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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2020

☐ **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 incorporation or organization)	(I.R.S. Employer Identification No.)
1325 Avenue of Americas, 28th 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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00005 par value	**BCLI**	**The Nasdaq Stock Market LLC (Nasdaq Capital Market)**

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 ☐

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 ☒ Smaller reporting company ☒

Emerging growth company ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report,. Yes ☒ No ☐

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

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the issuer as of June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter), was $278,374,634.

As of February 4, 2021, the number of shares outstanding of the registrant's Common Stock, $0.00005 par value per share, was 35,721,429.

BRAINSTORM CELL THERAPEUTICS INC.
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2020
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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 financial results for the most recent fiscal year, statements regarding the market potential for treatment of neurodegenerative disorders such as ALS, the sufficiency of our existing capital resources for continuing operations in 2021 and beyond, the safety and clinical effectiveness of our NurOwn® technology, our clinical trials of NurOwn® and its related clinical development, and our ability to develop collaborations and partnerships to support our business plan. In some cases you can identify such "forward-looking statements" by the use of words like "may," "will," "should," "could," "expects," "hopes," "anticipates," "believes," "intends," "plans," "projects," "targets," "goals," "estimates," "predicts," "likely," "potential," or "continue" or the negative of any of these terms or similar words. These 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, PMS, AD 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, heath reform legislation, demand for our services, currency exchange rates and product liability claims and litigation, disruptions in our business due to the COVID 19 outbreak, including our clinical development activities, and other factors described under "Risk Factors" in this annual report on Form 10-K for the fiscal year ended December 31, 2020. 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 annual report on Form 10-K for the fiscal year ended December 31, 2020, 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"); Alzheimer's disease (AD); and other neurodegenerative diseases. NurOwn®, our proprietary platform, leverages 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.

NurOwn® has been evaluated in a Phase 3 ALS trial, is currently being evaluated in a Phase 2 PMS clinical trials, and is planned to be evaluated in a Phase 2 AD clinical trial. We announced top-line data from our Phase 3 ALS trial on November 17, 2020. The U.S. Phase

2 PMS trial faced slight delays in enrollment due to the COVID- 19 pandemic, but as of June 2020, all the trial sites were back on track to continue with the trial. On December 18, 2020, we announced the completion of all dosing in the study participants in the trial and expect topline clinical trial results by the end of the first quarter of 2021. On June 24, 2020, we announced a new clinical program focused on the development of NurOwn® as a treatment for AD. As part of the newly announced program, we are planning a multi-national Phase 2 clinical trial in Europe to evaluate the safety and preliminary efficacy of NurOwn® treatment in patients with prodromal to mild AD.

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. Our Israeli Subsidiary was granted approval by the Israeli Ministry of Health ("MoH") to treat ALS patients with NurOwn® under the Hospital Exemption Pathway ("HE").

NurOwn® has a strong and comprehensive intellectual property portfolio and 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.

We currently employ 40 employees in the United States and in Israel. Most of the senior management team is based in the United States, and all of our ongoing clinical trial sites for ALS and PMS are in the United States. The clinical trial sites for our planned AD trial will be in Europe. Our R&D center is located in Petach Tikva, Israel. In addition, we currently lease a GMP certified manufacturing facility in Jerusalem, Israel, and have recently leased a new cleanroom facility, which includes three state-of-the-art cleanrooms, at the Tel Aviv Sourasky Medical Center to manufacture NurOwn® mainly for expanding our production capacity into The European Union (EU) and the local Israeli market.

The pandemic caused by the novel strain of coronavirus, SARS-CoV 2 (COVID-19) disease has currently impacted and may continue to adversely impact our business, including our preclinical studies and clinical trials. In December 2019, a novel strain of coronavirus, surfaced in Wuhan, China. Since then, COVID- 19 has spread worldwide, significantly impacting the United States, Europe and Israel, where the Company conducts its operations, as well as its clinical trials for NurOwn®. In response to the spread of COVID-19 and to ensure safety of employees and continuity of business operations, we closed our offices, with our administrative employees continuing their work remotely and limited the number of staff in any given research and development laboratory. Our research and development laboratory in Israel and manufacturing sites in U.S. and in Israel remain open. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted at this time, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Our management team is actively monitoring this situation and the possible effects on our financial condition, liquidity, operations, suppliers, industry, and workforce. For additional information on risks posed by the COVID-19 pandemic, please see Part II, Item 1A – Risk Factors – Risks Related to the COVID-19 Pandemic.

2020 and Recent Highlights

* We completed dosing of all participants in our Phase 3 ALS trial in July 2020, and announced top-line data from this trial on November 17, 2020. Results from the trial showed that NurOwn® was generally well tolerated in the population of rapidly progressing ALS patients. While showing a numerical improvement in the treated group compared to placebo across the primary and key secondary efficacy endpoints, the trial did not reach statistically significant results. In an important, pre-specified subgroup with early disease based on ALS Functional Rating Score ("ALSFRS-R") baseline score 35, NurOwn® demonstrated a clinically meaningful treatment response across the primary and key secondary endpoints and remained consistent with our pre-trial, data-derived assumption. In this subgroup, there were 34.6% responders who met the primary endpoint definition on NurOwn and 15.6% on Placebo (p=0.288), and the average change from baseline to week 28 in ALSFRS-R total score was -1.77 on NurOwn and -3.78 on Placebo (p=0.198), an improvement of 2.01 ALSFRS-R points favoring NurOwn®. When following the SAP to implement sensitivity to the primary endpoint, there is a slight change in the percentage of responders but no P value change. No new safety concerns were identified. Following the completion of our phase 3 ALS trial, we are diligently pursuing next steps, including active discussions with the FDA to identify regulatory pathways that may support NurOwn®'s approval in ALS. We are also in active dialog with the FDA around our Chemistry, Manufacturing and Controls (CMC) plans for registration, and completed a successful meeting in December 2020.

* Our Phase 2 trial of NurOwn® in Progressive Multiple Sclerosis (PMS), entitled 'A Phase 2, open-label, multicenter study to evaluate the safety and efficacy of repeated administration of NurOwn® (Autologous Mesenchymal Stem Cells Secreting Neurotrophic Factors; MSC-NTF cells) in participants with Progressive Multiple Sclerosis (PMS),' is ongoing at 5 leading U.S. Multiple Sclerosis centers. The Phase 2 PMS trial faced slight delays in enrollment due to the COVID-19 pandemic. Scheduled March and April 2020 new patient enrollments were deferred to May 2020 due to site closures related to COVID-19. As of June 2020, all the trial sites were back on track to continue with the trial. On December 18, 2020, we announced the completion of all dosing in the study participants in the trial and expect topline clinical trial results by the end of the first quarter of 2021.

* On March 6, 2020, we entered into a distribution agreement with Raymond James & Associates, Inc. (the "Agent"), pursuant to which we were able to sell from time to time, through the Agent, shares of Common Stock, having an aggregate offering price of up to $50,000,000 (the "March 6, 2020 ATM"). Sales under the March 6, 2020 ATM were made by any method permitted by law that is deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and the Agent. We sold an aggregate of 2,446,64 shares of Common Stock pursuant to the March 6, 2020 ATM at an average price of $9.45 per share, raising gross proceeds of approximately $23.11 million. The March 6, 2020 ATM Distribution Agreement was amended and restated in its entirety on September 25, 2020 (the "September 25, 2020 ATM") (please see details below).

* On March 7, 2019, the Israeli MoH approved our treatment of up to 13 ALS patients with NurOwn® under the Israeli HE regulatory pathway. This approval expired on March 7, 2020. Ichilov Hospital and the Company have since then received approval from the MoH for the extension of the program. Based on the approval, the Company has enrolled 12 out of the first 13 patients under the HE regulatory pathway as of December 31, 2020 and intends to enroll the maximum number of patients that have been approved. The Company is currently collecting clinical data for patients who have already received treatment at the Ichilov Hospital. Thus far, the Company has received $3.4 million in gross proceeds in connection with the treatment of the aforementioned patients.

* On April 3, 2020, we announced that our Israeli Subsidiary has been awarded a non-dilutive grant of approximately $1.5 million by the Israel Innovation Authority (IIA). The grant enables the Company to continue development of advanced cellular manufacturing capabilities, furthers the development of MSC-derived exosomes as a novel therapeutic platform, and will ultimately enable BrainStorm to expand its therapeutic pipeline in neurodegenerative disorders. As of December 31, 2020, the Israeli Subsidiary has received $940,000 out of the $1.5 million awarded.

* On May 7, 2020, we announced that we will be leasing a new cleanroom facility, which includes three state-of-the-art cleanrooms, at the Tel Aviv Sourasky Medical Center to manufacture NurOwn® for the European Union (EU). The new facility will significantly increase our capacity to manufacture and ship its product into the EU and the local Israeli market. The cleanroom facility is part of Sourasky's Institute for Advanced Cellular Therapies.

* On June 9, 2020, we announced that The ALS Association and I AM ALS have awarded us a combined grant of $500,000 to support an ALS biomarker research study.

* On June 15, 2020, we announced that we have been granted Small and Medium-Sized Enterprise (SME) status by the European Medicines Agency's (EMA) Micro, Small and Medium-Sized Enterprise (SME) office.

* On June 24, 2020, we announced a new clinical program focused on the development of NurOwn® as a treatment for AD. As part of the newly announced program, we are planning a multi-national Phase 2 clinical trial in Europe to evaluate the safety and preliminary efficacy of NurOwn® treatment in patients with prodromal to mild AD. The 52-week, open-label, proof-of-concept clinical trial in Europe is designed to evaluate NurOwn® in 40 participants with prodromal to mild AD. It is currently expected to be conducted at the VU University Medical Center (Amsterdam), Pitié-Salpêtrière Hospital (Paris), and other clinical trial sites in the Netherlands and France.

* On June 29, 2020, our Company's shares joined the Russell 2000® Index and the broad-market Russell 3000® Index.

* On July 23, 2020, we announced a groundbreaking pre-clinical study of NurOwn® derived Exosome-based treatment for COVID-19 acute respiratory distress syndrome (“ARDS”). Intratracheal administration of exosomes extracted from MSC’s using NurOwn® technology resulted in statistically significant improvement in multiple lung parameters in a mouse model. With this study, the Company has successfully completed its first milestone in developing an innovative exosome-based platform-technology for the treatment of severe COVID-19 infection.

* On August 19, 2020, we announced the publication of a Letter to the Editor titled, "Effects of MSC-NTF cells on T and B regulatory cell function in ALS" in the journal Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration.

* On August 25, 2020, we announced the acceptance of a clinical abstract documenting an association between magnetic resonance imaging (MRI) measures and functional improvement in a prospective natural history cohort of patients with progressive multiple sclerosis (PMS) matched to the NurOwn® Phase 2 inclusion criteria. The data was presented as a poster on September 11-13 at the eighth joint virtual meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) and the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and will be important in the analysis of our Phase 2 outcomes.

* On September 16, 2020, we announced that the Japanese Patent Office (JPO) has granted Brainstorm's Japanese Patent, number: 6,753,887, titled: “Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors”.

* On September 25, 2020, we entered into an Amended and Restated Distribution Agreement (the “Distribution Agreement”) with SVB Leerink LLC (“Leerink”) and Raymond James & Associates, Inc. (“Raymond James” and, together with Leerink, the “Agents”) pursuant to which the Company may sell from time to time, through the Agents, shares of Common Stock, having an aggregate offering price of up to $45,000,000, which aggregate amount includes any amount unsold pursuant to the March 6, 2020 ATM (the “September 25, 2020 ATM”). Sales under the September 25, 2020 ATM are made by any method permitted by law that is deemed to be an “at the market” offering as defined in Rule 415 promulgated under the Securities Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and the Agents. The Distribution Agreement amends and restates in its entirety the Company’s prior agreement in connection with the March 6, 2020 ATM. During the quarter ended December 31, 2020, we sold an aggregate of 3,564,385 shares of Common Stock pursuant to the September 25, 2020 ATM at an average price of $6.10 per share, raising gross proceeds of approximately $21.8 million.

* On October 22, 2020, we announced a partnership with Catalent, the leading global provider of advanced delivery technologies, for the manufacture of our Mesenchymal Stem Cell Platform Therapy NurOwn®, which is being currently investigated for the treatment of ALS.

* On October 26, 2020, we announced the selection of Rapid Reshore & Development (RR&D) as our partner to expedite site selection and design services for a state-of-the-art manufacturing facility for NurOwn® (autologous MSC-NTF) in the U.S.

* On November 17, 2020 we announced topline results from our NurOwn® Phase 3 ALS Study.

* On December 14, 2020, we announced the NurOwn® Expanded Access Program through which NurOwn® will be made available for ALS patients who completed all Phase 3 clinical trial assessments and meet specific eligibility criteria.

* On December 18, 2020, we announced that all dosing has been completed in the ongoing Phase 2 trial evaluating NurOwn® (MSC-NTF cells) as a treatment for PMS and expect top-line clinical trial results by the end of the first quarter of 2021.

* On January 20, 2021 we announced the peer-reviewed publication of a preclinical study in the journal Stem Cell and Research Therapy. The study, entitled "MSC-NTF (NurOwn®) exosomes: a novel therapeutic modality in the mouse LPS-induced ARDS model," evaluated the use of NurOwn® (MSC-NTF cell) derived exosomes in a mouse model of acute respiratory distress syndrome (ARDS).

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 motor neurons and have demonstrated important neuroprotective effects in ALS, PMS, AD and other neurodegenerative diseases as well as modulating neuroinflammation, a prominent, consistent and early feature of these diseases.

NurOwn® manufacturing involves a multi-step process that includes the following: harvesting and isolating undifferentiated stem cells from the patient's own bone marrow; processing of cells at the manufacturing site; cryopreservation of MSC 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 generally well tolerated in multiple CNS clinical trials to date. The completed NurOwn® U.S. Phase 3 ALS study, the ongoing NurOwn® U.S. Phase 2 PMS study and the planned EU Phase 2 clinical trial in prodromal to mild AD, all evaluated or are evaluating the therapeutic potential of repeated intrathecal MSC-NTF cell administration (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 owned to or developed by our Israeli Subsidiary. All granted patents related to NurOwn® (MSC-NTF cells) manufacturing process are fully assigned to or owned by our Israeli Subsidiary (please see Intellectual Property section for details).

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

We believe that 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.

NurOwn® ALS Clinical Program

We announced top-line data from the Phase 3 clinical trial of NurOwn® in ALS on November 17, 2020. We have been granted Fast Track designation by the U.S. Food and Drug Administration ("FDA") for this indication, and been granted Orphan Drug Status, in the U.S. and Europe, which provides us the potential for an extended period of exclusivity.

Phase 1/2 ALS Open Label Trials

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, Israel, as well as a Phase 2 double-blind, placebo-controlled, multicenter clinical trial at three prestigious U.S. Medical centers - the Massachusetts General Hospital (MGH) in Boston, Massachusetts Memorial Hospital in Worcester, Massachusetts, and the Mayo Clinic in Rochester, Minnesota - all highly experienced in the management and investigation of ALS.

The first two open-label trials were approved by the Israeli 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 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) the 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.

Results of this Phase 2 Study were published in the peer reviewed Journal 'Neurology'. The publication entitled NurOwn, Phase 2, Randomized, Clinical Trial in Patients with ALS: Safety, Clinical, and Biomarker Results was published in December 2019.

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 meaningful ALS clinical observations were evaluated in our Phase 3 study using repeat dosing in ALS rapid progressors.***

Phase 3 ALS Clinical Trial

Following successful completion of the Phase 2 study, we conducted a Phase 3 trial (a multi-dose double-blind, placebo-controlled, multicenter trial protocol) that was designed to generate data to potentially support a Biologic License Application ("BLA") submission in the U.S. for NurOwn® in ALS. The clinical trial completed enrollment in October 2019 of 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 study is registered at www.clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT03280056).

We announced top-line data from our Phase 3 ALS trial on November 17, 2020. Results from the trial showed that NurOwn® was generally well tolerated in the population of rapidly progressing ALS patients. However, the trial did not reach statistically significant results. No new safety concerns were identified. Following the completion of our phase 3 ALS trial, we are diligently pursuing next steps, including active discussions with the FDA to identify regulatory pathways that may support NurOwn®'s approval in ALS. We are also in active dialog with the FDA around our Chemistry, Manufacturing and Controls (CMC) plans for registration, and completed a successful meeting in December 2020.

Key findings from the trial were as follows:

* NurOwn® was generally well tolerated in this population of rapidly progressing ALS patients.

* While showing a numerical improvement in the treated group compared to placebo across the primary and key secondary efficacy endpoints, the trial did not reach statistically significant results.

* The primary efficacy endpoint, a responder analysis evaluating the proportion of participants who experienced a 1.25 points per month improvement in the post-treatment Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) slope compared to pre-treatment, was powered on assumed treatment response rates of 35% on NurOwn® versus 15% on Placebo. These estimates were based on available historical clinical trial data and the NurOwn® Phase 2 data. The primary endpoint was achieved in 34.7% of NurOwn® participants versus 27.7% for Placebo (p=0.453). Therefore, the trial met the expected 35% NurOwn® treatment group efficacy response assumption, however the high placebo response exceeded the placebo response expected based on contemporary ALS trials. When following the SAP to implement sensitivity to the primary endpoint, there is a slight change in the percentage of responders but no P value change.

* The secondary efficacy endpoint measuring average change in ALSFRS-R total score from baseline to Week 28, was -5.52 with NurOwn® versus -5.88 on Placebo, a difference of 0.36 (p= 0.693).

* In an important, pre-specified subgroup early in the disease course based on ALSFRS-R baseline score greater than 35, NurOwn® demonstrated a clinically meaningful treatment response across the primary and key secondary endpoints and remained consistent with our pre-trial, data-derived assumptions. In this subgroup, there were 34.6% responders who met the primary endpoint definition on NurOwn® and 15.6% on Placebo (p=0.288), and the average change from baseline to week 28 in ALSFRS-R total score was -1.77 on NurOwn® and -3.78 on Placebo (p=0.198), an improvement of 2.01 ALSFRS-R points favoring NurOwn®.

* Cerebrospinal fluid (CSF) biomarker analyses confirmed that treatment with NurOwn® resulted in a statistically significant increase of neurotrophic factors and reduction in neurodegenerative and neuroinflammatory biomarkers that was not observed in the placebo treatment group.

* Pre-specified statistical modeling designed to predict clinical response with high sensitivity and specificity based on ALS biomarkers and ALS Function confirmed that NurOwn® treatment outcomes could be predicted by baseline ALS function as well as key CSF neurodegenerative and neuroinflammatory biomarkers.

We have 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.

We contracted with City of Hope's Center for Biomedicine and Genetics to manufacture clinical supplies of NurOwn® adult stem cells for our Phase 3 clinical study. City of Hope supported the manufacturing of NurOwn® and placebo for the participants treated in the Phase 3 study. The Connell and O'Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute (DFCI) in Boston was also contracted to manufacture NurOwn® and placebo for Phase 3 ALS clinical study participants and commenced manufacturing in October 2018. DFCI core manufacturing facility has also been supplying NurOwn® for our Phase 2 PMS study.

On October 22, 2020, we announced a partnership with Catalent, the leading global provider of advanced delivery technologies, to manufacture NurOwn®, which is being currently evaluated for the treatment of ALS. If approved, Catalent will be our partner for manufacturing commercial quantities of NurOwn® to treat patients with ALS. Our tech transfer to Catalent has already been initiated and will allow for continuous supply of NurOwn® for future clinical trials and initial commercialization. On October 26, 2020, we announced the selection of RR&D as our partner to expedite site selection and design services for a state-of-the-art manufacturing facility for NurOwn® (autologous MSC-NTF) in the U.S. Our partnership with RR&D to help us establish in-house manufacturing capabilities will accelerate once a regulatory pathway is clear. These partnerships will ensure an ongoing cGMP clinical supply of NurOwn® and enable us to provide rapid treatment access to patients if we obtain regulatory approval.

Meeting with FDA senior management

In July 2019, the BrainStorm management team was invited to participate in a special in-person, high-level meeting with the senior management of the FDA Drug and Biologics Centers and, 'I AM ALS', a grassroots ALS advocacy group advocating for an ALS cure.

FDA's Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER) and Dr. Janet Woodcock Director of the Center for Drug Evaluation and Research (CDER) were in attendance with senior FDA staff. BrainStorm's Phase 3 ALS principal Investigators Dr. Robert Brown (Massachusetts Memorial Hospital, Worcester, Massachusetts) and Dr. Merit Cudkowicz (Massachusetts General Hospital, Boston) joined by teleconference.

The meeting's purpose was to discuss BrainStorm's ongoing Phase 3 ALS clinical trial as well as efforts to speed treatment access to the ALS patient community. The meeting enabled an open and effective dialogue between the FDA and BrainStorm, setting the stage for future meetings to explore practical options to quickly bring our investigational treatment to those living with ALS.

On February 11, 2020, the Company announced that it held a high-level meeting with the FDA to discuss potential NurOwn® regulatory pathways for approval in ALS. In the planned meeting with senior CBER leadership and several leading U.S. ALS experts, the FDA confirmed that the Phase 3 ALS trial is collecting relevant data critical to the assessment of NurOwn® efficacy. The FDA indicated that they would look at the "totality of the evidence" in the expected Phase 3 clinical trial data. Furthermore, based on their detailed data assessment, they are committed to working collaboratively with BrainStorm to identify a regulatory pathway forward, including opportunities to expedite statistical review of data from the Phase 3 trial.

Following the completion of our phase 3 ALS trial, we are diligently pursuing next steps, including active discussions with the FDA to identify regulatory pathways that may support NurOwn®'s approval in ALS. We are also in active dialog with the FDA around our Chemistry, Manufacturing and Controls (CMC) plans for registration, and completed a successful meeting in December 2020.

ALS Expanded Access Program

On December 14, 2020, we announced the NurOwn® Expanded Access Program (EAP) through which NurOwn® will be made available for ALS patients who completed all Phase 3 scheduled treatments and follow-up assessments and meet specific eligibility criteria.

The protocol for the EAP was developed in partnership with the FDA to provide access to NurOwn® for Phase 3 clinical trial participants who meet specific eligibility criteria. Initially, patients less severely affected by ALS, as measured by ALSFRS-R, will be the first to receive treatment. This approach is informed by recently announced topline data from the Company's Phase 3 clinical trial. According to the FDA, EAPs, alternatively known as "compassionate use" programs, provide a pathway for patients to receive an investigational medicine for a serious disease or condition outside of a clinical trial.

Through the EAP, the six clinical centers participating in the Phase 3 NurOwn® trial will each have the opportunity to treat ALS patients who completed the trial. These six centers are: University of California, Irvine; Cedars-Sinai Medical Center; California Pacific Medical Center; Massachusetts General Hospital; University of Massachusetts Medical School; and Mayo Clinic. EAP treatment of ALS patients who have completed the Phase 3 clinical trial will not interfere with data or regulatory timelines. The Dana Farber Cancer Institute will initially manufacture the investigational therapy, assisted by on-site BrainStorm personnel.

Patient Access Programs (ALS)

The Company, working collaboratively with the Tel Aviv Sourasky Medical Center (Ichilov Hospital), was approved on March 7, 2019 to treat up to 13 ALS patients with NurOwn®, under the Israel Hospital Exemption regulatory pathway for Advanced Therapy Medicinal Products (ATMP), which was adopted by the Israeli MoH from the EMA regulation. This pathway enables the Company to make NurOwn® accessible to ALS patients in Israel, for a fee. This approval expired on March 7, 2020. Ichilov Hospital and the Company has since then received approval from the MoH for the extension of the program. Based on the approval, the Company has enrolled 12 out of the first 13 patients under the HE regulatory pathway as of December 31, 2020 and intends to enroll the maximum number of patients that have been approved. The Company is currently collecting clinical data for patients who have already received treatment at the Ichilov Hospital. Thus far, the Company has received $3.4 million in gross proceeds in connection with the treatment of the aforementioned patients.

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 PMS (www.clinicaltrials.gov Identifier NCT03799718). The study entitled 'A Phase 2, open-label, multicenter study to evaluate the safety and efficacy of repeated administration of NurOwn® (Autologous Mesenchymal Stem Cells Secreting Neurotrophic Factors; MSC-NTF cells) in participants with Progressive Multiple Sclerosis (MS)' will recruit 20 PMS patients at 5 leading US PMS centers.

On December 18, 2019 the clinical trial independent Data Safety Monitoring Board (DSMB) for the PMS study completed the first, pre-specified interim analysis, of safety outcomes for the first 9 participants enrolled in the study. After careful review of all available clinical trial data, the DSMB unanimously concluded "the study should continue as planned without any protocol modification".

The U.S. Phase 2 PMS trial faced slight delays in enrollment due to the COVID 19 pandemic, but as of June 2020, all the trial sites were back on track to continue with the trial. On December 18, 2020, we announced the completion of dosing of all study participants and expect topline clinical trial results by the end of the first quarter of 2021.

On November 14, 2019, we received a $495,330 grant from the National Multiple Sclerosis Society, through its Fast Forward program, to advance BrainStorm's Phase 2 open-label, multicenter clinical trial of repeated intrathecal administration of NurOwn® in participants with progressive Multiple Sclerosis. As of December 31, 2020, we received $321,965 on account of the grant from which $74,300 was received during the year.

NurOwn® in Alzheimer's Disease

We are designing a multi-national Phase 2 clinical trial to evaluate the safety, preliminary efficacy and pharmacodynamics of NurOwn® treatment in patients with prodromal to mild AD. The 52-week study is expected to enroll 40 participants with prodromal to mild AD that will receive three intrathecal NurOwn® doses 8 weeks apart. Inclusion criteria include well-defined clinical criteria for prodromal to mild AD as well as CSF biomarker defined criteria for AD.

The Phase 2 clinical trial will evaluate safety, preliminary efficacy and pharmacodynamics of NurOwn®, including effects on inflammatory, Alzheimer's-specific, neurodegenerative, and synaptic biomarkers, as well as a range of key clinical measures of cognition and function. It is currently expected to be conducted at the VU University Medical Center (Amsterdam), Pitié-Salpêtrière Hospital (Paris), and other clinical trial sites in the Netherlands and France.

The lead investigators for the trial are two world renowned clinical experts in AD: Prof. Philip Scheltens, M.D., Ph.D., and Prof. Bruno Dubois, M.D., Ph.D. Prof. Scheltens, the principal investigator (PI) of the study, is Professor of Cognitive Neurology and Director of the Alzheimer Centre at Amsterdam University Medical Center. He has extensive experience as a principal investigator in many international clinical trials in this field. Prof. Dubois, the French national coordinator of the study, is Professor of Neurology at the Neurological Institute of the Salpétrière University Hospital. He is the past President of the Scientific Committee of France-Alzheimer, President of IFRAD (International Fund Raising for Alzheimer's Disease) as well as a member of the European Alzheimer Disease Consortium (EADC).

While many Alzheimer's therapies have focused on a single target such as tau or beta-amyloid, NurOwn® has the capability to simultaneously target multiple relevant biological pathways and bring a comprehensive approach to this multifactorial disease. Importantly, NurOwn®'s mechanism of action may allow the therapy to enable synergistic combinations with anti-tau or anti-beta-amyloid treatments, further underscoring its potential to address critical unmet needs in AD. In such a complex disease, addressing inflammation and neuroprotection is an innovative approach and a first in the world for this technology.

On July 8, 2020, the Company hosted a KOL webinar to discuss its NurOwn® Phase 2 AD Program. The webinar featured presentations from Prof. Scheltens and Prof. Dubois, the lead investigators in the trial. For more information on the KOL webinar and presentation, visit BrainStorm's website at www.brainstorm-cell.com.

Non-Dilutive Funding

In July 2017, we were awarded a grant in the amount of $15,912,390 from the California Institute for Regenerative Medicine (CIRM) to aid in funding the Company's pivotal Phase 3 study of NurOwn®, for the treatment of ALS. We received $12,550,000 of the CIRM grant from 2017 2019: $9,050,000 from 2017 through 2018, and an additional $3,500,000 in 2019. On March 16, 2020, we received $2,200,000 from CIRM for achieving our pre-determined milestones. In July 2020, we received an additional $700,000 for making further progress in our Phase 3 study. On December 1, 2020, we received our final payment of $462,390 for achieving our last milestone. We have now received in full the total amount of the $15,912,390 grant funding awarded by CIRM. The grant does not bear a royalty payment commitment nor is the grant otherwise refundable.

On November 14, 2019, we were awarded a $495,330 grant from the National Multiple Sclerosis Society (NMSS), through its Fast Forward program, for serum and CSF biomarkers analysis in BrainStorm's Phase 2 open-label, multicenter clinical trial of repeated intrathecal administration of NurOwn® in participants with PMS. As of December 31, 2020, we have received $321,965 out of the $495,330 awarded.

On April 3, 2020, we announced that our wholly owned subsidiary, BrainStorm Cell Therapeutics Ltd., has been awarded a new non-dilutive grant of approximately $1.5 million by the Israel Innovation Authority ("IIA"). The grant enables the Company to continue development of advanced cellular manufacturing capabilities, furthers development of MSC-derived exosomes as a novel therapeutic platform, and will ultimately enable BrainStorm to expand the therapeutic pipeline in neurodegenerative disorders. As of December 31, 2020, we have received $940,000 out of the $1.5 million awarded.

On June 9, 2020, we announced that The ALS Association and I AM ALS have awarded us a combined grant of $500,000 to support an ALS biomarker research study. The grant will be used to draw insights from data and samples collected from patients enrolled in BrainStorm's ongoing Phase 3 clinical trial of its NurOwn® treatment, and to further the understanding of critical biomarkers associated with treatment response for people with ALS. As of December 31, 2020, we have received $200,000 out of $500,000 awarded.

Intellectual Property Updates in 2020

A key element of our 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 23 granted patents 2 allowed patents and 22 patent applications in the United States, Canada, 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 27, 2020, the Israeli patent Office allowed application number 246943 titled 'Method of Qualifying Cells'. The allowed claims cover a method of qualifying whether a cell population is a suitable therapeutic for treating Amyotrophic Lateral Sclerosis (ALS) and an isolated population of cells that secrete neurotrophic factors which are qualified useful as a therapeutic for treating ALS.

On January 29, 2020, the European Patent Office (EPO) communicated its intention to grant a European patent titled 'Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors'. The allowed claims cover the method for manufacturing MSC-NTF cells (NurOwn®).

On February 18, 2020, the US Patent and Trademark Office (USPTO) issued US Patent No. 10,564,149 titled 'Populations of Mesenchymal Stem Cells That Secrete Neurotrophic Factors'. The allowed claims cover a pharmaceutical composition for MSC-NTF cells secreting neurotrophic factors (NurOwn®) comprising a culture medium as a carrier and an isolated population of differentiated bone marrow-derived MSCs that secrete neurotrophic factors.

On September 1, 2020, the Israeli Patent Office issued Israeli Patent No. 246943 titled 'Method of Qualifying Cells'. The granted claims include a cell population that secretes neurotrophic factors which is qualified useful as a therapeutic for treating ALS, and a method for qualifying said population.

On September 16, 2020, the Company announced that the Japanese Patent Office (JPO) has granted Brainstorm's Japanese Patent, number: 6,753,887, titled: "Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors". The allowed claims cover a method of generating cells which secrete neurotrophic factors from human undifferentiated mesenchymal stem cells (MSCs) derived from the bone marrow of a single donor. The said neurotrophic factors includes: brain derived neurotrophic factor (BDNF); glial derived neurotrophic factor (GDNF); hepatocyte growth factor (HGF); and vascular endothelial growth factor (VEGF).

On December 15, 2020, the Canadian Patent office sealed Patent no. 2,937,305 titled 'Pharmaceutical composition comprising bone-marrow derived mesenchymal stem cells'. The granted claims include a pharmaceutical composition for NurOwn® (MSC-NTF cells, Mesenchymal Stem Cells secreting Neurotrophic Factors), comprising a culture medium as a carrier and an isolated population of differentiated bone marrow-derived MSCs that secrete neurotrophic factors

Patents protecting NurOwn® have been issued in the United States, Canada, Japan, Europe, Hong Kong, and Israel.

For a complete list of our patent portfolio, please refer to "Intellectual Property" section below.

Scientific presentations in 2020

On January 12, 2020, Mr. Chaim Lebovits presented at the 3rd Annual Neuroscience Innovation Forum at the Marines' Memorial Club in San Francisco, California.

On January 12, 2020, Dr. Ralph Kern MD, MHSc participated on a Rare & Orphan Diseases Panel at the 3rd Annual Neuroscience Innovation Forum at the Marines' Memorial Club in San Francisco, California.

On January 24, 2020, Dr. Ralph Kern MD, MHSc delivered a podium presentation entitled "CIRM funded Stem Cell Clinical Trials in California – Updates" at the 10th Annual California ALS Research Summit hosted at the Cedars-Sinai Medical Center, Los Angeles, California.

On February 11, 2020, Mr. Chaim Lebovits presented at the BIO CEO and Investor Conference at the Marriott Marquis in New York City, New York.

On February 17, 2020, Dr. Ralph Kern MD, MHSc presented at the Noble Capital Markets' Sixteenth Annual Investor Conference at the Hard Rock Hotel and Casino, Hollywood, Florida.

On June 8, 2020, Dr. Ralph Kern MD, MHSc provided a corporate overview at the BIO Digital 2020 Virtual Conference.

On June 18, 2020, Dr. Ralph Kern MD, MHSc presented a corporate overview at the Raymond James Virtual Human Health Innovations Conference.

On August 13, 2020, Dr. Ralph Kern MD, MHSc presented a corporate overview at the 40th Annual Canaccord Genuity Growth Conference.

On September 9, 2020, Dr. Ralph Kern MD, MHSc made a presentation on "Stem Cells for neurological applications, clinical and stem cells-based product development" at the Advanced Therapies & Expo 2020 Virtual Conference.

On September 11, the Company presented a poster at the eighth joint virtual meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) and the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

On September 14, 2020, Dr. Ralph Kern MD, MHSc participated in a panel discussion on neurodegenerative diseases at the 2020 CIRM Grantee Virtual Conference.

On September 24, 2020, Dr. Ralph Kern MD, MHSc presented at the "WuXi Apptec - Collaborations That Transform Meeting (Multiple Sclerosis)" Virtual Conference.

On September 30, 2020, Dr. Stacy Lindborg, PhD presented a poster titled, "Advancing NurOwn® for ALS: Phase 3 Clinical Trial Design" at the Annual Northeast ALS (NEALS) Virtual Meeting.

Between October 12-16, 2020, Dr. Stacy Lindborg, Ph.D., delivered an on-demand webinar at the 2020 Cell & Gene Meeting on the Mesa, held virtually.

On October 20, 2020, the Company presented a poster titled, "MSC-NTF (NurOwn®) Exosomes: A Novel Therapeutic Modality in the Mouse LPS-induced ARDS model Analysis" at the NYSCF Conference Meeting, being held virtually.

On November 9, 2020, the Company presented results from the Company's placebo controlled, randomized, double-blind Phase 3 trial evaluating NurOwn® (MSC-NTF cells) as a treatment for ALS at the 31st International Symposium on ALS/MND virtual symposium.

Research and Development

We are actively engaged in research and development to evaluate the potential for clinical development of NurOwn® in neurodegenerative disorders, neurodegenerative eye disease and acute respiratory distress syndrome (ARDS). Research is currently ongoing to develop additional specialized derivative cell products such as MSC-NTF derived Exosomes. Exosomes are extracellular nano-vesicles (secreted by the cells) that carry various molecular components of their cell of origin, including nucleic acids, proteins and lipids. Exosomes can transfer molecules from one cell to another, thereby mediating cell-to-cell communication, ultimately regulating many cell processes, which are suitable for clinical applications in multiple neurodegenerative diseases. NurOwn® derived exosomes may possess unique features for the enhanced delivery of therapeutics to the brain, due to their ability to cross the blood brain barrier and to penetrate the brain and spinal cord.

In addition, NurOwn® derived exosomes have the potential to treat acute respiratory distress syndrome (ARDS) due to their ability to penetrate deep tissues and decrease the inflammatory response. ARDS is a type of respiratory failure associated with widespread inflammation and lung damage mediated by dysregulated cytokine production and is one of the severe features of COVID-19.

MSC exosomes may be delivered intravenously or directly into the lungs via intratracheal administration have several practical advantages over cellular therapy including ease of storage, stability, formulation and low immunogenicity.

The exosomes research efforts are primarily focused on:

1. Manufacturing of MSC-NTF exosomes from bone marrow derived MSC and umbilical cord derived MSC:
    a. Developing and optimizing large scale cell culture processes using bioreactors, to generate exosomes.
    b. Developing advanced scalable purification GMP methods that can be applied to commercial use.
2. Quantification, characterization of phenotype and exosome cargo.
3. Assessment of MSC-NTF exosomes potency and stability.
4. Establishment of a method for exosomes modification.
5. Preclinical experiments in neurodegenerative models.

In a pre-clinical study, we evaluated MSCs and NurOwn® derived exosomes in an LPS ARDS-mouse model, relevant to severe acute lung injury. The results from the study showed that intratracheal administration of NurOwn® derived exosomes resulted in a statistically significant improvement in multiple lung parameters. These included the clinically relevant factors: functional lung recovery, reduction in pro-inflammatory cytokines and most importantly, attenuation of lung damage. Moreover, MSC-NTF cell derived exosomes exhibited a superior effect when compared to treatment with exosomes derived from naïve MSCs from the same donor. On January 20, 2021 we announced the peer-reviewed publication of this preclinical study in the journal Stem Cell and Research Therapy. The study, entitled "MSC-NTF (NurOwn®) exosomes: a novel therapeutic modality in the mouse LPS-induced ARDS model," evaluated the use of NurOwn® (MSC-NTF cell) derived exosomes in a mouse model of acute respiratory distress syndrome (ARDS).

For the completed and ongoing multidose clinical studies in ALS and PMS, 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 NurOwn® 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, 28th Floor, New York, NY 10019, and our telephone number is (201) 488-0460. We also maintain an office in Petach Tikva, Israel. We maintain a 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 reincorporated in the State of Delaware on November 15, 2006, and previously was incorporated in the State of Washington. In October 2004, the Company formed the Israeli Subsidiary. The Israeli Subsidiary formed wholly owned subsidiaries Brainstorm Cell Therapeutics UK Ltd., in the United Kingdom on February 19, 2013 (currently inactive), Advanced Cell Therapies Ltd. in Israel on June 21, 2018 and Brainstorm Cell Therapeutics Limited in Ireland on October 1, 2019. 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 diseases. Our highest priority is to obtain regulatory approval of NurOwn® for ALS and the rapid execution of our U.S. open-label, multicenter Phase 2 clinical trial in PMS and planned multi-national Phase 2 clinical trial in Europe for AD. We expect topline clinical trial results from our Phase 2 PMS trial by the end of the first quarter of 2021.

We are leveraging our strong existing pre-clinical data to advance innovative IND-enabling pre-clinical programs in several neurodegenerative disease with high unmet medical need. We have developed NurOwn® exosome-based platform-technology to expand our technology platform and pipeline. The most advanced preclinical data using this platform technology for ARDS, one of the most severe complications of COVID-19 pandemic, has recently been accepted for publication by Stem Cell Research & Therapy. The data showed that intratracheal administration of exosomes extracted from MSC's using NurOwn® (MSC-NTF) resulted in statistically significant improvement in multiple lung parameters in a mouse model. MSC-NTF exosomes were superior to control in reducing ARDS markers, including physiological damage as well as increasing oxygenation levels. With this study, the Company has successfully completed its first milestone in developing an innovative exosome-based platform-technology for the treatment of severe ARDS. On January 20, 2021 we announced the peer-reviewed publication of this preclinical study in the journal Stem Cell and Research Therapy. The study, entitled "MSC-NTF (NurOwn®) exosomes: a novel therapeutic modality in the mouse LPS-induced ARDS model," evaluated the use of NurOwn® (MSC-NTF cell) derived exosomes in a mouse model of acute respiratory distress syndrome (ARDS).

We are also engaged in strategic partnerships to expand our cGMP capabilities. Our tech transfer to Catalent has already been initiated and will allow for continuous supply of NurOwn® for future clinical trials and initial commercialization, if approved. Our partnership with RR&D, to help us establish in-house manufacturing capabilities, will accelerate once a regulatory pathway is clear. These partnerships will ensure an ongoing cGMP clinical supply of NurOwn® and enable us to provide rapid treatment access to patients if we obtain regulatory approval.

We may also choose to seek a strategic partnership with a pharmaceutical or biotechnology company for the global commercialization of NurOwn® for ALS, if approved, or to support the execution of additional BLA-enabling clinical programs in other neurodegenerative diseases.

NurOwn® in CNS Disease

Our highest priority is to obtain regulatory approval of NurOwn® for ALS. We also strategically focused on fully executing the clinical development of NurOwn® in PMS, AD as well as continuing our pre-clinical evaluation of the NurOwn® technology platform in other CNS disorders based on our broad preclinical experience in ALS, PMS, AD, Huntington's Disease 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. Worldwide it is estimated that there are 450,000 patients with ALS.

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- 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 1.25 million people with PMS worldwide, with roughly 0.5 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 PMS can be as much as $80,000 a year per patient.

The lack of safe and effective therapies in PMS, 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.

Alzheimer’s Disease (AD)

Alzheimer’s Disease (AD) is the most common form of dementia, a progressive brain disease that slowly destroys memories and thinking skills. The Alzheimer’s pathology starts 15-20 years before symptoms appear. Symptoms usually start with difficulty storing and retrieving new information. In advanced stages, symptoms include confusion, as well as mood and behavior changes, and inability to perform basic life tasks. Throughout the disease process there is a steady, unstoppable death of brain cells. This is a fatal disease with an average time of 8 years from diagnosis to death. No cure exists, but medications and management strategies may temporarily improve symptoms, in a modest fashion.

Over 5 million people in the U.S. currently have AD. The number of Americans with AD is projected to triple to 16 million by 2050. In the EU, it is estimated that greater than 7.5 million people who currently have AD and is projected to reach over 13 million by 2050. Worldwide about 50 million people have some form of dementia, and someone in the world develops dementia every three seconds. Every 65 seconds someone in U.S. develops AD. By 2050 this is projected to be every 33 seconds. In the age group above 55, AD is the most feared disease of all diseases including cancer. It is estimated that the potential healthcare cost savings from early diagnosis of AD to be approximately $7.9 trillion.

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 23 granted patents 2 allowed patents and 22 patent applications in the United States, Canada, 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 (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.

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.

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 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, 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'. The 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.).

In March 2019, the European Patent Office ("EPO") granted a European-wide patent titled 'Mesenchymal Stem Cells for the treatment of CNS Diseases.' The European Patent Application published in the European Patent Bulletin 19/13 on March 27, 2019, under Patent No. 2620493. 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 August 27, 2019, the Canadian Intellectual Property Office granted Canadian Patent No. 2,877,223 entitled ‘Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors’. The allowed claims cover the method for generating the Mesenchymal Stem Cells Secreting Neurotrophic Factors (MSC-NTF cells).

On September 16, 2019, the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance for BrainStorm's new US Patent Application, number: 15/113,105, titled: ‘Method of Qualifying Cells'. The allowed claims cover a pharmaceutical composition for MSC-NTF cells secreting neurotrophic factors (NurOwn®) comprising a culture medium as a carrier and an isolated population of differentiated bone marrow-derived MSCs that secrete neurotrophic factors. US Patent No. 10,564,149 for this application was granted on February 18, 2020 and titled ‘Populations of Mesenchymal Stem Cells that secrete Neurotrophic Factors’.

On October 21, 2019, the Japan Patent Office (JPO) issued a Decision to Grant Japanese Patent Application, number: 2016-548691, titled: ‘Method of Qualifying Cells.’ The patent covers cell populations which are therapeutic for the treatment of ALS and the method of qualifying the cells for therapeutic use.

On December 6, 2019, the Hong Kong patent office granted patent No. HK1182133 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 January 9, 2020, the European Patent Office (EPO) communicated its intention to grant a European patent titled 'Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors' (Application No. 13767124.4). The allowed claims cover the method for manufacturing MSC-NTF cells (NurOwn®).

On January 27, 2020, the Israeli Patent Office issued a Notice of Acceptance for Israeli patent application No. 246943 titled ‘Method of Qualifying Cells'. The allowed claims cover the cells that secrete neurotrophic factors which are qualified to be useful as a therapeutic for treating ALS and a method for qualifying said cell population.

On January 29, 2020, the European Patent Office (EPO) has communicated its intention to grant a European patent titled 'Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors'. The allowed claims cover the method for manufacturing MSC-NTF cells (NurOwn®).

On February 18, 2020, the US Patent and Trademark Office (USPTO) issued US Patent No. 10,564,149 titled 'Populations of Mesenchymal Stem Cells That Secrete Neurotrophic Factors'. The allowed claims cover a pharmaceutical composition for MSC-NTF cells secreting neurotrophic factors (NurOwn®) comprising a culture medium as a carrier and an isolated population of differentiated bone marrow-derived MSCs that secrete neurotrophic factors.

On September 16, 2020, the Company announced that the Japanese Patent Office (JPO) has granted Brainstorm's Japanese Patent, number: 6,753,887, titled: "Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors". The allowed claims cover a method of generating cells which secrete neurotrophic factors from human undifferentiated mesenchymal stem cells (MSCs) derived from the bone marrow of a single donor. The said neurotrophic factors includes brain derived neurotrophic factor (BDNF); glial derived neurotrophic factor (GDNF); hepatocyte growth factor (HGF); and vascular endothelial growth factor (VEGF).

On September 1, 2020, the Israeli Patent Office issued Israeli Patent No. 246943 titled 'Method of Qualifying Cells'. The granted claims include a cell population that secretes neurotrophic factors which is qualified useful as a therapeutic for treating ALS, and a method for qualifying said population.

On December 15, 2020, the Canadian Patent office sealed Patent no. 2,937,305 titled 'Pharmaceutical composition comprising bone-marrow derived mesenchymal stem cells'. The granted claims include a pharmaceutical composition for NurOwn® (MSC-NTF cells, Mesenchymal Stem Cells secreting Neurotrophic Factors), comprising a culture medium as a carrier and an isolated population of differentiated bone marrow-derived MSCs that secrete neurotrophic factors.

Patents protecting NurOwn® have been issued in the United States, Canada, Japan, Europe, Hong-Kong and in Israel.

Additional PCT patent applications have been filed and National phase applications are currently under examination in several jurisdictions worldwide. Specifically, International Patent Application WO 2018/015945 was filed on July 17, 2017 and WO/2019/198077 was filed on April 10, 2019.

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.

Family No.	Patent Name/ Int. App. No.	Pending Jurisdictions	Allowed Jurisdictions	Granted Jurisdictions	Expiry Date
1	**Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases/PCT/IL2006/000699**		**US**	**Europe, US**	**2030**
2	**Mesenchymal Stem Cells for The Treatment of CNS Diseases PCT/ IL2009/000525**	**US**		**US, Israel, Europe, Hong Kong**	**2032**
3	**Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors / PCT/IL2013/050660**	**Brazil,**	**Hong Kong**	**US, Canada, Japan, Israel, Europe**	**2038**
4	**Method of Qualifying Cells /PCT IL2015/050159**	**Europe, Hong Kong, , Brazil**		**US, Japan, Israel**	
	Populations of Mesenchymal Stem Cells that secrete Neurotrophic Factors US 10,564,149			**US**	**2040**
	Pharmaceutical composition comprising bone-marrow derived mesenchymal stem cells Canadian Patent no. 2,937,305			**Canada**	
5	**Methods of treating ALS PCT/IL2017/050801**	**US, Europe, Israel, Japan, S. Korea, Australia, Canada**			**2042**

6	**Cell-Type Specific Exosomes and Use Thereof PCT/IL2019/050401**	**US, Europe, Israel, Japan, S. Korea, Australia, Canada**			**2043**

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 of families #1 and #2 (see table above) as well as relevant know-how and research results are either licensed or joint with Ramot. We intend to work with Ramot to protect and enhance our mutual intellectual property rights by filing continuations and divisional patent applications. The current NurOwn® proprietary technology is fully owned by Brainstorm Cell Therapeutics Ltd., our wholly-owned subsidiary (the "Israeli Subsidiary"). All granted patents related to NurOwn® (MSC-NTF cells) manufacturing process and clinical development (families #3 through #6) are fully assigned to and owned by Brainstorm Cell Therapeutics Ltd. 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

We have 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

We intend to pursue regulatory approval for 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

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Coverage and reimbursement status of any approved therapy carries significant uncertainty and risk related to the insurance coverage and reimbursement of newly approved products, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. Failure to obtain or maintain adequate coverage and reimbursement for any of our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. 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 third-party payor has its own process and standards for determining whether it will cover and reimburse a procedure or product. Factors payors consider in determining reimbursement are based on whether the product is:

* a covered benefit under its health plan;
* safe, effective and medically necessary;
* appropriate for the specific patient;
* cost-effective; and
* neither experimental nor investigational.

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 December 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. The US Food and Drug Administration (FDA) issued a comprehensive regenerative medicine policy framework. The final 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. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any therapy that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for therapies may be reduced by mandatory discounts or rebates required by government healthcare programs. 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. Further, due to the COVID-19 pandemic, millions of individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our stem cell therapies.

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 CMS, other divisions of the United States Department of Health and Human Services ("HHS") (e.g., the Office of Inspector General ("OIG")), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and similar state laws, each as amended, as applicable, including:

* the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government

may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute;

* the federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;

* the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

* HIPAA, which includes federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

* HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

* the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

* federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

* federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

In addition to the above, on November 20, 2020, the OIG finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others, yet removed safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain

fixed fee arrangements between pharmacy benefit managers and manufacturers. The final rule (with some exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information (e.g., the California Consumer Privacy Act), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We may also be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area, or EEA, including personal health data, is subject to the General Data Protection Regulation 2016/679 (GDPR), which became effective on May 25, 2018 and the United Kingdom General Data Protection Regulation, as tailored by the Data Protection Act 2018 ("UK GDPR"). The GDPR and UK GDPR are wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR/UK GDPR also impose strict rules on the transfer of personal data to countries outside the European Economic Area and the United Kingdom, respectively, including to the United States, and permit data protection authorities to impose large penalties for violations of the GDPR/UK GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR/UK GDPR also confer a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR/UK GDPR. In addition, the GDPR/UK GDPR include restrictions on cross-border data transfers. Compliance with the GDPR/UK GDOR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European and United Kingdom activities.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, imprisonment and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

The risk of our being found in violation of these laws is increased by the fact that many of these laws have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial cost.

Healthcare reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual, nondeductible fees based on pharmaceutical companies' share of sales to federal healthcare programs; imposed a new federal excise tax on the sale of certain medical devices; expanded healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance; expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; expanded the entities eligible for discounts under the Public Health Service Act's pharmaceutical pricing program, also known as the 340B Drug Pricing Program; created new requirements to report financial arrangements with physicians and teaching hospitals, commonly referred to as the Physician Payments Sunshine Act; created a new requirement to annually report the identity and quantity of drug samples that manufacturers and authorized distributors of record provide to physicians; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court; the Trump Administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The United States Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in early 2021. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, former President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to legislation amendments to the statute, including the BBA, will stay in effect through 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, and subsequent legislation, these Medicare sequester reductions are suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things,

further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the former Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration also previously released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has implemented certain of these initiatives. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. In addition, there have been several changes to the 340B. Legal challenges to certain 340B reimbursement calculations are ongoing, and it is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any. While a number of these and other proposed measures will require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

Further, on July 24, 2020 and September 13, 2020, former President Trump signed several Executive Orders aimed at lowering drug pricing that seek to implement several of the administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and legal challenge by certain industry advocacy groups and participants. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

Manufacturing

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 have already initiated activities to support commercial launch if our product is approved by regulatory authorities. These activities include scaling out production capacity, logistics and supply. In support of commercialization and to expand our cGMP capabilities we are engaged in several strategic partnerships. Our tech transfer to Catalent has already been initiated and will allow for continuous supply of NurOwn® for future clinical trials and initial commercialization. Our partnership with RR&D, to help us establish in-house manufacturing capabilities, will accelerate once a regulatory pathway is clear. These partnerships will ensure an ongoing cGMP clinical supply of NurOwn® and enable us to provide rapid treatment access to patients if we obtain regulatory approval.

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 Seneca Biopharma (Nasdaq: SNCA, formally Neuralstem) completed a Phase 2 intraspinal transplantation trial for its allogeneic, human (fetal) spinal cord derived neural stem cells, it is not clear if the sponsor will proceed with a further clinical trial. Q Therapeutics has gained FDA clearance for a Phase 1/2 cervical surgical transplantation study with its Q-Cells®, purified human glial progenitor cells isolated from brain tissue. The study is not recruiting patients yet. Corestem, a Korean company has commercialized its NEURONATA-R® inj., an autologous bone marrow mesenchymal stem cell (BM-MSC) therapy for ALS in South Korea and is searching for a subcontractor for a Phase 3 study in the US. Alexion has submitted an investigational new drug application (IND) for ULTOMIRIS (ravulizumab) in ALS to the FDA in the fourth quarter of 2019 and initiated a Phase 3 study in 2020.

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 and is now conducting another add-on trial of masitionib with Riluzole in ALS. Neuraltus Pharma was 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 failed to demonstrate efficacy in a phase 2 clinical trial. 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 published data from its CENTAUR trial demonstrating a clinically meaningful benefit and a favorable safety profile for people living with ALS and possibly a survival advantage over 2 years compared to placebo. 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).

Currently, there are only two FDA-approved ALS therapies, Riluzole and Radicava, that have demonstrated modest 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 approved by FDA in May 2017 based on a single Phase 3 study carried out in Japan.

Employees

We currently have 40 employees, all of whom are full-time. None of our employees is represented by a labor union.

Human Capital

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain

and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Additional Information

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

Item 1A. RISK FACTORS

Summary of our Risks:

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled "Risk Factors" in this Form 10-K. These risks include, among others:

* We will need substantial additional funding to pursue our business objectives and continue our operations. If we are unable to raise capital when needed, we may be required to delay, limit, reduce or terminate our research or product development efforts or future commercialization efforts.

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

* The continuing effects of the novel coronavirus disease, COVID-19, could adversely impact our business, including our clinical trials and supply chain.

* Our product development programs are based on novel technologies and are inherently risky. The field of stem cell therapy is relatively new and our development efforts may not yield an effective treatment of human diseases.

* Our NurOwn® stem cell therapy may not demonstrate safety and efficacy sufficient to obtain regulatory approval, and may not receive regulatory approval. 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.

* 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.

* 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.

* 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.

* 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.

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

* We face substantial competition in developing cell therapies for ALS and other neurodegenerative diseases, which may result in others discovering, developing or commercializing products before or more successfully than we do.

* It is uncertain to what extent the government, private health insurers and third-party payors 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.

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

Risks Related to the COVID-19 Pandemic

The current pandemic of COVID-19 and the future outbreak of other highly infectious or contagious diseases, could have a material adverse impact on our business, financial condition and results of operations, including our preclinical studies and clinical trials.

The pandemic caused by the novel strain of coronavirus, SARS-CoV 2 (COVID-19) disease has currently impacted and may continue to adversely impact our business, including our preclinical studies and clinical trials. In December 2019, a novel strain of coronavirus, surfaced in Wuhan, China. Since then, COVID-19 has spread worldwide, significantly impacting the United States, Europe and Israel, where the Company conducts its operations, as well as its clinical trials for NurOwn®. In response to the spread of COVID-19 and to ensure safety of employees and continuity of business operations, we closed our offices, with our administrative employees continuing their work remotely and limited the number of staff in any given research and development laboratory. Our research and development laboratory in Israel and manufacturing sites in U.S. and in Israel remain open. The full extent to which the COVID 19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted at this time, including new information that may emerge concerning COVID 19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Our management team is actively monitoring this situation and the possible effects on our financial condition, liquidity, operations, suppliers, industry, and workforce.

We completed dosing of all participants in our Phase 3 ALS trial in July 2020, and we announced top-line data from this trial on November 17, 2020. Results from the trial showed that NurOwn® was generally well tolerated in the population of rapidly progressing ALS patients. While showing a numerical improvement in the treated group compared to placebo across the primary and key secondary efficacy endpoints, the trial did not reach statistically significant results. In an important, pre-specified subgroup with early disease based on ALS Functional Rating Score (“ALSFRS-R”) baseline score 35, NurOwn® demonstrated a clinically meaningful treatment response across the primary and key secondary endpoints and remained consistent with our pre-trial, data-derived assumption. In this subgroup, there were 34.6% responders who met the primary endpoint definition on NurOwn and 15.6% on Placebo (p=0.288), and the average change from baseline to week 28 in ALSFRS-R total score was -1.77 on NurOwn and -3.78 on Placebo (p=0.198), an improvement of 2.01 ALSFRS-R points favoring NurOwn.. When following the SAP to implement sensitivity to the primary endpoint, there is a slight change in the percentage of responders but no P value change. No new safety concerns were identified. Following the completion of our phase 3 ALS trial, we are diligently pursuing next steps, including active discussions with the FDA to identify regulatory pathways that may support NurOwn®’s approval in ALS. We are also in active dialog with the FDA around our Chemistry, Manufacturing and Controls (CMC) plans for registration, and completed a successful meeting in December 2020.

The U.S. Phase 2 PMS trial faced slight delays in enrollment due to the COVID-19 pandemic, but as of June 2020, all the trial sites were back on track to continue with the trial. On December 18, 2020, we announced the completion of all dosing in the study participants in the trial and expects topline clinical trial results by the end of the first quarter of 2021.

We recently announced a new clinical program focused on the development of NurOwn® as a treatment for AD. As part of the newly announced program, we are planning a multi-national Phase 2 clinical trial in Europe to evaluate the safety and preliminary efficacy of NurOwn® treatment in patients with prodromal to mild AD.

Two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered

under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

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.

Although we have sufficient cash to continue with our operations for at least the next twelve months, we may 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 and commercial programs.

The amount of financing required will depend on many factors including our financial requirements to fund any additional research and clinical trials, our ability to secure partnerships and achieve partnership milestones and our ability to establish manufacturing and delivery processes for our NurOwn® stem cell therapy 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, including under the ATM Program. 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 Company has a history of losses and we expect to incur losses for the foreseeable future.

As a development stage pre-revenue 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, December 31, 2019 or December 31, 2020. We are currently in the process of introducing the Company to strategic partners. In the upcoming three years, the Company will focus on completing its ongoing clinical trials and commercialization of NurOwn® for ALS, if approved. We are unable, at this time, to foresee when we will generate operational revenues from strategic partnerships. If NurOwn® is approved by the FDA for ALS, we hope to commercialize and start generating revenues shortly thereafter., We expect to incur substantial and increasing operating losses for the next several years as we increase our spending to execute our development programs and commercialization efforts. These losses are expected to have an adverse impact on our working capital, total assets and stockholders' equity.

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. As part of the regulatory process, we are conducting 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. We have recently completed our Phase 3 ALS trial and are in active discussions with FDA for potential pathways for approval of NurOwn® for ALS. 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 of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

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.

Additionally, several of our past, planned and ongoing clinical trials utilize an “open-label” trial design. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

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.

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.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by NurOwn® could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. 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. Any of these occurrences may harm our business, financial condition and prospects significantly.

Despite our experience conducting and managing clinicals, we may not be able to be conduct and manage future trials successfully and have limited experience in the application process necessary to obtain regulatory approvals.

Despite our prior experience in conducting and managing clinicals, we may not be able to be conduct and manage future trials successfully. We have limited experience in the application process to obtain regulatory approvals. 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 NurOwn® for ALS involves a new approach using stem cells to treat ALS. Cell therapy is still a developing area of research, with few cell therapy products approved for clinical use. Many of the existing cellular therapy candidates are based on novel cell technologies that are inherently risky and may not be understood or accepted by the marketplace. The novel nature of our cell therapy technology creates significant challenges with respect to product development and optimization, manufacturing, government regulation and approval, third-party reimbursement.

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 payors. 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, PMS, AD 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, PMS, AD 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, PMS, AD 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 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 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 to expand or complement our research and development or commercialization capabilities, and to reduce the cost of such activities. 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. 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 may 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 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 our limited experience 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.

Although, several members of our management team have experience in commercial scale cell therapy manufacturing, we have no experience in commercial-scale stem cell therapy manufacturing. 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.

To this end, we are working with Catalent, a third party manufacturer for producing commercial quantities of NurOwn® to treat patients with We are also working with RR&D, to help us establish in-house manufacturing capabilities. Our current dependence on others for the manufacture of our drug candidates may adversely affect our ability to develop and deliver such drug candidates on a timely and competitive basis. Any performance failure on the part of a third-party manufacturer could delay clinical development, regulatory approval or, ultimately, sales of our NurOwn®. Our third-party manufacturers may encounter difficulties involving production yields, regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. Approval of our NurOwn® could be delayed, limited or denied if the FDA does not approve our or a third-party manufacturer's processes or facilities.

If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

In addition, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities while local, national and international conditions warrant. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials which the FDA continues to update. As of June 23, 2020, the FDA noted it was conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. On July 10, 2020, the FDA announced its goal of restarting domestic on-site inspections during the week of July 20, 2020, but such activities will depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. In 2020, several

companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If we are not successful in establishing regulatory compliant, scaled manufacturing capabilities, our commercialization could be delayed, which would further delay the period when we would be able to generate revenues from the sale of such of our products.

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. 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. 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. To date, approved conventional therapies have not shown significant clinical benefit as disease modifying therapies in the indications that we are currently working on.

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, PMS and AD. 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 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. 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 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.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws health information privacy and security laws, and other health care laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Act and Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to:

* the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties;

* the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can

be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

* the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

* the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

* HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

* The U.S. federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

* federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;

* federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

* Many states in the United States have enacted laws that regulate the privacy and/or security of certain types of personal information. For example, in California the California Consumer Protection Act (CCPA), which went into effect on January 1, 2020, establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. After a delay, the CCPA became subject to enforcement as of July 1, 2020. Although clinical trial data and protected health information

subject to HIPAA are currently exempt from CCPA, we may be subject to the CCPA with respect to other personal information regarding California residents.

In addition to the above, on November 20, 2020, the Office of Inspector General, or OIG finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others, yet removed safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. This rule (with exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the GDPR in the EEA, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers, some of whom receive share options as compensation for services provided, are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results.

It is uncertain to what extent the government, private health insurers and third-party payors 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.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. 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 payors, such as government and private insurance plans. Although we have commenced initial discussions with such parties, pricing for our product, if approved, is yet to determined. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be covered and paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other payors. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement is not available, or is available

only at limited levels, we may not be able to successfully commercialize our product candidates, if approved. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a payor not to cover our gene therapies could reduce physician utilization of our products once approved, and have a material adverse effect on our sales, results of operations and financial condition.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about coverage and reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow the CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Factors payors consider in determining reimbursement are based on whether the product is:

* a covered benefit under its health plan;
* safe, effective and medically necessary;
* appropriate for the specific patient;
* cost-effective; and
* neither experimental nor investigational.

These third-party payors 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 payors 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. Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court; the former Trump Administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The United States Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in early 2021. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.5 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and will remain in effect through 2030 unless additional Congressional action is taken; however, pursuant to the CARES Act, and subsequent legislation, these reductions are suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the former Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the U.S. government sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of

certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS implemented certain of these measures while others are under review. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities, though certain changes to the 340B pricing calculations are currently under legal challenge. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

Further, on July 24, 2020 and September 13, 2020, former President Trump signed several Executive Orders aimed at lowering drug pricing that seek to implement several of the administration's proposals. The FDA also released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Additionally, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge, including legal challenges from industry advocacy groups and participants. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, or restrictions on certain product access, and marketing cost disclosure and transparency measures, which, in some cases, are designed to encourage importation from other countries and bulk purchasing.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

* the demand for our product candidates, if we obtain regulatory approval;
* our ability to set a price that we believe is fair for our products;
* our ability to generate revenue and achieve or maintain profitability;
* the level of taxes that we are required to pay; and
* the availability of capital.

Any denial in coverage or reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

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.

Changes in Tax Law may Adversely Affect our Business and Financial Condition

The laws and rules dealing with U.S. federal, state and local income taxation are routinely being reviewed and modified by governmental bodies, officials and regulatory agencies, including the Internal Revenue Service and the U.S. Treasury Department. Since inception, many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, that could result in an increase in our or our stockholders' tax liability.

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.

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 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;
- 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

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, PMS and AD. 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. All granted patents related to NurOwn® (MSC-NTF cells) manufacturing process are fully assigned to or owned by BrainStorm Cell Therapeutics Ltd.

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 and trading volume of our stock is expected to be volatile.

The market price and trading volume of our Common Stock has fluctuated significantly over time, and is likely to continue to be highly volatile. To date, the trading volume and price of our stock has seen significant fluctuations. We expect such fluctuations could occur in the future. Investors should be aware of the risks of trading in our Common Stock due to such volatility.

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

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

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

Pursuant to the Subscription Agreement with ACCBT Corp. ("ACCBT"), a company under the control of Mr. Chaim Lebovits, our President and Chief Executive Officer, we granted ACCBT the right to acquire additional shares of our Common Stock whenever we issue additional shares of Common Stock or other securities of the Company, or options or rights to purchase shares of the Company or other securities directly or indirectly convertible into or exercisable for shares of the Company (including shares of any newly created class or series). This participation right could limit our ability to enter into equity financings and to raise funds from third parties. ACCBT is entitled to purchase its pro rata share of any additional securities we offer, so that its percentage ownership of the Company remains the same after any such issuance of additional securities. Such additional securities will be offered to ACCBT at the same price and on the same terms as the other investors in the transaction. ACCBT will have 30 days from the date of our notice to ACCBT of any intended transaction, to decide whether it wishes to exercise its participation rights in the transaction. We also are prohibited from taking certain corporate actions without the consent of ACCBT, including entering into transactions greater than $500,000. Further, ACCBT also has the right to appoint 30% of our Board. 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 Executive 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, 28th Floor, New York, NY 10019. Our Israeli Subsidiary is party to a 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.

In addition, we lease a GMP certified manufacturing facility with two cleanrooms in Jerusalem, Israel, and have recently leased a new GMP certified facility, which includes three state-of-the-art cleanrooms, at the Tel Aviv Sourasky Medical Center.

We believe that the current office, laboratory space, and cleanrooms are adequate to meet our needs for research and development, clinicals trials and administrative operations.

Item 3. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation relating to claims arising out of operations in the normal course of business, which we consider routine and incidental to our business. We currently are not a party to any legal proceedings the adverse outcome of which, in management's opinion, would have a material adverse effect on our business, results of operation or financial condition.

Item 4. MINE SAFETY DISCLOSURES.

Not required.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our Common Stock is currently traded on the Nasdaq Capital Market under the symbol "BCLI".

Record Holders

As of January 31, 2020, there were approximately 31 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

Exercises of 2018 Amended Warrants:

On June 6, 2018, the Company entered into Warrant Exercise Agreements with certain holders ("2018 Warrant Holders"), pursuant to which holders were issued warrants to purchase an aggregate 2,458,201 unregistered shares of Common Stock, at an exercise price of $9 per share, with an expiration date of December 31, 2020 (the "2018 Warrants"). In connection with the issuance of the 2019 Warrants (described below), certain 2018 Warrants were amended on August 2, 2019 to reduce the exercise price to $7.00 per share and to extend the expiration date to December 31, 2021 (the "Amended 2018 Warrants").

Between July 20, 2020 and July 24, 2020, 2018 Warrant Holders exercised an aggregate of 280,000 shares of the Amended 2018 Warrants (the "2018 Exercised Shares"), which exercises generated gross cash proceeds to the Company of $1.96 million.

The 2018 Warrants have not been registered under the Securities Act of 1933, as amended (the Securities Act), or state securities laws. The 2018 Exercised Shares have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-225995). The issuance of the 2018 Exercised Shares and 2018 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. The Company expects to use cash received from exercises for general corporate and working capital purposes.

Exercises of 2019 Warrants:

On August 2, 2019, the Company entered into Warrant Exercise Agreements with certain 2018 Warrant Holders ("2019 Warrant Holders"), pursuant to which holders were issued warrants to purchase an aggregate 842,000 shares of Common Stock (the "2019 Warrants"), at an exercise price of $7.00, with an expiration date of December 31, 2021 (the "2019 Warrants").

Between July 15, 2020 and July 24, 2020, 2019 Warrant Holders exercised an aggregate of 620,000 shares of the 2019 Warrants (the "2019 Exercised Shares"), which exercises generated gross cash proceeds to the Company of $4.34 million.

The 2019 Warrants have not been registered under the Securities Act, or state securities laws. The 2019 Exercised Shares have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-233349). The issuance of the 2019 Exercised Shares and 2019 Warrants is exempt from the registration requirements of the Securities Act pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act. The Company made this determination based on the representations that each party is an "accredited investor" within the meaning of Rule 501 of Regulation D. The Company expects to use cash received from exercises for general corporate and working capital purposes.

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

We are 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. We hold 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 FDA in ALS and has additionally been granted Orphan Drug Status by the FDA and the EMA. For more information, visit our website at www.brainstorm-cell.com.

We are 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, we are 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 ALS, PMS, AD and other neurodegenerative diseases. NurOwn® uses proprietary cell culture conditions to induce MSCs to secrete high levels of multiple neurotrophic factors to modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival and improve neurological function.

Results of Operations

For the period from inception (September 22, 2000) until December 31, 2020, we did not generate any revenues from operations. In addition, we incurred operating costs and expenses of approximately $31,811,000 during the year ended December 31, 2020.

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, 2020 were $22,329,000, an increase of $5,125,000 compared to $17,204,000 for the year ended December 31, 2019.

This increase is due to (i) an increase of $2,135,000 in connection with materials, consultants, depreciation, payroll and stock-based compensation expenses and other activities; (ii) a decrease of $1,481,000 received in connection with the treatment of patients under the hospital exemption regulatory pathway; (iii) a decrease of $2,576,000 in participation of the Israel Innovation Authority ("IIA") and CIRM in 2020, under various awarded grants and (iv) an increase of $269,000 for costs related to travel, patents and other costs. This increase was partially offset by a decrease of $1,336,000 in connection with the Phase 3 Clinical Trial. Excluding participation from IIA

and CIRM under the grants and proceeds received under the hospital exemption regulatory pathway, research and development expenses decreased by $133,000 from $24,741,000 in 2019 to $24,608,000 in 2020.

General and Administrative

General and administrative expenses for the years ended December 31, 2020 and 2019 were $9,355,000 and $5,797,000, respectively. The increase of $3,558,000 in general and administrative expenses is mainly due to: (i) an increase of $2,611,000 in payroll and stock-based compensation expenses; (ii) an increase of $1,031,000 in the rent, the costs of our stock costs, consultants, costs of our investor relations and public relations activities and various other expenses. This increase was partially offset by a decrease of $84,000 in travel costs.

Financial Expenses

Financial expense for the year ended December 31, 2020 was $127,000 as compared to financial expense of $252,000 for the year ended December 31, 2019 as a result of the adoption of the Accounting Standard Update ASU 2016-02 “Leases” and due to interest earned on our cash, cash equivalents and short-term deposits.

Net Loss

Net loss for the year ended December 31, 2020 was $31,811,000, as compared to a net loss of $23,253,000 for the year ended December 31, 2019. Net loss per share for the year ended December 31, 2020 and December 31, 2019 was $1.07 and $1.06, 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, 2020 was 29,848,217 compared to 21,906,257 for the year ended December 31, 2019.

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, 2020 was due to: (i) the issuance of shares to employees and directors, (ii) issuance and sale of shares of Common Stock pursuant to the Distribution Agreement and (iii) the exercise of options and warrants.

Since its inception, the Company has devoted substantially all of its efforts to research and development. The Company is still in its development and clinical stage and has not yet generated revenues. The extent of the Company's future operating losses and the timing of becoming profitable are uncertain.

Additional funding will be required to begin the commercialization efforts and to achieve a level of sales adequate to support the Company's cost structure.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional public and private sales of its Common Stock and warrants, the exercise of warrants, the issuance of convertible promissory notes, sales of Common Stock via its September 25, 2020 ATM program and other funding transactions. While the Company has been successful in raising financing recently and in the past, there can be no assurance that it will be able to do so in the future on a timely basis on terms acceptable to the Company, or at all.

The COVID-19 pandemic may continue to adversely disrupt the Company's operations, including the ability to complete the ongoing clinical trials and may have other adverse effects on Company's business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on Company's business, operations and ability to raise capital.

Management expects that the Company will continue to generate losses from the clinical development and regulatory activities, which will result in a negative cash flow from operating activity. The Company has recently completed its Phase 3 ALS clinical trial. The Company currently has sufficient cash to complete its ongoing Phase 2 PMS and Phase 2 AD clinical trials. Over the longer term, if the Company is granted a BLA approval, additional capital raise will be needed in connection with strategic partnerships and to commercialize Nurown® for ALS, and to conduct additional trials for other indications. If the Company is not able to raise additional capital for these purposes, management may need to slow the pace of commercialization or the Company may not be able to continue

to function as a going concern. The Company's consolidated financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

Liquidity and Capital Resources

Since inception, the Company has financed its operations primarily through public and private sales of its Common Stock and warrants, the exercise of warrants, the issuance of convertible promissory notes, sales via the ATM programs and through various grants. At December 31, 2020 cash, cash equivalents and short-term bank deposits amounted to $41,936,000.

Net cash used in operating activities for the year ended December 31, 2020 was $35,193,000. 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, 2020 was $4,452,000 representing primarily a net decrease in short-term deposits and purchase of property and equipment.

Net cash provided by financing activities for the year ended December 31, 2020 was $76,938,000 from the exercises of warrants during the year, issuance of new warrants, sales of common stock under March 6, 2020 registered direct offering and sales of common stock under the June 11, 2019 ATM, March 6, 2020 ATM and September 25, 2020 ATM programs.

On June 8, 2018, we filed a shelf registration statement on Form S-3 (File No. 333-225517) (the “Shelf Registration Statement”), which was declared effective by the SEC on 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. Other than the supplements filed on June 11, 2019, March 6, 2020 and on September 25, 2020 in connection with the ATM offerings discussed below, and the prospectus supplement filed on March 6, 2020 in connection with the registered direct offering discussed below, we have not filed any supplemental prospectus defining particular terms of securities to be offered under the shelf registration statement.

At-the-market (ATM) Offerings:

On June 11, 2019, the Company entered into the June 11, 2019 ATM in an “at the market” offering as defined in Rule 415 promulgated under the Securities Act, including, without limitation, by sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and the Agent. On February 21, 2020, the Company completed the sale of all remaining shares issuable under the June 11, 2019 ATM and exhausted its full ATM capacity. Under the June 11, 2019 ATM, the Company sold an aggregate of 4,141,569 shares of Common Stock at an average price of $4.83 per share, raising gross proceeds of approximately $20 million.

On March 6, 2020, the Company entered into a new distribution agreement with Raymond James (the “Agent”), pursuant to which the Company was able to sell from time to time, through the Agent, shares of Common Stock, having an aggregate offering price of up to $50,000,000 (the “March 6, 2020 ATM”). Sales under the March 6, 2020 ATM were made by any method permitted by law that is deemed to be an “at the market” offering as defined in Rule 415 promulgated under the Securities Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and Raymond James. Under the March 6, 2020 ATM, the Company sold an aggregate of 2,446,641 shares of Common Stock at an average price of $9.45 per share, raising gross proceeds of approximately $23.11 million.

On September 25, 2020, the Company entered into an Amended and Restated Distribution Agreement (the “Distribution Agreement”) with SVB Leerink LLC (“Leerink”) and Raymond James & Associates (together with Leerink, the “Agents”) pursuant to which the Company may sell from time to time, through the Agents, shares of Common Stock, having an aggregate offering price of up to $45,000,000, which aggregate amount includes amount unsold pursuant to the March 6, 2020 ATM (the “September 25, 2020 ATM”). Sales under the September 25, 2020 ATM are to be made by any method permitted by law that is deemed to be an “at the market” offering as defined in Rule 415 promulgated under the Securities Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and the Agents. The Distribution Agreement amends and restates in its entirety the Company’s prior agreement with Raymond James entered on March 6, 2020 (the “March 6, 2020 ATM”). The Company previously sold 2,446,641 shares of Common Stock for gross proceeds of approximately $23.11 million of Common Stock under the March 6, 2020 ATM. During the quarter ended December 31,

2020, the Company sold an aggregate of 3,564,385 shares of Common Stock pursuant to the September 25, 2020 ATM at an average price of $6.10 per share, raising gross proceeds of approximately $21.8 million.

The Company has no obligation under the September 25, 2020 ATM to sell any shares and may at any time suspend sales or terminate the September 25, 2020 ATM in accordance with its terms. Subject to the terms and conditions of the Distribution Agreement, the Agents will use their commercially reasonable efforts to sell on the Company's behalf, from time to time consistent with its normal sales and trading practices, such Shares based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company has provided the Agents with customary indemnification rights, and the Agents will be entitled to a fixed commission of 3.0% of the aggregate gross proceeds from the Shares sold. The Distribution Agreement contains customary representations and warranties, and the Company is required to deliver customary closing documents and certificates in connection with sales of the Shares. Shares sold under the ATMs are issued pursuant to the Company's existing Shelf Registration Statement, and the Prospectus Supplement to the Registration Statements filed June 11, 2019, March 6, 2020 and September 25, 2020, respectively.

Registered Direct Offering:

On March 6, 2020, the Company entered into and closed a $10.0 million registered direct offering of 1,250,000 shares of Common Stock at a per share purchase price equal to $8.00. Purchaser also received a three-year warrant to purchase up to 250,000 shares of Common Stock at an exercise price of $15.00 per share.

Recent Sales of Unregistered Securities:

Exercises of 2018 Amended Warrants: On June 6, 2018 the Company entered into Warrant Exercise Agreements with certain holders ("2018 Warrant Holders"), pursuant to which holders were issued warrants to purchase an aggregate 2,458,201 unregistered shares of Common Stock, at an exercise price of $9 per share, with an expiration date of December 31, 2020 (the "2018 Warrants"). In connection with the issuance of the 2019 Warrants (described below), certain 2018 Warrants were amended on August 2, 2019 to reduce the exercise price to $7.00 per share and to extend the expiration date to December 31, 2021 (the "Amended 2018 Warrants").

Between July 20, 2020 and July 24, 2020, 2018 Warrant Holders exercised an aggregate of 280,000 shares of the Amended 2018 Warrants (the "2018 Exercised Shares"), which exercises generated gross cash proceeds to the Company of $1.96 million.

The 2018 Warrants have not been registered under the Securities Act of 1933, as amended (the Securities Act), or state securities laws. The 2018 Exercised Shares have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-225995). The issuance of the 2018 Exercised Shares and 2018 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. The Company expects to use cash received from exercises for general corporate and working capital purposes.

Exercises of 2019 Warrants: On August 2, 2019, the Company entered into Warrant Exercise Agreements with certain 2018 Warrant Holders ("2019 Warrant Holders"), pursuant to which holders were issued warrants to purchase an aggregate 842,000 shares of Common Stock (the "2019 Warrants"), at an exercise price of $7.00, with an expiration date of December 31, 2021 (the "2019 Warrants").

Between July 15, 2020 and July 24, 2020, 2019 Warrant Holders exercised an aggregate of 620,000 shares of the 2019 Warrants (the "2019 Exercised Shares"), which exercises generated gross cash proceeds to the Company of $4.34 million.

The 2019 Warrants have not been registered under the Securities Act, or state securities laws. The 2019 Exercised Shares have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-233349). The issuance of the 2019 Exercised Shares and 2019 Warrants is exempt from the registration requirements of the Securities Act pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act. The Company made this determination based on the representations that each party is an "accredited investor" within the meaning of Rule 501 of Regulation D. The Company expects to use cash received from exercises for general corporate and working capital purposes.

With the recent warrant exercises in July 2020, the Company has reduced its outstanding warrants shares to non-affiliates by approximately 37% and reduced its overall warrants shares outstanding by approximately 19%. In total, 900,000 of the 4,724,868 Company warrant shares outstanding were exercised between July 15 and July 24, 2020. 2,266,667 of the remaining 3,824,868 outstanding warrants shares are owned by affiliates of the Company.

Our material cash needs for the next 12 months, assuming we do not expand our clinical trials beyond our ongoing Phase 2 PMS trials in the United States, and the Phase 2 AD trials in Europe will include (i) costs of the clinical trial in the U.S. and Europe, (ii) employee salaries, (iii) payments for rent and operation of the GMP facilities and manufacturing of NurOwn®, and (iv) fees to our consultants and legal advisors, patents, and fees for facilities to be used in our research and development.

We believe our existing cash will be sufficient to fund our anticipated operating cash requirements for at least twelve months following the date of this filing. We currently have sufficient cash to execute on our ongoing Phase 2 PMS and Phase 2 AD clinical trials and support our operating activities. We expect that we will continue to generate losses from the clinical development and regulatory activities, which will result in a negative cash flow from operating activity. If we are granted a BLA approval, additional capital raise will be needed to commercialize NurOwn® for ALS, and to conduct additional trials that may be needed for other indications. The actual amount of cash that the Company will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our product candidates along with cost to commercialize these product candidates.

We anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may incur debt, license certain intellectual property, and seek to sell additional equity or convertible securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of equity or convertible securities, these securities could have rights or preferences senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our future capital requirements will depend on many factors, including:

* 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;
* any product liability or other lawsuits related to our product candidates;
* the expenses needed to attract and retain skilled personnel;
* the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
* the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
* the general and administrative expenses related to being a public company;
* the effect of competition and market developments; and
* future pre-clinical and clinical trial results.

The full extent to which the COVID 19 pandemic will directly or indirectly impact our business, results of operations, financial condition, liquidity and capital resources will depend on future developments that are highly uncertain and cannot be accurately predicted at this

time, including new information that may emerge concerning COVID 19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Our management team is actively monitoring this situation and the possible effects on our financial condition and liquidity.

Contractual Obligations and Commitments

The following is a table of contractual obligations and commitments as of December 31, 2020 (in thousands):

	Payments Due by Period			
	Total	Less than 1 year	1-3 years	3-5 years
Operating Leases	6,851	2,760	3,239	852
Total	6,851	2,760	3,239	852

Off-Balance Sheet Arrangement

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.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S. The preparation of our consolidated financial statements and disclosures requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements

Accounting for stock-based compensation:

We grant equity-based awards under share-based compensation plans. We estimate the fair value of share-based payment awards using the Black-Scholes option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected life of the option. Share-based compensation expense is based on awards ultimately expected to vest, and therefore is reduced by expected forfeitures. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not required.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2020

U.S. DOLLARS IN THOUSANDS
(Except share data and exercise prices)

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2020

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 sheets of Brainstorm Cell Therapeutics Inc. and subsidiaries (the “Company”) as of December 31, 2020 and 2019 and the related consolidated statements of comprehensive loss, shareholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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 audits. 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 audits 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 audits, 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Stock-Based Compensation to Employees and Directors – Stock Options — Refer to Note 11 to the financial statements

Critical Audit Matter Description

The Company issues various types of equity awards, including stock options. During the year ended December 31, 2020, the Company issued stock options for 590,866 shares and recorded stock option related compensation expense of $1.3 million. The Company estimated the fair value of these stock options granted using the Black-Scholes option pricing model. The option pricing model required the Company to make a number of assumptions, of which the most significant are expected stock price volatility and the expected option term. Expected volatility was calculated based upon actual historical stock price movements over the period equal to the expected option term, which was calculated using the simplified method.

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Auditing the Company's accounting for stock options required auditor judgment due to the subjectivity of assumptions used to estimate the fair value of stock options granted.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the stock-based compensation included the following, among others:

- We assessed the accuracy and completeness of the awards granted during the year by reading the relevant Board of Directors minutes and grant documents.
- We evaluated the appropriateness of the valuation method used for the stock option grants and whether the method used for determining fair value was applied consistently with the valuation of similar grants in prior periods.
- We evaluated the significant assumptions used by management to calculate the fair value of stock options granted. Such evaluation included independent calculation of the expected volatility based upon actual historical stock price movements over the period equal to the expected option term and independent calculation of the stock option term using the simplified method.
- We developed an independent estimate of the fair value for all the grants during the year and compared our estimate of fair value to the fair value used by management.

Brightman Almagor Zohar & Co.
Certified Public Accountants
A Firm in the Deloitte Global Network

Tel Aviv, Israel
February 4, 2021

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

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BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands
(Except share data)

	December 31,	
	2020	2019
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 37,829	$ 536
Short-term deposit (Note 9)	4,107	33
Other accounts receivable (Note 4)	304	2,359
Prepaid expenses and other current assets (Note 5)	1,002	432
Total current assets	43,242	3,360
Long-Term Assets:		
Prepaid expenses and other long-term assets	26	32
Operating lease right of use asset (Note 6)	6,872	2,182
Property and Equipment, Net (Note 7)	1,119	960
Total Long-Term Assets	8,017	3,174
Total assets	$ 51,259	$ 6,534
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 5,417	$ 14,677
Accrued expenses	1,261	1,000
Operating lease liability (Note 6)	2,655	1,263
Other accounts payable	1,900	714
Total current liabilities	11,233	17,654
Long-Term Liabilities:		
Operating lease liability (Note 6)	4,562	1,103
Total long-term liabilities	4,562	1,103
Total liabilities	$ 15,795	$ 18,757
Stockholders' Equity (deficit):		
Stock capital: (Note 11)	12	11
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at December 31, 2020 and December 31, 2020 respectively; Issued and outstanding: 35,159,977 and 23,174,228 shares at December 31, 2020 and December 31, 2019 respectively.		
Additional paid-in-capital	184,655	105,042
Treasury stocks	(116)	—
Accumulated deficit	(149,087)	(117,276)
Total stockholders' equity (deficit)	35,464	(12,223)
Total liabilities and stockholders' equity	$ 51,259	$ 6,534

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

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S. dollars in thousands
(Except share data)

	Year ended December 31,	
	2020	2019
	U.S. $ in thousands	
Operating expenses:		
Research and development, net (Note 12)	$ 22,329	$ 17,204
General and administrative	9,355	5,797
Operating loss	(31,684)	(23,001)
Financial expenses, net	127	252
Net loss	$ (31,811)	$ (23,253)
Basic and diluted net loss per share	$ (1.07)	$ (1.06)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	29,848,217	21,906,257

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

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
U.S. dollars in thousands
(Except share data)

	Common stock		Additional paid-in capital	Receipts on account of shares	Accumulated deficit	Total stockholders' equity
	Number	Amount				
Balance as of January 1, 2019	20,757,816	$ 11	$ 94,620	$ 4,408	$ (94,023)	$ 5,016
	5,908	(*)	25	—	—	25
Stock-based compensation related to warrants and stock granted to service providers	107,104	(*)	764	—	—	764
Stock-based compensation related to stock and options granted to directors and employees	542,736	(*)	2,064	—	—	2,064
Exercise of options	1,741,999	(*)	7,534	(4,408)	—	3,126
Exercise and reissuance of warrants	18,665	(*)	35	—	—	35
Net loss	—	—	—	—	(23,253)	(23,253)
Balance as of December 31, 2019	23,174,228	$ 11	$ 105,042	$ —	$ (117,276)	$ (12,223)

* Represents an amount less than $1.

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

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
U.S. dollars in thousands
(Except share data)

	Common stock		Additional paid-in capital	Treasury stocks	Accumulated deficit	Total stockholders' equity (deficit)
	Number	Amount				
Balance as of January 1, 2020	23,174,228	$ 11	$ 105,042	—	$ (117,276)	$ (12,223)
Stock-based compensation related to stock and options granted to directors and employees	227,244	*	2,560	—	—	2,560
Issuance of shares and warrants in Registered Direct Offering (Note 11)	1,250,000	*	9,957	—	—	9,957
Treasury stocks	(25,000)	*	—	(116)	—	(116)
Issuance of shares in at-the-market (ATM) offering (Note 11)	9,609,859	1	60,728	—	—	60,729
Exercise of options	23,646	*	68	—	—	68
Exercise of warrants	900,000	*	6,300	—	—	6,300
Net loss	—	—	—	—	(31,811)	(31,811)
Balance as of December 31, 2020	35,159,977	12	184,655	(116)	(149,087)	35,464

* Represents an amount less than $1.

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

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands

	December 31,	
	2020	2019
	U.S. $ in thousands	
Cash flows from operating activities:		
Net loss	$ (31,811)	$ (23,253)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	219	164
Shares and options granted to service providers	—	25
Stock-based compensation related to options granted to employees and directors	2,560	764
Change in operating lease liability	161	184
Decrease in other accounts receivable and prepaid expenses	1,491	690
Increase(decrease) in accounts payables	(9,260)	10,129
Increase in other accounts payable and accrued expenses	1,447	50
Total net cash used in operating activities	$ (35,193)	$ (11,247)

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

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands

	Year ended December 31,	
	2020	2019
	U.S. $ in thousands	
Cash flows from investing activities:		
Purchase of property and equipment	(378)	(473)
Proceeds from (Investment in) short-term deposit	(4,074)	6,089
Total net cash provided by (used in) investing activities	$ (4,452)	$ 5,616
Cash flows from financing activities:		
Proceeds from exercise of options	68	35
Issuance of shares in at-the-market (ATM) offering (Note 11)	60,729	2,064
Proceeds from issuance of shares and warrants in Registered Direct Offering (Note 11)	9,957	—
Purchase of treasury stock	(116)	—
Proceeds from exercise of warrants	6,300	3,126
Total net cash provided by financing activities	$ 76,938	$ 5,225
Increase (decrease) in cash and cash equivalents	37,293	(406)
Cash and cash equivalents at the beginning of the period	$ 536	$ 942
Cash and cash equivalents at end of the period	$ 37,829	$ 536
Supplemental schedule of non-cash transactions		
Right of use lease asset and liability	(5,857)	(3,197)

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

NOTE 1 - GENERAL

A. 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. BCT formed wholly-owned subsidiaries Brainstorm Cell Therapeutics UK Ltd., in the United Kingdom on February 19, 2013 (currently inactive), Advanced Cell Therapies Ltd. in Israel on June 21, 2018 and Brainstorm Cell Therapeutics Limited in Ireland on October 1, 2019.

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

B. 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 Amytrophic Lateral Scelorosis (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.

C. Since its inception, the Company has devoted substantially all of its efforts to research and development. The Company is still in its development and clinical stage and has not yet generated revenues. The Company has incurred operating losses since its inception, and expects to continue to incur operating losses for the near-term. The extent of the Company's future operating losses and the timing of becoming profitable are uncertain. As of December 31, 2020, the Company had an accumulated deficit of approximately $148 million. The extent of the Company's future operating losses and the timing of becoming profitable are uncertain.

The Company's primary sources of cash have been proceeds from the issuance and sale of its Common Stock and warrants, the exercise of warrants, sales of Common Stock via its ATM program and other funding transactions. While the Company has been successful in raising financing recently and in the past, there can be no assurance that it will be able to do so in the future on a timely basis on terms acceptable to the Company, or at all. The Company has not yet commercialized any of its product candidates. Even if the Company commercializes one or more of its product candidates, it may not become profitable in the near-term. The Company's ability to achieve profitability depends on a number of factors, including its ability to obtain regulatory approval for its product candidates, successfully complete any post-approval regulatory obligations and successfully commercialize its product candidates alone or in partnership.

The Company believes its existing cash will be sufficient to fund its anticipated operating cash requirements for at least twelve months following the date of this filing. The Company currently has sufficient cash to execute on its ongoing Phase 2 PMS and Phase 2 AD clinical trials and support its operating activities. Management expects that the Company will continue to generate losses from the clinical development and regulatory activities, which will result in a negative cash flow from operating activity. If the Company is granted a BLA approval, additional capital raise will be needed to commercialize Nurown® for ALS, and to conduct additional trials that may be needed for other indications. The actual amount of cash that the Company will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for its product candidates along with cost to commercialize these product candidates.

NOTE 1 - GENERAL (Cont.)

In early 2020, the World Health Organization declared the rapidly spreading coronavirus disease (COVID-19) outbreak a pandemic. This pandemic has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. The Company considered the impact of COVID-19 on its operations and determined that there were no material adverse impacts on the Company's results of operations and financial position as of December 31, 2020. These estimates may change, as new events occur and additional information is obtained.

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.

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NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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 the 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, Advanced Cell Therapies Ltd, BCT, Brainstorm UK and Brainstorm Cell Therapeutics Limited (Irish Company). Intercompany balances and transactions have been eliminated upon consolidation.

E. Cash and cash equivalents:

Cash and cash equivalents include cash in hand and short-term highly liquid investments that are readily convertible to cash with maturities of three months or less as of the date acquired and that are exposed to insignificant risk of change in value.

F. Short-term deposits:

Short-term deposits are deposits with an original maturity of more than three months from the date of investment and which do not meet the definition of cash equivalents.

G. Property and equipment:

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

The annual depreciation rates are as follows:

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

H. 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.

I. Fair value of financial instruments:

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

J. 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 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. Expected volatility was calculated based upon actual historical stock price movements over the period, equal to the expected option term, which was calculated using the simplified method. 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 ASU No. 2018-07 "Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting." which 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.

K. Basic and diluted net loss per share:

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

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NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

K. Basic and diluted net loss per share: (Cont.)

All outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share for the years ended December 31, 2020 and December 31, 2019, since all such securities have an anti-dilutive effect.

L. Research and development expenses, net:

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

Royalty-bearing grants from the Israel Innovation Authorities ("IIA") and a non-dilutive, non-royalty-bearing grant from 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.

M. 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.

N. Lease accounting

The Company adopted ASC 842, leases effective January 1, 2019 using the modified retrospective approach. At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Arrangements that are determined to be leases at inception are recognized in long-term ROU assets and short and long-term lease liabilities in the consolidated balance sheet at lease commencement. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future fixed lease payments over the lease term at commencement date. As most of the Company's leases do not provide an implicit rate, the Company applies its incremental borrowing rate based on the economic environment at commencement date in determining the present value of future payments. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases or payments are recognized on a straight-line basis over the lease term.

The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less.

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NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

O. Treasury Stock

The Company records the aggregate purchase price of treasury stock at cost and includes treasury stock as a reduction to stockholders' equity.

P. Commitments and Contingencies

The Company follows ASC 450-20, Loss Contingencies, to report accounting for contingencies. Liabilities for loss contingencies arising from claims, assessments, litigation, fines and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated. As of December 31, 2020, the company recorded $600 for known commitments and contingencies.

Q. Recent Accounting Standards Updates Not Yet Effective:

In December 2019, the FASB issued ASU No. 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (“ASU 2019-12”), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This standard will be effective for the Company's interim and annual periods beginning with the first quarter of fiscal 2021 and must be applied on a modified retrospective basis. This standard will not materially impact the 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:

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

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

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

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NOTE 4 - OTHER ACCOUNTS RECEIVABLE

Composition:

	December 31	
	2020	2019
	U.S. $ in thousands	
Grants receivable from CIRM (Note 10)	—	2,200
Grants receivable from IIA	220	85
Government institutions and other	84	90
	304	2,359

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 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, 2019, $276 were recorded as current prepaid expense. As of December 31, 2020, the prepaid expenses from COH advance payment were fully reduced.

As of December 31, 2020, prepaid expenses includes directors insurance of $984.

NOTE 6 - LEASES

On January 1, 2019 the Company adopted ASU 2016-02, Leases (Topic 842) ("ASU 2016-02") using the modified retrospective approach for all lease arrangements at the beginning of the period of adoption. The Company leases facilities, clinical research rooms, and vehicles under operating leases.

As of December 31, 2020, the Company's ROU assets and lease liabilities for operating leases totaled $6,872 and $7,217, respectively. The impact of adopting the new lease standard was not material to the Company's condensed consolidated statement of operations for the periods presented.

As of December 31, 2020, and 2019, total right-of-use assets was approximately $6,872 and $2,182 and the operating lease liabilities for remaining long term lease was approximately $7,217 and $2,366, respectively. In the year ended December 31, 2020 and 2019, the Company recognized approximately $1,423 and $1,296, respectively in total lease costs for the leases. Variable lease costs for the year ended December 31, 2020 were immaterial.

As of December 31, 2020, the Company's operating leases had a weighted average remaining lease term of 3.93 years and a weighted average discount rate of 7.00%. Future lease payments under operating leases as of December 31, 2020 were as follows:

Supplemental cash flow information related to operating leases was as follows:

	Twelve Months ended December 31, 2020
Cash payments for operating leases	1,423
New operating lease assets obtained in exchange for operating lease liabilities	
	5,857

U.S. dollars in thousands

NOTE 6 - LEASES (Cont.)

As of December 31, 2020, the Company's operating leases had a weighted average remaining lease term of 3.93 years and a weighted average discount rate of 7.00%. Future lease payments under operating leases as of December 31, 2020 were as follows:

	Operating Leases
2021	2,760
2022	1,422
2023	1,437
2024	1,406
2025	1,265
Total future lease payments	8,290
Less imputed interest	(1,073)
Total lease liability balance	7,217

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NOTE 7 - PROPERTY AND EQUIPMENT

Composition:

	December 31	
	2020	2019
	U.S. $ in thousands	
Cost:		
Office furniture and equipment	75	73
Computer software and electronic equipment	237	209
Laboratory equipment	1,949	1,617
Leasehold improvements	811	795
	3,072	2,694
Accumulated depreciation:		
Office furniture and equipment	38	33
Computer software and electronic equipment	210	196
Laboratory equipment	964	777
Leasehold improvements	741	728
	1,953	1,734
Depreciated cost	1,119	960

Depreciation expenses for the years ended December 31, 2020 and December 31, 2019 were $219 and $164, respectively.

NOTE 8 - COMMITMENTS AND CONTINGENCIES

A. 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 2019, 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, 2020, total grants obtained amounted to $1,025.

B. 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, 2020, there are no outstanding obligations owed to Ramot in connection with the above.

NOTE 9 - SHORT TERM DEPOSITS

Short term investments on December 31, 2020 and December 31, 2019 include bank deposits bearing annual interest rates varying from 0.05% to 0.83%, with maturities of up to 4 months as of December 31, 2020 and 2019.

NOTE 10 - GRANTS RECEIVABLE

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 $3,362 and $12,550 related to the project was received through the year ended December 31, 2020 and December 31, 2019, respectively. As of December 31, 2020, there are no additional grants receivable from CIRM. The award does not bear a royalty payment commitment nor is the award otherwise refundable. $1,162 and $4,058 was recorded as participation by CIRM in research and development expenses during the year ended in December 31, 2020 and during the year ended December 31, 2019, respectively (see Note 12).

NOTE 11 - 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).

NOTE 11 - STOCK CAPITAL (Cont.)

2018 Warrant Exercise Agreement:

On June 6, 2018, the Company entered into a Warrant Exercise Agreement (the "2018 Warrant Exercise Agreement") with certain holders (the "2018 Warrant Holders") of warrants (the "2015 Warrants") to purchase Common Stock. The 2015 Warrants were originally issued in the Company's January 8, 2015 private placement. Pursuant to the 2018 Warrant Exercise Agreement, the 2018 Warrant 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. The warrant exercises generated gross cash proceeds to the Company of $12.3 million. In addition, the Company issued new warrants to the 2018 Warrant Holders to purchase an aggregate 2,458,201 unregistered shares of Common Stock, at an exercise price of $9.00, with an expiration date of December 31, 2020 (the "2018 Warrants"). In connection with the issuance of the 2019 Warrants (described below), certain 2018 Warrants were amended on August 2, 2019 to reduce the exercise price to $7.00 per share and to extend the expiration date to December 31, 2021 (the "Amended 2018 Warrants").

Between July 20, 2020 and July 24, 2020, 2018 Warrant Holders exercised an aggregate of 280,000 shares of the Amended 2018 Warrants (the "2018 Exercised Shares"), which exercises generated gross cash proceeds to the Company of $1,960,000.

The 2018 Warrants have not been registered under the Securities Act of 1933, as amended (the Securities Act), or state securities laws. The shares issuable upon exercise of the Amended 2018 Warrants have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-225995). 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 2018 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.

U.S. dollars in thousands

NOTE 11 - STOCK CAPITAL (Cont.)

Private placements and public offerings: (Cont.)

2019 Warrant Exercise Agreement:

On August 2, 2019, the Company entered into a Warrant Exercise Agreement which generated gross cash proceeds to the Company of approximately $3.3 million. Pursuant to the agreement, certain holders (the "2019 Warrant Holders") of the 2018 Warrants agreed to exercise 842,000 shares of Common Stock of their 2018 Warrants, at an amended exercise price of $3.90 per share, and the Company agreed to issue new warrant shares to the Holders to purchase 842,000 shares of Common Stock (the "2019 Warrants"), at an exercise price of $7.00, with an expiration date of December 31, 2021. The 2018 Warrants held by the 2019 Warrant Holders, to the extent not exercised, were also amended to reduce the exercise price to $7.00 per share and to extend the expiration date to December 31, 2021 (the "Amended 2018 Warrants").

Between July 15, 2020 and July 24, 2020, 2019 Warrant Holders exercised an aggregate of 620,000 shares of the 2019 Warrants (the "2019 Exercised Shares"), which exercises generated gross cash proceeds to the Company of $4,340,000.

The Amended 2018 Warrants and 2019 Warrants have not been registered under the Securities Act of 1933, as amended (the Securities Act), or state securities laws. The shares issuable upon exercise of the 2019 Warrants have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-233349), and the shares issuable upon exercise of the Amended 2018 Warrants have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-225995). The exercised shares have been registered for resale on the Company's registration statement on Form S-3 (File No. 333-225995). The issuance of the exercised shares, Amended 2018 Warrants and 2019 Warrants is exempt from the registration requirements of the Securities Act pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act. The Company made this determination based on the representations that each party is an "accredited investor" within the meaning of Rule 501 of Regulation D.

Warrants:

The following table sets forth the number, exercise price and expiration date of Company warrants outstanding as of December 31, 2020:

Issuance Date	Outstanding As Of December 31, 2020	Exercise price	Exercisable Through
Aug 2007- Jan 2011	2,016,666	3 - 4.35	Nov-2022
Jun-2018	877,999	7	Dec-2021
Aug - 2019	222,000	7	Dec-2021
March - 2020	250,000	15	March-2023
Total	**3,366,665**		

NOTE 11 - STOCK CAPITAL (Cont.)

At-the-market (ATM) Offering:

On June 11, 2019, the Company entered into a distribution agreement with Raymond James & Associates, Inc. ("Raymond James"), pursuant to which the Company sold, through the Raymond James, shares of Common Stock having an aggregate offering amount of $20,000,000 (the "June 11, 2019 ATM") in an "at the market" offering as defined in Rule 415 promulgated under the Securities Act, including, without limitation, by sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and Raymond James.

On March 6, 2020, the Company entered into a new distribution agreement with Raymond James (the "Agent"), pursuant to which the Company was able to sell from time to time, through the Agent, shares of Common Stock, having an aggregate offering price of up to $50,000,000 (the "March 6, 2020 ATM"). Sales under the March 6, 2020 ATM were made by any method permitted by law that is deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and Raymond James. Under the March 6, 2020 ATM, the Company sold an aggregate of 2,446,641 shares of Common Stock at an average price of $9.45 per share, raising gross proceeds of approximately $23.11 million.

On September 25, 2020, the Company entered into an Amended and Restated Distribution Agreement (the "Distribution Agreement") with SVB Leerink LLC ("Leerink") and Raymond James & Associates (together with Leerink, the "Agents") pursuant to which the Company may sell from time to time, through the Agents, shares of Common Stock, having an aggregate offering price of up to $45,000,000, which aggregate amount includes amount unsold pursuant to the March 6, 2020 ATM (the "September 25, 2020 ATM"). Sales under the September 25, 2020 ATM are to be made by any method permitted by law that is deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares, through a market maker or as otherwise agreed by the Company and the Agents. The Distribution Agreement amends and restates in its entirety the Company's prior agreement with Raymond James entered on March 6, 2020 (the "March 6, 2020 ATM"). The Company previously sold 2,446,641 shares of Common Stock for gross proceeds of approximately $23.11 million of Common Stock under the March 6, 2020 ATM. During the quarter ended December 31, 2020, the Company sold an aggregate of 3,564,385 shares of Common Stock pursuant to the September 25, 2020 ATM at an average price of $6.10 per share, raising gross proceeds of approximately $21.8 million.

The Company has no obligation under the September 25, 2020 ATM to sell any shares and may at any time suspend sales or terminate the September 25, 2020 ATM in accordance with its terms. Subject to the terms and conditions of the Distribution Agreement, the Agents will use their commercially reasonable efforts to sell on the Company's behalf, from time to time consistent with its normal sales and trading practices, such Shares based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company has provided the Agents with customary indemnification rights, and the Agents will be entitled to a fixed commission of 3.0% of the aggregate gross proceeds from the Shares sold. The Distribution Agreement contains customary representations and warranties, and the Company is required to deliver customary closing documents and certificates in connection with sales of the Shares. Shares sold under the ATMs are issued pursuant to the Company's existing Shelf Registration Statement, and the Prospectus Supplement to the Registration Statements filed June 11, 2019, March 6, 2020 and September 25, 2020, respectively.

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NOTE 11 - STOCK CAPITAL (Cont.)

Registered Direct Offering:

On March 6, 2020, the Company entered into and closed a $10.0 million registered direct offering of 1,250,000 shares of common stock at a per share purchase price equal to $8.00. The purchaser also received a three-year warrant to purchase up to 250,000 shares of Common Stock at any exercise price of $15.00 per share.

Capital Raised Since Inception:

Since its inception the Company and as of December 31, 2020, the Company has raised approximately $143,000 gross in cash in consideration for issuances of Common Stock and warrants in private placements and public offerings as well as proceeds from warrants exercises.

Stock Plans:

During the fiscal year ended December 31, 2020, 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 5,600,000 shares of Common Stock available for issuance. As of December 31, 2020, 3,018,413 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.

U.S. dollars in thousands

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NOTE 11 - STOCK CAPITAL (Cont.)

Stock-based compensation to employees and directors:

Stock Options:

Under the 2014 Plans, the Company may award stock options to certain employees, officers, directors, and 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 590,866 and 204,167 shares in 2020 and 2019, 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,	
	2020	2019
Expected volatility	57%-66 %	60 %
Risk-free interest	0.31%-0.57 %	1.44 %
Dividend yield	0 %	0 %
Expected life of up to (years)	5.04-7.0	5.5
Fair Value	$3.951-$9.183	$1.728-$4.020

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

	For the year ended December 31					
	2020			2019		
	Amount of options*	Weighted average exercise price	Aggregate intrinsic value	Amount of options*	Weighted average exercise price	Aggregate intrinsic value
		$	$		$	$
Outstanding at beginning of period	1,293,007	3.0142		1,496,287	3.0581	
Granted	590,866	8.7411		204,167	4.8937	
Exercised	(23,646)	2.8692		(18,665)	1.8943	
Cancelled	(105,333)	3.9731		(388,782)	4.2239	
Outstanding at end of period	1,754,894	4.8869	2,344,107	1,293,007	3.0142	1,636,630
Vested at end of period	998,527	2.3859	2,186,920	840,579	2.3765	2,048,529

* Represents Employee Stock Options only (not including RSUs)

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, 2020, 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.

U.S. dollars in thousands

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NOTE 11 - STOCK CAPITAL (Cont.)

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

As of December 31, 2020, there was $2,386 of total unrecognized compensation cost related to non-vested options under the Plan. The cost is expected to be recognized over a weighted average period of 1.88 years. 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, 2020 and 2019 amounted to $1,293 and $372, respectively.

The options outstanding as of December 31, 2020 and December 31, 2019, have been separated into exercise prices, as follows:

Exercise price	Options outstanding As of December 31,		Weighted average remaining contractual Life - Years As of December 31,		Options exercisable as of As of December 31,	
$	2020	2019	2020	2019	2020	2019
0.75	311,499	222,833	6.73	6.78	294,832	222,833
2.25	43,222	56,555	1.29	1.98	43,222	56,555
2.45	369,619	369,619	4.75	5.75	369,619	369,619
2.70	58,354	78,667	3.16	3.71	58,354	78,667
3.90	10,000	13,333	2.59	2.59	10,000	13,333
3.96	100,000	100,000	8.68	9.69	31,250	—
3.98	200,000	200,000	7.66	8.66	100,000	50,000
4.21	60,000	150,000	0.21	8.53	60,000	30,000
6.00	100,000	100,000	8.69	9.69	31,250	—
7.33	80,000	—	9.19	—	—	—
7.67	100,000	—	9.81	—	—	—
9.51	162,200	—	9.81	—	—	—
12.58	80,000	—	9.69	—	—	—
14.95	80,000	—	9.75	—	—	—
	1,754,894	1,293,007	6.97	7.32	998,527	823,007

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.

U.S. dollars in thousands

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NOTE 11 - STOCK CAPITAL (Cont.)

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

Restricted Stock:*(Cont.)*

	Number of Restricted Stock	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)
Nonvested as of December 31, 2018	152,908	3.96	1.56
Granted	113,012	3.98	
Vested	64,535	3.88	
Nonvested as of December 31, 2019	201,385	4.00	1.95
Granted	227,410	9.07	
Vested	140,714	5.09	
Nonvested as of December 31, 2020	288,081	7.71	1.10

The total compensation expense recorded by the Company in respect of its restricted stock awards to certain employees, officers, directors, and service providers for the year ended December 31, 2020 and 2019 amounted to $1,267 and $392, respectively.

As of December 31, 2020, there was $1,211 of total unrecognized compensation cost related to non-vested restricted stock under the Plan. The cost is expected to be recognized over a weighted average period of 1.52 years.

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.

On May 23, 2019, the Company granted to a former director, in consideration for services rendered to the Company, an option under the 2014 Global Plan to purchase up to 4,167 shares of Common Stock with an exercise price per share of $0.75. The option was fully vested and exercisable as of the date of grant.

NOTE 11 - STOCK CAPITAL (Cont.)

Shares and warrants issued to service providers:

Compensation expense recorded by the Company in respect of its stock-based service provider compensation awards for the year ended December 31, 2020 and 2019 amounted to $0 and $25, respectively.

Share-based compensation to employees, directors and service providers:

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:

	December 31	
	2020	2019
	U.S. $ in thousands	
Research and development	1,173	123
General and administrative	1,387	666
Total stock-based compensation expense	2,560	789

Treasury Stock

The Company may periodically repurchase shares of its common stock from employees for the satisfaction of their individual payroll tax withholding upon vesting of restricted stock awards in connection with the Company's incentive plans. The Company's repurchases of common stock are recorded at the stock price on the vesting date of the common stock. The Company repurchased 25,000 shares of its common stock for $116 thousands for the year ended December 31, 2020.

NOTE 12 - RESEARCH AND DEVELOPMENT, NET

Composition:

	Year ended December 31	
	2020	2019
	U.S. $ in thousands	
Research and development	25,808	24,741
Less : Participation by CIRM	(1,162)	(4,058)
Less: Participation by Israeli Hospital Exemption regulatory pathway	(900)	(2,381)
Less : Participation by the Israel Innovation Authorities	(1,143)	(732)
Less: Participation by other grants	(274)	(366)
	22,329	17,204

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NOTE 13 - 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 24% in the year 2017 and reduced to 23% in the year 2018 and onwards. Such tax rate changes had no significant impact on the Company's financial statements**.**

B. Tax rates applicable to the income of the US company:

BrainStorm Cell Therapeutics Inc. 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 Act did not have an effect on the financial results and position of the Company.

The Company is subject to state tax of 13%.

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NOTE 13 - TAXES ON INCOME (Cont.)

C. 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	
	2020	2019
	U.S. $ in thousands	
Operating loss carryforward	99,818	73,260
Net deferred tax asset before valuation allowance	26,664	19,911
Valuation allowance	(26,664)	(19,911)
Net deferred tax asset	—	—

As of December 31, 2020, the Company has provided a full valuation allowances of $26,664 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.

D. Available carryforward tax losses:

As of December 31, 2020, the Company has an accumulated tax loss carryforward of approximately $99,818. Carryforward tax losses in Israel are of unlimited duration. Under the Tax Cut and Jobs Act of 2017, or the Tax Act (subject to modifications under the Coronavirus Aid, Relief, and Economic Security Act), federal net operating losses (NOL) incurred in taxable years ending after December 31, 2017 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. Such limitations may result in the expiration of net operating losses before utilization.

NOTE 13 - TAXES ON INCOME (Cont.)

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

	Year ended December 31	
	2020	2019
	U.S. $ in thousands	
United States	(8,578)	(4,378)
Israel	(23,233)	(18,875)
	(31,811)	(23,253)

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

NOTE 14 - 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 2020 and 2019.

NOTE 15 - SUBSEQUENT EVENTS

From January 1, 2021 through January 31, 2021, the Company sold an aggregate of 679,443 additional shares of Common Stock pursuant to the September 25, 2020 ATM, at an average price of $6.54 per share, raising gross proceeds of approximately $4.45 million.

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, 2020 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, 2020. 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, 2020, 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.

Name	Age	Position
Chaim Lebovits	50	Chief Executive Officer
Ralph Kern, MD, MHSc	63	President and Chief Medical Officer
David Setboun, PharmD, MBA	46	EVP, Chief Operating Officer
Preetam Shah, PhD, MBA	48	EVP, Chief Financial Officer and Treasurer
Uri Yablonka	44	EVP, Chief Business Officer, Secretary and Director
Arturo O. Araya	50	Chief Commercial Officer
Stacy Lindborg, PhD	50	EVP, Head of Global Clinical Research
Anthony Waclawski, Ph.D	59	EVP, Global Head of Regulatory Affairs
Prof. Jacob Frenkel, PhD, MA	77	Chairperson and Director
Irit Arbel, PhD	61	Director
June S. Almenoff, MD, PhD	64	Director
Anthony Polverino, PhD	58	Director
Malcolm Taub	75	Director
Sankesh Abbhi	34	Director

Chaim Lebovits has been serving as our Chief Executive Officer since September of 2015. Mr. Lebovits joined the Company as President in connection with his arrangement of an equity investment by ACC Biotech in the Company in July 2007. On August 1, 2013, the Company appointed Mr. Lebovits as its Principal Executive Officer, and he assumed the duties and responsibilities of the Chief Executive Officer on an interim basis until June 2014. During his tenure with the Company, Mr. Lebovits has been instrumental in the various capital raises undertaken by the Company and in his capacity as President Mr. Lebovits managed relatively low burn rates and was very instrumental in the major decisions of the Company's focus and direction, including the decision to focus on Amyotrophic Lateral Sclerosis (ALS, also known as Lou Gehrig's Disease) as a first indication. Mr. Lebovits led efforts to attract the clinical sites first in Israel and later in the United States, building strong relationships for the Company with many leading Key Opinion Leaders and Centers of Excellence for ALS in the United States. Mr. Lebovits controls ACC Holdings International, and its subsidiaries including ACC BioTech, which is focused on the biotechnology sector. He has been at the forefront of natural resource management and has spent years leading the exploration and development of resources in Israel and served as a member of the boards 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. He currently serves as President and Chief Medical Officer since April 2020. 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).

Dr. David Setboun joined the Company on April 7, 2020 at Executive Vice President, Chief Operating Officer. Most recently, Dr. Setboun served as VP Corporate Development, Strategy & Business at Life Biosciences from July 2018 to April 2020. From June 2015 to June 2018, he served as President, Biogen, France where he launched Biogen's rare disease franchise. Prior to his tenure at Biogen, Dr. Setboun, served as President, AstraZeneca, Portugal from 2012 to 2015. Prior to this role, Dr. Setboun led the European Sales & Marketing function as AstraZeneca's VP Europe from 2002 to 2009. Dr. Setboun directed national and international teams and projects for Eli Lilly and Company in France and the USA. Dr. Setboun received his Pharmaceutical Doctorate (Pharm.D.) from University Paris XI in 1997 and his MBA from H.E.C Paris in 2001.

Dr. Preetam Shah joined the Company on September 6, 2019 as Executive Vice President, Chief Financial Officer and Treasurer. Prior to joining the Company, Preetam Shah served as Director, Healthcare Investment Banking at Barclays Capital Plc. since June 2016. He has also served as Vice President, Healthcare Investment Banking at Canaccord Genuity Inc. from 2013 to 2016. Dr. Shah founded Saisarva LLC. and was a financial consultant from 2010-2013 for healthcare-focused private equity firms, hedge funds, and global pharmaceutical companies. From 2006-2009, Dr. Shah served as Vice President, U.S. Operations and Investments at Reliance Capital USA Ventures LLC, an affiliate of Reliance ADA Group Companies. Dr. Shah completed his post-doctoral fellowship in Infectious Diseases from Stanford University School of Medicine. He holds a Ph.D. in Microbiology from the University of Mississippi Medical Center and a M.B.A. in Finance from the Wharton School, University of Pennsylvania.

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 to May 2014 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 and secretary of the 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 led 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.

Dr. Stacy Lindborg joined the Company on June 1, 2020 at Executive Vice President, Head of Global Clinical Research. Dr. Lindborg is an experienced healthcare executive and globally recognized medical statistician with over 2 decades of multinational experience in R&D, regulatory, strategy development, analytics and big data. Her experience includes senior roles at Eli Lilly & Company and Biogen. Dr. Lindborg served at Biogen Inc. from 2012 to 2020, where she was most recently Vice President, Analytics and Data Science. She also served on the R&D governance team during a time of significant growth for Biogen and was active in guiding the firm's long-term vision for growth through analytics and by stimulating innovative development platforms to increase productivity. Her team motivated novel analytic and development approaches, that contributed in material ways to products such as Spinraza® and Aducanumab®. At Eli Lilly & Company, she held positions of increasing responsibility including Head of R&D strategy, where she was responsible for characterizing the productivity of the portfolio and driving key R&D strategy projects including the annual R&D Long-Range Plan. In this role, she created seminal insights into R&D productivity by connecting individual drug program-based development decisions to portfolio risk practices, driving fundamental R&D decisions to increase number of drug launches. Additionally, she was Leader of Zyprexa Product Management in which she was responsible for R&D, Commercial and Manufacturing plans. She was accountable for driving market share through product differentiation, global registration and launching of an injectable

form of Zyprexa, working through regulatory manufacturing inspections and 483 citations. Dr. Lindborg holds a Ph.D. in statistics from Baylor University.

Dr. Anthony Waclawski joined the Company in September 2020 as Executive Vice President, Global Head of Regulatory Affairs. Dr. Waclawski is an experienced healthcare professional and a globally recognized regulatory leader with over 35 years of multinational experience in FDA regulatory approvals, biologics license applications (BLAs), New Drug Applications (NDAs), and FDA Advisory Committees. Prior to his appointment at BrainStorm, Dr. Waclawski spent 35 years of increasing responsibility. From November 2016 to September 2020, Dr. Waclawski served as Vice President, Head Regulatory and Pharmaceutical Sciences, Cardiovascular, Immunosciences, Fibrosis, and Genetically-defined diseases at Bristol-Myers Squibb. In this role, he was responsible for the strategic and operational deliverables of regulatory, biostatistics, clinical pharmacology, and pharmacometrics for the development assets in these areas. Dr. Waclawski's experience spans a broad range of regulatory capabilities across multiple therapeutic areas and geographies, guiding successful FDA interactions and establishing and executing successful global regulatory strategies. From June 2014 to October 2016, he served as Vice President, Global Submissions and Regulatory Policy at Bristol-Myers Squibb. Dr. Waclawski earned a Ph.D. and M.S. in pharmaceutical sciences and a B.S. in pharmacy from Rutgers University.

Dr. Jacob Frenkel joined the Company in March 2020 as a director and Chairperson. Dr. Frenkel serves Chairman of the Board of Trustees of the Group of Thirty, which is a private, nonprofit, Consultative Group on International Economic and Monetary Affairs. Dr. Frenkel served as Chairman of JPMorgan Chase International from 2009 to 2020 and is currently serving as a Senior Advisor to JPMorgan Chase. From 2001 to 2011 he served as Chairman and CEO of the G-30, from 2004 to 2009 as Vice Chairman of American International Group, Inc., and from 2000 to 2004 as Chairman of Merrill Lynch International. Between 1991 and 2000 he served two terms as the Governor of the Bank of Israel. Dr. Frenkel serves as Chairman of the Board of Governors of Tel Aviv University, where he is also Chairman of the Frenkel-Zuckerman Institute for Global Economics. He holds a B.A. in economics and political science from the Hebrew University of Jerusalem, and an M.A. and Ph.D. in economics from the University of Chicago. We believe Dr. Frenkel possesses specific attributes that qualify her to serve on our Board, including his valuable leadership skills and his deep knowledge of the financial industry.

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 Vice-Chairperson of the Board and the Chair of the Governance, Nominating and Compensation Committee. Dr. Arbel serves as CEO of Neurochords, a biotechnology firm developing graphene- based scaffold for nerve reconstruction in acute spinal cord and peripheral nerve injury, a position she has held since August 2018. Prior to Neurochords, Dr. Arbel served as Executive Vice President, Research and Development at Savicell Diagnostic Ltd from July 2012 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 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.

Sankesh Abbhi joined the Company in March 2020 as a director. Since 2016, Mr. Abbhi has been with ArisGlobal, a leading provider of cloud-based, end-to-end, drug development technology solutions for over 250 of the world's leading life sciences companies, CROs and government health authorities, serving as the President and CEO since December 2017. Mr. Abbhi also advises Abbhi Capital, his wholly owned family office, in its corporate investments in life sciences, healthcare and technology companies. Prior to leading ArisGlobal and Abbhi Capital, Mr. Abbhi founded Synowledge, a knowledge process outsourcing company. Mr. Abbhi earned a BA in Economics from Columbia University. We believe Mr. Abbhi possesses specific attributes that qualify him to serve on our Board including his valuable leadership skills and his deep knowledge of financial matters.

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. We believe Dr. Polverino possesses specific attributes that qualify him to serve on our Board including his deep knowledge of the pharmaceutical industry.

Dr. June S. Almenoff joined the Company on February 26, 2017 as a director. Dr. Almenoff has served as the Chief Scientific Officer of RedHill Biopharma Ltd. since May 2019. Dr. 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 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. She was a Director of Tigenix NV (Nasdaq: TIG) from 2016-18, until its acquisition for ~$600M. Dr. Almenoff currently serves on the investment advisory board of the Harrington Discovery Institute, a venture philanthropy (since 2015), and Kurome Therapeutics, a venture-backed oncology company (since 2020). 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 55 publications. We believe 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.

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), financial markets and accounting (Dr. Frenkel, Mr. Taub, Mr. Abbhi), business consulting and development (Dr. Polverino. Mr. Abbhi, and Mr. Yablonka), media (Mr. Yablonka) and law (Mr. Taub and 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 Chairman (Dr. Frenkel), a chief executive officer (Drs. Arbel, Dr. Frenkel, Mr. Abbhi), executive officer (Drs. Almenoff and Polverino, Mr. Abbhi, 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 valuable leader with deep knowledge of the financial industry and capital markets (Dr. Frenkel, Mr. Abbhi). 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 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 Vice Chairperson 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 is a member of the Audit Committee.

On March 6, 2020, the Company entered into a Securities Purchase Agreement with Abbhi Investments, LLC pursuant to which the Company sold 1,250,000 shares of the Company's Common Stock in a registered direct offering, at a purchase price per share of $8.00 for a total purchase price of $10,000,000. In connection therewith, the Company also issued a warrant to purchase 250,000 shares of Common Stock at an exercise price of $15.00 per share, with an expiration date of the third anniversary of the date of issuance. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-225517) and related March 6, 2020 prospectus supplement. Pursuant to the Securities Purchase Agreement, Abbhi Investments, LLC was entitled to appoint Sankesh Abbhi to serve as a member of the Board at any time prior to April 30, 2020 by giving notice to the Company of such appointment, and Mr. Abbhi shall continue to serve for so long as Abbhi Investments, LLC remains the beneficial owner of Common Stock.

Uri Yablonka serves as the Company's EVP, Chief Business Officer, Director and Secretary 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. The Audit Committee currently consists of Mr. Taub (Chair), Dr. Arbel and Dr Almenoff, each of whom is independent within the meaning of The Nasdaq Marketplace Rules and Rule 10A-3 under the Exchange Act. Mr. Schor, who was not independent, served on the Audit Committee in accordance with Nasdaq Rule 5605(c)(2)(B) until November 13, 2019. Dr. Almenoff joined the Audit Committee November 14, 2019. The Board of Directors has determined that Dr. Arbel 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, 2020.

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*. 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, 2020.

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 2020, 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, 2020 all Reporting Persons complied with the applicable requirements of Section 16(a) of the Exchange Act other than late Form 4s filed by Dr. Irit Arbel, Dr. June Almenoff, Dr. Anthony Polverino, Uri Yablonka and Malcolm Taub on February 14, 2020 and ACC International Holdings on July 16, 2020, reporting an aggregate seven transactions late. There are no known failures to file a required Form 3, Form 4 or Form 5.

Code of Ethics

On May 27, 2005, our Board 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*. 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, 2020 and 2019 earned by Chief Executive Officer, President and Chief Medical 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 ($) (1) (2)	All Other Compensation ($)(3)	Total ($)
Chaim Lebovits (*), Chief Executive Officer (4)	2020	500,000	860,000 (5)	486,174 (7)	279,680	2,125,854
	2019	500,000	250,000 (6)	125,364 (8)	180,912	1,056,276
Ralph Kern, President & Chief Medical Officer (9)	2020	500,000	290,000 (10)	684,065 (12)	54,216	1,528,281
	2019	500,000	150,000 (11)	139,000 (13)	63,145	852,145
Anthony Paul Waclawski, EVP, Global Head	2020	87,500	—	950,331	33,957	1,071,788
of Regulatory (14)	2019	—	—	—	—	—

(*) 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 2019 and 2020 daily rates between the U.S. dollar and the NIS as published by the Bank of Israel, the central bank of Israel.

(1) The amounts shown in the "Option and Stock Awards" column represent the aggregate grant date fair value of awards computed in accordance with ASC 718, not the actual amounts paid to or realized by the Named Executive Officer during fiscal 2019 and fiscal 2020. ASC 718 fair value amount as of the grant date for stock options generally is spread over the number of months of service required for the grant to vest.

(2) The fair value of each stock option award is estimated as of the date of grant using the Black-Scholes valuation model. Additional information regarding the assumptions used to estimate the fair value of all stock option awards is included in Note 11 to Consolidated Financial Statements.

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

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

(5) During 2020, the Company paid Mr. Lebovits a discretionary cash bonus payment of $860,000 in recognition of his contributions to the Company's performance in fiscal year 2020.

(6) During 2019, 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 2019.

(7) On July 26, 2020 Mr. Lebovits received a grant of 31,185 shares of restricted Common Stock.

(8) On July 26, 2019 Mr. Lebovits received a grant of 31,185 shares of restricted Common Stock.

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

(10) During 2020, the Company paid Dr. Kern a discretionary cash bonus payment of $290,000 in recognition of his contributions to the Company's performance in fiscal year 2020.

(11) In August 2019, the Company paid Dr. Kern a discretionary cash bonus payment of $150,000 in recognition of his contributions to the Company's performance in fiscal year 2019.

(12) On March 6, 2020 Dr. Kern received a grant of 35,885 shares of restricted Common Stock.

(13) On March 6, 2019 Dr. Kern received a grant of 35,885 shares of restricted Common Stock.

(14) Mr. Waclawski's employment with the Company began on September 8, 2020.

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 on March 7, 2016, July 26, 2017 and June 23, 2020 (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 will receive an annual cash bonus equal to 50% of his base salary.

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 to purchase up to 41,580 shares of Common Stock, with an exercise price per share of $4.81. The option was fully-vested and exercisable until the 2nd anniversary of the date of grant, when it expired unexercised.

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 is also 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 is evaluated through a performance management framework and a bonus range based on the target bonus. Dr. Kern also receives 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 vests as to twenty-five percent (25%) of the award on each of the first, second, third and fourth anniversary of the date of grant, provided Dr. Kern remains continuously employed by the Company from the date of grant through each applicable vesting date. Each equity grant is 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 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 until the 2nd anniversary of the date of grant, when it expired unexercised.

Pursuant to the Agreement, on March 9, 2020, Dr. Kern also received an option under the 2014 U.S. Plan to purchase up to 80,000 shares of Common Stock with an exercise price per share of $7.33. The option was fully vested and exercisable This option will vest and become exercisable as to 25% of the number of Shares on each of the first four anniversaries of the grant date until fully vested and exercisable on the fourth anniversary of the grant date.

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.

David Setboun

Dr. David Setboun, PharmD., MBA, the Company's EVP and Chief Operating Officer is party to a April 1, 2020 employment agreement with the Company, pursuant to which Dr. Setboun receives an annual base compensation of $400,000 and is eligible to receive an annual cash bonus equal to 40% of his base salary, subject to satisfaction of pre-established performance goals to be mutually agreed upon by the Chief Executive Officer and the Board based on an assessment of Dr. Setboun's performance each year. Performance is evaluated through a performance management framework and a bonus range based on the target bonus. Pursuant to the agreement, Dr. Setboun received a one-time grant under the 2014 Stock Incentive Plan of 50,000 shares of restricted common stock of the Company, which shall vest as to 100% of the award on the one-year anniversary of the grant date, provided Dr. Setboun remains continuously employed by

the Company from the date of grant through the vesting date. In the event of Dr. Setboun's termination of employment is prior to the vesting date, the restricted stock grant shall automatically be immediately forfeited to the Company, without the payment of any consideration to Dr. Setboun.

Pursuant to the agreement, Dr. Setboun is entitled to receive a one-time sign-on and relocation bonus of $40,000. In addition, commencing with the first anniversary of Dr. Setboun's employment, he is eligible to receive an annual grant of an option to purchase 20,000 shares of Common Stock under the Company's 2014 Stock Incentive Plan, at an exercise price per share equal to the closing price of Company's stock price on day of the grant. Vesting and exercisability of the options will be subject to pre-established performance goals as determined by the Board (or committee thereof), provided that he remains continuously employed by the Company from the date of grant through each applicable vesting date.

Preetam Shah

On September 5, 2019, the Company and Preetam Shah, PhD, MBA, the Company's Executive Vice President, Chief Financial Officer and Treasurer, entered into an employment agreement, pursuant to which Dr. Shah receives an annual salary of $350,000 and is eligible to receive an annual cash bonus equal to 40% of his base salary, subject to the satisfaction of performance goals to be established each year. Dr. Shah also receives other benefits that are generally made available to the Company's employees. Pursuant to the agreement, Dr. Shah received on September 6, 2019, a one-time grant of stock options under the Company's 2014 Stock Incentive Plan (i) to purchase up to 100,000 shares of Common Stock, at an exercise price equal to $3.96 per share, and (ii) to purchase up to 100,000 shares of Common Stock at an exercise price per share equal to $6.00 per share. Each option shall vest and become exercisable as follows: 25% of the shares underlying the option shall vest and become exercisable on the first anniversary of the date of grant, and the remaining shares underlying the option shall vest and become exercisable in equal quarterly installments thereafter, until fully vested and exercisable on the fourth anniversary of the date of grant, provided that Dr. Shah remains continuously employed by the Company from the date of grant through each applicable vesting date. Each option shall have a ten (10) year term. Any unvested shares underlying the options as of the date of Dr. Shah's employment termination shall automatically terminate.

Pursuant to the agreement, Dr. Shah received on September 6, 2019, a one-time grant under the 2014 Stock Incentive Plan of 25,000 shares of restricted common stock of the Company, which shall vest as to 100% of the award on the one-year anniversary of the grant date, provided Dr. Shah remains continuously employed by the Company from the date of grant through the vesting date. In the event of Dr. Shah's termination of employment prior to the one-year anniversary of the grant date, the restricted stock grant shall automatically be immediately forfeited to the Company, without the payment of any consideration to Dr. Shah.

The agreement contains termination provisions, pursuant to which if the Company terminates the agreement or Dr. Shah's employment without Cause (as defined in the agreement) or if Dr. Shah terminates the agreement or his employment thereunder with Good Reason (as defined in the agreement), the Company shall: (i) pay Dr. Shah, as severance pay, a lump sum equal to three (3) months of Base Salary; (ii) pay Dr. Shah any bonus compensation that Dr. Shah would be entitled to receive during the period of employment in that fiscal year; (iii) immediately vest such number of equity or equity based awards that would have vested during the three (3) months following the date of termination of employment; and (iv) continue to provide Dr. Shah's health insurance benefits during the three (3) months following the date of termination of employment, unless otherwise provided by a subsequent employer. The foregoing severance payments are conditional upon Dr. Shah executing a waiver and release in favor of the Company in a form reasonably acceptable to the Company.

Uri Yablonka

Uri Yablonka, the Company's Executive Vice President, Chief Business Officer, Director and Secretary, 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). This agreement was further amended on June 23, 2020 under which Uri Yablonka is paid a monthly salary of 53,334 NIS (approximately $15,538 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. Mr. Yablonka was granted 5,543 shares of Common Stock under the 2014 Global Plan on July 13, 2017. In addition, Mr. Yablonka was granted 10,000 shares on Common Stock under the 2014 Global Plan on June 23, 2020.

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. He ceased serving as a member of the Board on November 29, 2018.

Stacy Lindborg

Dr. Stacy Lindborg, PhD, the Company's EVP and Global Head of Clinical Research is party to a May 26, 2020 employment agreement with the Company, pursuant to which Dr. Lindborg receives an annual base compensation of $375,000 and is eligible to receive an annual cash bonus equal to 35% of her base salary, subject to satisfaction of pre-established performance goals. Pursuant to the agreement, she received on June 1 2020, a one-time grant under the 2014 Stock Incentive Plan of 25,000 shares of restricted common stock of the Company, which shall vest as to 100% of the award on December 31, 2020, provided Dr. Lindborg remains continuously employed by the Company from the date of grant through the vesting date. In the event of Dr. Lindborg's termination of employment is prior to the vesting date, the restricted stock grant shall automatically be immediately forfeited to the Company, without the payment of any consideration to Dr. Lindborg.

Pursuant to the agreement, Dr. Lindborg also received a one-time grant of an option to purchase 100,000 shares of Common Stock under the Company's 2014 Stock Incentive Plan, at an exercise price of $7.67 per share. 50% of the grant shall vest and become exercisable on February 28, 2021 and the remaining 50,000 shares underlying the Option shall vest and become exercisable in equal quarterly installments thereafter until fully vested and exercisable on the second anniversary of the First Vesting Date, provided that she remains continuously employed by the Company from the date of grant through each applicable vesting date. Each option shall have a ten (10)

year term. Any unvested shares underlying the options as of the date of Dr. Lindborg's employment termination shall automatically terminate.

Anthony Waclawski

Anthony Waclawski, the Company's Executive Vice President, Global Head of Regulatory Affairs, is party to a September 2, 2020 offer letter with the Company, pursuant to which Dr. Waclawski receives an annual base compensation of $300,000 and is eligible to receive an annual cash bonus equal to 30% of his base salary, subject to satisfaction of pre-established performance goals to be mutually agreed upon by the Chief Executive Officer and the Board based on an assessment of Dr. Waclawski's performance each year. Performance is evaluated through a performance management framework and a bonus range based on the target bonus. On September 8, 2020 he also received a one-time grant of an option to purchase 80,000 shares of Common Stock under the Company's 2014 Stock Incentive Plan, at an exercise price of $12.58 per share. 100% of the grant shall vest and become exercisable on the first anniversary of the date of the grant, provided Dr. Waclawski remains continuously employed by the Company from the date of grant through the vesting date. The grant is subject to accelerated vesting upon a Change of Control, as defined in the agreement, and has a 10-year term. The grant contains termination provisions, as set forth in the offer letter.

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, 2020. 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, 2020

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)(1)
Chaim Lebovits	369,619	—	2.45	9/28/2025	7,796 (2)	35,317
					15,593 (3)	70,634
					23,389 (4)	105,951
					31,185 (5)	141,268
Ralph Kern	—	80,000	7.33	03/09/2030	8,971 (6)	40,639
					17,943 (7)	81,282
					26,914 (8)	121,920
					35,885 (9)	162,559
Anthony Paul Waclawski	—	80,000	12.58	09/07/2030	35,000 (10)	158,550

(1) Based on the fair market value of our Common Stock on December 31, 2020 ($4.53 per share).

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

(3) Restricted stock award vests 25% on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (July 26, 2018), provided that Chaim Lebovits remains continuously employed by the Company from the date of grant through each applicable vesting date.

(4) Restricted stock award vests 25% on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (July 26, 2019), provided that Chaim Lebovits remains continuously employed by the Company from the date of grant through each applicable vesting date.

(5) Restricted stock award vests 25% on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (July 26, 2020), provided that Chaim Lebovits remains continuously employed by the Company from the date of grant through each applicable vesting date.

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

(7) Restricted stock award vests 25% on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (March 6, 2018), provided that Ralph Kern remains continuously employed by the Company from the date of grant through each applicable vesting date.

(8) Restricted stock award vests 25% on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (March 6, 2019), provided that Ralph Kern remains continuously employed by the Company from the date of grant through each applicable vesting date.

(9) Restricted stock award vests 25% on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (March 6, 2020), provided that Ralph Kern remains continuously employed by the Company from the date of grant through each applicable vesting date.

(10) Restricted stock award shall vest as to 100% of the award on July 1, 2021, provide Anthony Waclawski remains continuously employed by the Company from the date of grant through the vesting date.

Stock Incentive Plans

During the fiscal year ended December 31, 2020, 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 5,600,000 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, 2020 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 2020

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($) (1)(2)	Total ($)
Dr. Jacob Frenkel	—	—	200,353 (9)	200,353
Dr. Irit Arbel	—	—	— (3)	—
Dr. June S. Almenoff	30,000 (4)	—		30,000
Dr. Anthony Polverino	—	12,499 (5)	—	12,499
Mr. Chen Schor	3,125 (6)	—	—	3,125
Mr. Malcolm Taub	—	—	—	—
Uri Yablonka	—	—	— (7)	—
Sankesh Abbhi	—	21,655 (8)	—	21,655

(1) The amounts shown in the "Stock Awards" and "Option Awards" columns represent the aggregate grant date fair value of awards computed in accordance with ASC 718, not the actual amounts paid to or realized by the directors during fiscal 2020.

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

(3) At December 31, 2020, Dr. Arbel had options (vested and unvested) to purchase 220,554 shares of Common Stock.

(4) Represents the amount paid to Dr. Almenoff for her services as a director.

(5) At December 31, 2020, Dr. Polverino had 3,071 shares of (vested and unvested) restricted Common Stock.

(6) Represents the amount paid to Mr. Schor for his services as a director.

(7) At December 31, 2020, Mr. Yablonka had options (vested and unvested) to purchase 113,331 shares of Common Stock.

(8) At December 31, 2020, Mr. Sankesh Abbhi had 4,657 shares of (vested and unvested) restricted Common Stock.

(9) At December 31, 2020, Dr. Frenkel had options (vested and unvested) to purchase 50,000 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 serves as a member of the Audit Committee.

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 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 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 served as a member of the audit committee from November 2017 to November 2019.

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 December 12, 2019, 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; Dr. Almenoff received 2,000 shares of restricted stock for her 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.

On April 7, 2020, the following grants were made under the Director Compensation Plan to the eligible directors: Mr. Sankesh Abbhi received 4,657 shares of restricted stock for his service as a director; Dr Jacob Frenkel received a stock option to purchase 50,0000 shares of Common Stock for his service as Chairperson of the Board.

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 December 31, 2020 with respect to the beneficial ownership of our Common Stock by the following: (i) each of our current directors; (ii) the Named Executive Officers; (iii) all of the current executive officers and directors as a group; and (iv) each person known by the Company to own beneficially more than five percent (5%) of the outstanding shares of our Common Stock.

For purposes of the following table, beneficial ownership is determined in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as otherwise noted in the footnotes to the table, we believe that each person or entity named in the table has sole voting and investment power with respect to all shares of our Common Stock shown as beneficially owned by that person or entity (or shares such power with his or her spouse). Under the SEC's rules, shares of our Common Stock issuable under options that are exercisable on or within 60 days after February 14, 2020 ("Presently Exercisable Options") or under warrants that are exercisable on or within 60 days after February 14, 2020 ("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, 28th 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 35,159,977 shares of Common Stock outstanding as of December 31, 2020, 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 (Includes Common Stock, Presently Exercisable Options and Presently Exercisable Warrants) # of Shares	% of Class
Directors and Named Executive Officers		
Chaim Lebovits(1)	4,511,872 (1)	12.0 %
Ralph Kern	151,540	*
Preetam Shah	74,100	*
Uri Yablonka	130,874 (2)	*
June Almenoff	9,175 (3)	*
Irit Arbel	376,387 (4)	1.06 %
Sankesh Abbhi	2,419,187 (5)	6.80 %
Anthony Polverino	15,862	*
Malcolm Taub	53,332	*
Jacob Frenkel	89,995 (6)	*
David Setboun	55,000 (7)	*
Stacy Lindborg	45,000 (8)	*
Anthony Wacalawski	35,000 (9)	*
All current directors and executive officers as a group (13 persons)	**7,967,324 (10)**	**21.8 %**
5% Shareholders (other than listed above)		
N/A (see FN1)		

(1) Includes (i) 1,933,794 shares of Common Stock owned by ACCBT Corp. acquired through an investment into the Company and (ii) 2,016,666 shares of Common Stock issuable to ACCBT Corp. upon the exercise of Presently Exercisable Warrants acquired through an investment into the Company, (iii) 67,053 shares of Common Stock owned by ACC International Holdings Ltd., (iv) 369,619 shares of Common Stock issuable to Chaim Lebovits upon the exercise of Presently Exercisable Options and (v) 124,740 shares of restricted stock. 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 113,331 of shares of Common Stock issuable upon the exercise of Presently Exercisable Options.

(3) Consists of 7,175 shares owned by Meadowlark Management LLC and 2,000 shares of restricted stock. Dr. Almenoff disclaims beneficial ownership of the shares owned by Meadowlark Management LLC except to the extent of any pecuniary interest therein.

(4) Includes 220,554 shares of Common Stock issuable upon the exercise of Presently Exercisable Options. Dr. Arbel's address is 6 Hadishon Street, Jerusalem, Israel.

(5) Mr. Abbhi joined the board of directors of the Company on March 31, 2020. Includes (i) 2,164,530 shares of Common Stock owned by Abbhi Investments, LLC, (ii) 250,000 shares of Common Stock issuable to Abbhi Investments, LLC upon the exercise of Presently Exercisable Warrants and (iii) 4,657 shares of restricted stock. Sankesh Abbhi is the manager of Abbhi Investments, LLC and maintains sole voting and investment power with respect to the Common Stock and Presently Exercisable Warrants held by Abbhi Investments, LLC. The address of Abbhi Investments, LLC is 2821 S Bayshore Drive, Miami FL 33133.

(6) Dr. Jacob Frenkel joined the board of directors of the Company on March 31, 2020. Includes 56,667 shares of Common Stock owned prior to joining the board and 33,328 issuable upon the exercise of Presently Exercisable Options.

(7) Dr. Setboun's employment with the Company commenced on April 7, 2020.

(8) Dr. Linborg's employment with the Company commenced on June 1, 2020.

(9) Dr. Waclawski's employment with the Company commenced on September 8, 2020.

(10) Includes (i) 2,266,666 shares of Common Stock issuable upon the exercise of Presently Exercisable Warrants and (ii) 899,332 shares of Common Stock issuable upon the exercise of Presently Exercisable Options.

* Less than 1%.

Equity Compensation Plan Information

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2020:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise 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	1,754,894 (2)	$ 4.8869 (3)	3,018,413 (3)
Equity compensation plans not approved by security holders	—	—	—
Total	1,754,894	$ 4.8869	3,018,413 (1)

(1) Includes 1,754,894 shares of common stock issuable upon the exercise of outstanding options only.

(2) Since restricted stock units do not have any exercise price, such units are not included in the weighted average exercise price calculation.

(3) A total of 4,773,307 shares of our Common Stock are reserved for issuance in aggregate under the Equity Plans and the Prior Plans. Any awards granted under either the 2014 Global Plan or the 2014 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 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. Frenkel, Dr. Arbel, Dr. Almenoff, Dr. Polverino, Mr. Abbhi 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. Yablonka is not considered an "independent director."

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

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Independent Registered Public Accounting Firm

Principal Accountant Fees and Services

The following table presents fees for professional audit services rendered by Brightman Almagor Zohar & Co., a Firm in the Deloitte Global Network ("Deloitte") for the audit of our financial statements for the fiscal years ended December 31, 2020 and 2019 and fees billed for other services rendered by Deloitte during those periods.

	December 31,	
	2019	2020
Audit Fees (1)	$ 55,000	$ 75,000
Audit-Related Fees (2)	$ —	$ 30,000
Tax Fees (3)	$ 11,000	$ 11,000
All Other Fees	$ —	$ —
Total Fees	$ 66,000	$ 116,000

(1) Audit fees are comprised of fees for professional services performed by Deloitte for the audit of our annual 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) Audit-related fees are comprised of fees for professional services performed by Deloitte in connection with comfort letters and consents.

(3) Tax fees are comprised of tax compliance services to the Company performed by Deloitte.

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.

		Filed (or	Incorporated by Reference Herein		
Exhibit Number	**Description**	**Furnished) with this Form 10-K**	**Form**	**Exhibit & File No.**	**Date Filed**
2.1	Agreement and Plan of Merger, dated as of November 28, 2006, by and between Brainstorm Cell Therapeutics Inc., a Washington corporation, and Brainstorm Cell Therapeutics Inc., a Delaware corporation.		Definitive Schedule 14A	Appendix A File No. 333-61610	November 20, 2006
3.1	Certificate of Incorporation of Brainstorm Cell Therapeutics Inc.		Definitive Schedule 14A	Appendix B File No. 333-61610	November 20, 2006
3.2	Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc. dated September 15, 2014.		Form 8-K	Exhibit 3.1 File No. 000-54365	September 16, 2014
3.3	Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc. dated August 31, 2015.		Form 8-K	Exhibit 3.1 File No. 001-366641	September 4, 2015
3.4	ByLaws of Brainstorm Cell Therapeutics Inc.		Definitive Schedule 14A	Appendix C File No. 333-61610	November 20, 2006
3.5	Amendment No. 1 to ByLaws of Brainstorm Cell Therapeutics Inc., dated as of March 21, 2007.		Form 8-K	Exhibit 3.1 File No. 333-61610	March 27, 2007
4.1	Specimen Certificate of Common Stock of Brainstorm Cell Therapeutics Inc.		Form 8-K	Exhibit 4.1 File	September 16, 2014

				No. 000-54365	
10.1	Research and License Agreement, dated as of July 8, 2004, by and between the Company and Ramot at Tel Aviv University Ltd.		Form 8-K	Exhibit 10.1 File No. 333-61610	July 16, 2004
10.2	Research and License Agreement, dated as of March 30, 2006, by and between the Company and Ramot at Tel Aviv University Ltd.		Form 8-K	Exhibit 10.1 File No. 333-61610	April 4, 2006
10.3	Amendment Agreement, dated as of May 23, 2006, to Research and License Agreement, by and between the Company and Ramot at Tel Aviv University Ltd.		Form 8-K/A	Exhibit 10.1 File No. 333-61610	May 23, 2006
10.4	Amendment Agreement, dated as of March 31, 2006, among the Company, Ramot at Tel Aviv University Ltd. and certain warrantholders.		Form 8-K	Exhibit 10.2 File No. 333-61610	April 4, 2006
10.5	Second Amended and Restated Research and License Agreement, dated July 26, 2007, by and between the Company and Ramot at Tel Aviv University Ltd.		Form 10-QSB	Exhibit 10.4 File No. 333-61610	August 20, 2007
10.6	Second Amended and Restated Registration Rights Agreement, dated August 1, 2007, by and between the Company and Ramot at Tel Aviv University Ltd.		Form 10-QSB	Exhibit 10.5 File No. 333-61610	August 20, 2007
10.7	Waiver and Release, dated August 1, 2007, executed by Ramot at Tel Aviv University Ltd. in favor of the Company.		Form 10-QSB	Exhibit 10.6 File No. 333-61610	August 20, 2007
10.8	Letter Agreement, dated December 24, 2009, by and between the Company and Ramot at Tel Aviv University Ltd.		Form 8-K	Exhibit 10.1 File No. 333-61610	December 31, 2009
10.9	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.		Form 8-K	Exhibit 10.2 File No. 333-61610	December 31, 2009
10.10	Assignment Agreement, dated December 20, 2011, by and between the Company and Brainstorm Cell Therapeutics Ltd.		Form S-1	Exhibit 10.12 File No. 333-179331	February 3, 2012

10.11	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.		Form 10-K	Exhibit 10.11 File No. 001-36641	March 9, 2016
10.12	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.		Form 10-K	Exhibit 10.12 File No. 001-36641	March 9, 2016
10.13	Consulting Agreement, dated as of April 30, 2014, by and between Brainstorm Cell Therapeutics Ltd. and Dr. Daniel Offen.		Form S-1	Exhibit 10.15 File No. 333-179331	June 29, 2012
10.14*	Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.		Form 8-K	Exhibit 10.1 File No. 000-54365	August 15, 2014
10.15*	Amendment No. 1 to the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.		Schedule 14A	Appendix A File No. 001-36641	May 11, 2016
10.16*	Amendment No. 2 to the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.		Form 8-K	Exhibit 10.1 File No. 001-36641	November 30, 2018
10.17*	Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.		Form 8-K	Exhibit 10.2 File No. 000-54365	August 15, 2014
10.18*	Amendment No. 1 to the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.		Schedule 14A	Appendix B File No. 001-36641	May 11, 2016
10.19*	Amendment No. 2 to the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.		8-K	Exhibit 10.2 File No. 001-36641	November 30, 2018
10.20*	Form of Incentive Stock Option Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.		Form 8-K	Exhibit 10.1 File No. 001-36641	November 4, 2014
10.21*	Form of Nonstatutory Stock Option Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.		Form 8-K	Exhibit 10.2 File No. 001-36641	November 4, 2014

10.22*	Form of Restricted Stock Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.		Form 8-K	Exhibit 10.3 File No. 001-36641	November 4, 2014
10.23*	Form of Option Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.		Form 8-K	Exhibit 10.4 File No. 001-36641	November 4, 2014
10.24	Subscription Agreement, dated July 2, 2007, by and between the Company and ACCBT Corp.		Form 8-K	Exhibit 10.1 File No. 333-61610	July 5, 2007
10.25	Amendment to Subscription Agreement, dated as of July 31, 2009, by and between the Company and ACCBT Corp.		Form 8-K	Exhibit 10.1 File No. 333-61610	August 24, 2009
10.26	Form of Common Stock Purchase Warrant issued by the Company to ACCBT Corp.		Form 8-K	Exhibit 10.2 File No. 333-61610	July 5, 2007
10.27	Form of Registration Rights Agreement by and between the Company and ACCBT Corp.		Form 8-K	Exhibit 10.3 File No. 333-61610	July 5, 2007
10.28	Form of Security Holders Agreement, by and between ACCBT Corp. and certain security holders of the Company.		Form 8-K	Exhibit 10.4 File No. 333-61610	July 5, 2007
10.29	Warrant Amendment Agreement, dated as of May 10, 2012, by and between Brainstorm Cell Therapeutics Inc. and ACCBT Corp.		Form 10-Q	Exhibit 10.1 File No. 000-54365	May 11, 2012
10.30	Amendment of Warrants dated May 19, 2014 by and among Brainstorm Cell Therapeutics Inc., ACCBT Corp. and ACC International Holdings Ltd.		Form 10-Q	Exhibit 10.4 File No. 000-54365	August 12, 2014
10.31	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.		Form 8-K	Exhibit 10.1 File No. 001-36641	November 3, 2017
10.32	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.		Form 10-Q	Exhibit 10.1 File No. 000-54365	August 15, 2011

10.33	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.		Form 10-Q	Exhibit 10.2 File No. 000-54365	August 15, 2011
10.34*	Amended and Restated Executive Director Agreement, dated November 11, 2011, by and between the Company and Chen Schor.		Form 8-K/A	Exhibit 10.1 File No. 333-61610	November 16, 2011
10.35*	Employment Agreement dated June 6, 2014 between Brainstorm Cell Therapeutics Ltd. and Uri Yablonka.		Form 8-K	Exhibit 10.1 File No. 000-54365	June 9, 2014
10.36*	Restricted Stock Award Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan, regarding July 26, 2017 grant to Chaim Lebovits.		Form 10-Q	Exhibit 10.2 File No. 001-36641	October 17, 2017
10.37	Form of Securities Purchase Agreement.		Form 8-K	Exhibit 10.1 File No. 000-54365	June 13, 2014
10.38	Form of Warrant.		Form 8-K	Exhibit 10.2 File No. 000-54365	June 13, 2014
10.39	Form of Registration Rights Agreement.		Form 8-K	Exhibit 10.3 File No. 000-54365	June 13, 2014
10.40	Form of Warrant.		Form 8-K	Exhibit 4.1 File No. 001-36641	January 8, 2015
10.41	Warrant Exercise Agreement, dated as of January 8, 2015.		Form 8-K	Exhibit 10.2 File No. 001-36641	January 8, 2015
10.42	Form of Warrant.		Form 8-K	Exhibit 4.1 File No. 001-36641	June 7, 2018
10.43	Warrant Exercise Agreement.		Form 8-K	Exhibit 10.1 File	June 7, 2018

				No. 001-36641	
10.44	Leak-Out Agreement.		Form 8-K	Exhibit 10.2 File No. 001-36641	June 7, 2018
10.45	Share Cap Agreement.		Form 10-Q	Exhibit 10.4 File No. 001-36641	July 23, 2018
10.46*	Employment Agreement dated September 28, 2015 between Brainstorm Cell Therapeutics Inc. and Chaim Lebovits.		Form 8-K	Exhibit 10.1 File No. 001-36641	September 28, 2015
10.47*	First Amendment to Employment Agreement dated March 7, 2016 between Brainstorm Cell Therapeutics Inc. and Chaim Lebovits.		Form 10-K	Exhibit 10.53 File No. 001-36641	March 9, 2016
10.48*	Second Amendment to Employment Agreement dated July 26, 2017 between the Company and Chaim Lebovits.		Form 10-Q	Exhibit 10.3 File No. 001-36641	October 17, 2017
10.49*	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.		Form 8-K	Exhibit 10.1 File No. 001-36641	March 6, 2017
10.50*	Employment Agreement by and between Brainstorm Cell Therapeutics Ltd. and Eyal Rubin, dated October 31, 2017.		Form 8-K	Exhibit 10.2 File No. 001-36641	November 3, 2017
10.51*	Restricted Stock Award Agreement under the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan, regarding November 20, 2017 grant to Eyal Rubin.		Form 10-K	Exhibit 10.45 File No. 001-36641	March 8, 2018
10.52*	Employment Agreement by and between Brainstorm Cell Therapeutics Inc. and Arturo Araya effective August 28, 2018.		Form 10-K	Exhibit 10.52 File No. 001-36641	March 29, 2019
10.53*	Brainstorm Cell Therapeutics Inc. Second Amended and Restated Director Compensation Plan.		Form 8-K	Exhibit 10.1 File No. 001-36641	July 10, 2014

10.54*	Brainstorm Cell Therapeutics Inc. First Amendment to the Second Amended and Restated Director Compensation Plan.		Form 10-Q	Exhibit 10.2 File No. 001-36641	May 14, 2015
10.55*	Brainstorm Cell Therapeutics Inc. Second Amendment to the Second Amended and Restated Director Compensation Plan dated February 26, 2017.		Form 10-K	Exhibit 10.54 File No. 001-36641	March 29, 2017
10.56*	Brainstorm Cell Therapeutics Inc. Third Amendment to the Second Amended and Restated Director Compensation Plan.		Form 10-Q	Exhibit 10.1 File No. 001-36641	October 17, 2017
10.57	Notice of Award - CLIN2: Partnering Opportunity for Clinical Trial Stage Projects California Institute for Regenerative Medicine, August 25, 2017.		Form 10-K	Exhibit 10.50 File No. 001-36641	March 8, 2018
10.58	Distribution Agreement, dated June 11, 2019, by and between Brainstorm Cell Therapeutics Inc. and Raymond James & Associates, Inc.		Form 8-K	Exhibit 1.1	June 11, 2019
10.59	Form of Warrant		Form 8-K	Exhibit 4.1	August 2, 2019
10.60	Warrant Exercise Agreement		Form 8-K	Exhibit 10.1	August 2, 2019
10.61*	Offer letter, dated September 5, 2019, by and between Brainstorm Cell Therapeutics Inc. and Preetam Shah		Form 10-Q	Exhibit 10.3	November 14, 2019
10.62*	Offer letter, dated April 1, 2020, by and between Brainstorm Cell Therapeutics Inc. and David Setboun		Form 8-K	Exhibit 10.1	April 3, 2020
10.63*‡	Offer letter, dated May 26, 2020, by and between Brainstorm Cell Therapeutics Inc. and Stacey Lindborg				
10.64*	Third Amendment to Employment Agreement dated June 23, 2020 between the Company and Chaim Lebovits.		Form 10-Q	Exhibit 10.1	August 5, 2020
10.65*	Amendment to Employment Agreement dated June 23, 2020 between the Company and Uri Yablonka.		Form 10-Q	Exhibit 10.2	August 5, 2020
10.66*	Offer letter, dated September 3, 2020, by and between Brainstorm Cell Therapeutics Inc. and Anthony Waclawski		Form 8-K	Exhibit 10.1	September 3, 2020

10.67*	Amended and Restated Distribution Agreement, dated September 25, 2020, by and among Brainstorm Cell Therapeutics, Inc., SVB Leerink LLC and Raymond James & Associates, Inc.		Form 8-K	Exhibit 1.1	September 25, 2020
21	Subsidiaries of the Company.	‡			
23.1	Consent of Brightman Almagor Zohar & Co., a Firm in the Deloitte Global Network.	‡			
31.1	Certification by the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	‡			
31.2	Certification by the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	‡			
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	‡‡			
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	‡‡			
101.SCH	Inline XBRL Taxonomy Extension Document.	‡			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase.	‡			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	‡			
101.PRE	Inline XBRL Taxonomy Extension Presentation Label Linkbase Document.	‡			
101 DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	‡			
104	Cover Page Interactive Data File (formatted in inline XBRL with applicable taxonomy extension information contained in Exhibits 101)				
*	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: February 4, 2021

By: /s/ Chaim Lebovits
Name: Chaim Lebovits
Title: Chief Executive Officer

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

Signature	***Title***	***Date***
/s/ Chaim Lebovits *Chaim Lebovits*	*Chief Executive Officer* *(Principal Executive Officer)*	*February 4, 2021*
/s/ Preetam Shah *Preetam Shah*	*Chief Financial Officer and Treasurer* *(Principal Financial and Accounting Officer)*	*February 4, 2021*
/s/ Irit Arbel *Irit Arbel*	*Director*	*February 4, 2021*
/s/ June S. Almenoff *June S. Almenoff*	*Director*	*February 4, 2021*
/s/ Jacob Frenkel *Jacob Frenkel*	*Director*	*February 4*, 2021
/s/ Anthony Polverino *Anthony Polverino*	*Director*	*February 4, 2021*
/s/ Malcolm Taub *Malcolm Taub*	*Director*	*February 4, 2021*
/s/ *Uri Yablonka* *Uri Yablonka*	*Director*	*February 4, 2021*
/s/ Sankesh Abbhi *Sankesh Abbhi*	*Director*	*February 4, 2021*

May 26, 2020

Stacy Lindborg

Re: Offer of Employment

Dear Dr. Lindborg:

I am pleased to confirm an offer for you, by way of this offer letter (this "**Letter**"), to join BRAINSTORM CELL THERAPEUTICS INC., a Delaware corporation (the "**Company**"), on a full-time basis, in the position of Executive Vice President, Head of Global Clinical Research. Your employment commencement date shall be June 1, 2020 (the "**Effective Date**") and shall continue until terminated pursuant to the terms hereof (collectively, the "**Employment Period**").

The terms of your employment and compensation will consist of the following:

(i) Hours Commitment: You will be expected to work those days and hours to be mutually agreed upon by the parties (other than weeks that include Company recognized holidays or weeks during which you take vacation days). You may be required to travel in connection with your position. Your office shall be located at the Company's office suite in New Jersey or Manhattan. Additionally, you agree to travel to the Company's other offices and to other destinations in connection with the provision of services by you as the Company's, including as and when you are directed to do so, from time to time, by your direct supervisor.

(ii) Title: Executive Vice President, Head of Global Clinical Research.

(iii) Nature of Services: You will directly report to our Chief Executive Officer, and your primary responsibilities will consist of those listed on **Exhibit A** (collectively, the "**Executive Duties**") or as may otherwise be directed from time to time by your manager.

(iv) Compensation*:

a. In consideration of the performance of the Executive Duties, you shall be entitled to receive an annual base compensation of Three Hundred Seventy-Five Thousand U.S. Dollars (USD$375,000.00) (the "**Base Salary**"), payable in installments in accordance with the general payroll practices of the Company in effect at the time such payment is made, during the Employment Period (*e.g.*, timing of payments and standard employee deductions, such as income and employment tax withholdings). No additional compensation shall be payable to you by reason of the number of hours worked or any hours worked on Saturdays, Sundays or holidays, by reason of special responsibilities assumed (whether on behalf of the Company or any of its subsidiaries or affiliates), special projects completed, or otherwise.

b. You shall be eligible to receive an annual cash bonus during the Employment Period

equal to 35% of the Base Salary, subject to your satisfaction of pre-established performance goals to be mutually agreed upon by you and the Board of Directors (the "Board") of the Company (or a committee thereof) each year during the Employment Period. Performance shall be evaluated through a performance management framework and a bonus range based on the target bonus. Your bonus for 2020 fiscal year shall be pro-rated based on the number of days you worked in fiscal year 2020.

c. Upon the Effective Date you shall receive a one-time grant under the 2014 Stock Incentive Plan or 2014 Global Share Option Plan, as applicable, or successor plan thereto (collectively, the "Plan") of 25,000 shares of restricted common stock of the Company (the "Restricted Stock Grant"). The Restricted Stock Grant shall vest in full on the 31st of December 2020, provided that you remain continuously employed by the Company. The Restricted Stock Grant shall be contingent upon your execution of one or more restricted stock agreements in such form and substance as may reasonably be determined by the Company. In the event of your termination of employment for any reason prior to December 31, 2020, the Restricted Stock Grant shall automatically be immediately forfeited to the Company, without the payment of any consideration to you.

d. Upon the Effective Date you shall receive a one-time grant of a stock option under the Plan to purchase up to 100,000 shares of Company common stock, at an exercise price per share equal to the fair market value on the date of grant, as determined based on the closing price per share of Company common during normal trading hours on the Effective Date, according to Nasdaq (the "Option"). The Option shall vest and become exercisable as follows: 50,000 of the shares underlying the Option shall vest and become exercisable on February 28, 2021 ("First Vesting Date"), and the remaining 50,000 shares underlying the Option shall vest and become exercisable in equal quarterly installments thereafter until fully vested and exercisable on the second anniversary of the First Vesting Date, provided that you remain continuously employed by the Company from the date of grant through each applicable vesting dates. The Option shall have a ten (10) year term. Any unvested shares underlying the Option as of the date of your employment termination shall automatically terminate. Unless otherwise provided in the Plan, you shall have 90 days after termination of employment with the Company to exercise the Option to the extent then vested. The grant of the Option is contingent upon the prior approval of the Board or the Compensation Committee of the Board and your execution of one or more stock option agreements in such form and substance as may reasonably be determined by the Company, which the parties will endeavor to execute within ten (10) days from the Effective Date. Immediately prior to a Change of Control (as defined below) during the Employment Period, any then unvested shares underlying the Option shall vest and become exercisable in full.

e. You hereby acknowledge that you are responsible for obtaining the advice of the your own tax advisors with respect to the acquisition of the Option and Restricted Stock

Grant and are relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating thereto. You acknowledge that you understand that you (and not the Company) shall be responsible for your tax liability that may arise in connection with the acquisition, vesting and/or disposition of the Restricted Stock Grant and any accrued dividends with respect thereto. You acknowledge that you have been informed of the availability of making an election under Section 83(b) of the Internal Revenue Code, as amended, with respect to the issuance of the Restricted Stock Grant.

f. Upon presentation of vouchers and similar receipts, you shall be entitled to receive reimbursement in accordance with the policies and procedures of the Company maintained from time to time for all reasonable business expenses actually incurred in the performance of the Executive Duties.

*Subject to all mandatory withholdings required by applicable law.

(v) Employee Benefits: You shall be entitled to participate in such employment benefits, including but not limited to a Section 401(k) retirement plan, health, dental, and long term disability plans as are established by the Company and as in effect from time to time applicable to executives of the Company. The Company shall provide health and dental insurance plans or, if the Company is unable to provide such plans, the Company will reimburse you for your health and dental insurance costs. The Company shall not be required to establish, continue or maintain any other specific benefits or benefit plans other than health and dental insurance.

(vi) Other Employee Benefits; Vacation: You shall be entitled to those other employee benefits which are generally offered to the Company's full-time employees, and as required by applicable law. Notwithstanding, you shall also be entitled to vacation during each year of the Employment Period in accordance with the policies and procedures of the Company maintained from time to time; provided that you shall be entitled to 20 days of vacation per fiscal year.

(vii) No Additional Compensation. Except as provided herein or as determined in the discretion of the Compensation Committee of the Board, you shall not be entitled to any other compensation, salary or bonuses for services as an employee of Company.

(viii) Confidentiality; Work for Hire: You will be required to execute the Company's standard Assignment, Non-Competition, Non-Solicitation and Confidentiality Agreement on or prior to your Start Date. A copy of this Assignment, Non-Competition, Non-Solicitation and Confidentiality Agreement has been appended to this Letter for your review and execution.

(ix) Termination and Consequences.

(a) Notwithstanding any other provision of this Agreement to the contrary, you may terminate this Agreement at any time during the Employment Period, (i) for Good Reason (as defined below), or (ii) without Good Reason on (A) thirty (30) days' prior written notice to the Company through the first anniversary of the Effective Date; or (B) sixty (60) days' prior written notice following the first anniversary of the Effective Date.

(b) Notwithstanding any other provision of this Agreement to the contrary, the Company may terminate this Agreement at any time during the Employment Period, upon notice to you.

(c) If the Company terminates this Agreement or your employment hereunder without Cause or if you terminate this Agreement or your employment hereunder with Good Reason, the Company shall: pay you, as severance pay, an amount equal to three (3) months of your Base Salary payable in a lump sum payment within ninety (90) days following the termination date; and (ii) pay you within thirty (30) days of the termination of your employment any portion of the bonus that you would otherwise be entitled to receive during the period of employment in that fiscal year (giving you credit for those milestones and performance goals that you successfully completed through the effective termination date); and (iii) shall continue to provide to or pay the cost of continuation of your and your eligible dependents' health insurance benefits for three (3) months following termination date. Should you become eligible for health insurance benefits provided by a new employer, then the Company's obligation to pay for or reimburse you for health insurance costs will terminate when your new health insurance benefit begins. Notwithstanding anything to the contrary, no compensation of any kind shall be payable to you under this section unless or until you execute and deliver a full and general waiver and release to the Company (in favor of the Company, its successors, assigns, Board members, officers, employees, affiliates, subsidiaries, parent companies and representatives), in a form reasonably acceptable to the Company and you, such waiver and release to be delivered by you within ten (10) days after the termination of your employment (unless applicable law requires a longer time period, in which case this date will be extended to the minimum time required by applicable law).

(d) If the Company terminates this Agreement or your employment hereunder with Cause or you terminate this Agreement or your employment hereunder without Good Reason, then (i) your Base Salary shall be discontinued upon the termination of the Agreement or your employment hereunder, (ii) no bonus compensation, accrued or otherwise, shall be payable for the year in which the termination with Cause or without Good Reason occurs, (iii) to the extent permitted by applicable law, you shall cease to be entitled to participate in any benefit plans or programs maintained by the Company, and (iv) you shall forfeit all rights to any Company stock options if terminated by the Company for Cause and shall forfeit all rights with respect to any Company unvested restricted stock if terminated by the Company for Cause or if terminated by you without Good Reason. You shall be entitled to receive payment for all accrued Base Salary and benefits earned through and including the date of termination, including, but not limited to all bonus earned, but not yet paid, for the year preceding the year in which such termination occurs, payment for all accrued, unused vacation, reimbursement of all business expenses incurred through the date of termination, and all vested benefits to which the employee is entitled. In addition, you and your eligible

dependents shall be entitled to continue all group health benefits at your or their expense, pursuant to applicable law.

(e) If you die or are unable to perform your duties and/or any other obligations hereunder because of a Disability (as defined herein) during the term of this Agreement, then the Agreement shall terminate, except that the Company shall pay within thirty (30) days of such event all accrued Base Salary and any bonus that you would otherwise have been entitled to receive through the date that your employment with the Company is terminated and for a period of three (3) months thereafter. In the case of a Disability, you shall also receive any applicable payments and benefits pursuant to any disability plan or policy sponsored or maintained by the Company. The unvested Options shall remain outstanding in accordance with their existing terms and conditions.

(f) "**Good Reason**" means (i) a material reduction of your base salary and benefits from the levels in effect immediately prior to the reduction, (ii) a material reduction of your duties and responsibilities from those in effect immediately prior to the reduction, or (iii) material breach by the Company of any provision of this Agreement after receipt of written notice thereof from the you and failure by the Company to cure the breach within thirty (30) days thereafter. A termination by you will not be considered a termination for Good Reason unless within thirty (30) days of the later of the last event relied upon by you to establish Good Reason or knowledge thereof, you furnish the Company with a written statement specifying the reason or reasons why you believe you are entitled to terminate employment for Good Reason and afford the Company at least thirty (30) days during which to remedy the cause thereof. Such 30 day notice period may run concurrently with the 30 day notice specified in (ix)(a) above. Any termination for Good Reason shall not be deemed a breach of the Agreement. If the Company timely cures the condition giving rise to Good Reason for your resignation, the notice of termination shall become null and void. If the Company does not timely cure the condition giving rise to Good Reason, your termination of employment shall be effective as of the end of such cure period.

(g) "**Cause**" means a good faith finding by the Company of: (i) gross negligence or willful misconduct by you in connection with the your duties, (ii) your indictment for, conviction of, or entry of a plea of guilty or no contest or similar plea with respect to any felony, acts of fraud, misrepresentation, embezzlement, theft, dishonesty or breach of fiduciary duty of loyalty to the Company or any of its subsidiaries, or a material and intentional breach of any material term of this Agreement, (iii) willful or repeated failure to follow specific directives of your manager, the CEO and/or the Board (or its committees or other designees), (iv) willful failure by you (except where due to Disability or where performance of your duties is prohibited by law) or refusal to perform the your Duties, which failure or refusal is not corrected by you within ten (10) business days following receipt by the you of written notice from the Company of such failure or refusal, and the actions required to correct the same, to the satisfaction of your manager, (v) misappropriation by you of the assets or business opportunities of the Company or its affiliates, (vi) any intentionally wrongful act or omission by you that has a material adverse effect on the reputation or business of the Company or any of its subsidiaries or affiliates, (vii) a willful and/or knowing breach by you of any representations or warranties included in this Agreement, or (viii) you

knowingly allowing any third party to commit any of the acts described in any of the preceding clause (v) against the Company.

(h) "**Disability**" means your inability to perform your duties pursuant to the terms of this Agreement, because of physical or mental disability where such disability shall have existed for a period of more than ninety (90) consecutive days in any two hundred and seventy (270) day period. The existence of a Disability means that you cannot perform the essential functions of your position with or without reasonable accommodation. The fact of whether or not a Disability exists hereunder shall be determined by a professionally qualified medical expert reasonably chosen by the Company.

(x) Special Payment Provision. Notwithstanding any provision herein to the contrary:

a. This agreement is intended to comply with the requirements of Section 409A of the Code ("Section 409A") and regulations promulgated thereunder such that no payment provided hereunder shall be subject to an "additional tax" within the meaning of Section 409A. To the extent that any provision in this agreement is ambiguous as to its compliance with Section 409A, the provision shall be read in such a manner so that all payments due under this agreement shall not be subject to any additional tax. For purposes of Section 409A, each payment made under this agreement shall be treated as a separate payment. In no event may you, directly or indirectly, designate the calendar year of payment. All reimbursements provided under this agreement shall be made or provided in accordance with the requirements of section 409A, including, where applicable, the requirement that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in this agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and (iv) the right to reimbursement is not subject to liquidation or exchange for another benefit.

b. If payment or provision of any amount or other benefit that is a "deferral of compensation" subject to section 409A of the Code at the time otherwise specified in this agreement or elsewhere would subject such amount of benefit to additional tax pursuant to section 409A(a)(1)(B) of the Code, and if payment or provision thereof at a later date would avoid any such additional tax, then the payment or provision thereof shall be postponed to the earliest date on which such amount or benefit can be paid or provided without incurring such additional tax. In the event this Section 11(o)(ii) requires a deferral of any payment, such payment shall be accumulated and paid in a single lump sum on such earliest date together with interest for the period of delay, compounded annually, equal to the prime rate (as published in The Wall Street Journal), and in effect as of the date of the payment should otherwise have been provided.

c. If any payment or benefit permitted or required under this agreement is reasonably determined by either party to be subject for any reason to a material risk of additional tax pursuant to section 409A(a)(1)(B) of the Code, then the parties shall promptly agree in good faith on appropriate provisions to avoid such risk without materially changing the economic value of this agreement to either party.

As you are aware, you will be a full-time employee with the Company and must devote your full

attention and efforts to the Company during regular work hours; your employment with the Company is "at will," which means your employment may be terminated at any time for any reason, by either party, with or without notice; and this Letter is an outline of the terms of our offer and is not intended to create a contract of employment between you and the Company.

This Letter will be governed solely by the laws of the State of New York without giving effect to the conflict of laws principles thereof. You further agree to submit to the exclusive jurisdiction of the courts situated in the State of New York in respect of any issue and/or dispute which arises hereunder and/or in connection with your employment with the Company.

By signing this Letter, you confirm that you are not subject to any agreements or other restrictions that would prevent you from working for the Company and carrying out the services described above. You further confirm that your employment with the Company will not violate or breach any confidential relationship between you and any third party, and that you will not disclose to the Company or use for the Company's benefit any confidential or trade secret information of any third party. You agree that at no time during the period of your employment with the Company will you undertake responsibilities or obligations which will present a conflict of interest with, or limit your ability to fulfill the duties of your position with the Company.

You are required by law to provide documentation necessary to complete U.S. Government Form I-9. Your employment will not commence until the Company has received such materials/documentation. In addition, this offer is contingent on verification of the information you have provided on your employment application and in your job interview.

We look forward to having you join the Brainstorm team, and we are confident that you'll contribute to its overall success. If you should have any questions, please feel free to contact me at your earliest convenience.

Sincerely,

BRAINSTORM CELL THERAPEUTICS INC.

By: _____
Name: Chaim Lebovits
Title: Chief Executive Officer

ACKNOWLEDGED AND AGREED
AS OF THE DATE SET FORTH BELOW:

By: _____
Name: Stacy Lindborg
Title: In her individual capacity

EXHIBIT A

Executive Duties and Responsiblities

Title: Executive Vice President, Head of Global Clinical Research

· Drive the creation of clinical development strategies from first-in-human (FIH) through registration – including framing innovative development paths and identifying the best opportunities, ensuring evidence is generated as required by key constituents (scientific community, regulatory, commercial/payer) and resourcing them adequately so they can be realized.

· Oversee execution of clinical development strategy, biometrics, regulatory, and other related functions as needed. Contribute to effective practices and a culture that will ensure high quality and regulatory compliance while maintaining high integrity and ethical standards.

· Drive an analytics strategy that is fit-for-purpose and leverages quantitative approaches to optimize allocation of capital across global clinical development opportunities.

· Serve as a member of the Executive Leadership team, contributing to overall corporate strategy, including but not limited to: long term business model, M&A, business development strategy and outreach, HR, and culture.

· Establish and maintain relationships and serve as a liaison between the Company and its external scientific advisors, public media, and the investment community in support of global development efforts.

· Identify opportunities and lead new global clinical development collaborations to gain access to key capabilities.

ASSIGNMENT, NON-COMPETITION, NON-SOLICITATION AND CONFIDENTIALITY AGREEMENT

This Assignment, Non-Competition, Non-Solicitation and Confidentiality Agreement (this "**Agreement**") is hereby effective as of June 1, 2020. As a condition of my employment with BRAINSTORM CELL THERAPEUTICS INC.**,** its subsidiaries, affiliates, successors or assigns (collectively, the "**Company**"), and in consideration of my employment with the Company and my receipt of the compensation now and hereinafter paid to me by the Company, I, the undersigned, agree to the following:

1. **At-Will Employment**. I understand and acknowledge that, unless I enter into a written employment agreement with the Company my employment with the Company is for an unspecified duration and constitutes "at-will" employment. I also understand that any representation to the contrary is unauthorized and not valid unless obtained in writing and signed by an authorized representative of the Company. I acknowledge that this employment relationship may be terminated at any time, with or without good cause or for any or no cause, at the option either of the Company or me, with or without notice.

2. **Confidential Information**.

2.1 **Company Information**. I recognize that the Company has devoted substantial money, time and resources in developing Confidential Information, and that the Company pays its employees, among other things, to develop and preserve its business information. Accordingly, I agree at all times during the term of my employment and thereafter, to hold in strictest confidence, and not to use, except for the benefit of the Company, or to disclose to any person, firm or corporation without written authorization of an authorized representative of the Company, any Confidential Information of the Company. I understand that "Confidential Information" means any Company technology or economic competitively valuable proprietary information, technical data, patients advocacy strategies, communications relating to patients (both internal and external), trade secrets or know-how, including, but not limited to, research, product plans, company business or working plans, products, Public Relations & Investor Relation strategies or communications, pricing and pricing methods, services, customer lists and customers (including, but not limited to, prospective and actual customers of the Company on whom I called or with whom I became acquainted during the term of my employment), markets, software, developments, inventions, processes, technology, designs, drawings, models, engineering, marketing, finances, employee compensation data or other business information disclosed to me by the Company either directly or indirectly in writing, orally or by drawings or observation of parts or equipment. In addition, I agree not to do any of the following: (a) disclose or disseminate Confidential Information to anyone, including any Company employee or volunteer, who lacks a need to know; (b) remove proprietary information from the Company's premises without the express written authorization from Company; and (c) use the Confidential Information for my own or any third party's benefit. I further understand that Confidential Information does not include any of the foregoing items which have become publicly known and made generally available through no wrongful act of mine or of others who were under confidentiality obligations as to the item or items involved or improvements or new versions thereof.

2.2 **Former Employer Information.** I agree that I will not, during my employment with the Company, improperly use or disclose any proprietary information or trade secrets of any former or concurrent employer or other person or entity and that I will not bring onto the premises of the Company any unpublished document or proprietary information belonging to any such employer, person or entity unless consented to in writing by such employer, person or entity.

2.3 **Third Party Information.** I recognize that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. I agree to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person, firm or corporation or to use it except as necessary in carrying out my work for the Company consistent with the Company's agreement with such third party.

2.4 **Governmental Limitations**. Nothing set forth in the Agreement or in any other agreement or policy of the Company shall prohibit any person from reporting possible violations of federal or state law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal or state law or regulation. No person shall require prior authorization of any party to make any such reports or disclosures, and no person shall be required to notify the Company that he or she has made such reports or disclosures. Furthermore, nothing in the Agreement shall prohibit or limit a person from receiving a whistleblower award or other financial benefit for participating in a government investigation.

3. **Inventions**.

3.1 **Assignment of Inventions**. I agree that I will promptly make full written disclosure to the Company, will hold in trust for the sole right and benefit of the Company, and hereby assign to the Company, or its designee, all my right, title, and interest in and to: (a) any and all inventions, developments, concepts, designs, discoveries, ideas, patents, patent applications, improvements, and all other worldwide rights of inventorship; (b) all copyrights in copyrightable works, all copyright registrations and/or applications, all original works of authorship, any derivations thereof and all moral rights appurtenant thereto; (c) all trademarks, service marks, trade names, trade dress, product names and slogans and any common law rights and good will appurtenant thereto, and all applications and registrations thereof; (d) all registered and unregistered domain names, uniform resource locators and keywords; (e) all computer and electronic data, documentation and software, including both source and object code, computer and database applications and operating programs; (f) all trade secrets and Confidential Information, including ideas, research notes, client lists, development notes, know-how, formulas, business methods and techniques and marketing, financial and pricing data; and (g) all other intellectual property rights relating to any or all of the foregoing, including any renewals, continuations or extensions thereof, whether or not patentable or registrable under copyright, trademark or similar laws (collectively hereinafter, the "**Inventions**"), which I may solely or jointly conceive or develop or reduce to practice, or cause to be conceived or developed or reduced to practice, during the period of time I am in the employ of the Company. I further acknowledge that all original works of authorship, as mentioned in this Section 3, which are or have been made by me (solely or jointly with others) within the scope of and during the period of my employment with the Company and which are protectible by copyright, patent and/or trademark are "works made for hire," as that term is defined in the United States Copyright Act. I understand and agree that the decision whether or not to commercialize or market any Invention developed by me solely or jointly with others is within the Company's sole discretion and for the Company's sole benefit and that no royalty will be due to me as a result of the Company's efforts to commercialize or market any such Invention.

3.2 **Maintenance of Records.** I agree to keep and maintain adequate and current written records of all Inventions made by me (solely or jointly with others) during the term of my employment with the Company. The records will be in the form of notes, sketches, drawings, and any other format that

may be specified by the Company. The records will be deemed Confidential Information and will be available to and remain the sole property of the Company at all times.

3.3 **Patent, Copyright and Trademark Registrations.** I agree to assist the Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in the Inventions and any copyrights, trademarks, patents, mask work rights or other intellectual property rights relating thereto in any and all countries, including the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments which the Company shall deem necessary in order to apply for and obtain such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title and interest in and to such Inventions, and any copyrights, trademarks, patents, mask work rights or other intellectual property rights relating thereto. I further agree that my obligation to execute or cause to be executed, when it is in my power to do so, any such instrument or papers shall continue after the termination of this Agreement. If the Company is unable because of my mental or physical incapacity or for any other reason to secure my signature to apply for or to pursue any application for any United States or foreign patents or copyright registrations covering Inventions or original works of authorship assigned to the Company as above, then I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, to act for and in my behalf and stead to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of patent, trademark, copyright or other intellectual property registrations thereon with the same legal force and effect as if executed by me.

4. **Solicitation of Customers**. I recognize that the Company pays its employees, among other things, to develop and preserve customer and client goodwill, customer loyalty and customer and client contacts for and on behalf of the Company. Accordingly, for the period of twelve (12) months after the date of termination of my employment with the Company for any reason, whether with or without cause, I will not solicit the business of any client or customer of the Company, directly or indirectly, who is such on or prior to the date of such termination. In addition, I will not solicit the business of any defined prospective client or customer. A defined prospective client or customer is one that is (a) an assigned account of any Company employee or (b) on an account list in any employee's sales or pipeline report within the last year from the termination date. I expressly agree that the limitation of this Section protects a legitimate business interest of the Company. Nevertheless, in the event that any of the restrictions and limitations contained in this Section are deemed unreasonable or to otherwise exceed the time and/or geographic limitations permitted by applicable law, such provisions of this Section shall be reformed to the maximum time and/or geographic limitations permitted by applicable law.

5. **Conflicting Employment**. I agree that, during the term of my employment with the Company and for a period of three (3) months after the date of termination of my employment with the Company for any reason, whether with or with cause, I will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of my employment, nor will I engage in any other activities that conflict with my obligations to the Company. I expressly agree that the limitation of this Section protects a legitimate business interest of the Company. Nevertheless, in the event that any of the restrictions and limitations contained in this Section are deemed unreasonable or to otherwise exceed the time and/or geographic limitations permitted by applicable law, such provisions of this Section shall be reformed to the maximum time and/or geographic limitations permitted by applicable law. Further, the non-competition provision in this Section shall not apply to employment and other statuses set forth in

this Section in any other jurisdiction in which they are prohibited. The remainder of this Agreement shall apply within and outside of such jurisdictions.

6. **Returning Company Property**. I agree that, at the time of leaving the employ of the Company, I will deliver and return to the Company (and will not keep in my possession, recreate or deliver to anyone else) any and all Company-owned devices, records, data, files, notes, reports, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, materials, equipment, other documents or property, or reproductions of any of the aforementioned items developed by me or in my possession, including, without limitation, those records maintained pursuant to paragraph 3.3.

7. **Notification of New Employer**. In the event that I leave the employ of the Company, I hereby grant to the Company the right to notify my new employer about my rights and obligations under this Agreement.

8. **Solicitation of Employees**. I agree that for a period of twelve (12) months immediately following the termination of my relationship with the Company for any reason, whether with or without cause, I shall not either directly or indirectly solicit, induce, recruit, hire, offer employment or encourage any of the Company's employees, independent contractors or vendors to leave their employment / engagement, either for myself or for any other person or entity. I expressly agree that the limitation of this Section protects a legitimate business interest of the Company. Nevertheless, in the event that any of the restrictions and limitations contained in this Section are deemed unreasonable or to otherwise exceed the time and/or geographic limitations permitted by applicable law, such provisions of this Section shall be reformed to the maximum time and/or geographic limitations permitted by applicable law.

9. **Representations**. I agree to execute any proper oath or verify any proper document required to carry out the terms of this Agreement. I represent that my performance of all the terms of this Agreement will not breach any prior agreement to keep in confidence proprietary information acquired by me in confidence or in trust prior to my employment by the Company. I have not entered into, and I agree I will not enter into, any oral or written agreement in conflict with this Agreement.

10. **Equitable Relief**. I acknowledge and agree that it is impossible to measure in money the damages which will accrue to the Company if I should breach or be in default of any of my representations or agreements set forth in this Agreement. Accordingly, if I breach or am in default of any such representations or agreements, the Company shall have the full right to seek injunctive relief, in addition to any other existing rights provided in this Agreement or by operation of law, without the requirement of posting bond. If any action or proceeding is instituted by or on behalf of the Company to enforce any term of this Agreement, I hereby waive any claim or defense thereto that the Company has an adequate remedy at law or that the Company has not been, or is not being, irreparably injured by my breach or default. The rights and remedies of the Company pursuant to this Section are cumulative, in addition to, and shall not be deemed to exclude, any other right or remedy which the Company may have pursuant to this Agreement or otherwise, at law or in equity.

11. **Governing Law; Venue.** This Agreement will be governed solely by the laws of the State of New York without giving effect to the conflict of laws principles thereof. I further agree to submit to the exclusive jurisdiction of the courts situated in the State of New York in respect of any issue and/or dispute which arises hereunder.

12. **Entire Agreement.** This Agreement sets forth the entire agreement and understanding between the Company and me relating to the subject matter herein and supersedes all prior discussions

between us. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing signed by the party to be charged. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

13. **Full Knowledge and Volition**. I acknowledge and agree that I have received a copy of this Agreement, that I have read and understood all of the terms and conditions of this Agreement, and that I have had full opportunity to be advised of my right and to discuss all aspects of this Agreement with counsel of my own choosing prior to execution hereof.

14. **Severability.** If one or more of the provisions in this Agreement are deemed void by law, then the remaining provisions will continue in full force and effect.

15. **Waiver**. No course of dealing or omission on the party of the Company in asserting or exercising any right, power or remedy conferred by this Agreement shall constitute or operate as a waiver thereof or otherwise prejudice its rights, powers and remedies conferred by this Agreement or shall preclude any other or further exercise thereof of any other right, power and remedy.

16. **Successors and Assigns.** This Agreement will be binding upon my heirs, executors, administrators and other legal representatives and will be for the benefit of the Company, its successors, and its assigns.

17. **Attorney's Fees**. Should I be found liable for any action taken to enforce this Agreement, I will reimburse the Company for all reasonable attorney's fees and court costs.

18. **Waiver**. No act or failure to act by Company waives any rights herein. To be effective, any waiver by Company must be in writing and executed by an executive officer of the Company.

19. **Headings**. Section and other headings contained in this Agreement are for reference purposes only and are not intended to describe, interpret, define or limit the scope or intent of this Agreement or any provision hereof.

20. **Counterparts**. This Agreement may be executed in one or more counterparts each of which shall be deemed one in the same original instrument.

Signature Page Follows

BRAINSTORM CELL THERAPEUTICS INC.

By: _____
Name: Chaim Lebovits
Title: Chief Executive Officer and President

EMPLOYEE

By: _____
Name: Stacy Lindborg
Title: In her individual capacity

EXHIBIT 21

Subsidiaries of Brainstorm Cell Therapeutics Inc.

Subsidiary	**Jurisdiction of Incorporation**
BrainStorm Cell Therapeutics Ltd.	Israel
Advanced Cell Therapies Ltd.*	Israel
BrainStorm Cell Therapeutics UK Ltd.*	United Kingdom
Brainstorm Cell Therapeutics Limited*	Ireland

* Wholly owned subsidiary of BrainStorm Cell Therapeutics Ltd.

Deloitte.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-201704, 333-201705, 333-225517, 333-225995 and 333-233349 on Form S-3 and Registration Statement Nos. 333- 333-131880, 333-168763, 333-175460, 333-182546, 333-198391, 333-213714 and 333-228981 on Form S-8 of our report dated February 4, 2021, relating to the financial statements of Brainstorm Cell Therapeutics Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2020

Brightman Almagor Zohar & Co.
Certified Public Accountants
A Firm in the Deloitte Global Network

Tel Aviv, Israel
February 4, 2021

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EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

I, Chaim Lebovits, certify that:

1. I have reviewed this Annual Report on Form 10-K of Brainstorm Cell Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 4, 2021

/s/ Chaim Lebovits

Name: Chaim Lebovits

Title: President and Chief Executive Officer (Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

I, Preetam Shah, certify that:

1. I have reviewed this Annual Report on Form 10-K of Brainstorm Cell Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 4, 2021

/s/ Preetam Shah

Name: Preetam Shah
Title: Chief Financial Officer (Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

In connection with the accompanying Annual Report on Form 10-K of Brainstorm Cell Therapeutics Inc.(the "Company") for the year ended December 31, 2020, the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) such Annual Report on Form 10-K for the year ended December 31, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in such Annual Report on Form 10-K for the year ended December 31, 2020 fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 4, 2021

/s/ Chaim Lebovits

Name: Chaim Lebovits
Title: President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

In connection with the accompanying Annual Report on Form 10-K of Brainstorm Cell Therapeutics Inc.(the "Company") for the year ended December 31, 2020 the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) such Annual Report on Form 10-K for the year ended December 31, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in such Annual Report on Form 10-K for the year ended December 31, 2020 fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 4, 2021

/s/ Preetam Shah

Name: Preetam Shah
Title: Chief Financial Officer
(Principal Financial Officer)