics Inc. and Chaim Lebovits.</u>	<u>Form 10-K</u>	<u>Exhibit 10.53 File No. 001-36641</u>	<u>March 9, 2016</u>
<u>10.42*</u>	<u>Second Amendment to Employment Agreement dated July 26, 2017 between the Company and Chaim Lebovits.</u>	<u>Form 10-Q</u>	<u>Exhibit 10.3 File No. 001-36641</u>	<u>October 17, 2017</u>
<u>10.43*</u>	<u>Employment Agreement dated February 28, 2017 between Brainstorm Cell Therapeutics Inc. and Dr. Ralph Kern, as amended by Amendment No. 1 dated March 3, 2017.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1 File No. 001-36641</u>	<u>March 6, 2017</u>
<u>10.44*</u>	<u>Employment Agreement by and between Brainstorm Cell Therapeutics Ltd. and Eyal Rubin, dated October 31, 2017.</u>	<u>Form 8-K</u>	<u>Exhibit 10.2 File No. 001-36641</u>	<u>November 3, 2017</u>
<u>10.45*</u>	<u>Restricted Stock Award Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan, regarding November 20, 2017 grant to Eyal Rubin.</u>			
<u>10.46*</u>	<u>Brainstorm Cell Therapeutics Inc. Second Amended and Restated Director Compensation Plan.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1 File No. 001-36641</u>	<u>July 9, 2014</u>

<u>10.47*</u>	<u>Brainstorm Cell Therapeutics Inc. First Amendment to the Second Amended and Restated Director Compensation Plan.</u>	<u>Form 10-Q</u>	<u>Exhibit 10.2 File No. 001-36641</u>	<u>May 14, 2015</u>
<u>10.48*</u>	<u>Brainstorm Cell Therapeutics Inc. Second Amendment to the Second Amended and Restated Director Compensation Plan dated February 26, 2017.</u>	<u>Form 10-K</u>	<u>Exhibit 10.54 File No. 001-36641</u>	<u>March 29, 2017</u>
<u>10.49*</u>	<u>Brainstorm Cell Therapeutics Inc. Third Amendment to the Second Amended and Restated Director Compensation Plan.</u>	<u>Form 10-Q</u>	<u>Exhibit 10.1 File No. 001-36641</u>	<u>October 17, 2017</u>
<u>10.50</u>	<u>Notice of Award - CLIN2: Partnering Opportunity for Clinical Trial Stage Projects California Institute for Regenerative Medicine, August 25, 2017.</u>	‡		
<u>21</u>	<u>Subsidiaries of the Company.</u>	‡		
<u>23.1</u>	<u>Consent of Brightman Almagor &amp; Co., a member of Deloitte Touche Tohmatsu.</u>	‡		
<u>31.1</u>	<u>Certification by the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	‡		
<u>31.2</u>	<u>Certification by the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	‡		
<u>32.1</u>	<u>Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>	‡‡		
<u>32.2</u>	<u>Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>	‡‡		
<u>101</u>	The following financial information from the Annual Report on Form 10-K of Brainstorm Cell Therapeutics Inc. for the year ended December 31, 2017, formatted in XBRL (eXtensible Business Reporting Language): (1) Consolidated Balance Sheets as of December 31, 2016, and 2017; (2) Consolidated Statements of Operations for the years ended December 31, 2016 and 2017 and from September 22, 2000 (Inception) to December 31, 2017; (3) Statements of Changes in Stockholders' Equity (Deficit) from September 22, 2000 (Inception) through December 31, 2017; (4) Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2017 and			

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from September 22, 2000 (Inception) to December 31, 2017;  
and (5) Notes to Financial Statements.

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

‡ Filed herewith.

‡‡Furnished herewith.

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