

BRAINSTORM CELL THERAPEUTICS INC.

Form 10-K

March 29, 2019

**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, 2018**

**.. 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.)

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1325 Avenue of Americas, 28<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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes  No

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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 x      Smaller reporting company x

Emerging growth company "

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), was \$71,031,012.

As of March 28, 2019, the number of shares outstanding of the registrant's Common Stock, \$0.00005 par value per share, was 29,490,610.

**BRAINSTORM CELL THERAPEUTICS INC.**

**ANNUAL REPORT ON FORM 10-K**

**YEAR ENDED DECEMBER 31, 2018**

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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 2019, the safety and clinical effectiveness of our NurOwn® technology, our clinical trials of NurOwn® and its related clinical development, and our ability to develop collaborations and partnerships to support our business plan. In some cases you can identify such “forward-looking statements” by the use of words like “may,” “will,” “should,” “could,” “expects,” “hopes,” “anticipates,” “believes,” “intends,” “plans,” “projects,” “targets,” “goals,” “estimate,” “potential,” or “continue” or the negative of any of these terms or similar words. These statements, descriptions, forecasts and projections constitute “forward-looking statements,” and as such involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance and achievements to be materially different from any results, levels of activity, performance and achievements expressed or implied by any such “forward-looking statements.” These risks and uncertainties include, but are not limited to our need to raise additional capital, our ability to continue as a going concern, regulatory approval of our NurOwn® treatment candidate, the success of our product development programs and research, regulatory and personnel issues, development of a global market for our services, the ability to secure and maintain research institutions to conduct our clinical trials, the ability to generate significant revenue, the ability of our NurOwn® treatment candidate to achieve broad acceptance as a treatment option for ALS or other neurodegenerative diseases, our ability to manufacture and commercialize our NurOwn® treatment candidate, obtaining patents that provide meaningful protection, competition and market developments, our ability to protect our intellectual property from infringement by third parties, health reform legislation, demand for our services, currency exchange rates and product liability claims and litigation, and other factors described under “Risk Factors” in this annual report on Form 10-K for the fiscal year ended December 31, 2018. These “forward-looking statements” are based on certain assumptions that we have made as of the date hereof. To the extent these assumptions are not valid, the associated “forward-looking statements” and projections will not be correct. Although we believe that the expectations reflected in these “forward-looking statements” are reasonable, we cannot guarantee any future results, levels of activity, performance or achievements. It is routine for our internal projections and expectations to change as the year or each quarter in the year progresses, and therefore it should be clearly understood that the internal projections and beliefs upon which we base our expectations may change prior to the end of each quarter or the year. Although these expectations may change, we may not inform you if they do and we undertake no obligation to do so, except as required by applicable securities laws and regulations. We caution investors that our business and financial performance are subject to substantial risks and uncertainties. In evaluating our business, prospective investors should carefully consider the information set forth under the caption “Risk Factors”*

*in this report, 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 leading biotechnology company committed to the development and commercialization of best-in-class autologous cellular therapies for the treatment of neurodegenerative diseases including: Amyotrophic Lateral Sclerosis (“ALS”, also known as Lou Gehrig’s disease); Progressive Multiple Sclerosis (“PMS”); and Parkinson’s disease (“PD”).

NurOwn® leverages proprietary cell culture methods to induce autologous bone marrow-derived mesenchymal stem cells (MSCs) to secrete high levels of neurotrophic factors (NTFs), modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival and improve neurological function.

Our wholly-owned Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. (“Israeli Subsidiary”), holds exclusive rights to commercialize NurOwn® technology through a licensing agreement with Ramot (“Ramot”), the technology transfer company of Tel Aviv University, Israel.

NurOwn® has a strong and comprehensive intellectual property portfolio.

NurOwn® was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) and Orphan Drug status by the FDA and the European Medicines Agency (EMA) for ALS. For more information, visit BrainStorm's website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com).

Brainstorm Cell Therapeutics Inc. currently employs 31 employees in the United States and in Israel.

## 2018 and Recent Highlights

The Company has made significant progress in 2018, advancing the NurOwn® ALS Phase 3 clinical trial at all 6 U.S. investigative sites (Mass General Hospital, UMass, Mayo Clinic, CPMC, Cedars Sinai and UC Irvine). Approximately 50% of the participants in this randomized, double-blind, placebo-controlled, repeat-dose clinical trial are currently enrolled. This clinical trial builds upon promising efficacy seen in 3 prior early-stage ALS clinical trials, including a U.S. randomized placebo-controlled Phase 2 trial. We expect to complete NurOwn® ALS Phase 3 study enrollment of US & Canadian ALS trial participants by mid-2019 and the trial is expected to generate data for a BLA filing to support FDA approval of NurOwn® in ALS.

The Phase 3 ALS trial pre-specified interim safety analysis by an independent Data Safety Monitoring Board (DSMB) was successfully completed in August 2018.

We effectively doubled our manufacturing capabilities by contracting the (Connell and O'Reilly Families) Cell Manipulation Core Facility (CMCF), at the Dana-Farber Cancer Institute (DFCI) in Boston as a second U.S. manufacturing site to supply NurOwn® and placebo for the ongoing Phase 3 ALS trial ([www.clinicaltrials.gov](http://www.clinicaltrials.gov) Identifier: NCT03280056) and to support additional clinical indications. DFCI has decades of cell therapy manufacturing experience and a proven track record of manufacturing NurOwn® for the Company's U.S. Phase 2 ALS trial

The Company was granted FDA approval for its NurOwn® IND Application for Progressive Multiple Sclerosis indication ([www.clinicaltrials.gov](http://www.clinicaltrials.gov) Identifier NCT03799718). In March, 2019, we enrolled the first patient in a Phase 2 open-label, multicenter study of repeated intrathecal administration of autologous MSC-NTF cells in participants with progressive Multiple Sclerosis (MS), and plan to continue enrolling at 5 leading U.S. MS centers in the second quarter of 2019.

The Company received gross cash proceeds of approximately \$12.3 million in a warrant exercise transaction with certain existing Company warrant holders.

We strengthened our operational and executive teams in 2018 with the appointment of Susan Ward Ph.D. as Head of Clinical Operations (from Pfizer); Joseph Petroziello as Vice President of Scientific and Corporate Communications (from Juno); and Arturo Araya in the capacity of Chief Commercial Officer (previously at Novartis). Mr. Araya served as a member of the Company's Board of Directors (the "Board") from February 2017 through November 2018. These individuals were chosen for their deep neuroscience and/or cell therapy experience, significant industry expertise and long track record of industry achievements.



Our Board was also strengthened in 2018 with the addition of Anthony Polverino, Ph.D. Dr. Polverino is EVP, Early Development and Chief Scientific Officer of Zymeworks Inc. 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.

We received Good Manufacturing Practice (GMP) approval from the Israel Ministry of Health (MoH) for our Israeli contract manufacturing facility at the Hadassah Medical Center in Jerusalem. The GMP certificate confirms the Company's manufacturing site compliance with Israeli GMPs which are in line with EU standards. This approval also supports an application to the Israel Ministry of Health (MoH) for the treatment of ALS patients under the Hospital Exemption regulation. The GMP certificate was granted after a thorough review of the Company's contract manufacturing facilities.

### **NurOwn® Proprietary Technology**

NurOwn® technology is based on an innovative manufacturing protocol, which induces the differentiation of purified and expanded bone marrow-derived mesenchymal stem cells ("MSC") and consistently generates cells that release high levels of multiple neurotrophic factors ("MSC-NTF" cells) to modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival and improve neurological function. These factors are known to be critical for the growth, survival and differentiation of neurons, including: glial-derived neurotrophic factor ("GDNF"); brain-derived neurotrophic factor ("BDNF"); vascular endothelial growth factor ("VEGF"); and hepatocyte growth factor ("HGF"), among others. GDNF is one of the most potent survival factors for peripheral motoneurons. VEGF and HGF have demonstrated important neuroprotective effects in ALS and other neurodegenerative diseases.

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

The proprietary technology and manufacturing processing of NurOwn® (MSC-NTF cells) for clinical use is conducted in full compliance with current Good Manufacturing Practice (“cGMP”). The NurOwn® proprietary technology is fully licensed to and developed by Brainstorm Cell Therapeutics Ltd., our wholly-owned subsidiary (the “Israeli Subsidiary”).

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

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

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

The ability to induce autologous adult mesenchymal stem cells into differentiated MSC-NTF cells makes NurOwn® uniquely suited for the treatment of neurodegenerative diseases.

The specialized MSC-NTF cells secrete multiple neurotrophic factors and immunomodulatory cytokines that may result in:

- Protection of existing neurons;
- Promotion of neuronal repair;
- Neuronal functional improvement; and
- Immunomodulation and reduced neuroinflammation.

*Autologous (Self-transplantation)*

The NurOwn® technology platform is autologous, using the patient’s own bone-marrow derived stem cells for “self-transplantation.” In autologous transplantation, there is no introduction of unrelated donor antigens that may lead to alloimmunity, 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 several ethical concerns associated with the use of embryonic-derived stem cells in some countries.

**The ALS Clinical Program**

NurOwn® is currently in a Phase 3 late stage clinical development program for the treatment of ALS. It has been granted Fast Track designation by the U.S. Food and Drug Administration (“FDA”) for this indication, and has been granted Orphan Drug Status, in the U.S. and Europe, which provides the potential for an extended period of exclusivity. We have completed two early stage Phase 1/2 and 2 open-label clinical trials of NurOwn® in patients with ALS at the Hadassah Medical Center (“Hadassah”) in Jerusalem as well as a Phase 2 double-blind, placebo-controlled, clinical trial at three prestigious U.S. Medical centers, all highly experienced in the management and investigation of ALS.

*Phase 1/2 ALS Open Label Trials*

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

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

### ***Phase 2 ALS Randomized Trial***

The Phase 2 U.S. study was conducted under an FDA Investigational New Drug (“IND”) application. This randomized, double-blind, placebo-controlled multi-center U.S. Phase 2 clinical trial evaluating NurOwn® in ALS patients was conducted at three clinical sites: (i) the Massachusetts General Hospital (MGH) in Boston, (ii) Massachusetts Memorial Hospital in Worcester, Massachusetts, and (iii) Mayo Clinic in Rochester, Minnesota. For this trial, NurOwn® was manufactured at the Connell and O’Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute in Boston and at the Human Cellular Therapy Lab at the Mayo Clinic. In this study, 48 patients were randomized 3:1 to receive NurOwn® or placebo.

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

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

NurOwn® achieved multiple secondary efficacy endpoints, showing evidence of a clinically meaningful benefit. Notably, response rates in the ALS functional rating scale (48-point ALSFRS-R outcome measure) were higher in NurOwn®-treated participants, compared to placebo, at all study timepoints over 24 weeks.

A pre-specified *responder analysis* examined percentage improvements in the post treatment ALSFRS-R slope (change/month) compared to pre-treatment slope and demonstrated that a higher proportion of NurOwn® treated participants achieved a 100% improvement in the post-treatment vs. pre-treatment slope, compared to the placebo group. This analysis also demonstrated that a higher proportion of the NurOwn® treated participants achieved a 1.5 point per month or greater improvement in the post-treatment vs. pre-treatment ALSFRS-R slope, compared to the

placebo group.

The beneficial treatment effects were greater in the *rapid progressor subgroup* (in which pretreatment ALSFRS-R declined by 2 or more points in the three months pre-treatment).

As an important confirmation of NurOwn®'s mechanism of action, levels of neurotrophic factors and inflammatory markers were measured in the cerebrospinal fluid ("CSF") samples collected from participants pre and two weeks post treatment. In the samples of those participants treated with NurOwn®, statistically significant increases in levels of neurotrophic factors VEGF, HGF and LIF and a statistically significant reduction in inflammatory markers MCP-1, SDF-1 and CHIT-1 were observed post-transplantation. Furthermore, the observed reduction in inflammatory markers correlated with ALS functional improvements. These clinical-biomarker correlations were not seen in placebo-treated participants, consistent with the proposed combined neuroprotective and immunomodulatory mechanism of action of NurOwn® in ALS.

In summary, a higher proportion of NurOwn® treated participants, particularly those with more rapid disease progression, experienced stabilization or improvement in ALS function, as measured by the post-treatment vs. pre-treatment ALSFRS-R slope change. ***These are new and meaningful ALS clinical observations that are being evaluated in the ongoing Phase 3 study using repeat dosing in ALS rapid progressors.***

### ***Phase 3 ALS Clinical Trial***

Following successful completion of the Phase 2 study, the Company is currently enrolling a Phase 3 trial (a multi-dose double-blind, placebo-controlled, multicenter trial protocol) that has been designed to generate data to support a Biologic License Application ("BLA") for NurOwn® in ALS. The clinical trial is actively enrolling an enriched patient population of rapid progressors (~50% of ALS patients) based on superior outcomes observed in the Phase-2 pre-specified sub-group.

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

The independent Data Safety Monitoring Board (“DSMB”) for the study completed its pre-specified interim analysis of safety outcomes for the first 31 participants treated with NurOwn® in the Phase 3 trial in ALS (NCT03280056) in August. The DSMB indicated there were no significant safety concerns and recommended that the trial continue, as planned without any modifications to the study protocol.

Top-line efficacy data is expected in the first half of 2020. The study is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (ClinicalTrials.gov Identifier: NCT03280056).

The Company has developed a validated cryopreservation process for the long-term storage of MSC, that allows multiple doses of NurOwn® to be created from a single bone marrow harvest procedure in the multi-dose clinical trial and to avoid the need for patients to undergo repeated bone marrow aspiration. A validation study was conducted in 2017 comparing NurOwn® derived from fresh MSC to those derived from cryopreserved MSC. Company scientists were successful in showing that the MSC can be stored in the vapor phase of liquid nitrogen for prolonged periods of time, while maintaining their characteristics. Cryopreserved MSC are capable of differentiating into NurOwn®, similar to the NurOwn® derived from fresh MSC from the same patient/donor, prior to cryopreservation and maintain their key functional properties including immunomodulation and neurotrophic factor secretion.

The Company has contracted with City of Hope's Center for Biomedicine and Genetics to produce clinical supplies of NurOwn® adult stem cells for the ongoing Phase 3 clinical study. City of Hope is currently supporting the production of NurOwn® and placebo for the participants treated in the Phase 3 trial. The Connell and O'Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute in Boston has also been contracted to manufacture NurOwn® and placebo for Phase 3 clinical study participants, and commenced manufacturing in October 2018.

### **Patient Access Programs (ALS)**

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

### **NurOwn in Progressive Multiple Sclerosis**

On December 15, 2018 the FDA approved the Company's IND to conduct a Phase 2 open label trial of repeated intrathecal administration of NurOwn® in progressive MS (www.clinicaltrials.gov Identifier NCT03799718). This clinical trial will be conducted at 5 leading US MS centers. The trial enrolled the first study participant in the first quarter of 2019 and is expected to generate top line data in mid-2020.

### **Non-Dilutive Funding**

In July 2017, the Company was awarded a grant in the amount of \$15,912,000 from CIRM to aid in funding the Company's pivotal Phase 3 study of NurOwn®, for the treatment of ALS. To date, the Company has received \$12,550,000 of the CIRM grant: \$7,050,000 was received in 2017 and an additional \$5.5 million was received during 2018. The grant does not bear a royalty payment commitment nor is the grant otherwise refundable.

In 2017 and 2018, the Company was awarded aggregate grants of approximately \$3.2 million from the Israel Innovation Authority ("IIA"). To date the Company has received approximately \$2 million from IIA, made under the 2018 as well as under previous IIA grants.

### **Intellectual Property**

A key element of the Company's overall strategy is to establish a broad portfolio of patents and other methods described below to protect its proprietary technologies and products. Brainstorm is the sole licensee or assignee of 12 granted patents 2 allowed patents and 19 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 January 30, 2018, the U.S. Patent and Trademark Office (“USPTO”) granted U.S. patent, No. 9,879,225 which claims priority from this same PCT application. This patent relates to methods of treating ALS and Parkinson's disease using mesenchymal stem cells that secrete neurotrophic factors, specifically glial derived neurotrophic factor (GDNF).

On June 19, 2018, the Japanese Patent Office ("JPO") issued a decision to Grant notice to a Japanese patent entitled: 'Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors’ (Japanese Patent Application number 2015-526006). The Decision to Grant notice is the final approval stage and precedes actual granting which is expected shortly. When granted, this patent is expected to provide protection for MSC-NTF cells (NurOwn®) in Japan until 2033. The allowed claims cover a method of generating cells which secrete brain derived neurotrophic factor (BDNF), glial derived neurotrophic factor (GDNF), hepatocyte growth factor (HGF) and vascular endothelial growth factor (VEGF).

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

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

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

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

On October 10<sup>th</sup> 2018 the European Patent Office allowed the European Patent Application No. 13164650.7 titled “Mesenchymal stem cells for the treatment of CNS diseases” which claims priority from WO 2009/144718. The allowed claims cover the isolated cells as well as their use in the manufacture of a medicament for treating a CNS disease or disorder (selected from the group consisting of Parkinson's, multiple sclerosis, epilepsy, amyotrophic lateral sclerosis, stroke, autoimmune encephalomyelitis, diabetic neuropathy, glaucomatous neuropathy, Alzheimer's disease



and Huntingdon's disease)

In December 2018, the Israel Patent Office granted a patent titled “Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors.” The allowed claims cover the method of generating the cells, the cells generated according to the method of manufacturing, and the use of the cells for preparation of a medicament for treating a disease (including a neurodegenerative disease, a neurological and an immune disease)

### **Scientific presentations in 2018**

On January 19<sup>th</sup>, at the 8<sup>th</sup> Annual California Research Summit at Stanford University in Palo Alto, CA, Brainstorm's Chief Medical Officer, Dr. Ralph Kern, made an oral presentation entitled, “NurOwn ALS Phase 3 Study Update”.

At the 70<sup>th</sup> Annual American Academy of Neurology Meeting in Los Angeles CA, Dr. Merit Cudkowicz, Neurology Chair at the Massachusetts General Hospital and Brainstorm's Chief Operating & Chief Medical Officer, Dr. Ralph Kern made oral scientific presentations on the Phase 2 ALSFRS-R subscale responder analyses and CSF micro-RNA biomarker analyses, respectively.

On April 29<sup>th</sup>, at the 14<sup>th</sup> Annual ALS Canada Research Forum, Brainstorm's Chief Medical Officer, Dr. Ralph Kern, made a scientific presentation entitled, “BrainStorm Phase 2 results & Phase 3 setup”.

On August 8<sup>th</sup>, at the Role of Innate Immunity, Glia, Neurons, and the Blood-Brain Barrier in the Pathogenesis of Neurodegeneration, Gordon Research Conference in Castelldefels, Spain, Brainstorm's Chief Medical Officer, Dr. Ralph Kern, made a scientific presentation entitled, “Development of MSC-NTF Cell Exosomes for the Treatment of Neurodegenerative Disease”.

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

On October 3<sup>rd</sup>, Dr. James Berry (MGH, Boston) presented a clinical poster entitled, “MicroRNA Changes in the NurOwn® Phase 2 ALS Randomized Clinical Trial: Relationship to Neuroprotection and Innate Immunity” at the Annual Northeast Amyotrophic Lateral Sclerosis (NEALS) Conference. The poster won the NEALS' conference 'Best Clinical Poster' award.

On November 7<sup>th</sup>, Brainstorm's Chief Medical Officer, Dr. Ralph Kern, presented a scientific abstract at the Society for Neuroscience in San Diego CA, entitled ‘Development of MSC-NTF cell exosomes for the treatment of neurodegenerative diseases’.

On December 7<sup>th</sup>, Dr. Namita Goyal, Associate Clinical Professor and Director of the Neuromuscular Medicine Fellowship Program for the Department of Neurology at UCI Health, Irvine CA, presented a scientific abstract entitled, “A Systematic Review of Enrichment Strategies for Current Clinical Trials in ALS,” in the Clinical Trials and Clinical Designs poster session.

## **Research and Development**

In addition to its active clinical program in ALS, the Company is focusing on further in-depth molecular and functional characterization of NurOwn®. A study profiling NurOwn®'s unique miRNA signature was published in 2017 in *Stem Cell Research & Therapy*. The publication, entitled "miRNA profiling of NurOwn®: mesenchymal stem cells secreting neurotrophic factors" shows that NurOwn® MSC-NTF cells induced to secrete neurotrophic factors have both an enhanced secretion of NTFs as well as a distinct miRNA expression profile that distinguishes them from their MSC of origin. miRNAs have been shown to play critical roles in neuronal and glial cell biological processes. These findings may form the basis for the development of sensitive identity release assays for clinical trials, in vivo cell identification assays, and to elucidate MSC-NTF cells' mechanism of action in ALS and other neurodegenerative diseases. On August 23, 2018 the Company announced a positive Phase 3 interim safety analysis by the Data Safety Monitoring Board (DSMB). There were no significant safety issues and the DSMB recommended that the trial continue as planned. Confirmation of the safety of repeated injections in the first cohort of 62 active study subjects is an important milestone for the Company.

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

For the Phase 3 study in ALS, the Company has improved the efficiency of NurOwn® production and improved its stability, allowing manufacturing to take place at centralized clean room facilities from which it is distributed to the

clinical trial sites, where the cells are then administered to patients. The Company is also engaged in several research initiatives to further improve and scale-up manufacturing capacity and extend the shelf life of NurOwn®.

## **Corporate Information**

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 1325 Avenue of Americas, 28<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 and on June 21, 2018, the Israeli Subsidiary formed its wholly-owned subsidiary, Advanced Cell Therapies Ltd. 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® for the treatment of neurodegenerative disease. The highest company priority is rapid execution of the U.S. randomized, double-blind, placebo-controlled ALS Phase 3 trial and initiation of the Phase 2 clinical trial in progressive MS. Both clinical programs are expected to read out in mid-2020.

We are also leveraging strong existing pre-clinical data in several neurodegenerative diseases, to advance innovative IND-enabling pre-clinical programs in several neurodegenerative disease and we are engaging scientific and regulatory experts and our scientific advisory board to identify and pursue the most attractive scientific, clinical and business opportunities. The Company is actively engaged in several ongoing development projects with the goal of increasing the scale and efficiency of NurOwn® manufacturing. We are also preparing our manufacturing and supply chain systems for commercial launch.

Therefore, our core business strategy is to fully execute the Phase 3 Clinical Trial, generate the highest quality clinical trial data and 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 BLA-enabling clinical programs in other neurodegenerative diseases.

#### **NurOwn® in CNS Disease**

We are strategically focused on fully executing the clinical development of NurOwn® in ALS and progressive MS as well as continuing our pre-clinical evaluation of the NurOwn® technology platform in other CNS disorders based on a broad preclinical experience in ALS, Parkinson's Disease, Huntington's Disease, MS and Autism.

#### **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 individuals affected in the territory of the European Single Market. Estimated annual treatment and health care 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.

### **Progressive Multiple Sclerosis (PMS)**

Progressive Multiple Sclerosis (PMS) is characterized by the relentless accumulation of central nervous system injury due to peripheral and compartmentalized inflammation, demyelination, axonal damage, and neuronal degeneration and results in increasing motor, visual, and cognitive impairment and significant disability that impacts daily living, employment, and socioeconomic status. There is currently no effective regenerative therapy for this disabling disease that affects approximately one million individuals in the US.

There are currently over 2.3 million people with MS worldwide, with roughly 1 million of these patients located in the U.S. 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.

The lack of safe and effective therapies in progressive MS, the intrinsic immunomodulatory properties of MSC-NTF cells and the potential of MSC-NTF secreted neurotrophic factors to promote neuronal repair and remyelination makes NurOwn® an attractive treatment option to evaluate in PMS.

### **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. Multiple other cell types throughout the central and peripheral autonomic nervous system are also involved and the disease is associated with many non-motor symptoms that add to overall disability. The cause of the disease is presently unknown.

PD is the second-most common neurodegenerative disorder. 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 symptomatic treatment through 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 the effective management of PD and the MSC-NTF cell technology platform represents a promising approach.

## **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 12 granted patents 2 allowed 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 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 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 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 on October 25, 2016 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 patent No. 209604 by Israel's Patent Office for our application titled "Mesenchymal stem cells for 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 July, 2018, the European Patent Office ("EPO") granted a Europe-wide patent for Patent No 2285951, which claims priority from WO 2009/144718. The allowed claims cover methods of treating ALS using mesenchymal stem cells that secrete neurotrophic factors, including brain derived neurotrophic factor (BDNF). This patent will provide protection for MSC-NTF cells (NurOwn®) in the EU validated states until 2029.

In August, 2018, the USPTO granted US Patent No 10,052,363 which relates to methods of treating ALS, Parkinson's disease and Huntington Disease with NurOwn®. This patent will provide protection for MSC-NTF cells (NurOwn®) in the US until 2029.

On August 6, 2013, an International Patent Application (Publication No. WO 2014/024183) was filed entitled "Methods of generating Mesenchymal stem cells which secrete neurotrophic factors". National phase applications were filed in the US, Europe, Hong Kong, Canada, Brazil, Japan and Israel.

On July 6, 2018, the Japanese Patent Office ("JPO") granted Japanese patent No. 6,362,596, entitled: 'Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors' which claims priority from WO 2014/024183. This patent will provide protection for MSC-NTF cells (NurOwn®) in Japan until 2033. The allowed claims cover a method of generating cells which secrete brain derived neurotrophic factor (BDNF), glial derived neurotrophic factor (GDNF), hepatocyte growth factor (HGF) and vascular endothelial growth factor (VEGF).

On August 24, 2018, the U.S. Patent and Trademark Office ("USPTO") granted US Patent No. 10,046,010 titled 'Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors'. Allowed claims cover the method for generating MSC-NTF cells (NurOwn®) in industrial amounts for clinical practice. This patent will provide protection for MSC-NTF cells (NurOwn®) in the US until 2033.

On October 10<sup>th</sup> 2018 the European Patent Office allowed the European Patent Application No. 13164650.7 titled "Mesenchymal stem cells for the treatment of CNS diseases" which claims priority from WO 2009/144718. The allowed claims cover the isolated cells as well as their use in the manufacture of a medicament for treating a CNS disease or disorder (selected from the group consisting of Parkinson's, multiple sclerosis, epilepsy, amyotrophic lateral sclerosis, stroke, autoimmune encephalomyelitis, diabetic neuropathy, glaucomatous neuropathy, Alzheimer's disease and Huntingdon's disease)

On December 21, 2018, the Israel Patent Office granted patent No. 237124 titled 'Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors'. Allowed claims cover the isolated population of cells, the method of manufacturing the cells, and the use of the isolated population of cells for preparation of a medicament for treating a disease (consisting of a neurodegenerative disease, a neurological disease and an immune disease etc.).

Additional PCT patent applications have been filed and National phase applications are currently under examination in several jurisdictions worldwide. Specifically, International Patent Application 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>US, Hong Kong</b>	<b>Europe, Hong Kong</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>US, Japan, Israel, Europe</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. No joint inventions resulted from this consulting agreement and it 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 Israel.

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, Medicaid and the Veterans Affairs Health programs, 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. We are also initiating activities to support commercial launch post approval by regulatory authorities. These activities include scaling out production capacity, logistics and supply. In support of commercialization we are actively pursuing strategic partnerships.

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

incorporating it by reference into, this Annual Report on Form 10-K.

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

### **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 2018 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, 2018 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 the end of 2020 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 the end of 2020, 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 Levovits, 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. 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.

#### **Item 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **Item 2. PROPERTIES**

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

Our United States corporate headquarters are located at 1325 Avenue of Americas, 28<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 December 31, 2021, with a right to terminate the agreement on December 31, 2019 with 4 months' notice. Rent is paid on a monthly basis in the amount of NIS 42,000 (approximately U.S. \$11,500).

As part of the clinical trials with Hadassah, we pay approximately \$41,000 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.

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## **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".

#### *Record Holders*

As of March 28, 2019, there were approximately 38 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 June 6, 2018, the Company entered into a Warrant Exercise Agreement (the “Warrant Exercise Agreement”) with certain holders (the “Holders”) of warrants (the “2015 Warrants”) to purchase Company Common Stock, which 2015 Warrants were originally issued in the Company’s January 8, 2015 private placement. Pursuant to the Warrant Exercise Agreement, the Holders exercised their 2015 Warrants for a total of 2,458,201 shares of Common Stock (the “Exercised Shares”) at an amended exercise price of \$5 per share. The warrant exercises generated gross cash proceeds to the Company of \$12.3 million. In addition, the Company issued new warrants to the Holders to purchase an aggregate 2,458,201 unregistered shares of Common Stock, at an exercise price of \$9, with an expiration date of December 31, 2020 (the “New Warrants”). Certain Holders of New Warrants also entered into a Share Cap Agreement with the Company, whereby the Holders agreed to a 6-month delay (from the date of issuance) in exercisability of any shares at or in excess of 20% limitation on the size of the entire transaction, pursuant to Nasdaq Listing Rules.

The Warrant Exercise Agreement also requires that to the extent that a Holder’s exercise of 2015 Warrants would result in such Holder exceeding the Beneficial Ownership Limitation (as defined in the 2015 Warrants), such excess warrant shares shall be held for the benefit of such Warrant Holder until such time as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation. Per this requirement, as of December 31, 2018, 899,999 of 2,458,201 shares to be issued pursuant to exercise of the 2015 Warrants have not yet been issued and the relating proceeds at an amount of \$4.4 million were recorded as receipts on account of shares.

The New Warrants have not been registered under the Securities Act of 1933, as amended (the Securities Act), or state securities laws. The Exercised Shares have been registered for resale on the Company’s registration statement on Form S-3 (File No. 333-201704). The issuance of the Exercised Shares and New Warrants was exempt from the registration requirements of the Securities Act pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act. The Company made this determination based on the representations that each party is an “accredited investor” within the meaning of Rule 501 of Regulation D.

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

Not required.

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

*The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. For further information regarding forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements" at the beginning of Part I of this Annual Report on Form 10-K.*

**Company Overview**

Brainstorm Cell Therapeutics Inc. is a leading biotechnology company engaged in the development of best-in-class autologous cellular therapies derived from a patient's own bone marrow cells for the treatment of neurodegenerative diseases. The Company holds the rights to clinical development and commercialization of the NurOwn® technology platform through an exclusive, worldwide licensing agreement (see details herein). NurOwn® has received Fast Track designation from the U.S. Food and Drug Administration (U.S. FDA) in ALS and has additionally been granted Orphan Status by the U.S. FDA and the European Medicines Agency (EMA). For more information, visit BrainStorm's website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com).

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

**Results of Operations**

For the period from inception (September 22, 2000) until December 31, 2018, the Company did not generate any revenues from operations. In addition, the Company incurred operating costs and expenses of approximately \$14,063,000 during the year ended December 31, 2018.

### ***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, 2018 were \$8,293,000, an increase of \$7,316,000 compared to \$977,000 for the year ended December 31, 2017. 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 \$1,770,000 in 2018 and \$1,393,000 in 2017 while CIRM grant included in research and development expenses were \$6,267,000 in 2018 and \$4,425,000 in 2017. Excluding OCS grant and CIRM grants, research and development expenses increased by \$9,535,000 from \$6,795,000 in 2017 to \$16,330,000 in 2018.

This increase is primarily due to an increase of \$8,514,000 to \$11,483,000 for the year ended December 31, 2018, from \$2,969,000 for the year ended December 31, 2017 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 \$467,000 in payroll and stock-based compensation expenses, (ii) an increase of \$140,000 in the costs of activities related to the Israeli clinical trials and costs of materials and (iii) an increase of \$414,000 in travel, rent, costs of patents and various other expenses.

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

General and administrative expenses for the years ended December 31, 2018 and 2017 were \$5,770,000 and \$4,022,000, respectively. The increase of \$1,748,000 in general and administrative expenses is mainly due to: (i) an increase of \$1,711,000 in payroll and stock-based compensation expenses; (ii) an increase of \$416,000 in the rent, stock costs and various other expenses. This increase was partially offset by a decrease of \$379,000 in the costs of our investor relations and public relations activities, consultants and travel costs.

### ***Financial Expenses***

The financial income of \$115,000 for the year ended December 31, 2018 is mainly due to interest earned on our cash, cash equivalents and short-term deposits. Financial income for the year ended December 31, 2017 was \$47,000.

### ***Net Loss***

Net loss for the year ended December 31, 2018 was \$13,948,000, as compared to a net loss of \$4,952,000 for the year ended December 31, 2017. Net loss per share for the year ended December 31, 2018 and December 31, 2017 was \$0.70 and \$0.26, 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, 2018 was 19,997,710 compared to 18,777,348 for the year ended December 31, 2017.

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, 2018 was due to: (i) the issuance of shares to service providers, employees 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**

Since inception, the Company has financed its operations since inception primarily through public and private sales of its Common Stock and warrants, the exercise of warrants, and the issuance of convertible promissory notes. At December 31, 2018, the Company had net working capital of \$4,058,000 including cash, cash equivalents and short-term bank deposits amounting to \$7,064,000.



Net cash used in operating activities for the year ended December 31, 2018 was \$12,388,000. 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 used in investing activities for the year ended December 31, 2018 was \$1,218,000 representing primarily a net increase in short-term deposits and purchase of property and equipment.

Net cash provided by financing activities for the year ended December 31, 2018 was \$12,065,000 from the exercises of warrants and options during the year and issuance of new warrants.

On June 6, 2018, the Company received gross cash proceeds to the Company of \$12.3 million pursuant to the Warrant Exercise Agreement (described in greater detail above) with certain holders 2015 Warrants, pursuant to which holders exercised their 2015 Warrants for a total of 2,458,201 shares of Common Stock at an amended exercise price of \$5 per share, and the Company issued new warrants to the holders to purchase an aggregate 2,458,201 unregistered shares of Common Stock, at an exercise price of \$9, with an expiration date of December 31, 2020.

On June 8, 2018, we filed a shelf registration statement, effective June 29, 2018, 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.

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

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARIES**

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2018**

**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 2018 and the related consolidated statements comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2018, 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 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, 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 29, 2019

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)

	<b>December 31,</b>	
	2018	2017
	U.S. \$ in thousands	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$942	\$2,483
Short-term deposit (Note 8)	6,122	5,273
Accounts receivable (Note 4)	2,009	672
Prepaid expenses and other current assets	1,197	1,195
Total current assets	10,270	9,623
Long-Term Assets:		
Prepaid expenses and other long-term assets (Note 5)	307	1,408
Property and Equipment, Net (Note 6)	651	392
Total Long-Term Assets	958	1,800
Total assets	\$11,228	\$11,423
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$4,548	\$1,424
Accrued expenses	1,042	817
Deferred grant income (Note 9)	-	2,625
Other accounts payable	622	677
Total current liabilities	6,212	5,543
Total liabilities	\$6,212	\$5,543
Stockholders' Equity:		
Stock capital: (Note 10)	11	11
Common Stock of \$0.00005 par value - Authorized: 100,000,000 shares at December 31, 2018 and December 31, 2017 respectively; Issued and outstanding:		

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20,757,816 and 18,976,169 shares at December 31, 2018 and December 31, 2017 respectively.

Additional paid-in-capital	94,620	85,944
Receipts on account of shares	4,408	-
Accumulated deficit	(94,023)	(80,075)
Total stockholders' equity	5,016	5,880
Total liabilities and stockholders' equity	\$11,228	\$11,423

**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,	
	2018	2017
	U.S. \$ in thousands	
Operating expenses:		
Research and development, net (Note 11)	\$8,293	\$977
General and administrative	5,770	4,022
Operating loss	(14,063 )	(4,999 )
Financial expenses (income), net	(115 )	(47 )
Net loss	\$(13,948 )	\$(4,952 )
Basic and diluted net loss per share from continuing operations	\$(0.70 )	\$(0.26 )
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	19,997,710	18,777,348

**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		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Number	Amount			
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 SUBSIDIARIESSTATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

U.S. dollars in thousands

(Except share data)

	Common stock		Additional on paid-in capital	Receipts account of shares	Accumulated deficit	Total stockholders' equity
	Number	Amount				
Balance as of January 1, 2018	18,976,169	\$ 11	\$ 85,944	\$ -	\$ (80,075 )	\$ 5,880
Stock-based compensation related to warrants and stock granted to service providers	42,293	(*)	102	-	-	102
Stock-based compensation related to stock and options granted to directors and employees	147,820	(*)	917	-	-	917
Exercise of options	33,332	(*)	25	-	-	25
Exercise and reissuance of warrants	1,558,202	(*)	7,632	4,408	-	12,040
Net loss	-	-	-	-	(13,948 )	(13,948 )
Balance as of December 31, 2018	20,757,816	\$ 11	\$ 94,620	\$ 4,408	\$ (94,023 )	\$ 5,016

\* 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, 2018 U.S. \$ in thousands	2017
Cash flows from operating activities:		
Net loss	\$ (13,948 )	\$ (4,952 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	110	85
Shares and options granted to service providers	102	62
Deferred Stock-based compensation related to options granted to employees and directors	917	554
Increase in accounts receivable and prepaid expenses	(238 )	(2,792 )
Increase in trade payables	3,124	1,079
Deferred grant income	(2,625 )	2,625
Increase in other accounts payable and accrued expenses	170	975
Total net cash used in operating activities	\$ (12,388 )	\$ (2,364 )

**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,	
	2018	2017
	U.S. \$ in thousands	
Cash flows from investing activities:		
Purchase of property and equipment	(369 )	(180 )
Changes in short-term deposit	(849 )	4,170
Investment in lease deposit	-	(4 )
Total net cash provided by (used in) investing activities	\$(1,218 )	\$ 3,986
Cash flows from financing activities:		
Proceeds from exercise of options	25	314
Exercise and reissuance of warrants	12,040	-
Total net cash provided by financing activities	\$ 12,065	\$ 314
Increase (decrease) in cash and cash equivalents	(1,541 )	1,936
Cash and cash equivalents at the beginning of the period	\$ 2,483	\$ 547
Cash and cash equivalents at end of the period	\$ 942	\$ 2,483

**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 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, also known as Lou Gherig Disease), Progressive Multiple Sclerosis (PMS) and Parkinson's disease. The Company developed a proprietary process, called NurOwn, for the propagation of Mesenchymal Stem Cells and their differentiation into neurotrophic factor secreting cells. These cells are then transplanted at or near the site of damage, offering the hope of more effectively treating neurodegenerative diseases. The process is currently autologous, or self-transplanted.

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

The Company made significant progress in 2018 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, 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.** The Phase 3 ALS trial pre-specified interim safety analysis by an independent Data Safety Monitoring Board (DSMB) was successfully completed in August 2018.

**F.** The Company was granted FDA clearance for its NurOwn® IND Application for Progressive Multiple Sclerosis indication (ClinicalTrials.gov Identifier NCT03799718).

**G.** The Company received Good Manufacturing Practice (GMP) approval from the Israel Ministry of Health (MoH) for our Israeli contract manufacturing facility at the Hadassah Medical Center in Jerusalem. The GMP certificate confirms the Company's manufacturing site compliance with Israeli GMPs which are recognized as equivalent to EU standards.

**BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY**

U.S. dollars in thousands

(Except share data and exercise prices)

**Notes to Consolidated Financial Statements**

**GOING CONCERN:**

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

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

**NOTE 2 - 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.

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.):

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

**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.

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 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, 2018 and December 31, 2017, 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.

#### 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. As the Company has not incurred revenues to date, the adoption of the standard did not have an impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02 (Topic 842) "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. The Company 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.

Based on our portfolio of leases as of December 31, 2018, approximately \$500 of lease assets and liabilities will be recognized on our balance sheet.



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 (Cont.):

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

In June 2018, the FASB issued ASU No. 2018-07 “Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.” These amendments expand the scope of Topic 718, Compensation - Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity - Equity-Based Payments to Non-Employees. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. ASU 2018-07 does not have a material impact on Company’s 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:

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, a) the Company shall pay Ramot a royalty of 5% of the Net Sales received by the Company and resulting from such Commercialization; and

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 b) 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.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

Notes to Consolidated Financial Statements

## NOTE 4 - ACCOUNTS RECEIVABLE

	December 31,	
	2018	2017
Grants receivable from CIRM (Note 9)	\$1,642	\$-
Grants receivable from IIA	277	574
Government institutions and other	90	98
	\$2,009	\$672

## 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. In 2017 the Company has paid COH \$2,665 advance payment. The advance was recorded as prepaid expense and is amortized over the term of the agreement. As of December 31, 2018, \$1,103 and \$276 were recorded as current and long-term prepaid expense, respectively.

## NOTE 6 - PROPERTY AND EQUIPMENT

	December 31,	
	2018	2017
Cost:		
Office furniture and equipment	\$73	\$73
Computer software and electronic equipment	202	189
Laboratory equipment	1,173	875
Leasehold improvements	772	716
	2,220	1,853
Accumulated depreciation:		
Office furniture and equipment	28	23

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Computer software and electronic equipment	186	176
Laboratory equipment	639	552
Leasehold improvements	716	710
	1,569	1,461
Depreciated cost	\$651	\$392

Depreciation expenses for the years ended December 31, 2018 and December 31, 2017 were \$110 and \$85, respectively.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

U.S. dollars in thousands

(Except share data and exercise prices)

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 The Company A. leased approximately 220 square meters of office space for a term of 63 months commencing October 1, 2014. Rent is paid on a monthly basis in the amount of approximately U.S. \$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, 2018 are as follows:

Period ending December 31,	Facilities	Vehicles	Total
2019	199	13	212
2020	43	-	43
	\$ 242	\$ 13	\$255

Total facilities rent expense for the years ended December 31, 2018 and 2017 were \$262 and \$198, respectively.

C. Commitments to pay royalties to the IIA:

BCT obtained from the Chief Scientist of the Israel Innovation Authority (“IIA”) grants for participation in research and development for the years 2007 through 2018, 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, 2018, total grants obtained amounted to \$2,009.

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, 2018, there are no outstanding obligations owed to Ramot in connection with the above.

#### NOTE 8 - SHORT TERM DEPOSITS

Short term investments on December 31, 2018 and December 31, 2017 include bank deposits bearing annual interest rates varying from 0.05% to 3.15%, with maturities of up to 8 months as of December 31, 2018 and 2017.

#### NOTE 9 - DEFERRED GRANT INCOME

In July 2017 the Company received an award in the amount of \$15,912 from CIRM to aid in funding the Company's Phase 3 study of NurOwn®, for the treatment of ALS. An aggregate amount of \$9,050 and \$7,050 related to the project was received through December 31, 2018 and December 31, 2017, respectively. As of December 31, 2018, there are grants receivable from CIRM of \$1,642 (Note 4). The award does not bear a royalty payment commitment nor is the award otherwise refundable. \$6,267 and \$4,425 was recorded as participation by CIRM in research and development expenses during the year ended in December 31, 2018 and during the year ended December 31, 2017, respectively (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 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 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 \$10,500 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 2,800,000 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 3,858,200 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.):

Gross proceeds from the exercise of the warrants were approximately \$13,300. 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 \$12,400.

On June 6, 2018, the Company entered into a Warrant Exercise Agreement (the “Warrant Exercise Agreement”) with certain holders (the “Holders”) of warrants (the “2015 Warrants”) to purchase Company Common Stock, which 2015 Warrants were originally issued in the Company’s January 8, 2015 private placement. Pursuant to the Warrant Exercise Agreement, the Holders exercised their 2015 Warrants for a total of 2,458,201 shares of Common Stock (the “Exercised Shares”) at an amended exercise price of \$5 per share. The warrant exercises generated gross cash proceeds to the Company of \$12,291 (\$12,040 net of issuance expenses). In addition, the Company issued new warrants to the Holders to purchase an aggregate 2,458,201 unregistered shares of Common Stock, at an exercise price of \$9, with an expiration date of December 31, 2020 (the “New Warrants”).

The Warrant Exercise Agreement also requires that to the extent that a Holder’s exercise of 2015 Warrants would result in such Holder exceeding the Beneficial Ownership Limitation (as defined in the 2015 Warrants), such excess warrant shares shall be held for the benefit of such Warrant Holder until such time as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation. Per this requirement, as of December 31, 2018, 899,999 of 2,458,201 shares to be issued pursuant to exercise of the 2015 Warrants have not yet been issued and the relating proceeds at an amount of \$4,408 were recorded as receipts on account of shares.

Since its inception the Company has raised approximately \$59,000, 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.

**Warrants:**

The following table sets forth the number, exercise price and expiration date of Company warrants outstanding as of December 31, 2018:

Issuance Date	Outstanding As Of December 31, 2018	Exercise price	Exercisable Through
Apr-Oct 2009	20,000	1.005 - 1.5	Apr-Oct-2019
Aug 2007- Jan 2011	2,016,666	3 - 4.35	Nov-2022
Jun-2014	84,000	4.5	Jun-2019
Jun-2018	2,458,201	9	Dec-2020
Total	4,578,867		

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.):

Stock Plans:

During the fiscal year ended December 31, 2018, the Company had outstanding awards for stock options under four stockholder approved plans: (i) the 2004 Global Stock Option Plan and the Israeli Appendix thereto (the “2004 Global Plan”) (ii) the 2005 U.S. Stock Option and Incentive Plan (the “2005 U.S. Plan,” and together with the 2004 Global Plan, the “Prior Plans”); (iii) the 2014 Global Share Option Plan and the Israeli Appendix thereto (which applies solely to participants who are residents of Israel) (the “2014 Global Plan”); and (iv) the 2014 Stock Incentive Plan (the “2014 U.S. Plan” and together with the 2014 Global Plan, the “2014 Plans”).

The 2004 Global Plan and 2005 U.S. Plan expired on November 25, 2014 and March 28, 2015, respectively. Grants that were made under the Prior Plans remain outstanding pursuant to their terms. The 2014 Plans were approved by the stockholders on August 14, 2014 (at which time the Company ceased to issue awards under each of the 2005 U.S. Plan and 2004 Global Plan) and amended on June 21, 2016 and November 29, 2018. 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 4,000,000 shares of Common Stock available for issuance. As of December 31, 2018, 2,080,755 shares were available for future issuances under the 2014 Plans. The exercise price of the options granted under the 2014 Plans may not be less than the nominal value of the shares into which such options are exercised. Any options under the 2014 Plans that are canceled or forfeited before expiration become available for future grants. The Governance, Nominating and Compensation Committee (the “GNC Committee”) of the Board of Directors of the Company administers the Company’s stock incentive compensation and equity-based plans.

Share-based compensation to employees and to directors:

*Employees:*

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, July 26, 2018, and is entitled to receive on each anniversary thereafter (provided he remains Chief Executive Officer), a grant of 31,185 shares of restricted stock, each of which vests as to twenty-five percent (25%) of the award on the first, second, third and fourth anniversary of the date of grant and is subject to accelerated vesting upon a Change of Control (as defined in the Lebovits employment agreement) of the Company; and (iii) was granted on July 26, 2017 a fully vested and exercisable option 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.

Dr. Ralph Kern, Chief Operating Officer and Chief Medical Officer of the Company, received on March 6, 2017, March 6, 2018, and is entitled to receive on each anniversary thereafter (provided he remains employed by the Company), a grant of 35,885 shares of restricted stock, each of which vests as to twenty-five percent (25%) of the award on the first, second, third and fourth anniversary of the date of grant and is subject to accelerated vesting upon a Change of Control (as defined in the agreement) of the Company.

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 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 is granted a stock option for the purchase of up to 13,333 shares of Common Stock on the first business day after each annual meeting of stockholders (or special meeting in lieu thereof) of the Company (including on November 10, 2017 and November 30, 2018), each with an exercise price per share of \$0.75, and each of which vests and becomes exercisable in 12 monthly installments. The Company also granted Mr. Yablonka 5,543 shares of restricted Common Stock on July 13, 2017.

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.

On November 20, 2017, the Company granted to Eyal Rubin, the Company's Chief Financial Officer, 25,000 shares of restricted Common Stock, which fully vested on April 1, 2018. On November 20, 2017 the Company also granted to Mr. Rubin an option to purchase up to 93,686 shares of Common Stock, at an exercise price per share equal to \$4.30 per share, which shall vest and become exercisable as to 25% of the shares underlying the Option on each of the first, second, third and fourth anniversary of the date of grant, subject to accelerated vesting upon a Change of Control of

the Company or a Material Secondary Public Offering of the Company (each as defined in Mr. Rubin's employment agreement).

On August 28, 2018, the Company granted Arturo Araya, Chief Commercial Officer of the Company an option to purchase 200,000 shares of Common Stock, at an exercise price of \$3.98 per share. 25% of the grant shall vest and become exercisable on each of the first, second, third and fourth anniversaries of the grant date and subject to accelerated vesting upon a Change of Control (as defined in the agreement). On August 28, 2018, Mr. Araya resigned from the GNC Committee, and the restricted stock previously granted to him in connection with his service on the Board and the GNC Committee ceased vesting.

The Company granted Mary Kay Turner, an employee, 9,924 shares of restricted Common Stock on August 17, 2017 and 11,198 shares of restricted Common Stock on August 1, 2018, each of which vests as to 25% of the grant yearly over the course of four (4) years.

On July 30, 2018, the Company granted Joseph Petroziello, an employee, an option to purchase 200,000 shares of Common Stock at an exercise price of \$4.11 per share, which vests and becomes exercisable as to 25% of the grant on each of the first, second, third and fourth anniversaries of the date of grant.

On July 9, 2018, the Company granted Susan Ward, an employee, an option to purchase 150,000 shares of Common Stock at an exercise price of \$4.21 per share, which vests and becomes exercisable as to 20% of the option on each of the first, second, third, fourth and fifth anniversaries of the date of grant.

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:*

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

The Company's Second Amended and Restated Director Compensation Plan was approved in July 9, 2014 and amended on April 29, 2015, February 26, 2017 and July 13, 2017 (as amended, the "Director Compensation Plan"). The Director Compensation Plan governs Company compensation of eligible non-employee director of the Company, except that certain non-employee directors have individualized compensation and are not entitled receive annual director awards under the Director Compensation Plan, but are entitled to committee compensation under the Director Compensation Plan in the event that they qualify for and serve as a member of any committee of the Board. The Director Compensation Plan also determines the annual awards to be granted to qualified directors for their services in future periods, which annual awards have had the same terms since 2014, as further detailed in the Director Compensation Plan.

During the year (12 months) ended December 31, 2018, the following grants were made under the 2014 Plans to eligible directors:

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

commenced employment with the Company).

On November 30, 2018 Dr. Anthony J. Polverino received 2,000 shares of restricted stock for his service as a director and 1,667 shares of stock for his service as a member of the GNC Committee.

On November 30, 2018 Malcolm Taub received 12,000 shares of restricted stock for service as a member of the Board and its Committees.

On November 30, 2018 Chen Schor received 2,000 shares of restricted stock for service as a member of the Audit Committee.

On November 30, 2018, Irit Arbel received an option to purchase up to 25,333 shares of Common Stock at an exercise price of \$0.75, for service as a member of the Board and its Committees.



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.):

*Restricted Stock:*

The Company awards stock and restricted stock to certain employees, officers, directors, and/or service providers. The restricted stock vests in accordance with such conditions and restrictions determined by the GNC Committee. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with the Company through a specified restricted period. The purchase price (if any) of shares of restricted stock is determined by the GNC Committee. If the performance goals and other restrictions are not attained, the grantee will automatically forfeit their unvested awards of restricted stock to the Company. Compensation expense for restricted stock is based on fair market value at the grant date.

	<b>Number of Shares</b>	<b>Weighted Average</b>	<b>Weighted Average</b>
	<b>of Restricted</b>	<b>Grant Date Fair</b>	<b>Remaining</b>
	<b>Stock</b>	<b>Value</b>	<b>Contractual</b>
			<b>Term</b>
			<b>(Years)</b>
Nonvested as of December 31, 2016	28,666	3.31	0.59
Granted	148,628	4.27	
Vested	50,486	3.79	
Forfeitures	-	-	
Nonvested as of December 31, 2017	126,808	4.25	1.31
Granted	144,447	3.59	

Vested	118,347	3.81	
Forfeitures	-	-	
Nonvested as of December 31, 2018	152,908	3.96	1.56

Compensation expense recorded by the Company in respect of its stock and restricted stock awards to certain employees, officers, directors, and/or service providers for the year ended December 31, 2018 and 2017 amounted to \$506 and \$361, respectively.

*Stock Options:*

Under the 2014 Plans, the Company may award stock options to certain employees, officers, directors, and/or service providers. The stock options vest in accordance with such conditions and restrictions determined by the GNC Committee. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with the Company through a specified period. Stock options awarded are valued based upon the Black-Scholes option pricing model and the Company recognizes this value as stock compensation expense over the periods in which the options vest. Use of the Black Scholes option-pricing model requires that the Company make certain assumptions, including expected volatility, risk-free interest rate, expected dividend yield, and the expected life of the options. The Company granted stock options to purchase 588,665 and 240,446 shares in 2018 and 2017, respectively.

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.):

*Stock Options (Cont.):*

Stock option fair value assumptions for the stock options granted during the year ended December 31, 2018 and 2017 are as follows:

	For the year ended December 31,	
	2018	2017
Option life (years)	10	2-10
Risk free interest rate	2.77%-2.87 %	0.97%-2.13 %
Dividend yield	0	0
Expected volatility	65%-66 %	54%-70 %
Expected life (years)	5.25-5.5 years	1-5.5 years
Weighted average fair value of stock options granted	2.58	2.29

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

<b>For the year ended</b>		<b>For the year ended</b>	
<b>December 31, 2018</b>		<b>December 31, 2017</b>	
Amount	Weighted Aggregate	Amount	

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	of	average	intrinsic	of	Weighted	Aggregate
	options	exercise	value	options	average	intrinsic
		price			exercise	value
					price	
		\$	\$		\$	\$
Outstanding at beginning of period	940,954	2.4681		874,841	2.1258	
Granted	588,665	3.8706		240,446	3.5178	
Exercised	-	-		(129,888)	3.9175	
Cancelled	(33,332 )	-		(44,445 )	1.6104	
Outstanding at end of period	1,496,287	3.0581	735,992	940,954	2.4681	1,366,213
Vested and expected-to-vest at end of period	840,579	2.3765	986,447	811,824	2.3317	1,289,457

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, 2018 and December 31, 2017 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.):

*Stock Options (Cont.):*

The options outstanding as of December 31, 2018 and December 31, 2017, 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, 2018	2017	As of December 31, 2018	2017	As of December 31, 2018	2017
0.75	218,666	213,333	7.73	6.99	183,222	177,889
1.005	5,333	5,333	0.5	1.50	5,333	5,333
2.25	69,889	69,889	2.57	3.57	69,889	69,889
2.45	369,619	369,619	6.75	7.75	369,619	369,619
2.70	82,667	82,667	4.65	5.65	82,667	82,667
3.90	15,000	15,000	3.59	4.59	15,000	15,000
3.98	200,000	-	9.66	-	-	-
4.11	200,000	-	9.58	-	-	-
4.18	47,847	47,847	0.18	1.18	47,847	47,847
4.21	150,000	-	9.53	-	-	-
4.3	93,686	93,686	8.89	9.89	23,422	-
4.80	2,000	2,000	1.11	2.11	2,000	2,000

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4.81	41,580	41,580	0.56	1.56	41,580	41,580
	1,496,287	940,954	7.32	6.59	840,579	811,824

Compensation expense recorded by the Company in respect of its stock-based employees and directors compensation awards in accordance with ASC 718-10 for the year ended December 31, 2018 and 2017 amounted to \$917 and \$554, 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,			
	2018		2017	
Expected volatility	65%-66	%	67%-70	%
Risk-free interest	2.77%-2.87	%	0.97%-2.13	%
Dividend yield	0	%	0	%
Expected life of up to (years)	5.5		5.5	

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:

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 for the year ended December 31, 2018 and 2017 amounted to \$102 and \$62, 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.

On October 3, 2018, the Company granted to its legal advisor 6,524 shares of Common Stock for 2018 legal services. The related compensation expense was recorded as general and administrative expense.

On November 29, 2018, the Company granted 24,519 shares of Common Stock to a consultant for services rendered from 2016 through 2018. The related compensation expense was recorded as research and development 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,	
	2018	2017
Research and development	\$ 175	\$ 164
General and administrative	844	452
Total stock-based compensation expense	\$ 1,019	\$ 616



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,	
	2018	2017
Research and development	\$16,330	\$6,795
Less : Participation by the Israel Innovation Authorities	(1,770 )	(1,393 )
Less : Participation by CIRM	(6,267 )	(4,425 )
	\$8,293	\$977

NOTE 12 - TAXES ON INCOME

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

BCT is taxed according to Israeli tax laws.

The Israeli corporate tax rate was 25% in the year 2016, 24% in year 2017 and 23% in year 2018 and onwards. Such tax rate changes have no significant impact on the Company's financial statements.

The Company is taxed according to U.S. tax laws.

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (the "Act"), which among other provisions, reduced the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018.

The Company is currently evaluating the impact the Act will have on the future financial condition and results of operations and believe the Act will have a beneficial positive net impact. The Act did not have an effect on the financial results and position of the Company.

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,	
	2018	2017
Operating loss carryforward	\$57,768	\$51,107
Net deferred tax asset before valuation allowance	15,916	14,090
Valuation allowance	(15,916)	(14,090)
Net deferred tax asset	\$-	\$-

As of December 31, 2018, the Company has provided valuation allowances of \$15,916 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, 2018, the Company has an accumulated tax loss carryforward of approximately \$57,768. 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,	
	2018	2017
United States	\$ (3,617 )	\$ (2,532 )
Israel	(10,331 )	(2,420 )
	\$ (13,948 )	\$ (4,952 )

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

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 2018 and 2017.

NOTE 14 -SUBSEQUENT EVENTS

On March 22<sup>nd</sup> 2019, the Company received payment of \$3,500 from CIRM under the existing CIRM grant. To date the Company has received \$12,550 of the \$15,912 CIRM grant.

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, 2018 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, 2018. 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, 2018, 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 (“Board”) and serve at the discretion of the Board. 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	48	President and Chief Executive Officer
Dr. Ralph Kern	61	Chief Operating Officer and Chief Medical Officer
Eyal Rubin	43	Chief Financial Officer
Arturo O. Araya	48	Chief Commercial Officer
Uri Yablonka	42	Executive Vice President, Chief Business Officer and Director
Dr. Irit Arbel	59	Chairperson and Director
Dr. June S. Almenoff	62	Director
Chen Schor	46	Director
Dr. Anthony Polverino	56	Director
Malcolm Taub	73	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.

**Arturo O. Araya** has served as the Chief Commercial Officer of the Company since August, 2018. He also served as a director of the Company from February, 2017 to November, 2018. 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.



**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 CEO of Neurchords, a biotechnology firm developing graphene-based scaffold for nerve reconstruction in acute spinal cord and peripheral nerve injury. Dr. Arbel served as Executive Vice President, Research and Development at Savicell Diagnostic Ltd until August 2018. 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 Executive Vice President Early Development and Chief Scientific Officer of Zymeworks Inc., which he joined in September of 2018, and where he is responsible for establishing the vision, strategy, and general management of the organization and overseeing the advancement of products from discovery research through translational research/early development to create a seamless link to clinical development. Prior to Zymeworks Dr. Polverino was the interim chief scientific officer of Kite (now a wholly-owned subsidiary of Gilead Sciences), which he joined in 2015, and where he was 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. June Almenoff is an accomplished executive with 20+ years of experience in the pharmaceutical industry. She has broad therapeutic development and strategic experience including gastroenterology, rare disease, immune-inflammation, infectious diseases, CNS. She served as President and CMO of Furiex Pharmaceuticals (from 2010 to 2014). During her 4-year tenure, the company's valuation increased ~10-fold, culminating in its acquisition by Actavis plc for ~\$1.2B in 2014. Furiex's lead product, eluxadoline (Viberzi TM), a novel gastrointestinal drug, is approved and marketed in US and EU. Prior to joining Furiex, Dr. Almenoff was at GlaxoSmithKline (GSK) from 1997 to 2010, where she held various positions of increasing responsibility in the R&D organization. During her 12 years 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 also served as CMO and COO of Innovate Biopharmaceuticals (2018). Dr. Almenoff is currently an independent Board Director and drug development consultant with broad therapeutic expertise. She has served as Executive Chair of RDD Pharma, a private, GI clinical stage biopharma company (2015-18) where she helped the company secure Series B as well as US Govt. Dept of Defense funding and currently serves as an independent director (since 2015). She was a Director of Tigenix NV (Nasdaq: TIG) from 2016-18, until its acquisition for ~\$600M. Dr. Almenoff has served on the Board of Ohr Pharmaceuticals (Nasdaq: OHRP) since 2013, and serves on the investment advisory board of the Harrington Discovery Institute, a venture philanthropy, and the Scientific Advisory Board of Redhill Biopharma (RDHL). She is a consultant and advisor to numerous biopharma companies and investors in the areas of translational medicine, clinical development, and commercial strategy in product development. 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 an adjunct Professor at Duke and a Fellow of the American College of Physicians (FACP) and has authored more than 50 publications. 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.

**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 Mr. Schor), accounting (Mr. Schor), business consulting and

development (Dr. Polverino and Mr. Yablonka), media (Mr. Yablonka) and law (Mr. Taub, Mr. Yablonka), each of which the Board believes provides valuable knowledge about important elements of our business. Most of our directors have leadership experience at major companies or firms with operations inside and outside the United States and/or experience on other companies' boards, which provides an understanding of ways other companies address various business matters, strategies and issues. As indicated in the foregoing biographies, the directors have each demonstrated significant leadership skills, including as a chief executive officer (Drs. Arbel and Mr. Schor), executive officer (Drs. Almenoff and Polverino, and Mr. 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. Mr. Schor serves as a member of the Audit Committee.

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 received 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. Mr. Araya also received a grant of 1,249 shares of restricted stock for his service on the GNC Committee. All grants ceased vesting and Mr. Araya resigned as a member of the GNC effective August 28, 2018, in connection with Mr. Araya commencing employment with the Company as its Chief Commercial Officer.

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 (“Board”) established a standing Audit Committee in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, which assists the Board in fulfilling its responsibilities to stockholders concerning our financial reporting and internal controls, and facilitates open communication among the Audit Committee, Board, 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’s 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, to engage such independent legal, accounting and other advisors as it

deems necessary or appropriate to carry out its responsibilities. The Board 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) and Dr. Arbel, each of whom is independent within the meaning of The NASDAQ Marketplace Rules and Rule 10A-3 under the Exchange Act, as well as Mr. Schor, who is not currently independent but serves on the Audit Committee in accordance with Nasdaq Rule 5605(c)(2)(B). 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, 2018.

### *GNC Committee*

On June 27, 2011, the Board established a standing Governance, Nominating and Compensation Committee (the “GNC Committee”), which assists the Board in fulfilling its responsibilities relating to (i) compensation of the Company’s executive officers, (ii) the director nomination process and (iii) reviewing the Company’s compliance with SEC corporate governance requirements. The Board has adopted a written charter for the GNC Committee, which is available in the corporate governance section of our website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com). The GNC Committee currently consists of Dr. Arbel (Chair), Dr. Polverino and Mr. Taub, each of whom is independent as defined under applicable NASDAQ listing standards. The GNC Committee held four meetings during the fiscal year ended December 31, 2018.

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 2018, we made no material changes to the procedures by which stockholders may recommend nominees to our Board, 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, 2018 all Reporting Persons complied

with the applicable requirements of Section 16(a) of the Exchange Act other than one late Form 4 filed by Ralph Kern on March 26, 2018, 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 adopted a Code of Ethics that applies to, among other persons, members of our Board, 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, 2018 and 2017 earned by our President and Chief Executive Officer, Chief Financial Officer, and our Chief Operating 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 (4)	2018	500,000	750,000(6)	133,472	(8)	195,398	1,578,870
Ralph Kern, Chief Operating Officer (9)	2018	500,000	150,000(10)	119,000	(12)	72,650	841,650
Eyal Rubin (*), Chief Financial Officer (13)	2017	417,000	-	200,000	(11)	59,000	676,000
	2018	197,000	49,000			105,000	351,000
	2017	20,200	5,000	347,843	(14)	9,207	382,250

(\*) 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 2018 daily rates between the U.S. dollar and the NIS as published by the Bank of Israel, the central bank of Israel.

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 2018 and fiscal 2017. 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.

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.

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.

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

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.

In April and in July 2018, the Company paid Mr. Lebovits a discretionary cash bonus payment of \$250,000 and \$500,000 in recognition of his contributions to the Company’s performance in fiscal year 2018.

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.

On July 26, 2018 Mr. Lebovits received a grant of 31,185 shares of restricted Common Stock.

Dr. Kern’s employment with the Company began on March 6, 2017.

In March 2018, the Company paid Mr. Kern a discretionary cash bonus payment of \$150,000 in recognition of his contributions to the Company’s performance in fiscal year 2018.

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.

On March 6, 2018 Dr. Kern received a grant of 35,885 shares of restricted Common Stock.

Mr. Rubin’s employment with the Company began on November 20, 2017.

On November 20, 2017, Mr. Rubin received a grant of 25,000 shares of restricted Common Stock and also an (14) 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.

### ***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 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. 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 \$16,200 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 \$11,300 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.



*Arturo Araya*

Arturo Araya, the Company's Chief Commercial Officer, is party to an August 28, 2018 employment agreement with the Company, pursuant to which Mr. Araya receives an annual base compensation of \$300,000 and is eligible to receive an annual cash bonus equal to 20% of his base salary, subject to satisfaction of pre-established performance goals. On August 28, 2018 he also received a one-time grant of an option to purchase 200,000 shares of Common Stock under the Company's 2014 Stock Incentive Plan, at an exercise price of \$3.98 per share. 25% of the grant shall vest and become exercisable on each of the first, second, third and fourth anniversaries of the grant date, so that the grant becomes fully vested and exercisable on the fourth anniversary of the grant date. The grant is subject to accelerated vesting upon a Change of Control, as defined in the agreement, and has a 10-year term. Any unvested shares underlying the grant as of the date of the termination of his employment with the Company shall automatically terminate. In connection with the employment agreement Mr. Araya resigned from the GNC Committee, and the restricted stock previously granted to him in connection with his service on the Board and the GNC Committee ceased vesting.

***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, 2018. 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, 2018**

Name	Option Awards	Stock Awards	
		Number	Market

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	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	of Shares or Units of Stock That Have Not Vested Not Vested (#)	Value of Shares or Units of Stock That Have Not Vested (\$)(1)
Chaim Lebovits	369,619	-	2.45	9/28/2025	23,389(2)	78,820
	41,580	-	4.81	7/26/2019	31,185(3)	105,093
Ralph Kern	47,847	-	4.18	3/6/2019	26,914(4)	90,699
					35,885(5)	120,932
Eyal Rubin	23,421	70,264	(6) 4.30	11/20/2027		

(1)Based on the fair market value of our Common Stock on December 28, 2018 (\$3.37 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.

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, 2018),

(3)provided that Chaim Lebovits remains continuously employed by the Company from the date of grant through each applicable vesting date.

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.

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, 2018),

(5)provided that Ralph Kern remains continuously employed by the Company from the date of grant through each applicable vesting date.

Options for the purchase of 23,422 shares were vested and exercisable on December 31, 2018. Options for the

(6)purchase of 23,422 shares will vest and become exercisable yearly until the option is fully vested and exercisable on the fourth anniversary of the date of grant.

## Stock Incentive Plans

During the fiscal year ended December 31, 2018, 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 and November 29, 2018. 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 4,400,000 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, 2018 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 2018

Fees Earned or Paid in	Stock Awards	Option Awards (\$)	Total
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Name	Cash (\$)	(\$)(1)	(1)(2)	(\$)
Dr. Irit Arbel	—	—	66,040(3)	66,040
Dr. June S. Almenoff	30,000 (4)	—		30,000
Arturo O. Araya	12,500 (5)	7,944		20,444
Dr. Anthony Polverino	—	23,904(6)	—	23,904
Mr. Chen Schor	30,000 (7)	6,220 (8)	—	36,220
Mr. Malcolm Taub	—	37,320(9)	—	37,320
Uri Yablonka	-	-	34,758(10)	34,758

The amounts shown in the “Stock Awards” and “Option Awards” columns represent the aggregate grant date fair (1) value of awards computed in accordance with ASC 718, not the actual amounts paid to or realized by the directors during fiscal 2018.

(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, 2018, Dr. Arbel had options (vested and unvested) to purchase 221,886 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, 2018, Mr. Polverino had 1,834 shares of unvested restricted Common Stock.

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

(8) At December 31, 2018, Mr. Schor had 1,834 shares of unvested restricted Common Stock.

(9) At December 31, 2018, Mr. Taub had 11,000 shares of unvested restricted Common Stock.

(10) At December 31, 2018, Mr. Yablonka had options (vested and unvested) to purchase 99,998 shares of 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 (until he commenced service as an employee in August, 2018) 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, Dr. Polverino 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 vests 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. Dr. Polverino does not receive annual director awards under the Director Compensation Plan, but in the event that he serves as a member of any committee of the Board he is entitled to committee compensation under the Director Compensation Plan. Dr. Polverino serves on the GNC Committee. In November 2018 he received a grant of 1,667 shares of Common Stock for prior GNC Committee services.

Pursuant resolution of the Board, Mr. Araya received 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. Mr. Araya also received a grant of 1,249 shares of restricted stock for his service on the GNC Committee. All grants ceased vesting and Mr. Araya resigned as a member of the GNC effective August 28, 2018, in connection with Mr. Araya commencing employment with the Company as its Chief Commercial Officer. Mr. Araya ceased serving as a member of the Board on November 29, 2018.

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 serves 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 30, 2018, 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. Polverino received 2,000 shares of restricted stock for his service as 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 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

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

The following table sets forth certain information as of March 7, 2019 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 March 7, 2019 ("Presently Exercisable Options") or under warrants that are exercisable on or within 60 days after March 7, 2019 ("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., 1325 Avenue of Americas, 28<sup>th</sup> 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 21,084,702 shares of Common Stock outstanding as of March 7, 2019, 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		
	# of Shares	(% of Class)	
Directors and Named Executive Officers			
Chaim Lebovits <sup>(1)</sup>	4,562,835	(1)	19.4 %
Ralph Kern	112,655		*
Eyal Rubin	48,421	(2)	*
Uri Yablonka	99,763	(3)	*

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June Almenoff	7,175	(4)	*	
Irit Arbel	362,941	(5)	1.7	%
Chen Schor	125,558	(6)	*	
Anthony Polverino	10,791		*	
Malcolm Taub	41,332		*	
All current directors and executive officers as a group (10 persons)	5,377,079	(7)	22.6	%
5% Shareholders (other than listed above)				
N/A (see FN1)				

\*Less than 1%.

(1) Includes (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. Chaim Lebovits, our Chief Executive Officer, may be deemed the beneficial owner of these shares. The address of ACCBT Corp. and ACC International Holdings Ltd. is Morgan & Morgan Building, Pasea Estate, Road Town, Tortola, British Virgin Islands.

(2) Includes 23,421 shares of Common Stock issuable upon the exercise of Presently Exercisable Options.

(3) Includes 92,220 of shares of Common Stock issuable upon the exercise of Presently Exercisable Options.



(4) Consists of shares owned by Meadowlark Management LLC. Dr. Almenoff disclaims beneficial ownership of these shares except to the extent of any pecuniary interest therein.

(5) Includes 207,108 shares of Common Stock issuable upon the exercise of Presently Exercisable Options. Dr. Arbel's address is 6 Hadishon Street, Jerusalem, Israel.

(6) Includes 121,558 shares owned by The C. Schor Irrevocable Trust, an irrevocable trust for the benefit of Mr. Schor and other individuals. Mr. Schor disclaims beneficial ownership of these shares except to the extent of any pecuniary interest therein.

(7) 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, 2018:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans	
Equity compensation plans approved by security holders	1,496,287	\$ 3.0581	2,080,755	(1)
Equity compensation plans not approved by security holders	—	—	—	
Total	1,496,287	\$ 3.0581	2,080,755	(1)

A total of 3,577,042 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. No such joint inventions have resulted from this consulting agreement and it 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 and any of our committees and the Board of Directors of our subsidiaries.

· 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, Dr. Pulverino 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. Mr. Schor and Mr. Yablonka are not considered "independent directors." Mr. Araya was considered an independent director until he commenced service as Chief Commercial Officer of the Company in August, 2018, and he ceased serving as a director November 29, 2018

The Board 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, 2018 and 2017 and fees billed for other services rendered by Deloitte during those periods.

	December 31,	
	2018	2017
Audit Fees (1)	\$58,000	\$55,000
Audit-Related Fees	\$-	\$-
Tax Fees (2)	\$28,000	\$-
All Other Fees	\$-	\$-
Total Fees	\$86,000	\$55,000

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) Tax fees are comprised of fees for preparation of tax returns to the Company and the services performed by Deloitte in connection with Inter-Company matters.

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.**

#### **(1) Financial Statements.**

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

#### **(2) Financial Statement Schedules.**

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

(3)

## Exhibits.

Exhibit Number	Description	Filed (or Furnished) with this Form 10-K	Incorporated by Reference Herein		
			Form	Exhibit & File No.	Date Filed
2.1	<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>
3.1	<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>
3.2	<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>
3.3	<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>
3.4	<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>
3.5	<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>
4.1	<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>



<p><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></p>	<p><u>Form 8-K</u></p>	<p><u>Exhibit 10.1 File No. 333-61610</u></p>	<p><u>July 16, 2004</u></p>
<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 File No. 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 File No. 333-61610</u></p>	<p><u>May 23, 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 File No. 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 File No. 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 File No. 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 File No. 333-61610</u></p>	<p><u>August 20, 2007</u></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>	<u>Form 8-K</u>	<u>Exhibit 10.1 File No. 333-61610</u>	<u>December 31, 2009</u>
<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>	<u>Form 8-K</u>	<u>Exhibit 10.2 File No. 333-61610</u>	<u>December 31, 2009</u>
<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</u>	<u>Exhibit 10.12 File No. 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 File No. 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 File No. 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 File No. 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 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 No. 001-36641</u>	<u>May 11, 2016</u>

<u>10.16*</u>	<u>Amendment No. 2 to the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1 File No. 001-36641</u>	<u>November 30, 2018</u>
<u>10.17*</u>	<u>Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.</u>	<u>Form 8-K</u>	<u>Exhibit 10.2 File No. 000-54365</u>	<u>August 15, 2014</u>
<u>10.18*</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 No. 001-36641</u>	<u>May 11, 2016</u>
<u>10.19*</u>	<u>Amendment No. 2 to the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.</u>	<u>8-K</u>	<u>Exhibit 10.2 File No. 001-36641</u>	<u>November 30, 2018</u>
<u>10.20*</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 No. 001-36641</u>	<u>November 4, 2014</u>
<u>10.21*</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>10.22*</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>10.23*</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>10.24</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>10.25</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>10.26</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>10.27</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>10.28</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>10.29</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>10.30</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 File No. 000-54365</u>	<u>August 12, 2014</u>
<u>10.31</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 File No. 001-36641</u>	<u>November 3, 2017</u>

<u>10.32</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>10.33</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>10.34*</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>10.35*</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>10.36*</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>10.37</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>10.38</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>10.39</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>10.40</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>10.41</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>10.42</u> <u>Form of Warrant.</u>	<u>Form 8-K</u>	<u>Exhibit 4.1 File No. 001-36641</u>	<u>June 7, 2018</u>
<u>10.43</u> <u>Warrant Exercise Agreement.</u>	<u>Form 8-K</u>	<u>Exhibit 10.1 File No. 001-36641</u>	<u>June 7, 2018</u>
<u>10.44</u> <u>Leak-Out Agreement.</u>	<u>Form 8-K</u>	<u>Exhibit 10.2 File No. 001-36641</u>	<u>June 7, 2018</u>
<u>10.45</u> <u>Share Cap Agreement.</u>	<u>Form 10-Q</u>	<u>Exhibit 10.4 File No. 001-36641</u>	<u>July 23, 2018</u>

<p><u>10.46*</u> <u>Employment Agreement dated September 28, 2015 between Brainstorm Cell Therapeutics Inc. and Chaim Lebovits.</u></p>	<p><u>Form 8-K</u></p>	<p><u>Exhibit 10.1 File No. 001-36641</u></p>	<p><u>September 28, 2015</u></p>
<p><u>10.47*</u> <u>First Amendment to Employment Agreement dated March 7, 2016 between Brainstorm Cell Therapeutics Inc. and Chaim Lebovits.</u></p>	<p><u>Form 10-K</u></p>	<p><u>Exhibit 10.53 File No. 001-36641</u></p>	<p><u>March 9, 2016</u></p>
<p><u>10.48*</u> <u>Second Amendment to Employment Agreement dated July 26, 2017 between the Company and Chaim Lebovits.</u></p>	<p><u>Form 10-Q</u></p>	<p><u>Exhibit 10.3 File No. 001-36641</u></p>	<p><u>October 17, 2017</u></p>
<p><u>10.49*</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></p>	<p><u>Form 8-K</u></p>	<p><u>Exhibit 10.1 File No. 001-36641</u></p>	<p><u>March 6, 2017</u></p>
<p><u>10.50*</u> <u>Employment Agreement by and between Brainstorm Cell Therapeutics Ltd. and Eyal Rubin, dated October 31, 2017.</u></p>	<p><u>Form 8-K</u></p>	<p><u>Exhibit 10.2 File No. 001-36641</u></p>	<p><u>November 3, 2017</u></p>
<p><u>10.51*</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></p>	<p><u>Form 10-K</u></p>	<p><u>Exhibit 10.45 File No. 001-36641</u></p>	<p><u>March 8, 2018</u></p>
<p><u>10.52*</u> <u>Employment Agreement by and between Brainstorm Cell Therapeutics Inc. and Arturo Araya effective August 28, 2018.</u></p>	<p>‡</p>		
<p><u>10.53*</u> <u>Brainstorm Cell Therapeutics Inc. Second Amended and Restated Director Compensation Plan.</u></p>	<p><u>Form 8-K</u></p>	<p><u>Exhibit 10.1 File No. 001-36641</u></p>	<p><u>July 10, 2014</u></p>

<u>10.54*</u>	<u>Brainstorm Cell Therapeutics Inc. First Amendment to the Second Amended and Restated Director Compensation Plan.</u>	Form 10-Q	<u>Exhibit 10.2</u> <u>File No.</u> <u>001-36641</u>	<u>May 14,</u> <u>2015</u>
<u>10.55*</u>	<u>Brainstorm Cell Therapeutics Inc. Second Amendment to the Second Amended and Restated Director Compensation Plan dated February 26,</u>	Form 10-K	<u>Exhibit</u> <u>10.54 File</u> <u>No.</u> <u>001-36641</u>	<u>March</u> <u>29, 2017</u>
-	-			
<u>10.56*</u>	<u>Brainstorm Cell Therapeutics Inc. Third Amendment to the Second Amended and Restated Director Compensation</u>	Form 10-Q	<u>Exhibit 10.1</u> <u>File No.</u> <u>001-36641</u>	<u>October</u> <u>17, 2017</u>
-	-			
<u>10.57</u>	<u>Notice of Award - CLIN2: Partnering Opportunity for Clinical Trial Stage Projects California Institute for Regenerative Medicine, August 25, 2017.</u>	Form 10-K	<u>Exhibit</u> <u>10.50 File</u> <u>No.</u> <u>001-36641</u>	<u>March</u> <u>8, 2018</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>	‡‡		

101 The following financial information from the Annual Report on Form 10-K of Brainstorm Cell Therapeutics Inc. for the year ended December 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (1) Consolidated Balance Sheets as of December 31, 2017, and 2018; (2) Consolidated Statements of Operations for the years ended December 31, 2017 and 2018 and from September 22, 2000 (Inception) to December 31, 2018; (3) Statements of Changes in Stockholders' Equity (Deficit) from September 22, 2000 (Inception) through December 31, 2018; (4) Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2018 and from September 22, 2000 (Inception) to December 31, 2018; 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.

**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 29, 2019 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><b>Signature</b></i>	<i><b>Title</b></i>	<i><b>Date</b></i>
<i>/s/ Chaim Lebovits Chaim Lebovits</i>	<i>President and Chief Executive Officer (Principal Executive Officer)</i>	<i>March 29, 2019</i>
<i>/s/ Eyal Rubin Eyal Rubin</i>	<i>Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)</i>	<i>March 29, 2019</i>
<i>/s/ Irit Arbel Irit Arbel</i>	<i>Director</i>	<i>March 26, 2019</i>
<i>/s/ June S. Almenoff June S. Almenoff</i>	<i>Director</i>	<i>March 26, 2019</i>
<i>/s/ Chen Schor Chen Schor</i>	<i>Director</i>	<i>March 26, 2019</i>
<i>/s/ Anthony Polverino Anthony Polverino</i>	<i>Director</i>	<i>March 26, 2019</i>
<i>/s/ Malcolm Taub Malcolm Taub</i>	<i>Director</i>	<i>March 26, 2019</i>
<i>/s/ Uri Yablonka Uri Yablonka</i>	<i>Director</i>	<i>March 26, 2019</i>

