Table of Contents

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, 2023

☐ **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 (State or other jurisdiction of incorporation or organization)	20-7273918 (I.R.S. Employer Identification No.)
1325 Avenue of Americas, 28th Floor New York, NY (Address of principal executive offices)	10019 (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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023 (the last business day of the registrant's most recently completed second fiscal quarter), was $78,886,897.

As of March 27, 2024, the number of shares outstanding of the registrant's Common Stock, $0.00005 par value per share, was 68,341,857.

BRAINSTORM CELL THERAPEUTICS INC.
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2023
TABLE OF CONTENTS

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 2023 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 continuing concerns resulting from the COVID-19 or any other pandemic or endemic or other events, 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, 2023. 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, 2023, 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 cell therapy 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 completed its Phase 3 ALS and Phase 2 PMS clinical trials. On November 17, 2020, we announced top-line data from our Phase 3 ALS trial. On March 24, 2021, we announced positive top-line data from our Phase 2 trial evaluating three repeated intrathecal administrations of NurOwn®, each given 2 months apart, as a treatment for PMS. On June 24, 2020, we announced a new clinical program focused on the development of NurOwn® as a treatment for AD. On August 15, 2022, we announced our decision to submit a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for NurOwn® for the treatment of ALS. On September 9, 2022, we filed a BLA to the FDA for NurOwn® for the treatment of ALS. On November 10, 2022, we announced that we had received a refusal to file ("RTF") letter from the FDA regarding our BLA. The FDA indicated that we may request a Type A meeting to discuss the content of the RTF letter. On December 12, 2022, we announced the submission of a Type A meeting request with the FDA to discuss the contents of the RTF letter previously issued by the FDA regarding the BLA for NurOwn® for the treatment of ALS. On December 27, 2022, we announced that the FDA granted a Type A meeting to discuss the contents of the RTF letter previously issued regarding our BLA for NurOwn® for the treatment of ALS. The Type A Meeting was held on January 11, 2023. The perspective shared by the FDA review team reflected what was in the previously issued RTF letter. Conversations with the FDA on the best pathway to resolve the outstanding questions that remained continued, following the Type A meeting. During these discussions, BrainStorm was presented with multiple options to return the BLA to regulatory review, which included the regulatory procedure to File over Protest. Additionally, within these discussions, the FDA committed to review amendments that were filed to address items raised in the RTF letter. These discussions resulted in BrainStorm requesting the FDA to file our BLA over Protest, as this was the regulatory procedure that would allow us to reach an ADCOM in the shortest amount of time. BrainStorm notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn® BLA for ALS over Protest. We received confirmation from the FDA that the BLA was re-filed on February 7, 2023. We received the FDA Type A meeting minutes on February 9, 2023. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. Written feedback was received on March 22, 2023, from the FDA project manager associated with the BLA confirming the FDA's decision to grant an ADCOM for the NurOwn® BLA for ALS. On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company's BLA for NurOwn® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 22, 2023, we submitted an amendment to our BLA to revise the indication to NurOwn® for the treatment of mild to moderate ALS. On September 27, 2023, we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that FDA invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS. BrainStorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the BLA for NurOwn® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision to withdraw the BLA was coordinated with FDA and is viewed by FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a Special Protocol Assessment (SPA) with FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS.

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

NurOwn® has a strong and comprehensive intellectual property portfolio and was granted Fast Track designation by the FDA and Orphan Drug status by the FDA and the European Medicines Agency ("EMA") for ALS.

Our human capital resource objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors and consultants to accomplish our goal of developing and launching a novel cell therapy for neurodegenerative diseases. 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 our success by motivating such individuals to perform to the best of their abilities and achieve our objectives. We currently employ 29 employees in the United States and in Israel. Most of the senior management team are based in the United States, and all of our clinical trial sites for ALS and PMS from our late phase trials are in the United States. Our R&D center is located in Petach Tikva, Israel. In addition, we currently lease the GMP manufacturing center in Tel Aviv at the Sourasky Medical Center ("Sourasky Hospital") to manufacture NurOwn®. This center increases our capacity and expand our ability to manufacture and ship NurOwn® into the EU and local Israeli markets.

Recent Highlights

- On May 17 and 18, 2023, Brainstorm joined an international audience of patient advocacy groups, physicians, research organizations, industry representatives, key thought leaders and decision makers dedicated to ALS research, at The 2023 ALS Drug Development Summit in Boston, Massachusetts. Dr. Stacy Lindborg, Ph.D., Co-Chief Executive Officer BrainStorm presented an invited talk entitled "Reviewing ALSFRS-R as the Established Endpoint for ALS Clinical trials". Mr. Trejo Diez participated in a panel entitled "A Year in Review: Showcasing the Breakthrough Developments in ALS Drug Development".

- On July 7, 2023, we announced the presentation of new biomarker data from the Phase 3 trial of its late-stage investigational ALS treatment, NurOwn® at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference in Les Diablerets, Switzerland. The data presented by Dr. Stacy Lindborg, Ph.D., Co-Chief Executive Officer BrainStorm showed that treatment with NurOwn® significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, including neurofilament light ("NfL") over time compared to placebo in all trial participants.

- On July 12, 2023, we announced the hiring of Dr. Bob Dagher as EVP and Chief Development Officer, responsible for the portfolio strategy and advancement of clinical development plans towards regulatory approval, including the expansion of NurOwn® into new diseases and the translation of pre-clinical research into first-in-human trials. His appointment was central to the targeted capability build led by Dr. Lindborg to hire and bring expertise inside Brainstorm.

- On November 17, 2023, we announced a podium presentation and panel discussion at the 6th Annual ALS Research Symposium hosted by ALS ONE. The presentation features new analyses from the NurOwn® placebo-controlled Phase 3 ALS trial that highlight the biological effect of NurOwn® through CSF biomarker data. The presentation, titled, "NurOwn® for ALS: Biomarker exploration of NurOwn® multimodal mechanism of action on neuroinflammation, neuroprotection and neurodegeneration" was presented by Bob Dagher, MD, Executive Vice President and Chief Development Officer at BrainStorm.

- On December 7, 2023, we announced the completion of a productive face-to-face meeting with the FDA to discuss NurOwn®, its investigational treatment for ALS. The primary objective of the meeting was to discuss key considerations for a SPA for a planned Phase 3b registrational trial for NurOwn®.

- On February 23, 2024, we announced the submission of a SPA request to the FDA for a planned Phase 3b clinical trial of NurOwn® for treatment of ALS.

- On February 28, 2024, Dr. Stacy Lindborg, Co-Chief Executive Officer at Brainstorm Cell Therapeutics, provided a corporate update at 17th Annual European Life Sciences CEO Forum in Zurich, Switzerland. Dr. Lindborg also participated in a panel discussion entitled "Neuro Advances Panel: Highlighting the Main Opportunities".

- On March 4, 2024, Dr. Bob Dagher, EVP and Chief Development Officer at Brainstorm Cell Therapeutics, presented a scientific poster titled "Design of A Phase 3B Trial of Debamestrocel (NurOwn®) in ALS" the 2024 Muscular Dystrophy Association Clinical and Scientific Conference in Orlando, Florida held March 3-6, 2024. The presentation provided an overview into the key features of the phase 3b trial design.

NurOwn® Proprietary Technology

NurOwn® technology is based on an innovative manufacturing protocol, which induces the differentiation of purified and expanded bone marrow-derived 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"); hepatocyte growth factor ("HGF"), and Galectin-1 among others. VEGF is one of the most potent neuronal and motor neuron survival factors and has demonstrated important neuroprotective effects in ALS and several other neurodegenerative 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") administration 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 and the NurOwn® U.S. Phase 2 PMS trials evaluated the therapeutic potential of repeated intrathecal MSC-NTF cell administration (three doses at bi-monthly intervals). Our highest priority is to obtain regulatory approval of NurOwn® for ALS. We are also strategically focused on fully executing the clinical development of NurOwn® in PMS, reviewing the optimal approach in AD and will consider the best course of action based on recent scientific and regulatory insights.

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 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® Treatment 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

- Intrathecal administration into the patient's cerebrospinal fluid by standard lumbar puncture.

Differentiation before Treatment

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 treatment

The NurOwn® technology platform is autologous, using the patient's own bone-marrow derived stem cells for treatment. In autologous cellular treatment, 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, autologous 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 FDA for this indication, and have been granted Orphan Drug Status, in the U.S. and Europe, which provides us the potential for an extended period of exclusivity. On August 15, 2022, we announced our decision to submit a BLA to the FDA for NurOwn® for the treatment of ALS. The BLA was filed on September 9, 2022. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA. The FDA indicated that we could request a Type A meeting to discuss the content of the RTF letter, and Type A meeting was held on January 11, 2023. On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company's BLA for NurOwn® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 22, 2023, we submitted an amendment to our BLA to revise the indication to NurOwn® for the treatment of mild to moderate ALS. On September 27, 2023 we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that the FDA invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS. BrainStorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the BLA for NurOwn® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision to withdraw the BLA was coordinated with the FDA and is viewed by the FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a SPA with the FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS.

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, investigation, and treatment of ALS.

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

In January 2016, the results of the two completed Phase 1/2 study and Phase 2 open label trials were published in JAMA Neurology. The results demonstrated a slower rate of disease progression following MSC-NTF cell treatment 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 titled "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® treatment was well-tolerated. There were no discontinuations from the trial due to adverse events ("AEs") and there were no deaths in the study. The most common AEs 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 (in points change per 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 treatment effects were greater in the rapid progressor subgroup (a pre-specified definition, 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-treatment 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-treatment. 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 change in post-treatment vs. pre-treatment ALSFRS-R rate of decline or slope.

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 BLA submission in the U.S. for NurOwn® in ALS. In October 2019, the clinical trial completed enrollment of an enriched patient population of rapid progressors 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. On February 9, 2021, we announced feedback from our Type-C Meeting with the FDA to review specific aspects of our planned manufacturing modifications to support the development of a semi-automated commercial manufacturing process for NurOwn® (MSC-NTF cell). On February 22, 2021, we announced high-level FDA feedback on NurOwn® ALS clinical development program. The FDA concluded from their initial review that the clinical data provided at the time did not provide the threshold of substantial evidence that the FDA seeks to support a BLA. In addition, the FDA advised that this recommendation did not preclude the Company from proceeding with a BLA submission.

Key findings from the trial were as follows (which include the update to the data published in Muscle & Nerve 65(3):291-302 on August 12, 2022):

- 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 at least a 1.25 points per month improvement in the post-treatment 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 response definition for the primary endpoint was met by 32.6% 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 rate of response in placebo participants exceeded the placebo response expected based on contemporary ALS trials.
- 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 an ALSFRS-R baseline score of 35 or greater, 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=0.305), and the average change from baseline to week 28 in ALSFRS-R total score was -1.56 on NurOwn® and -3.65 on Placebo (p=0.050), an improvement of 2.09 ALSFRS-R points favoring NurOwn®.

- Additional sensitivity analyses have demonstrated consistent treatment effects with NurOwn® after accounting for the impact of the ALSFRS-R floor effect. Two methods include: (1) Total Score Threshold ("TST"), which removed participants with ALSFRS-R scores ≤ 25; and (2) Item Level Threshold ("ITL"), which removed participants with a baseline score of 0 or 1 in at least 5 of 6 of the ALSFRS-R's Fine and Gross Motor scale items. Applying the TST and ITL sensitivity analysis methods resulted in the exclusion of 23% (n=44) and 16% (n=30) of trial participants from analyses, respectively. Both the TST and ILT sensitivity analysis methods show that, after controlling for the impact of the ALSFRS-R floor effect, participants treated with NurOwn® had a higher rate of clinical response (primary endpoint) and less function lost across 28 weeks (secondary endpoint), compared to placebo. Additional post-hoc analyses published for the secondary endpoint (average change from baseline in ALSFRS-R), showed a statistically significant benefit following treatment with NurOwn® in all subgroups with ALSFRS-R baseline total score of at least 26 to 35 ($p \leq 0.050$).

- The NurOwn® Phase 3 trial enrolled a broad set of participants, including some with advanced ALS disease (ALSFRS-R≤25) at baseline, making this trial subject to the impact of floor effects of the ALSFRS-R and reduced ALSFRS-R sensitivity. A post-hoc analysis was done using participants with baseline ALSFRS-R>25 for the primary endpoint and the % response for NurOwn® was 34.7% and 20.5% for Placebo, p=0.053. This analysis suggests a treatment effect with NurOwn® in participants with less advanced disease. CSF biomarker analyses confirmed that treatment with NurOwn® resulted in a statistically significant increase of neurotrophic factors (VEGF) and reduction in neurodegenerative (neurofilament) and neuroinflammatory biomarkers (MCP-1) 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. Additional analyses focused on the trajectory of biomarkers for the subgroups of participants with baseline ALSFRS-R scores >25 and ≤25, those most likely to be impacted by the floor effect of the scale, indicate that NurOwn® had similar biological effects on ALS participants regardless of the level of disease progression at baseline. Specifically, we observe decreases in neuroinflammatory and neurodegenerative markers and increases in neuroprotective markers in NurOwn® treated participants compared to placebo in both subgroups.

Decision to Submit BLA

New clinical analyses of NurOwn's® Phase 3 clinical trial in ALS published August 12, 2022, led to a correction of data originally published in Muscle & Nerve in December 2021 and strengthened the Company's original conclusions from the trial. The correction resulted in a statistically significant treatment difference (p=0.050) of more than 2 points for an important secondary endpoint, average change from baseline in ALSFRS-R, in the pre-specified efficacy subgroup of participants with a baseline score of at least 35. Analyses reported in the original publication utilized an efficacy model that unintentionally deviated from the trial's pre-specified statistical analysis plan by erroneously incorporating interaction terms between the subgroup and treatment. The newly published results employ the efficacy model as pre-specified in the trial's statistical analysis plan, correcting the analyses. The correction also relates to the other subgroup analyses published for this endpoint, demonstrating that all subgroups with ALSFRS-R baseline scores of greater than 26 to 35 showed a statistically significant benefit following treatment with NurOwn® ($p \leq 0.050$).

On August 15, 2022, we announced the decision to submit a BLA to the FDA for NurOwn® for the treatment of ALS. The BLA was filed on September 9, 2022. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA for NurOwn® for the treatment of ALS. The FDA informed us that the BLA is not sufficiently complete to enable a substantive review and that the FDA would therefore not file the BLA. The RTF letter contained a list of topics the FDA provided to BrainStorm as rationale for the BLA file being not sufficiently complete to enable a substantive review. According to the FDA, these reasons included one item related to the trial not meeting the standard for substantial evidence of effectiveness and Chemistry, Manufacturing and Controls ("CMC") related items. The FDA indicated that we may request a Type A meeting to discuss the content of the RTF letter. On December 12, 2022, we announced the submission of a Type A meeting request with the FDA to discuss the contents of the RTF letter previously issued by the FDA regarding the BLA for NurOwn® for the treatment of ALS. On December 27, 2022, we announced that the FDA granted a Type A meeting to discuss the contents of the RTF letter previously issued regarding our BLA for NurOwn® for the treatment of ALS. The Type A Meeting was held on January 11, 2023.

The perspective shared by the FDA review team reflected what was in the previously issued RTF letter. Conversations on the best pathway to resolve the outstanding questions that remained continued, following the Type A meeting. During these discussions, BrainStorm was presented with multiple options to return the BLA to regulatory review, which included the regulatory procedure to File over Protest. Additionally, within these discussions, the FDA committed to review amendments that were filed to address items raised in the RTF letter. These discussions resulted in BrainStorm requesting the FDA to file our BLA over Protest, as this was the regulatory procedure that would allow us to reach an ADCOM in the shortest amount of time. BrainStorm notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn® BLA for ALS over Protest. We received confirmation from the FDA that the BLA was re-filed on February 7, 2023.

We received the FDA Type A meeting minutes on February 9, 2023. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. Written feedback was received on March 22, 2023, from the FDA project manager associated with the BLA confirming the FDA's decision to grant an ADCOM for the NurOwn® BLA for ALS. On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company's BLA for NurOwn® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 22, 2023, we submitted an amendment to our BLA to revise the indication to NurOwn® for the treatment of mild to moderate ALS. On September 27, 2023 we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that the FDA invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS. BrainStorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the BLA for NurOwn® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision to withdraw the BLA was coordinated with the FDA and is viewed by the FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a SPA with the FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS.

NurOwn® Clinical Manufacturing

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 trials 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 our Phase 3 ALS clinical study participants and commenced manufacturing in October 2018. DFCI core manufacturing facility also supplied 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 has been evaluated for the treatment of ALS in our Phase 3 clinical trial. If we receive FDA approval for NurOwn® in ALS, Catalent will be our partner for manufacturing commercial quantities of NurOwn® to treat patients with ALS. Our technology transfer to Catalent Houston was successfully completed and enabled continuous supply of NurOwn® for the Expanded Access program.

As of November 1, 2023, the Company optimized its manufacturing capabilities, particularly in the production of NurOwn®, by strategically leveraging partnerships and optimizing operational resources. The Company currently leases a GMP-certified cleanroom manufacturing center located at Sourasky Hospital, which serves as a critical hub for the production and distribution of NurOwn®. This facility significantly enhances the Company's capacity to manufacture and distribute NurOwn® within both the European Union (EU) and local Israeli markets.

On December 7, 2021, we and Catalent announced completion of technology transfer for NurOwn® manufacturing at the Catalent's cell therapy facility in Houston, Texas.

Catalent Houston manufactured NurOwn® for the Expanded Access Program. As of December 31, 2022, seven participants have completed treatment with NurOwn® that was manufactured at the Catalent facility as well as all Expanded Access protocol follow-up visits. We are currently negotiating a contract with a leading manufacturing contract development organization.

Meetings with the FDA and 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, former 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 (MGH, 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, we announced that we 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 was 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.

On February 9, 2021, we announced feedback on a Type-C Meeting with the FDA on future NurOwn® manufacturing plans and to review specific aspects of our planned manufacturing modifications to support the development of a semi-automated commercial manufacturing process for NurOwn® (MSC-NTF cell). The meeting included a detailed review of the requirements for comparability testing to support future modifications along with geographic considerations in the sourcing of starting materials and future manufacturing production. We plan to incorporate feedback from the FDA meeting in 2021, our experience from Phase 3 manufacturing, in addition to feedback received in recent interactions with FDA including the Type A meeting on December 6, 2023, to formalize our plan to satisfy FDA's expectations for CMC for a product in Phase 3 development.

On February 22, 2021, we announced high-level FDA feedback on NurOwn® ALS Clinical Development Program. The FDA concluded from their initial review that the current level of clinical data does not provide the threshold of substantial evidence that the FDA is seeking to support a BLA. In addition, the FDA advised that this recommendation does not preclude the Company from proceeding with a BLA submission. Following extensive consultations with principal investigators, ALS experts, expert statisticians, regulatory advisors, and ALS advocacy groups to discuss the best path forward to provide NurOwn® for ALS patients, Brainstorm filed a BLA on September 9, 2022. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA, which informed us that the BLA was not sufficiently complete to enable a substantive review and that the FDA. The RTF letter contained a list of topics the FDA provided to BrainStorm as rationale for the BLA file being not sufficiently complete to enable a substantive review. According to the FDA, these reasons included one item related to the trial not meeting the standard for substantial evidence of effectiveness and CMC related items. The FDA indicated that we could request a Type A meeting to discuss the content of the RTF letter, and the Type A meeting was held on January 11, 2023. We notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn® BLA for ALS over Protest. Written feedback was received on March 22, 2023 from the FDA project manager associated with the BLA confirming the FDA's decision to grant an ADCOM for the NurOwn® BLA for ALS. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. The BLA for NurOwn® to treat ALS is currently under active review by the FDA.

On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company's BLA for NurOwn® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 22, 2023, we submitted an amendment to our BLA to revise the indication to NurOwn® for the treatment of mild to moderate ALS. On September 27, 2023 we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that the FDA invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS. BrainStorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the BLA for NurOwn® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision to withdraw the BLA was coordinated with the FDA and is viewed by the FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a SPA with the FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS.

ALS Expanded Access Program

On December 14, 2020, we announced the NurOwn® Expanded Access Program ("EAP") through which NurOwn® would 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, participants less severely affected by ALS, as measured by ALSFRS-R, were the first to receive treatment. This approach is informed by recently announced top-line 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 each had the opportunity to treat ALS participants 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 the Mayo Clinic. EAP treatment of ALS participants who have completed the Phase 3 clinical trial did not interfere with data or regulatory timelines. The Cell Manipulation Core Facility ("CMCF") at the Dana Farber Cancer Institute manufactured the investigational therapy, assisted by on-site Brainstorm personnel.

In the course of 2021, 10 eligible patients that had completed the Phase 3 study, were enrolled in the EAP at the six participating medical centers to receive three additional doses of NurOwn® eight weeks apart. Eight patients completed the program receiving all three treatment doses. Two participants withdrew consent after receiving two treatment doses. There were no serious adverse events ("SAEs") in the treated participants.

On December 27, 2021, we announced plans for a dosing extension of NurOwn® for participants who completed the EAP. The FDA recommended that Brainstorm submit an EAP protocol amendment to provide additional dosing for these participants. Under the original EAP protocol, participants who had completed the Phase 3 NurOwn® trial and who met specific eligibility criteria had the opportunity to receive 3 doses of NurOwn®. Under the amended EAP protocol, these eligible participants will receive up to 3 additional doses. Data collected from the original EAP treatments informed the decision to move forward with additional doses for participants who completed it. Seven participants completed treatment with NurOwn® manufactured at the Catalent Houston manufacturing site and all follow-up visits.

Patient Access Programs (ALS)

The Company, had worked collaboratively with the Sourasky Hospital, to treat ALS patients with NurOwn®, under the Israel Hospital Exemption ("HE") regulatory pathway for Advanced Therapy Medicinal Products ("ATMP"), which was adopted by the Israeli MoH from the EMA regulation. Between the first quarter of 2019 and the fourth quarter of 2020, the Company enrolled and treated 12 ALS patients with NurOwn®, under the HE pathway. The Company received $3.4 million in gross proceeds in connection with the treatment of the aforementioned patients, which did not cover the costs of the trial. The remaining cost associated with the HE pathway were paid by Brainstorm.

NurOwn® in Progressive Multiple Sclerosis (PMS)

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 titled "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")" was designed to recruit 20 PMS participants at 5 leading U.S. Multiple Sclerosis centers.

On December 18, 2019, the clinical trial independent Data Safety Monitoring Board ("DSMB") for the U.S. Phase 2 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".

In August 2021, the clinical trial independent DSMB for the U.S. Phase 2 PMS study issued an end-of-study statement concluding that, based on the data, the procedures and treatment involved in BCT-101-US were relatively safe and tolerable. Given that the study was "open-label" with no active comparator arm(s), it was not possible to evaluate efficacy, except through comparison to non-contemporaneous natural history data sets or to prior clinical trials of similar populations.

Phase 2 PMS Clinical Trial

On March 24, 2021, the Company announced positive top-line data in the Phase 2 study evaluating three repeated administrations of NurOwn®, each given 2 months apart, as a treatment for PMS. The 28-week open-label Phase 2 clinical trial enrolled 20 primary and secondary progressive MS patients based on the 2017 revised McDonald Criteria, ages 18-65, with baseline Expanded Disability Status Scale ("EDSS") scores between 3-6.5, without evidence of relapse within 6 months of enrollment, able to walk 25 feet in 60 seconds or less and were permitted to be on a stable dose of disease modifying therapy. Of the 20 patients enrolled, 18 were treated and 16 (80)% completed the study. Two patients discontinued related to procedure-related AEs. There were no study deaths or AEs related to multiple sclerosis worsening. The mean age of study patients was 47, 56% were female, and mean baseline EDSS score was 5.4. The clinical trial compared clinical efficacy outcomes with a 48-patient matched clinical cohort from the Comprehensive Longitudinal Investigations in MS at the Brigham & Woman's Hospital (CLIMB Study). MS Function and Cognition measures in the top-line results included the timed 25-foot walk (T25FW); 9-hole peg test (9-HPT); Low Contrast Letter Acuity (LCLA); Symbol Digit Modality Test (SDMT); and the 12 item MS Walking Scale (MSWS-12).

Key findings from the trial were as follows:

- Prespecified 25% improvements in the timed T25FW and 9-HPT (combined average) from baseline to 28 weeks were observed in 14% and 13% of NurOwn® treated patients, respectively, and improvement in 9-HPT (combined average) was observed in 0% of the pre-specified matched historical controls in the CLIMB registry.

- 38% of NurOwn® treated patients showed at least a 10-point improvement in the MSWS-12 from baseline to week 28, a patient reported outcome that evaluates walking function.

- 47% of NurOwn® treated patients showed at least an 8-letter improvement across 28 weeks in the LCLA binocular 1.25%, a visual function test. Additionally, 27% of NurOwn® treated patients showed at least an 8-letter improvement across 28 weeks in the LCLA binocular 2.5%,

- 67% of NurOwn® treated patients showed at least a 3-point improvement in the SDMT, a measure of cognitive processing.

- NurOwn® treated patients showed a mean improvement from baseline of 10% in T25FW and a 4.8% improvement from baseline on the 9-HPT dominant hand, compared to 1.8% and 1.4% worsening respectively in matched historical controls from the CLIMB registry.

- NurOwn® treated patients showed a 6% improvement from baseline in MSWS-12.

All results reported are based on observed data. Cerebrospinal fluid (CSF) biomarkers were obtained at 3 consecutive time points, just prior to each intrathecal administration of NurOwn®. We observed increases in neuroprotective molecules (VEGF, HGF) and decreases in neuroinflammatory biomarkers (MCP-1, and Osteopontin).

Additionally, we completed secondary efficacy data and detailed CSF and blood biomarker analyses. We presented a detailed summary of the study outcomes at the 37th Congress of the ECTRIMS on October 14, 2021 and published our findings in the peer reviewed journal Multiple Sclerosis Journal in September 15, 2022. We are currently considering how best to advance NurOwn® as an innovative treatment option in PMS.

NurOwn® in Alzheimer's Disease (AD)

On June 24, 2020, we announced a new clinical program focused on the development of NurOwn® as a treatment for Alzheimer's disease, or AD. We are currently evaluating next steps based on emerging scientific insights and the changing regulatory landscape for AD following the recent FDA decision to grant accelerated approval of Aducanumab and pending regulatory reviews of other investigational anti-amyloid therapies.

While many Alzheimer's therapies have focused on a single target such as tau or beta-amyloid, we believe 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.

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. 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, 2023, we have received $352,156 out of the $495,330 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 who participated in Brainstorm's Phase 3 clinical trial and treated with NurOwn®, and to further the understanding of critical biomarkers associated with treatment response for people with ALS. As of December 31, 2023, we have received $400,000 out of $500,000 awarded.

Intellectual Property

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 27 granted patents, and 23 patent applications in the United States, Canada, Europe, Israel and Brazil, as well as in additional countries worldwide, including countries in the Far East and South America (in calculating the number of granted patents and patent applications, each European patent validated in multiple jurisdictions was counted as a single patent).

On February 18, 2020, the U.S. Patent and Trademark Office ("USPTO") issued U.S. 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 June 3, 2020, the European Patent Office ("EPO") granted European patent No. 2880151 titled 'Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors'. The allowed claims cover the method for manufacturing MSC-NTF cells (NurOwn®).

On September 1, 2020, the Israeli Patent Office issued Israeli Patent No. 246943 titled 'Method of Qualifying Cells'. The granted claims cover a method of qualifying whether a cell population is a suitable therapeutic for treating ALS and an isolated population of cells that secrete neurotrophic factors which are qualified useful as a therapeutic for treating ALS.

On September 16, 2020, the Company announced that the Japanese Patent Office ("JPO") has granted Brainstorm's Japanese Patent No. 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 MSCs derived from the bone marrow of a single donor. The said neurotrophic factors includes: BDNF; GDNF; HGF; and 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.

On December 22, 2020 the USPTO issued U.S. Patent No. 10,869,899 titled 'Isolated cells and populations comprising same for the treatment of CNS diseases'. Granted claims cover an isolated cell population secreting GDNF, a pharmaceutical composition comprising the isolated cells, and a device comprising the pharmaceutical composition, including a device that is adapted for administration of the isolated cell population into the spinal cord.

On February 19, 2021, the Hong Kong patent office sealed Patent No. HK1209453 titled 'Methods of Generating Mesenchymal Stem Cells which secrete Neurotrophic Factors'. Allowed claims cover the method for manufacturing MSC-NTF cells (NurOwn®).

On November 30, 2021, the USPTO issued US Patent No. 11,185,572 titled 'Mesenchymal stem cells for the treatment of CNS diseases'. The granted claims are for a method of treating a disease selected from the group consisting of Parkinson's disease, ALS, Alzheimer's disease, stroke and Huntington's disease using MSC-NTF cells (NurOwn).

On February 15, 2022, we announced that the Brazilian Patent Office granted patent application BR112015001435-6 titled '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), wherein said cells do not Secrete Nerve Growth Factor (NGF)'. The granted claims cover a method of manufacturing MSC-NTF cells (NurOwn®).

On April 6, 2023, the EPO accepted European Patent Application No.: 15710010.8 titled 'Method of Qualifying cells'. Allowed claims include a method of qualifying whether a cell population is a suitable therapeutic for treating ALS and an isolated population of mesenchymal stem cells for use in treating ALS.

On June 2, 2023, the Australian Patent Office accepted Application No. 2019252987 titled "Cell-Type Specific Exosomes and Use Thereof". Accepted claims include an isolated Exosomes population derived form MSC-NTF cells as well as a pharmaceutical composition for the treatment of neurodegenerative diseases.

On August 22, 2023 The Israel Patent Office accepted Application No. 277447 titled “Cell-Type Specific Exosomes and Use Thereof”. Accepted claims include an isolated Exosomes population derived from MSC-NTF cells as well as a pharmaceutical composition for the treatment of neurodegenerative diseases.

On Dec. 26, 2023, we announced the European grant for NurOwn® as well as the Australian grant and Israeli allowance for the NurOwn® exosomes.

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

Recent Scientific and Industry Presentations

- On March 20, 2023, Dr. Stacy Lindborg, Co-Chief Executive Officer at Brainstorm Cell Therapeutics, presented a scientific poster titled “Measuring the rate of impairment in ALS patients using the Revised-ALS Functional Rating Scale: Key Insights into the Floor Effect of the Scale” at the 2023 Muscular Dystrophy Association Clinical and Scientific Conference in Dallas, Texas held March 19-22, 2023. The presentation showed that a floor effect was observed in the PRO-ACT database, and a pattern of a plateau in ALSFRS-R total score was accompanied by scale items of 0 suggesting measurement challenges in those with advanced ALS due to the floor effect of the ALSFRS-R in the NurOwn® phase 3 trial and historical studies which are included in the PRO-ACT database. Analyses conducted in those not impacted by the floor effect at baseline of the NurOwn® phase 3 trial revealed statistically significant, clinically meaningful effects with NurOwn® on the primary and key secondary endpoints

- On May 3, 2023, Dr. Lindborg, presented “A discussion of NurOwn’s® Full Data Package” at the Everything ALS Experts Talk Series. The presentation summarized key dates in the FDA regulatory review process for NurOwn’s® including the current status of being under active review. Data illustrating the extent of impact of participants with Advanced ALS disease who were included in the trial and resulted in the inability to accurately measure disease progression in the trial, confounding the treatment effect from the Phase 3 trial, in addition to sharing analyses minimizing this impact which demonstrate an important treatment effect across study endpoints.

- On May 17 and 18, 2023, Dr. Lindborg and Antonio Trejo Diaz, Vice President, Regulatory Affairs of the Company, participated as invited expert speakers at the 2023 ALS Drug Development summit which was focused on transforming translational tools to accelerate future ALS approvals. Dr. Lindborg presented an invited talk entitled “Reviewing ALSFRS-R as the Established Endpoint for ALS Clinical trials.”

- On June 21, 2023, Dr. Lindborg and Mr. Lebovits participated in a fireside chat at the Maxim Group Healthcare Virtual Conference

- During the week of July 7, 2023, Dr. Lindborg presented new biomarker data from the Phase 3 trial of its late-stage investigational ALS treatment, NurOwn® at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference. These data show that treatment with NurOwn® significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, including neurofilament light (“NfL”) over time compared to placebo in all trial participants. The presentation provides further evidence of the importance of NfL as a prognostic biomarker for ALS and predictive biomarker following NurOwn® treatment. A causal inference model demonstrated that NurOwn® driven NfL reductions were associated with better clinical outcomes.

- On November 17, 2023, we announced a podium presentation and panel discussion at the 6th Annual ALS Research Symposium hosted by ALS ONE. The presentation features new analyses from the NurOwn® placebo-controlled Phase 3 ALS trial that highlight the biological effect of NurOwn® through CSF biomarker data. The presentation, titled, “NurOwn® for ALS: Biomarker exploration of NurOwn® multimodal mechanism of action on neuroinflammation, neuroprotection and neurodegeneration” was presented by Bob Dagher, MD, Executive Vice President and Chief Development Officer at BrainStorm.

- On February 28, 2024, Dr. Stacy Lindborg, Co-Chief Executive Officer at Brainstorm Cell Therapeutics, provided a corporate update at 17th Annual European Life Sciences CEO Forum in Zurich, Switzerland. Dr. Lindborg also participated in a panel discussion entitled “Neuro Advances Panel: Highlighting the Main Opportunities”.

- On March 4, 2024, Dr. Bob Dagher, EVP and Chief Development Officer at Brainstorm Cell Therapeutics, presented a scientific poster titled "Design of A Phase 3B Trial of Debamestrocel (NurOwn®) in ALS" the 2024 Muscular Dystrophy Association Clinical and Scientific Conference in Orlando, Florida held March 3-6, 2024. The presentation provided an overview into the key features of the phase 3b trial design.

Research and Development

We are actively engaged in research and development to evaluate the potential for clinical development of NurOwn® and MSC-NTF derived Exosomes in various neurodegenerative disorders, neurodegenerative eye disease and acute respiratory distress syndrome ("ARDS"). MSC-NTF derived Exosomes are an example of ongoing research in additional specialized derivative cell products. 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.

The exosome research efforts are primarily focused on manufacturing of MSC-NTF exosomes from bone marrow derived MSC:

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

NurOwn® derived exosomes have the potential to treat 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.

In a preclinical 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 ARDS.

On May 4, 2022, we made a presentation titled "MSC-NTF derived small extracellular vesicles display superior macrophage immunomodulation compared with vesicles derived from naïve MSCs" at the International Society of Cell & Gene Therapy ("ISCT") 2022 Meeting in San Francisco, CA May 4-7. The presentation highlighted results of a preclinical study undertaken to understand the mechanisms underlying the superior preclinical efficacy of Exo MSC-NTF versus Exo-MSC in acute lung injury models.

On May 25, 2021, we made a scientific presentation of NurOwn® Exosome preclinical ARDS data at the ISCT 2021 New Orleans Virtual Meeting demonstrating that intrathecal administration of NurOwn-derived exosomes resulted in statistically significant improvements in multiple lung parameters in a mouse model of ARDS.

On May 26, 2022, we presented a poster titled “Therapeutic effect of MSC-NTF exosomes in experimental bleomycin-induced lung injury” at the ISEV 2022 Annual Meeting, Lyon France. Results from a preclinical study demonstrating superior outcomes of exosomes derived from MSC-NTF cells compared to exosomes derived from MSC cells were presented.

A poster titled, “Therapeutic Benefits of MSC-NTF (NurOwn®) Exosomes in Acute Lung Injury Models” was presented on October 19, 2021 at the NYSCF 2021 Virtual Meeting, which was held on October 19-20, 2021. Results in two different acute lung injury models showed that the beneficial effects of intratracheal administration of Exo MSC-NTF (MSC-NTF derived exosomes) were more active than Exo MSC (MSC-derived Exosomes) in multiple parameters, including increase in blood oxygen saturation and reduction in lung pathology, inflammatory infiltration and levels of proinflammatory cytokines in bronchoalveolar lavage fluid (“BALF”), in addition to reduction of lung fibrosis in the Bleomycin model.

The observed positive preclinical results suggest that intratracheal administration of Exo MSC-NTF may have clinical potential as a therapy for acute lung related pathologies and has the potential to modify physiological, pathological, and biochemical outcomes with greater activity than sEVs isolated from naïve MSCs.

For the completed 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 and in Burlington, Massachusetts. 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 . Positive top-line clinical trial results from our Phase 2 PMS trial evaluating three repeated intrathecal administrations of NurOwn®, each given 2 months apart, as a treatment for PMS was announced on March 24, 2021. We are also strategically focused on fully executing the clinical development of NurOwn® in PMS, reviewing the optimal approach in AD.

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, 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).

NurOwn® in CNS Disease

Our highest priority is to obtain regulatory approval of NurOwn® for ALS. We are also strategically focused on fully executing the clinical development of NurOwn® in PMS, reviewing the optimal approach in 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.

Approved treatments for Amyotrophic Lateral Sclerosis (ALS) primarily focus on managing symptoms rather than disease modification. Key opinion leaders and researchers suggest that a combination of therapies may be necessary for disease modification. Treatment decisions are typically determined by the patient's symptoms, preferences and the stage of the disease. Currently, there are four FDA-approved ALS therapies—Riluzole, Radicava, Relyvrio, and Qalsody—each showing modest improvements in survival or ALS function.

- Riluzole –approved by the FDA to treat ALS in 1995. 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- originally approved by the FDA (May 2017) as an intravenous (IV) infusion based on a single Phase 3 study carried out in Japan. In 2022, Radicava ORS, an oral suspension, was approved by the FDA. The effectiveness of Radicava ORS was based on a study demonstrating comparable levels of Radicava ORS in the bloodstream to the levels from the IV formulation of Radicava.

- Relyvrio (sodium phenylbutyrate and taurursodiol)-approved by the FDA in September of 2022. Relyvrio is taken orally. The efficacy of Relyvrio for the treatment of ALS was demonstrated in a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group study.

- Qalsody (tofersen) – was approved by the FDA in 2023. Qalsody was granted accelerated approval based on a reduction of neurofilament, a marker of neurodegeneration. Tofersen targets the ultra-rare genetic form of ALS known as Superoxide dismutase 1 (SOD1)-amyotrophic lateral sclerosis.

Progressive Multiple Sclerosis (PMS)

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)

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. Recently the FDA approved Aduhelm, a monoclonal antibody directed against amyloid for the treatment of AD. The implications of Aduhelm approval on the AD treatment market is evolving and we are actively reviewing the implications on the development of AD disease modifying therapies.

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 27 granted patents and 23 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 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 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 USPTO granted US patent, No. 9,879,225 which claims priority from this same PCT application This patent relates to methods of treating ALS and Parkinson's disease using mesenchymal stem cells that secrete neurotrophic factors, specifically 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, 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 BDNF and 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 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 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 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 BDNF, GDNF, HGF and VEGF.

On August 24, 2018, the 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 EPO 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 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 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 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 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 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 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 MSCs derived from the bone marrow of a single donor. The said neurotrophic factors includes BDNF; GDNF; HGF; and 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.

On January 18, 2022 the Brazilian Patent Office granted patent No BR112015001435-6 titled: “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), wherein said cells do not Secrete Nerve Growth Factor (NGF).” The granted claims cover a method of manufacturing MSC-NTF cells (NurOwn®).

On April 6, 2023, the EPO accepted European Patent Application No.: 15710010.8 titled ‘Method of Qualifying cells’. Allowed claims include a method of qualifying whether a cell population is a suitable therapeutic for treating ALS and an isolated population of mesenchymal stem cells for use in treating ALS.

On June 2, 2023, the Australian Patent Office accepted Application No. 2019252987 titled “Cell-Type Specific Exosomes and Use Thereof”. Accepted claims include an isolated Exosomes population derived form MSC-NTF cells as well as a pharmaceutical composition for the treatment of neurodegenerative diseases.

On August 22, 2023 The Israel Patent Office accepted Application No. 277447 titled “Cell-Type Specific Exosomes and Use Thereof”. Accepted claims include an isolated Exosomes population derived from MSC-NTF cells as well as a pharmaceutical composition for the treatment of neurodegenerative diseases.

On December 26, 2023, we announced the European grant for NurOwn® as well as the Australian grant and Israeli allowance for the NurOwn® exosomes.

Patents protecting NurOwn® have been issued in the United States, Canada, Japan, Europe, Hong-Kong, Brazil 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, WO/2019/198077 was filed on April 10, 2019, WO 2022/018729 was filed on July 20, 2021, and WO 2023/281502 was filed July 5, 2022.

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**			**Europe, US**	**2026-2030**
2	**Mesenchymal Stem Cells for the treatment of CNS Diseases PCT/ IL2009/000525**			**US, Europe, Hong Kong**	**2029-2030**
	Isolated population of cells, methods of generating same and uses thereof in the treatment of CNS diseases PCT IL2009/000525			**Israel**	**2029-2030**
3	**Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors / PCT/IL2013/050660**			**US, Canada, Japan, Israel, Europe Hong Kong**	**2033**
	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), wherein said cells do not Secrete Nerve Growth Factor (NGF)			**Brazil**	**2033**
4	**Method of Qualifying Cells /PCT IL2015/050159**	**Hong Kong,**		**Japan, Israel,Europe**	**2035**
	Populations of Mesenchymal Stem Cells that secrete Neurotrophic Factors US 10,564,149			**US**	**2035**
	Pharmaceutical composition comprising bone-marrow derived mesenchymal stem cells Canadian Patent no. 2,937,305			**Canada**	**2035**
5	**Cell-Type Specific Exosomes and Use Thereof PCT/IL2019/050401**	**Europe, Japan, S. Korea, , Canada**	**Israel**	**Australia**	**2039**
	MSC-NTF Specific Exosomes and Use Thereof	**US**			
6	**Methods and Compositions for Treating Lung Conditions PCT/IL2021/050885**	**US, Australia, Canada, Israel, Japan and Europe**			**2041**
7	**Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors in A Bioreactor System PCT/IL2022/050718**	**US, Europe,**			

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 our 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.

Non-Proprietary (generic) name

In June 2022, the United States Adopted Names ("USAN") Council adopted 'Demabestrocel' as the non-proprietary (generic) name for the MSC-NTF cells for the treatment of neurodegenerative diseases with unmet need, such as ALS, MS and AD. The name was approved by the International Nonproprietary Names ("INN") of the World Health Organization ("WHO") and published on USAN's website at https://searchusan.ama-assn.org/finder/usan/search/DEBAMESTROCEL/relevant/1/.

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 treatment 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. Biological Products Development Process

The FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), the Public Health Service Act (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 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 Practice ("cGTP") requirements 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 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 ("GLP"), requirements or other regulations;
- Submission to the FDA of an IND application which must become effective before human clinical trials may begin;
- Performance of adequate and well-controlled clinical trials according to Good Clinical Practices ("GCP") to establish the safety and efficacy of the proposed biological product for its intended use;
- Submission to the FDA of a BLA 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 current Good Manufacturing Practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity; and
- The FDA's review and approval of the BLA.

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.

Safety reports detailing the adverse events identified in the course of the clinical trials must be submitted 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.

At times during the development of a biological product, sponsors are given opportunities to meet with the FDA. This commonly occurs prior to submission of an IND, at the end of Phase 2 testing, and before a BLA is submitted. Meetings at other times may also be requested. These meetings provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. For example, prior to initiating a Phase 3 study, sponsors have the option to submit a request for Special Protocol Assessment, or SPA, to the FDA which, if granted provides the FDA's concurrence that the study, if conducted as designed and if successful, could support a regulatory approval for the product candidate.

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 a BLA, requesting approval to market the product. The submission of a 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 if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the FDA's threshold determination that it is sufficiently complete to permit a substantive review. If the FDA determines that the BLA is incomplete, the FDA may refuse to file the application. If the FDA refuses to file a BLA, the applicant may refile the application with information addressing the FDA identified deficiencies, which refiling would be subject to FDA review before it is accepted for filing, or the applicant may request an informal meeting with the FDA about whether the application should be filed. After the meeting, the applicant may request that the application be Filed over Protest. When an application is Filed over Protest, the FDA is required to review the application as filed. Generally, the FDA does not favor the File over Protest procedure. There may also be certain consequences of filing an application over Protest. For example, such an application would not be eligible for certain FDA communications over the course of the review cycle.

In addition, an applicant that receives an RTF can, in some circumstances, appeal the decision using the FDA's dispute resolution procedures. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether a product meets the FDA's approval standards and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act, or PDUFA, for standard applications for original BLAs, the FDA targets ten months from the date the FDA files the application (i.e., the filing date) in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application granted priority review by the FDA. The FDA does not always meet its PDUFA goal dates. The review process and the PDUFA goal date may be extended by an additional three-month review period when a major amendment, such as a major new clinical safety/efficacy study report or a major re-analysis of a previously submitted study, is submitted. However, when an application is filed with the FDA over Protest, the FDA generally will not review amendments to the application during any review cycle and will not issue information requests to the applicant during the agency's review.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, for its intended use, and whether the product is being manufactured in accordance with cGMP to ensure its continued safety, purity and potency. The FDA may refer applications for novel biological products or biological products that present difficult or novel questions of safety, efficacy, or quality to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Where applicable, the FDA also will not approve the product if the manufacturer is not in compliance with the cGTPs. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP, cGTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a novel product (e.g., new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the drug product will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. When an application is Filed over Protest, the performance goals implemented by the FDA under PDUFA do not apply to any resubmission of the application following an FDA complete response action, and any such resubmission is reviewed as available resources permit.

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 biologic's safety and effectiveness after BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or 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 a 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 to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or 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 EU has similar but not identical benefits in the EU.

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.

Fast Track Designation

To be eligible for Fast Track designation, new biological product candidates must be intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a biologic may request the FDA to designate the biologic as a Fast Track product at any time during the clinical development of the product. One benefit of Fast Track designation, for example, is that the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

ACT for ALS and Congressional Hearing on Advancing Treatments and cures for Neurodegenerative Diseases including ALS

The U.S. House of Representatives Subcommittee on Health of the Committee on Energy and Commerce held a hearing on July 29, 2021. The hearing was entitled, "The Path Forward: Advancing Treatments and Cures for Neurodegenerative Diseases." The aim of the hearing was to discuss the challenge of advancing treatments and cures for neurodegenerative diseases to ensure collaboration and multidiscipline coordination between the FDA, the National Institutes of Health (the "NIH"), academic researchers, private drug companies, and patients. Leading ALS neurologists and advocates testified regarding the immense unmet medical need in ALS and the urgency to exercise for regulatory flexibility when evaluating therapies for 100% fatal and heterogenous diseases such as ALS. The following are excerpts from the testimonies from the E and C Hearing:

Jinsy Andrews, MD, MSc representing Herself, The ALS Association, and Columbia University at this hearing stated, "We have seen the ability for regulatory flexibility and speed in other areas. The reality is that ALS is 100 percent fatal. The pipeline and our understanding have grown significantly in the last five years." "Approving a new drug for ALS — or Alzheimer's or other diseases — can have a bigger impact than just providing people with a single new treatment. New approvals can spur innovation and investment by industry in a disease space with few available treatments available. But in cases of fatal neurological diseases without cures, when a promising drug comes along that has the potential to retain function and extend life, patients' needs are paramount."

Merit Cudkowicz, MD Chair, Dept of Neurology, Mass General Hospital Director Sean M. Healey & AMG Center for ALS, Mass General Hospital Julianne Dorn Professor of Neurology, Harvard Medical School testified the following at this hearing, "We must disrupt the current, slow approach to therapy development and partner expertise from our field and other fields with the FDA to think more creatively and become more effective in choosing the best treatments for the right person at the right time. We have begun to do this with the AMX035 (Centaur), NurOwn® and Tofersen (SOD1 gene therapy) trials and the new Healey ALS Platform Trial." Specifically, she remarked, "We have heard reports from people in the NurOwn® trial and expanded access program of improvements in function. This is not something we typically see or hear in ALS. There were important changes in important biomarkers in the phase 3 trial and better responses in people who started treatment in an earlier stage of the disease. The manuscript with full results is under review. Continued dialogue with the FDA on how to identify subsets of responder is critical as it is very likely that this treatment and many future treatments will work better in one group of people than another."

Brian Wallach & Sandra Abrevaya Co-Founders, I AM ALS cited the 2019 ALS therapy Guidance document in their testimony and stated the following: “When the Guidance was finally released, the ALS community was filled with hope as it stressed the need for “regulatory flexibility in applying the statutory standards to drugs for serious diseases with unmet medical needs.” Moreover, it explicitly stated that “[w]hen making regulatory decisions about drugs to treat ALS, FDA will consider patient tolerance for risk and the serious and life-threatening nature of the condition in the context of statutory requirements for safety and efficacy.” They further addressed specific therapies and remarked, “The second, NurOwn, involves the extraction, enrichment and injection of a patient’s own stem cells. The Phase III trial for NurOwn® did not meet its overall primary endpoint. Going into the trial the drug company identified a score of 35 on the ALSFRS, the clinical assessment of a patient’s disease progression, as the mean expected score of patients when they first enrolled. In the end, more patients with lower ALSFRS scores enrolled in the trial than was expected. Thus, the actual mean ALSFRS was below 35. Of the patients who started the trial with a score of more than 35, they not only had a significantly higher response rate than those on placebo, but also their ALSFRS was two points higher than those on the placebo at the end of the trial. Given these results, why didn’t the FDA approve NurOwn® for at least those patients with ALSFRS scores above 35 and at the same time require the company to complete a confirmatory trial on the larger group? That is an approach that gives people living with ALS today a chance while giving the FDA more data. With a disease as complex and heterogeneous as ALS we need this type of flexibility and urgency from the FDA.” They closed their testimony with the following: “This generation of patients and our families demand better from ourselves, the medical community and policymakers. You have the power to help make ALS like MS, to change ALS from a “rare disease” to a disease that more than 1 million Americans are living with. Moreover, ALS is linked to Alzheimer’s, Parkinson’s and Frontotemporal Dementia, among others. Meaning if we cure ALS, we can help unlock cures for all. That is a future worth fighting for.”

The Act for ALS was signed into law on December 23, 2021. The law establishes grant programs to address neurodegenerative diseases, such as ALS and contains other related provisions. It authorized up to 100 million dollars per year for 5 years, $500 million dollars total. The Department of Health and Human Services (“HHS”) shall award grants to eligible entities for scientific research utilizing data from expanded access to investigational ALS treatments for individuals who are not otherwise eligible for clinical trials. The FDA shall award grants to public and private entities to cover the costs of research and development of drugs that diagnose or treat ALS and other rare neurodegenerative diseases. HHS shall also establish the Public-Private Partnership for Neurodegenerative Diseases between the NIH, the FDA, and at least one eligible entity (generally, an institution of higher education or a nonprofit organization). The partnership shall support the development and regulatory review of drugs that address ALS and other rare neurodegenerative diseases.

On June 23, 2022, the FDA released its Action Plan for Rare Neurogenerative Diseases including ALS. The action plan contains the FDA’s five-year strategy for bolstering scientific achievement and promoting innovation for rare neurodegenerative diseases by engaging in targeted activities including establishing the FDA Rare Neurodegenerative Diseases Task Force, establishing the public-private partnership for rare neurodegenerative diseases, developing disease-specific science strategies, and leveraging ongoing FDA regulatory science efforts. The action plan also includes a science strategy developed for ALS, which outlines activities that the FDA will conduct between June 2022 and June 2027 to address current challenges to ALS drug development. Further, on September 14, 2022, the FDA and NIH announced the launch of the Critical Path for Rare Neurodegenerative Diseases (CP-RND), a public-private partnership aimed at advancing the understanding of neurodegenerative diseases and fostering the development of treatments for ALS and other rare neurodegenerative diseases. The Critical Path Institute (C-Path) was selected as the convener of this partnership.

Brian Wallach, ALS patient and co-founder of the organization I AM ALS, stated regarding the passage of Act for ALS: “For 160 years, there has been no hope for those diagnosed with ALS. That changed tonight. Tonight, as a result of tens of thousands of ALS advocates working nonstop to make their voices heard and demanding the chance to live, hope has finally come to people living with ALS.”

In February 2023, the National Institute of Neurological Disorders and Stroke (“NINDS”), the lead institute for ALS research within the NIH, completed a strategic planning process to identify the highest priorities for research that will lead to the discovery of effective interventions for the diagnosis, treatment, management, prevention, or cure of ALS. Extensive feedback from a large and diverse group of contributors resulted in a comprehensive list of priorities for the ALS community.

Significant policy changes and Congressional actions taken have elevated the focus on research for ALS and other neurodegenerative diseases and increased funding sources to expedite therapy development. Examples of this include increased funding through Government Programs such as ACT for ALS and Congressionally Directed Medical Research Programs in addition to the growth and mobilization of ALS Congressional Caucus.

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 plus (b) the time between the submission date of a BLA 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 USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Post-Approval Requirements

Any biological products 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, 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 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. Biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of 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.

Biological product manufacturers and other entities involved in the manufacturing and distribution of approved biological products, and those supplying products, ingredients, and components of them, 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, cGTP 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 biological product. 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. Manufacturers and other parties involved in the drug supply chain for prescription drugs must also comply with applicable product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States.

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.

Regulation of Combination Products in the United States

Certain products that we develop may be comprised of components that are regulated under separate regulatory authorities and by different centers at the FDA. These products are known as combination products. A combination product is comprised of a combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, a device, and a biological product.

A combination product with a biological primary mode of action generally would be reviewed and approved pursuant to the biological product approval processes under the FDCA and PHSA. Under FDA regulations, combination products are subject to cGMP requirements applicable to both biological products and devices, including the requirements of the Quality System Regulation ("QSR"), applicable to medical devices.

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 (the "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 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 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 EU, 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 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 ("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 ("HITECH"), 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. 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;

- the federal transparency requirements under the Affordable Care Act ("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 HHS, CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- 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.

In addition to requirements of US federal and state law, we may also be subject to additional privacy restrictions around the world including Israel. Israel has implemented data protection laws and regulations, including the Israeli Protection of Privacy Law, 5741-1981 (the "PPL"). The PPL imposes certain obligations on the owners of databases containing personal data, including, e.g., a requirement to register databases with certain characteristics, an obligation to notify data subjects of the purposes for which their personal data is collected and processed and of the disclosure of such data to third parties, a requirement to respond to certain requests from data subjects to access, rectify, and/or delete personal data relating to them and an obligation to maintain the security of personal data. In addition, the Protection of Privacy Regulations (Data Security), 5777-2017, that entered into force in May 2018, impose comprehensive data security requirements on the processing of personal data. The Protection of Privacy Regulations (Transfer of Data to Overseas Databases), 5761-2001, further impose certain conditions on cross-border transfers of personal data from databases in Israel. Certain violations of the PPL are considered a criminal and/or a civil offense and could expose the violating entity to criminal, administrative, and financial sanctions, as well as to civil actions. Additionally, the Israel Privacy Protection Authority, or the Privacy Protection Authority, may issue a public statement that an entity violated the PPL, and such a determination could potentially be used against such entity in civil litigation. The Israeli Ministry of Justice has introduced amendments to the PPL designed, among other things, to enhance the Privacy Protection Authority's investigative and enforcement powers (including powers to impose fines) and to broaden data subject rights.

Further, should we begin trials in or otherwise have operations in or collect data from individuals in the European Economic Area (the "EEA"), we will be subject to stringent European data protection rules. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EEA including personal health data, is subject to the General Data Protection Regulation 2016/679 (the "EU 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 EU GDPR and UK GDPR are wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to ensuring an appropriate legal basis or condition applies to the processing of personal data, stricter requirements relating to the processing of sensitive data (such as health data), where necessary 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, conducting data protection impact assessment where there is high risk processing and taking certain measures when engaging third-party processors. The EU GDPR/UK GDPR also impose strict rules on the transfer of personal data to countries outside the EEA and the United Kingdom, respectively, including to the United States, and permit data protection authorities to impose large penalties for violations, including potential fines of up to €20 million or 4% of annual global revenues under the EU GDPR and up to £17.5 million or 4% of worldwide revenue for violations of the UK GDPR, whichever is greater. The EU 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 EU GDPR/UK GDPR. In addition, the EU GDPR/UK GDPR include restrictions on cross-border data transfers.

Despite Brexit, the EU GDPR and UK GDPR remain largely aligned. The UK has announced plans to reform the country's data protection legal framework in its Data Reform Bill, which will introduce changes to the UK GDPR. Currently, the most impactful point of divergence relates to transfer mechanisms (i.e., the ability for EU/UK companies to transfer personal information to third countries, including the United States), because it requires us to implement a variety of different contractual clauses approved by EU or UK regulators. The European Commission has issued standard contractual clauses for data transfers from controllers or processors in the EU (or otherwise subject to the EU GDPR) to controllers or processors established outside the EU. The new standard contractual clauses require exporters to assess the risk of a data transfer on a case-by-case basis, including an analysis of the laws in the destination country. The UK is not subject to the European Commission's new standard contractual clauses but has published a UK-specific transfer mechanism, which enables transfers from the UK. The UK-specific mechanism, the "International Data Transfer Agreement", requires a similar risk assessment of the transfer as the standard contractual clauses. Further, the EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework (the "Framework"), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with EU GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. This complexity and the additional contractual burden increases our overall risk exposure. There may be further divergence in the future, including with regard to administrative burdens.

Compliance with the EU GDPR and UK GDPR is 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 or UK activities.

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 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 was enacted, which, among other things, 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 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, 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 requirements to report financial arrangements, commonly referred to as the Physician Payments Sunshine Act; created a requirement to annually report the identity and quantity of drug samples that manufacturers and authorized distributors of record provide to physicians; created a Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; created a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% 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 established the Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. 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 2031 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, 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. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

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, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. 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, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. 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. On November 3, 2023, the U.S. District Court of South Carolina issued an opinion in Genesis Healthcare Inc. v. Becerra et al. that may lead to an expansion of the scope of patients eligible to access prescriptions at 340B pricing. The outcome of this judicial proceeding is uncertain. We continue to review developments impacting the 340B program.

The Inflation Reduction Act of 2022 (the "IRA") includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

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 expanded and cryopreserved in order to produce doses of NurOwn®. Each individual patient MSCs would be cryopreserved and maintained for production of 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.

Competition

There are several clinical trials underway evaluating experimental treatments for ALS, of which only one is a cell-based trials being conducted by other commercial entities. 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 based on the results from a phase 2 Korean trial and although it has been reported that a phase 3 trial was authorized by the FDA, it is only being conducted in South Korea. The ongoing Phase 3 trial has an estimated completion of Q2 2026. Kadimastem's AstroRx, derived from human embryonic stem cells, completed a Phase 1/2 trial, and a Phase 2a trial is set to begin in the US. Coya and Rapa Therapeutics are evaluating Tregs in Phase 2 and Phase 1/2, respectively. Ongoing Phase 3 trials involve AB Science (masitinib as an add-on to riluzole) and Ionis/Biogen (Ionis 363) in FUS-ALS.

Neuraltus Pharma's NP001, which modulates macrophages, failed in Phase 2 but is being advanced by Neuvivo based on a potential subgroup showing efficacy.

The Healy platform trial includes seven ALS investigational therapies to date: Zilucoplan; Pridopidine; Trehalose; Verdiperstat; CNM-Au8; ABBV-CLS-7262: DNL343. To date none of the Healy Platform regimens have met primary or secondary endpoints. The Zilucoplan arm was stopped after futility analysis. Post-Hoc analysis and open label extension data from Pridopidine and CNM-Au8 have led to planned Phase 3 trial due to initiate in 2024. The Trehalose arm is fully enrolled and due to be read out. ABBV-CLS-7262 and DNL343 are both actively enrolling.

Approved treatments for Amyotrophic Lateral Sclerosis (ALS) primarily focus on managing symptoms rather than disease modification. Key opinion leaders and researchers suggest that a combination of therapies may be necessary for disease modification. Treatment decisions are typically determined by the patient's symptoms, preferences and the stage of the disease. Currently, there are four FDA-approved ALS therapies—Riluzole, Radicava, Relyvrio, and Qalsody—each showing modest improvements in survival or ALS function.

Human Capital

We currently have 29 employees, all of whom are full-time. None of our employees is represented by a labor union. 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 our success 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:

- If we fail to regain compliance with the continued listing requirements of Nasdaq, our Common Stock may be delisted and the price and liquidity of our common stock may be negatively impacted.
- We are and could be further subject to securities class action litigation and other types of stockholder litigation.
- 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.
- We have a history of losses and we expect to incur losses for the foreseeable future.
- The continuing effects of the novel coronavirus disease, COVID-19, including the emergence of new variants, 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.

- Political, economic and military instability in Israel may impede our ability to execute our plan of operations. For example, due to the Israel-Hamas war and/or other military conflicts with Lebanon, Syria, Iran or other hostile countries may lead to difficulties in bringing operational personnel and equipment into Israel.

Risks Related to our Financial Condition and Capital Requirements

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

We will need to raise additional funds to meet our anticipated expenses so that we can execute our business plan. We expect to incur substantial and increasing net losses for the foreseeable future as we increase our spending to execute our development 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.

We have 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, 2020, December 31, 2021 December 31, 2022, or December 31, 2023. We are currently in the process of introducing the Company to strategic partners. In 2024 and the upcoming years, the Company will focus on initiating and completing a Phase 3b trial 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 conduct 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 completed our Phase 3 ALS trial and announced on February 2021 that the FDA concluded from their initial review that the current level of clinical data does not provide the threshold of substantial evidence that FDA is seeking to support a BLA. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA. The FDA indicated that we could request a Type A meeting to discuss the content of the RTF letter, and the Type A meeting was held on January 11, 2023. We notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn® BLA for ALS over Protest. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. Written notification was received on March 22, 2023 from the FDA project manager associated with the BLA confirming the FDA's decision to grant an ADCOM for the NurOwn® BLA for ALS. On September 27, 2023, we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that the FDA invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for ALS. BrainStorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the BLA for NurOwn® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision to withdraw the BLA was coordinated with the FDA and is viewed by the FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a SPA with the FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. As an outcome of the meeting, BrainStorm will submit relevant documentation as outlined by the FDA to support the SPA. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of 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.

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 autologous stem cell therapy creates significant challenges with regard to product development and optimization, manufacturing, government regulations, and market acceptance. For example, although cell therapy has been available in oncology, the FDA's experience with mesenchymal stem cell therapies is limited. None have been approved by the FDA for commercial sale in the US, 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 clinical trials, we may not be able to 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 clinical trials, we may not be able to 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 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 growth in the number of our employees, which could be significant in nature as we near regulatory approval, 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.

If any contract manufacturing organization ("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. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of 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 ongoing COVID-19 pandemic or future epidemics 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 and cGTP regulations 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. For more information, see *"Business – Other Healthcare Laws and Compliance Requirements.*

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 Privacy Act (the "CCPA"), created a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, established new data privacy rights for consumers in the State of California, imposed special rules on the collection of consumer data from minors, and created 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. In addition, the California Privacy Rights Act (the "CPRA") was passed in November 2020, and as of January 1, 2023, has imposed additional obligations on companies covered by the legislation. The CPRA significantly modified the CCPA, including by expanding consumers' rights with respect to sensitive personal information and created a new state agency that is vested with authority to implement and enforce the CCPA. 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.

The CCPA mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. Similar laws have been passed in numerous other states. These enacted consumer data privacy laws are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data and limited obligations for entities regulated by HIPAA. These comprehensive consumer privacy laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. A number of other states have also proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

There are also states that are specifically regulating health information. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

The evolving compliance and operational requirements related to these various state data privacy and security laws impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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. For more information, see *"Business – Third Party Payor Coverage and Reimbursement."*

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.

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 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.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. 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.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

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.

Our business could be adversely affected by the effects of health epidemics, including any ongoing public health crises, in regions where we operate.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Although the U.S. government has declared an end to the Public Health Emergency related to COVID-19, there may be lingering effects of the COVID-19 pandemic on our business. The COVID-19 may continue to impact the United States, Europe and Israel, where we conduct our operations, as well as our clinical trials for NurOwn®. The full extent to which the COVID 19 pandemic will continue to 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.

The adverse impact of public health crises such as pandemics or similar outbreaks in the countries and regions where we have concentrations of potential clinical trial sites or other business operations and where several of our third-party suppliers and contractors are located could adversely affect our business, including by causing significant disruption in the operations of third parties upon whom we rely. The COVID-19 endemic presented a substantial public health and economic challenge around the world and affected employees, patients, communities and business operations, as well as the U.S. economy and financial markets.

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 and operations are directly affected by economic, political, geopolitical and military conditions in Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries and terrorist organizations active in the region. Acts of random terrorism periodically occur which could affect our operations or personnel. The conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel. 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 October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict.

Although we currently do not expect the ongoing conflict to affect our customers, manufacturing, research and development, supply chain, commercialization activities and current clinical studies, there can be no assurances that further unforeseen events will not have a material adverse effect on us or our operations in the future.

The Israel Defense Force (the "IDF"), the national military of Israel, is a conscripted military service, subject to certain exceptions. Since October 7, 2023, the IDF has called up more than 350,000 of its reserve forces to serve. It is possible that there will be further military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, for example, may have unintended negative effects and adversely impact our results of operations, liquidity or cash flows.

It is currently not possible to predict the duration or severity of the ongoing conflict or its efforts on ours business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations, interrupt our sources and availability of supply and hamper our ability to raise additional funds or sell our securities, among others.

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.

The Israeli government is currently pursuing extensive reforms to Israel's judicial system. In response to the foregoing developments, many individuals, organizations and institutions, both within and outside of Israel, have voiced concerns that the proposed reforms may negatively impact the business environment in Israel including due to increased currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in securities markets, and other changes in macroeconomic conditions. To the extent that any of these negative developments do occur, they may have an adverse effect on our business, our results of operations and our ability to raise additional funds, if deemed necessary by our management and board of directors.

If our or our vendors' security measures are breached or unauthorized access to individually identifiable health information or other personally identifiable information is otherwise obtained, our reputation may be harmed, and we may incur significant liabilities.

Unauthorized access to, or cybersecurity incidents relating to, our or our vendors' systems and databases could result in unauthorized access to data and information loss, compromise, or corruption of such data and information. Cybersecurity incidents have been increasing in sophistication and frequency and can include third parties gaining access to employee or customer data using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks, ransomware, social engineering, and other deliberate attacks and attempts to gain unauthorized access. Because the techniques used by threat actors who may attempt to penetrate and sabotage our network security or our website change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques.

In the event of a cybersecurity incident, we could suffer loss of business, severe reputational damage adversely affecting investor confidence, regulatory investigations and orders, litigation, indemnity obligations, damages for contract breach, penalties for violation of applicable laws or regulations, significant costs for remediation and other liabilities. For example, the loss of preclinical study or clinical trial data from completed or future preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or cybersecurity incident were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

We have incurred and expect to incur significant expenses to try to prevent cybersecurity incidents, including costs related to deploying additional personnel and protection technologies, training employees, and engaging third-party solution providers and consultants. Although we expend resources in an effort to protect our customer data against potential theft and cybersecurity incidents, we have been subject to attempted cyber-attacks in the past, and such measures cannot provide absolute security. Moreover, as we outsource more of our information systems to vendors and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems.

Despite our efforts, we remain at risk for cybersecurity incidents, including, without limitation, incidents that may occur as a result of third-party action, or employee, vendor or contractor error or malfeasance and other causes. If, in the future, we experience a material cybersecurity incident, we would likely experience harm to our reputation, financial performance, and customer and vendor relationships, and the possibility of litigation or regulatory investigations or actions by state and federal governmental authorities and non-U.S. authorities. Additionally, actual, potential, perceived or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants.

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 .

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 cGMP 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; and
- 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.

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.

On February 22, 2021, we announced high-level FDA feedback on NurOwn® ALS Clinical Development Program. The FDA concluded from their initial review that the current level of clinical data does not provide the threshold of substantial evidence that FDA is seeking to support a BLA. On March 2, 2021, the FDA issued a public statement that the data from the Phase 3 ALS study do not support the proposed clinical benefit of NurOwn® and that the FDA would continue to provide advice to us on our development program.

On August 15, 2022, we announced our decision to submit a BLA to the FDA for NurOwn® for the treatment of ALS. The BLA was filed on September 9, 2022. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA for NurOwn® for the treatment of ALS. The FDA informed us that the BLA is not sufficiently complete to enable a substantive review and that the FDA would therefore not file the BLA. The RTF letter contained a list of topics the FDA provided to BrainStorm as rationale for the BLA file being not sufficiently complete to enable a substantive review. According to the FDA, these reasons included one item related to the trial not meeting the standard for substantial evidence of effectiveness and CMC related items. The FDA indicated that we may request a Type A meeting to discuss the content of the RTF letter. On December 12, 2022, we announced the submission of a Type A meeting request with the FDA to discuss the contents of the RTF letter previously issued by the FDA regarding our BLA for NurOwn® for the treatment of ALS. On December 27, 2022, we announced that the FDA granted a Type A meeting to discuss the contents of the RTF letter previously issued regarding our BLA for NurOwn® for the treatment of ALS. The Type A Meeting was held on January 11, 2023.

The perspective shared by the FDA review team reflected what was in the previously issued RTF letter. Conversations on the best pathway to resolve the outstanding questions that continued following the Type A meeting. During these discussions, we were presented with multiple options to return the BLA to regulatory review, which included the regulatory procedure to File over Protest. These discussions resulted in our requesting the FDA to file our BLA over Protest, as this was the regulatory procedure that would allow us to reach an ADCOM in the shortest amount of time. We notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn® BLA for ALS over protest.

We received the FDA Type A meeting minutes on February 9, 2023. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. Written feedback was received on March 22, 2023 from the FDA project manager associated with the BLA confirming the FDA's decision to grant an ADCOM for the NurOwn® BLA for ALS.

The approval process is lengthy and difficult and the FDA, Israeli MoH, or other regulatory authorities may refuse to approve a BLA or equivalent marketing application if the applicable regulatory criteria are not satisfied. Generally, the FDA does not favor the File over Protest procedure. There are also certain consequences of filing an application over Protest. For example, such an application would not be eligible for certain FDA communications over the course of the review cycle. When an application is filed with the FDA over Protest, the FDA generally will not review amendments to the application during any review cycle and will not issue information requests to the applicant during the agency's review. When an application is Filed over Protest, the performance goals implemented by the FDA under PDUFA do not apply to any resubmission of the application following an FDA complete response action, and any such resubmission is reviewed as available resources permit.

If convened, an advisory committee may recommend against approval of a BLA or may recommend that the FDA require, as a condition of approval, additional preclinical studies, clinical trials or investigations, limitations on approved labeling or distribution and use restrictions. Even if an advisory committee makes a favorable recommendation, the FDA may still not approve the product candidate.

On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company's BLA for NurOwn® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 27, 2023, we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a Special Protocol Assessment (SPA) with FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS. 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.

Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.

NurOwn® is being developed, and future product candidates may be developed, as combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug/biologic components. Medical products containing a combination of new drugs, biological products or medical devices may be regulated as "combination products." In the United States, a combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate premarket review of combination products, the FDA designates one of its centers to have primary jurisdiction for the premarket review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug or biologic and device is sought under a single application, there could be delays in the approval process due to the increased complexity of the review process.

The FDA's agreement to any Special Protocol Assessment with respect to the study design of our planned Phase 3b clinical trial of NurOwn® for the treatment of ALS does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a successful review or approval process.

We have submitted a SPA request to the FDA for a Phase 3b clinical trial of NurOwn® for the treatment of ALS. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs and biologics by allowing the FDA to evaluate the proposed design and size of certain clinical or animal studies, including clinical trials that are intended to form the primary basis for determining a product candidate's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding protocol design and scientific and regulatory requirements. The FDA aims to complete SPA reviews within 45 days of receipt of the request. The FDA ultimately assesses whether specific elements of the protocol design of the trial, such as entry criteria, dose selection, endpoints and/or planned analyses, are acceptable to support regulatory approval of the product with respect to the effectiveness of the indication studied. All exchanges between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Although the FDA may agree to an SPA, an SPA agreement does not guarantee approval of a product. Even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts.

In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol. Generally, such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

Moreover, if the FDA revokes or alters any agreement reached under a SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval of NurOwn® for the treatment of ALS.

Even though we have obtained Fast Track designation for NurOwn® for the treatment of ALS in the United States, Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

If a biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation for a particular indication. The FDA has granted Fast Track designation for NurOwn® for the treatment of ALS and we may seek Fast Track designation for certain other of our current or future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. If granted, Fast Track designation makes a product eligible for more frequent interactions with the FDA to discuss the

development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Marketing applications of products candidates with Fast Track designation may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide any assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

Even though we have obtained Orphan Drug Designation for NurOwn® for the treatment of ALS in the United States and EU, and we may apply for Orphan Drug Designation for other product candidates, we may not be able to obtain such designations or maintain the benefits associated with orphan drug status, including orphan drug marketing exclusivity.

Regulatory authorities in some jurisdictions, including the United States and EU, may designate drugs or biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In order to obtain Orphan Drug Designation, the request must be made before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has Orphan Drug Designation subsequently receives the first FDA approval of that particular product for the disease 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 biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or orphan drug exclusivity can be overcome if a subsequent applicant demonstrates clinical superiority over our product.

In the EU, the Committee for Orphan Medicinal Products of the EMA grants orphan designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, which either affects not more than five in 10,000 persons in the EU, or products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that the medicine would generate sufficient return to justify the necessary investment in its development. In each case, there must be no satisfactory method of diagnosis, prevention, or treatment which is authorized for marketing in the EU, or, if a method exists, the product would be of significant benefit to those affected by the condition.

We have obtained from the FDA and EMA Orphan Drug Designations for NurOwn® for the treatment of ALS. We may seek Orphan Drug Designation for other product candidates. Even if we obtain Orphan Drug Designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective, if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products. In addition, although we may seek Orphan Drug Designation for other product candidates, we may never receive such designations. Any failure to obtain, maintain or otherwise recognize the benefits of orphan drug designation for our products or product candidates could have a material adverse effect on our prospects.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017 (“FDARA”). FDARA, among other things, codified the FDA’s pre-existing regulatory interpretation to require that a sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The legislation

reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and product listing, as well as continued compliance by us and/or any future CMOs CROs for any post-approval clinical trials that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of cell therapies and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, GCP, cGTP, and other regulations. For certain commercial prescription and biologic products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products;

- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, withdraw or modify regulatory approval;
- suspend or modify any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice ("DOJ"), the Office of Inspector General ("OIG") of the HHS, state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any current or future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained. Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

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 cGTP 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.

For certain commercial prescription biologic products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States.

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

If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business; we may in the future also license or purchase patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

If the scope of the patent protection we or our potential licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot assure you that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed (21 years if first filed as a provisional application). Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Even if they are unchallenged, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product

candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. We currently own or have exclusively in-licensed all of our patents or patent applications. Similar risks would apply to any patents or patent applications that we may own and those which we may license in the future. In many cases, in-licensed intellectual property is at greater risk, as we may not have access to all information or to prosecution and other aspects of the acquisition, maintenance and enforcement of the in-licensed intellectual property.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. No consistent policy governing the scope of claims allowable in the fields of antibodies and radiopharmaceuticals has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, corporate collaborators, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not until issuance as a patent. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications.

The issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even where patent applications we currently own, license, or that we may license in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade our patent rights by developing alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the USPTO or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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.

These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensors may have the right to terminate the licenses, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

These agreements impose numerous obligations, such as diligence and payment obligations. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. These licenses do and future licenses may include provisions that impose obligations and restrictions on us. This could delay or otherwise negatively impact a transaction that we may wish to enter into.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including disputes concerning:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

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 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.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.The intellectual property landscape around our product candidates is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving the infringement of patents and other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights and who allege that our product candidates, uses and/or other proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk that our product candidates may give rise to claims of infringement of the patent rights of others increases. Moreover, it is not always clear to industry participants, including us, which patents exist which may be found to cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications currently pending in our fields, there may be a risk that third parties may allege they have patent rights which are infringed by our product candidates, technologies or methods.

If a third party alleges that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property misappropriation which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement or misappropriation, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds we have willfully infringed intellectual property rights, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- an injunction prohibiting us from manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party agrees to license its patent rights to us;
- even if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights protecting our products; and
- we may be forced to try to redesign our product candidates or processes so they do not infringe third-party intellectual property rights, an undertaking which may not be possible or which may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If any of our product candidates are approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we may believe that patent claims or other intellectual property rights of a third party would not have a materially adverse effect on the commercialization of our product candidates, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that may be infringed by our product candidates. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents, held now or obtained in the future by a third party, were found by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product or methods use of the product, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover any aspect of our formulations, any combination therapies or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to take legal action to enforce our patents or our licensors' patents against such infringing activity. Such enforcement proceedings against infringers can be expensive and time-consuming.

In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the compositions or activities in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense against these assertions, non-infringement, invalidity or unenforceability regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Post-grant proceedings provoked by third parties or brought by the USPTO may be brought to determine the validity or priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as those within the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares.

Issued patents covering our products and product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are various grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Some of our pending patent applications may not be allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that cause withdrawal of the allowance of a patent application. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the applicant may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will issue the application in view of the new material. Further, periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign countries may require the payment of maintenance fees or patent annuities during the lifetime of a patent application and/or any subsequent patent that issues from the application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application. Such noncompliance can result in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Such an event could have a material adverse effect on our business.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other drug and biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the drug and biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has passed wide-ranging patent reform legislation under the AIA. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

Our European patents and patent applications could be challenged in the recently created Unified Patent Court (UPC) for the European Union, that is expected to be fully ratified in 2023. We may decide to opt out our European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Under the UPC, a granted European patent would be valid and enforceable in numerous European countries. A successful invalidity challenge to a European patent under the UPC would result in loss of patent protection in those European countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European countries, rather than in each validated European country separately as such patents always have been adjudicated. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

Certain of our key patent families have been filed in the United States; however, we have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue patent coverage of our product candidates in certain countries outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. The breadth and strength of our patents issued in foreign jurisdictions or regions may not be the same as the corresponding patents issued in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to certain territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protections, particularly those relating to drug and biopharmaceutical products. This difficulty with enforcing patents could make it difficult for us to stop the infringement of our patents or marketing of competing products otherwise generally in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other biotechnology companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, financial condition and results of operations.

If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply for a patent extension within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we believe we are entitled to, our competitors may obtain approval of competing products sooner than we would expect, and our business, financial condition, results of operations, and prospects could be materially harmed.

Risks related to our Common Stock

If we fail to regain compliance with the continued listing requirements of Nasdaq, our Common Stock may be delisted and the price and liquidity of our common stock may be negatively impacted.

On November 1, 2023, we received a letter from the listing qualifications department staff (the "Staff") of Nasdaq Stock Market ("Nasdaq") indicating that we are not in compliance with the $1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market (the "Bid Price Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have an initial compliance period of 180 calendar days from the date of the letter, or until April 29, 2024, to regain compliance with respect to the Bid Price Requirement. To regain compliance with the Bid Price Requirement, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during the initial compliance period. In accordance with Nasdaq Listing Rule 5810(c)(3)(A)(ii), we may be eligible for an additional 180-day compliance period to demonstrate compliance with the Bid Price Requirement, subject to certain conditions.

On November 6, 2023, we received a letter from the Staff notifying us that from September 25, 2023 to November 3, 2023, our Market Value of Listed Securities ("MVLS") was below the minimum of $35 million for continued listing on The Nasdaq Capital Market pursuant to Nasdaq listing Rule 5550(b)(2) (the "MVLS Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have a compliance period of 180 calendar days from receipt of this letter, or until May 6, 2024, to regain compliance with respect to the MVLS Requirement. To regain compliance with the MVLS Requirement, our MVLS must close at $35 million or more for a minimum of ten consecutive business days during the compliance period.

These letters had no immediate effect on the listing of the Common Stock on the Nasdaq Capital Market, and the Common Stock will continue to trade on The Nasdaq Capital Market under the symbol "BCLI." However, if we do not regain compliance with the relevant listing requirement during the applicable compliance period, Nasdaq will notify us in writing of its determination to delist the Common Stock, at which point we would have an opportunity to appeal the delisting determination. However, there can be no assurance that, if we receive a delisting notice from the Staff and appeals the delisting determination, such appeal would be successful.

We intend to actively monitor the closing bid price of the Common Stock and MVLS and will take all reasonable measures available to us to regain compliance with the Bid Price Requirement and the MVLS Requirement. There can be no assurance that we will be able to regain compliance with these listing requirements or otherwise maintain compliance with any other listing requirements. Delisting from the Nasdaq market could make trading the Common Stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of the Common Stock, the sale or purchase of the Common Stock would likely be made more difficult and the trading volume and liquidity of the Common Stock could decline. Delisting from Nasdaq could also result in negative publicity, could also make it more difficult for us to raise additional capital through alternative financing sources on terms acceptable to us, or at all, and may result in potential loss of confidence by investors, employees, and could result in fewer business development opportunities. We cannot assure you that the Common Stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system.

We are and could be further subject to securities class action litigation and other types of stockholder litigation.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. For example, in November 2023, a purported stockholder filed a lawsuit against us and certain of our officers captioned *Sporn v. Brainstorm Cell Therapeutics, Inc. et al.* in the U.S. District Court for the Southern District of New York, and in February 2024, two derivative actions were filed in the same court (see *"Item 3. Legal Proceedings"* for a more detailed description of these matters). We could also be subject to other types of litigation, which may involve claims of breach of fiduciary duties by our directors or officers for misuse/mismanagement of company assets/resources or conflicts of interest. Any such litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

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 1C. CYBERSECURITY SECTION

Cybersecurity Risk Management and Strategy

In recognition of the evolving cybersecurity threat landscape, we acknowledge the increasing sophistication and frequency of cybersecurity incidents, including unauthorized access to critical health information and other personal data. Although we cannot completely protect against the possibility of a cybersecurity incident occurring, we take proactive measures designed to help prevent and mitigate risks from cybersecurity threats, including measures implemented by our third-party managed services provider. We are dedicated to investing in our cybersecurity infrastructure in an effort to safeguard our data confidentiality, integrity, and availability, and uphold the trust of our stakeholders.

As part of our cybersecurity procedures, we leverage a number of security tools, including but not limited to email filters, firewalls, and antivirus protection. We also test certain of our applications for vulnerabilities. In an effort to raise cybersecurity awareness, we work with an external partner to send email notices to our employees regarding cybersecurity best practices.

We work to mitigate risks from cybersecurity threats stemming from third-party vendors by providing them with access only to systems that they need to provide services to us. We are currently developing processes to enhance our vendor management processes.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, like other companies in our industry, we and our third-party vendors have from time to time experienced threats that could affect our information or systems.

Cybersecurity Governance

Our Chief Business Officer (“CBO”) is responsible for day-to-day management of our cybersecurity strategy. Our CBO manages the Company’s response to risks from cybersecurity threats, and works with our managed services provider to implement cybersecurity controls.

The Audit Committee of our Board of Directors is primarily responsible for overseeing the Company’s compliance and risk management obligations.

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. We also maintain an office in Burlington, Massachusetts. Our Israeli Subsidiary is party to a lease agreement for the lease of premises in 12 Basel Street, Petach Tikva, Israel, which include approximately 950 square meters of office and laboratory space.

In addition, we currently lease the GMP manufacturing center in Tel Aviv at the Sourasky Hospital to manufacture NurOwn®. This center increases our capacity and expand our ability to manufacture and ship NurOwn® into the EU and local Israeli markets.

We believe that the current office, laboratory space, and cleanroom 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.

Between November 1, 2023 and February 15, 2024, three lawsuits were filed in the U.S. District Court for the Southern District of New York by purported shareholders of the Company.

On November 1, 2023, a purported shareholder of the Company filed a putative securities class action complaint against the Company and certain of its officers, captioned *Sporn v. Brainstorm Cell Therapeutics Inc., et al.*, Case No. 1:23-cv-09630 (the "Securities Complaint"), in the United States District Court for the Southern District of New York (the "Securities Action"). The Securities Action alleges violations of Sections 10(b) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder against all defendants and control person violations of Section 20(a) against the individual defendants, relating to NurOwn® for the treatment of ALS, the Company's submissions to and communications with the FDA in support of the approval of NurOwn® for the treatment of ALS, and the prospects of future approval of NurOwn® by the FDA. The Securities Action seeks, among other things, damages in connection with an allegedly inflated stock price between August 15, 2022 and September 27, 2023, as well as attorneys' fees and costs. The lead plaintiff's deadline to file an Amended Complaint in the Securities Action is April 1, 2024; and the Company's and individual defendants' deadline to respond to the Amended Complaint is May 31, 2024.

On February 14, 2024, February 15, 2024, and March 21, 2024, three purported shareholders of the Company filed derivative action complaints against the Company as nominal defendant and certain of its officers, current and former directors, and members of its scientific advisory board, captioned *Porteous v. Lebovits, et al.*, Case No. 1:24-cv-01095; *Andrev v. Lebovits, et al.*, Case No. 1:24-cv-1101; and *Holtzman v. Lebovits, et al.*, Case No. 1:24-cv-02139 (the "Derivative Complaints") in the United States District Court for the Southern District of New York (the "Derivative Actions"). The Derivative Actions, brought on behalf of the Company, each assert state law claims for breach of fiduciary duty and unjust enrichment against the individual defendants. The complaint in *Holtzman* also asserts state law claims against the individual defendants for abuse of control, gross mismanagement, corporate waste, a claim against the individual defendants for violations of Section 14(a) of the Securities and Exchange Act of 1934, as amended, and a claim against two officer defendants for contribution under Sections 10(b) and 21D of the Exchange Act. The Derivative Complaints allege that the individual defendants breached their fiduciary duties and duties under the Exchange Act in connection with the Company's internal controls relating to, as with the allegations in the Securities Complaint, NurOwn® for the treatment of ALS, the Company's submissions to and communications with the FDA in support of the approval of NurOwn® for the treatment of ALS, and the prospects of future approval of NurOwn® by the FDA their actions or omissions could not have been a good faith exercise of prudent business. The Derivative Actions seek among other things, monetary damages and disgorgement of performance-based compensation granted in connection with an allegedly inflated stock price between August 15, 2022 and September 27, 2023, as well as attorneys' fees and costs.

The Company intends to vigorously defend against the lawsuits.

Item 4. MINE SAFETY DISCLOSURES.

Not applicable.

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 March 27, 2024, there were approximately 30 holders of record of our Common Stock.

Dividends

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

Equity Compensation Plans

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

Recent Sales of Unregistered Securities

On July 17, 2023, the Company entered into a Securities Purchase Agreement with the purchaser named therein, pursuant to which the Company agreed to sell, in a public offering (the "Offering"), an aggregate of 4,054,055 shares of Common Stock, together with accompanying warrants (the "Common Warrants") to purchase 4,054,055 shares of Common Stock, at a purchase price of $1.85 per share and accompanying warrants for gross proceeds to the Company of approximately $7.5 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Offering closed on July 19, 2023. The Common Warrants are immediately exercisable, expire five years following the date of issuance and have an exercise price of $2.00 per share.

Item 6. Reserved.

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.

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, 2023, we did not generate any revenues from operations. In addition, we incurred operating costs and expenses of approximately $17,192,000 during the year ended December 31, 2023.

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, 2023 were $10,746,000, a decrease of $3,210,000 compared to $13,956,000 for the year ended December 31, 2022.

This decrease is due to: (i) a decrease of $2,204,000 in connection with costs related to the Phase 3 Clinical Trials; (ii) a decrease of $1,146,000 for costs related to payroll expenses and (iii) a decrease of $841,000 in connection with materials, depreciation and rent and other costs. This decrease was partially offset by (i) an increase of $726,000 for costs related to stock-based compensation expenses; (ii) a decrease of $200,000 in participation under various awarded grants in 2022 and (iii) an increase of $55,000 for costs related to travel and depreciation.

General and Administrative

General and administrative expenses for the years ended December 31, 2023 and 2022 were $10,693,000 and $10,866,000, respectively. The decrease of $173,000 in general and administrative expenses is mainly due to: (i) a decrease of $919,000 in stock-based compensation expenses and (ii) a decrease of $782,000 in the rent costs, depreciation and costs of our investor relations and public relations activities. This decrease was partially offset by an increase of $1,013,000 in payroll expenses and increase of $515,000 in the travel costs, consultants and stock costs.

Financial Expenses

Financial expense for the year ended December 31, 2023 was $447,000 as compared to financial income of $545,000 for the year ended December 31, 2022 due to interest earned on our cash, cash equivalents and short-term deposits and due to conversion exchange rates that was offset by financial expenses of $169 related to issuance costs of warrants that were classified as a liability.

Net Loss

Net loss for the year ended December 31, 2023 was $17,192,000, as compared to a net loss of $24,277,000 for the year ended December 31, 2022. Net loss per share for the year ended December 31, 2023 and December 31, 2022 was $0.40 and $0.66, 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, 2023 was 43,075,938 compared to 36,509,060 for the year ended December 31, 2022.

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, 2023 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) issuance of shares for private placement.

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 August 9, 2021 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.

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 completed regulatory review of the BLA for NurOwn for the treatment of ALS with the withdrawal of the BLA on November 3, 2023. The decision to withdraw the BLA was coordinated with FDA and is viewed by FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn®. The primary objective of the meeting was to discuss plans for a Special Protocol Assessment (SPA) with FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn®. The ultimate goal of the SPA is to secure the FDA's agreement that critical elements of the overall protocol design (e.g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn® for the treatment of ALS.

If the Company is not able to raise additional capital for these purposes, 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, 2023 cash, cash equivalents and restricted cash amounted to $1,485,000.

Net cash used in operating activities for the year ended December 31, 2023 was $20,627,000. Cash used for operating activities was primarily attributed to cost of clinical trials, rent of clean rooms and materials for clinical trials, payroll costs, rent, outside legal fee expenses and public relations expenses.

Net cash provided by investing activities for the year ended December 31, 2023 was $2,008,000 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, 2023 was $19,147,000 from sales of common stock under the August 9, 2021 ATM programs and proceeds from issuance of shares for private placement.

On August 9, 2021, the Company entered into an Amended and Restated Distribution Agreement (the "New Distribution Agreement") with 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 $100,000,000 (the "August 9, 2021, ATM"). Sales under the August 9, 2021, 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. In connection with the New Distribution Agreement, the Company terminated the previous Distribution Agreement and the September 25, 2020, ATM. During the year ended December 31, 2023, the Company has sold 19,110,741 shares of Common Stock for gross proceeds of approximately $12,937,268 under the August 9, 2021, ATM.

At-the-market (ATM) Offerings:

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 into 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 September 30, 2021, the Company did not sell any additional shares of its Common Stock pursuant to the September 25, 2020, ATM. Since inception and as of September 30, 2021, the Company has sold 4,721,282 shares of Common Stock for gross proceeds of approximately $29.1 million under the September 25, 2020, ATM.

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.

On August 9, 2021, the Company entered into an Amended and Restated Distribution Agreement (the "New Distribution Agreement") with 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 $100,000,000 (the "August 9, 2021, ATM"). Sales under the August 9, 2021, 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. In connection with the New Distribution Agreement, the Company terminated the previous Distribution Agreement and the September 25, 2020, ATM. During the year ended December 31, 2023, the Company has sold 19,110,741 shares of Common Stock for gross proceeds of approximately $12,937,268 under the August 9, 2021, ATM.

Recent Sales of Unregistered Securities:

On July 17, 2023, the Company entered into a Securities Purchase Agreement with the purchaser named therein, pursuant to which the Company agreed to sell, in a public offering (the "Offering"), an aggregate of 4,054,055 shares of Common Stock, together with accompanying warrants (the "Common Warrants") to purchase 4,054,055 shares of Common Stock, at a purchase price of $1.85 per share and accompanying warrants for gross proceeds to the Company of approximately $7.5 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Offering closed on July 19, 2023. The Common Warrants are immediately exercisable, expire five years following the date of issuance and have an exercise price of $2.00 per share.

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 an SPA with the FDA, additional capital raise will be needed to conduct a Phase 3b trial in ALS, to commercialize NurOwn® for ALS, and for future 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.

Critical Accounting Policies

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, 2023

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

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2023

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

INDEX

Deloitte.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the shareholders and the Board of Directors 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, 2023 and 2022 and the related consolidated statements of comprehensive loss, Stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our 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 10 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, 2023, the Company issued stock options for 418,600 shares and recorded stock option related compensation expense of $137 thousand. 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.

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.

/s/ Brightman Almagor Zohar & Co.

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

Tel Aviv, Israel
April 1, 2024

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

BRAINSTORM CELL THERAPEUTICS INC.

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

	December 31,	
	2023	2022
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,300	$ 772
Short-term deposit (Note 8)	—	2,211
Other accounts receivable	51	91
Prepaid expenses and other current assets (Note 4)	548	32
Total current assets	$ 1,899	$ 3,106
Long-Term Assets:		
Prepaid expenses and other long-term assets	$ 22	$ 23
Restricted Cash	185	—
Operating lease right of use asset (Note 5)	1,416	4,389
Property and Equipment, Net (Note 6)	686	933
Total Long-Term Assets	$ 2,309	$ 5,345
Total assets	$ 4,208	$ 8,451
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payables	$ 4,954	$ 6,224
Accrued expenses	1,240	84
Operating lease liability (Note 5)	603	1,427
Employees related liability	1,003	1,065
Total current liabilities	$ 7,800	$ 8,800
Long-Term Liabilities:		
Operating lease liability (Note 5)	672	2,666
Warrants liability (Note 9)	594	—
Total long-term liabilities	$ 1,266	$ 2,666
Total liabilities	$ 9,066	$ 11,466
Stockholders' Deficit:		
Stock capital: (Note 10)	13	12
Common Stock of $0.00005 par value - Authorized: 100,000,000 shares at December 31, 2023 and December 31, 2022 respectively; Issued and outstanding: 60,489,208 and 36,694,078 shares at December 31, 2023 and December 31, 2022 respectively.		
Additional paid-in-capital	210,258	194,910
Treasury stocks	(116)	(116)
Accumulated deficit	(215,013)	(197,821)
Total stockholders' deficit	$ (4,858)	$ (3,015)
Total liabilities and stockholders' deficit	$ 4,208	$ 8,451

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,	
	2023	2022
	U.S. $ in thousands	
Operating expenses:		
Research and development, net (Note 12)	$ 10,746	$ 13,956
General and administrative	10,693	10,866
Operating loss	(21,439)	(24,822)
Financial income (expense), net	(447)	545
Gain on change in fair value of Warrants liability (Note 9)	4,694	—
Net loss	$ (17,192)	$ (24,277)
Basic and diluted net loss per share	$ (0.40)	$ (0.66)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	43,075,938	36,509,060

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, 2022	36,401,413	$ 12	$ 192,990	(116)	$ (173,544)	$ 19,342
Stock-based compensation related to stock and options granted to directors and employees	140,366	*	1,682	—	—	1,682
Issuance of shares in at-the-market (ATM) offering (Note 10)	152,299	*	238	—	—	238
Net loss	—	—	—	—	(24,277)	(24,277)
Balance as of December 31, 2022	36,694,078	12	194,910	(116)	(197,821)	(3,015)

* 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
	Number	Amount				
Balance as of January 1, 2023	36,694,078	$ 12	$ 194,910	(116)	$ (197,821)	$ (3,015)
Stock-based compensation related to stock and options granted to directors and employees	630,334	*	1,490	—	—	1,490
Issuance of shares in at-the-market (ATM) offering (Note 10)	19,110,741	1	11,880	—	—	11,881
Issuance of shares for private placement (Note 10)	4,054,055	*	1,978	—	—	1,978
Net loss	—	—	—	—	(17,192)	(17,192)
Balance as of December 31, 2023	**60,489,208**	**13**	**210,258**	**(116)**	**(215,013)**	**(4,858)**

* 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,	
	2023	2022
	U.S. $ in thousands	
Cash flows from operating activities:		
Net loss	$ (17,192)	$ (24,277)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	265	285
Stock-based compensation related to options granted to employees and directors	1,490	1,682
Change in operating lease liability, net	155	(594)
Decrease (increase) in prepaid expenses and other accounts receivable	(475)	1,067
Increase (decrease) in trade payables	(1,270)	2,524
Gain on change in fair value of warrants (Note 9) (*)	(4,525)	—
Increase (decrease) in employees related liability and accrued expenses	1,094	(7)
Total net cash used in operating activities	$ (20,458)	$ (19,320)

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

(*) Presented after neutralizing costs of issuance.

BRAINSTORM CELL THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,	
	2023	2022
	U.S. $ in thousands	
Cash flows from investing activities:		
Purchase of property and equipment	(18)	(29)
Changes in short-term deposit	2,211	1,027
Total net cash provided by investing activities	$ 2,193	$ 998
Cash flows from financing activities:		
Proceeds from issuance of shares in at-the-market (ATM) offering (Note 10)	11,881	238
Proceeds from Issuance of shares for private placement (Note 10) (*)	7,097	—
Total net cash provided by financing activities	$ 18,978	$ 238
Increase (decrease) in cash and cash equivalents	713	(18,084)
Cash, cash equivalents and restricted cash at the beginning of the period	$ 772	$ 18,856
Cash, cash equivalents and restricted cash at end of the period	$ 1,485	$ 772

(*) Presented after neutralizing costs of issuance.

	Year ended December 31,	
	2023	2022
Non-Cash Activities:	USD in thousands	
Right of use ("ROU") asset recognized with corresponding lease liability, resulted from new lease agreement (Note 5)	—	1,576
ROU asset decreased, resulted from lease modification (Note 5)	1,695	—
Lease liability decreased, resulted from lease modification (Note 5)	1,395	
Finance expenses resulted from lease modification (Note 5)	300	

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

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to 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 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 Company's common stock, $0.00005 par value per share (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 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. As of December 31, 2023, the Company had an accumulated deficit of approximately $215,000. The extent of the Company's future operating losses and the timing of becoming profitable are uncertain.

On October 24, 2023 the Company announced a strategic realignment to enable accelerated development of NurOwn® for the treatment of ALS. To fund the Phase 3b study and ALS priorities, the Company is actively exploring various options to raise capital including non-dilutive grants and capitalizing on its exosome technology. At the same time, the Company reduced and refocused resources by streamlining clean room operations and undertaking a targeted reduction in headcount of approximately 30 percent. Positions most critical to the implementation of the Phase 3b trial and regulatory submission and review were retained. The strategic realignment included approximately 50% reduction in key operating expenses, including payroll, clean room facilities, lab materials and rent. As a result of the reduction in headcount, the company incurred compensation expenses for termination of employment agreements with employees in the total amount of $ 910, which was recorded on December 31, 2023 as accrued expenses.

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 at-the-market ("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 several 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.

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 1 - GENERAL (Cont.)

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

A. Basis of presentation:

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

B. Use of estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company's management believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect reported amounts and disclosures made. Actual results could differ from those estimates.

C. Financial statements in U.S. dollars:

The functional currency of the Company is the U.S dollar ("dollar") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. Part of the transactions of BCT is recorded in new Israeli shekels ("NIS"); however, a substantial portion of 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.

BRAINSTORM CELL THERAPEUTICS INC.
U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

E. Cash and cash equivalents and restricted cash:

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.

Restricted cash consists of deposits pledged to a bank that provided guarantee in connection with a long-term operating lease.

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

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.

BRAINSTORM CELL THERAPEUTICS INC.
U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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.

ASC 820, "Fair Value Measurements and Disclosures, ("ASC 820"), defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact. The Company also considers assumptions that market participants would use when pricing the asset or liability, such as, inherent risk, transfer restrictions and risk of nonperformance. Hierarchical levels are directly related to the amount of subjectivity with the inputs to the valuation of these assets or liabilities as follows:

Level 1 - Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 - Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable inputs for similar assets or liabilities. These include quoted prices for identical or similar assets or liabilities in active markets and quoted prices for identical or similar assets of liabilities in markets that are not active;

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's warrants liability is classified within Level 3 of the fair value hierarchy because of the volatility input incorporated in the Company's Black-Scholes model at inception and on subsequent valuation dates involves unobservable inputs.

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.

BRAINSTORM CELL THERAPEUTICS INC.
U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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

The Company 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".

All outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share for the years ended December 31, 2023 and December 31, 2022, 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, based on 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.

BRAINSTORM CELL THERAPEUTICS INC.
U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

N. Lease accounting (Cont)

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.

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, 2023, the company didn't record any commitments and contingencies.

Q. Recent Accounting Standards Updates Not Yet Effective:

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) – "Improvements to Income Tax Disclosures". The ASU requires that an entity disclose specific categories in the effective tax rate reconciliation as well as provide additional information for reconciling items that meet a quantitative threshold. Further, the ASU requires certain disclosures of state versus federal income tax expense and taxes paid. The amendments in this ASU are required to be adopted starting January 1, 2025. Early adoption is permitted, and the amendments should be applied on a prospective basis. The Company is currently evaluating the effect of adopting the ASU on its disclosures.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures, which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses. In addition, it provides new segment disclosure requirements for entities with a single reportable segment. The guidance will be effective for the Company for annual periods beginning January 1, 2024 and for interim periods beginning January 1, 2025. Early adoption is permitted. The Company is currently evaluating the impact on its financial statement disclosures.

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 3 - RESEARCH AND LICENSE AGREEMENT

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

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

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

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

NOTE 4 - PREPAID EXPENSES

As of December 31, 2023, and 2022, prepaid expenses include directors' insurance of $525 and zero, accordingly.

NOTE 5 - LEASES

A. During November 2021, BCT entered into a new lease agreement, which replaced the previous agreement that was valid until December 31, 2021, in 12 Basel Street, Petach Tikva, Israel. The rental area is approximately 1,000 square meters of office and laboratory space, including an animal research facility. The new lease agreement came into force on January 1, 2022 and is valid for 60 months and includes an extension option for an additional 60 months. The extension period was not considered by the Company as part of the right of period of use, since the Company has not reasonably certain to exercise that option. The monthly lease payments under this lease agreement will be $18. As a result, the Company recognized a new ROU asset from January 2022 in the amount of $1,576.

B. On October 31, 2023, BCT reached agreements with its lessor to change the original lease agreement for the lease of 3 clean rooms at 6 Weizman Street, Tel Aviv, so that the change will include an amendment to the lease contract so that starting on October 31, 2023, the company will lease one clean room and an office till November 30, 2025. The amendment was accounted as a lease modification that decreased the scope of the lease ("partial termination") and was treated as a separate lease component. As a result of the partial termination, the Company remeasured its lease liability and reflect the change as an adjustment to the premodification lease liability. The right of use asset was reduced on the same time on a proportionate basis. As a result, the Company decreased its lease liability and its ROU in the amount of $1,395 and $1,695 respectively. The difference was recorded as finance expenses.

C. As of December 31, 2023, and 2022, total right-of-use assets was approximately $1,416 and $4,389 and the operating lease liabilities for remaining long term lease was approximately $1,275 and $4,093, respectively. In the year ended December 31, 2023 and 2022, the Company recognized approximately $1,467 and $975, respectively in total lease costs for the leases. Variable lease costs for the year ended December 31, 2023 were immaterial.

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 5 - LEASES (Cont.)

Supplemental cash flow and total lease cost information was as follows:

	Twelve Months Ended December 31, 2023	Twelve Months Ended December 31, 2022
Cash payments for operating leases	1,313	1,538
Operating lease expense	1,321	1,514
Finance lease expense (income)	146	(569)

For supplemental noncash information on lease liabilities arising from obtaining right-of-use assets, refer to non-cash activities note in the consolidated statements of cash flows.

As of December 31, 2023, the Company's operating leases had a weighted average remaining lease term of 2.36 years and a weighted average discount rate of 8.66%. Future lease payments under operating leases as of December 31, 2023 were as follows:

	Operating Leases
2024	611
2025	576
2026	189
Total future lease payments	1,376
Less imputed interest	(101)
Total lease liability balance	1,275

NOTE 6 - PROPERTY AND EQUIPMENT

Composition:

	December 31,	
	2023	2022
	U.S. $ in thousands	
Cost:		
Office furniture and equipment	75	75
Computer software and electronic equipment	249	246
Laboratory equipment	2,288	2,273
Leasehold improvements	837	837
	3,449	3,431
Accumulated depreciation:		
Office furniture and equipment	51	48
Computer software and electronic equipment	246	237
Laboratory equipment	1,680	1,442
Leasehold improvements	786	771
	2,763	2,498
Depreciated cost	686	933

Depreciation expenses for the years ended December 31, 2023 and December 31, 2022 were $265 and $285, respectively.

BRAINSTORM CELL THERAPEUTICS INC.
U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 7 - COMMITMENTS AND CONTINGENCIES

A. Commitments to pay royalties to the IIA:

BCT obtained from the Chief Scientist of IIA grants for participation in research and development for the years 2007 through 2020, 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, 2023, there were no grants obtained.

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, 2023, there are no outstanding obligations owed to Ramot in connection with the above.

C. On November 1, 2023, a purported shareholder of the Company filed a putative securities class action complaint against the Company and certain of its officers, captioned Sporn v. Brainstorm Cell Therapeutics Inc., et al., Case No. 1:23-cv-09630 (the "Securities Complaint"), in the United States District Court for the Southern District of New York (the "Securities Action"). The Securities Action alleges violations of Sections 10(b) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder against all defendants and control person violations of Section 20(a) against the individual defendants, relating to NurOwn® for the treatment of ALS, the Company's submissions to and communications with the FDA in support of the approval of NurOwn® for the treatment of ALS, and the prospects of future approval of NurOwn® by the FDA. The Securities Action seeks, among other things, damages in connection with an allegedly inflated stock price between August 15, 2022 and September 27, 2023, as well as attorneys' fees and costs. The lead plaintiff's deadline to file an Amended Complaint in the Securities Action is April 1, 2024; and the Company's and individual defendants' deadline to respond to the Amended Complaint is May 31, 2024.

D. On February 14, 2024, February 15, 2024 and March 21, 2024, three purported shareholders of the Company filed derivative action complaints against the Company as nominal defendant and certain of its officers, current and former directors, and members of its scientific advisory board, captioned Porteous v. Lebovits, et al., Case No. 1:24-cv-01095; Andrev v. Lebovits, et al., Case No. 1:24-cv-1101; and Holtzman v. Lebovits, et al., Case No. 1:24-cv-02139 (the "Derivative Complaints") in the United States District Court for the Southern District of New York (the "Derivative Actions"). The Derivative Actions, brought on behalf of the Company, each assert state law claims for breach of fiduciary duty and unjust enrichment against the individual defendants. The complaint in Holtzman also asserts state law claims against the individual defendants for abuse of control, gross mismanagement, corporate waste, a claim against the individual defendants for violations of Section 14(a) of the Securities and Exchange Act of 1934, as amended, and a claim against two officer defendants for contribution under Sections 10(b) and 21D of the Exchange Act. The Derivative Complaints allege that the individual defendants breached their fiduciary duties and duties under the Exchange Act in connection with the Company's internal controls relating to, as with the allegations in the Securities Complaint, NurOwn® for the treatment of ALS, the Company's submissions to and communications with the FDA in support of the approval of NurOwn® for the treatment of ALS, and the prospects of future approval of NurOwn® by the FDA their actions or omissions could not have been a good faith exercise of prudent business. The Derivative Actions seek among other things, monetary damages and disgorgement of performance-based compensation granted in connection with an allegedly inflated stock price between August 15, 2022 and September 27, 2023, as well as attorneys' fees and costs.

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 8 - SHORT TERM DEPOSITS

Short term deposits on December 31, 2022 include bank deposits bearing annual interest rate of 0.15% to 1.66%. The Company does not have short term deposits on December 31, 2023.

NOTE 9 - WARRANTS LIABILITY

In July 2023, the Company issued 4,054,055 shares of common stock and 4,054,055 private placement warrants ("July 2023 warrants") to purchase shares of common stock. The gross proceeds from this transaction were approximately $7.5 million. The Common Warrants contain provisions regarding settlement in the event of a fundamental transaction that calculate the fair value of the warrants using a prespecified volatility assumption that was not consistent with the input used to value the warrants at issuance which causes the warrants to be classified as liabilities. The Common Warrants will be measured at fair value at inception and in subsequent reporting periods with changes in fair value recognized as financial income or expense as change in fair value of warrant liabilities in the period of change in the condensed consolidated statements of comprehensive loss. The total issuance cost of $ 403 was allocated proportionally to the warrants liability, $169, and to the equity, $234, according to its fair value on the grant date. The fair value of the warrants at issuance was $5,288, and its related issuance costs were classified to finance expenses. July 2023 warrants are classified as Level 3 financial instruments in the fair value hierarchy (refer to Note 11, *Fair Value Measurement*). As of December 31, 2023, the July 2023 warrants were outstanding with fair values of $594. The fair value of the warrant liability for the period since issuance through December 31, 2023 decreased by $4,694. The change has been recognized as gain on change in fair value of derivatives in the Company's Consolidated Statements of Comprehensive Loss.

NOTE 10 - STOCK CAPITAL

The rights of Common Stock:

Holders of Common Stock have the right to receive notice to participate and vote in general meetings of the Company, the right to a share in the excess of assets upon liquidation of the Company and the right to receive dividends, if declared.

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

Private placements and public offerings:

At-the-market (ATM) Offering:

On August 9, 2021, the Company entered into an Amended and Restated Distribution Agreement (the "New Distribution Agreement") with 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 $100,000,000 (the "August 9, 2021, ATM"). Sales under the August 9, 2021, 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. In connection with the New Distribution Agreement, the Company terminated the previous Distribution Agreement and the September 25, 2020, ATM. During the year ended December 31, 2023, the Company has sold 19,110,741 shares of Common Stock for gross proceeds of approximately $12,305 under the August 9, 2021, ATM.

BRAINSTORM CELL THERAPEUTICS INC.
U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 10 - STOCK CAPITAL (Cont.)

Securities Purchase Agreement:

On July 17, 2023, the Company entered into a Securities Purchase Agreement, pursuant to which the Company agreed to sell, in a public offering (the "Offering"), an aggregate of 4,054,055 shares of Common Stock, together with accompanying warrants (the "Common Warrants") to purchase 4,054,055 shares of Common Stock, at a purchase price of $1.85 per share and accompanying warrants for gross proceeds to the Company of approximately $7.5 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Offering closed on July 19, 2023. The Common Warrants are immediately exercisable, expire five years following the date of issuance and have an exercise price of $2.00 per share. Please refer to Note 9.

Capital Raised Since Inception:

Since its inception and as of December 31, 2023, the Company has raised approximately $171,000 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, 2023, the Company has 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, 2023, 2,108,070 shares were available for future issuances under the 2014 Plans. The exercise price of the options granted under the 2014 Plans may not be less than the nominal value of the shares into which such options are exercised. Any options under the 2014 Plans that are canceled or forfeited before expiration become available for future grants. The Governance, Nominating and Compensation Committee (the "GNC Committee") of the Board of Directors of the Company administers the Company's stock incentive compensation and equity-based plans.

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 10 - 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 418,600 and 245,700 shares in 2023 and 2022, 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,	
	2023	2022
Expected volatility	91-118 %	79-81 %
Risk-free interest	3.40-4.49 %	1.42-3.61 %
Dividend yield	0 %	0 %
Expected life of up to (years)	5.04-5.5	5.5-6.03
Fair Value	$ 1.296-$2.890	$ 2.055-$3.146

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,					
	2023			2022		
	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	1,510,117	3.9632		1,310,417	4.1734	
Granted	418,600	1.7300		245,700	3.2975	
Exercised	—	—		—	—	
Forfeited	(322,934)	4.5297		(46,000)	6.3965	
Outstanding at end of period	1,605,783	3.2671	—	1,510,117	3.9632	—
Vested at end of period	1,201,133	3.4487	—	1,152,850	3.2355	—

- 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, 2023, 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.

As of December 31, 2023, there was $443 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 1.61 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, 2023 and 2022 amounted to $137 and $969, respectively.

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 10 - STOCK CAPITAL (Cont.)

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

The options outstanding as of December 31, 2023 and December 31, 2022, 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,	
$	2023	2022	2023	2022	2023	2022
0.75	488,831	488,831	5.30	6.30	488,831	472,164
1.73	281,400	—	9.60	—	—	—
2.25	—	12,000	—	0.30	—	12,000
2.45	369,619	369,619	1.75	2.75	369,619	369,619
2.70	33,333	56,667	0.43	1.25	33,333	56,667
3.04	26,400	26,400	8.18	9.18	11,550	—
4.09	127,000	169,300	8.72	9.72	42,325	—
7.33	—	80,000	—	7.19	—	40,000
7.67	100,000	100,000	6.42	7.42	100,000	93,750
9.51	119,200	127,300	6.81	7.81	95,475	63,650
14.95	60,000	80,000	0.05	7.75	60,000	45,000
	1,605,783	1,510,117	5.30	5.95	1,201,133	1,152,850

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.

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 10 - 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, 2021	272,596	5.49	1.23
Granted	95,366	3.66	
Vested	150,935	5.03	
Forfeited	—	—	—
Nonvested as of December 31, 2022	217,027	5.01	1.40
Granted	684,161	2.27	
Vested	542,464	2.91	
Forfeited	53,828	4.09	
Nonvested as of December 31, 2023	304,896	2.86	1.32

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, 2023 and 2022 amounted to $1,353 and $713, respectively.

As of December 31, 2023, there was $379 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 1.72 years.

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,	
	2023	2022
	U.S. $ in thousands	
Research and development	1,170	444
General and administrative	320	1,238
Total stock-based compensation expense	1,490	1,682

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. As of December 31, 2023, the Company repurchased 25,000 shares of its common stock for $116 thousands.

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 11 - FAIR VALUE MEASUREMENT

The Company's financial instruments consist of cash and cash equivalents, accounts payable and warrants.
Accounting standards establish a hierarchy, which prioritizes the inputs to valuation techniques used to measure fair value into three levels. The fair value hierarchy gives the highest priority to quoted market prices (unadjusted) in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Accounting standards require financial assets and liabilities to be classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and the exercise of this judgment may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The carrying value of cash and cash equivalents, restricted cash, accounts receivable, contract assets, contract liabilities and accounts payable are considered to be representative of their fair value due to the short maturity of these instruments.

Warrants Liabilities

The July 2023 warrants are classified as Level 3 financial instruments. The Company estimated the fair value of the July 2023 warrants using the Black-Scholes model at inception and on subsequent valuation dates. This model incorporates inputs such as the stock price of the Company, risk-free interest rate, volatility, and time to expiration. The volatility involves unobservable inputs classified as Level 3 of the fair value hierarchy. The assumptions used to determine the fair value of the July 2023 warrants are as follows:

	July 19, 2023	December 31, 2023
Time to expiration	5 years	4.56 years
Common stock price	$ 1.81	$ 0.27
Risk-free interest rate	3.98	3.88
Volatility	94 %	116 %

NOTE 12 - RESEARCH AND DEVELOPMENT, NET

Composition:

	Year ended December 31,	
	2023	2022
	U.S. $ in thousands	
Research and development	10,746	14,156
Less: Participation by grants	—	(200)
	10,746	13,956

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

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 from the year 2018 and onwards is 23%.

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

BrainStorm Cell Therapeutics Inc. is taxed according to U.S. tax laws and is subject to federal tax rate of 21% and additional state tax as required.

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,	
	2023	2022
	U.S. $ in thousands	
Operating loss carryforward	182,489	155,310
Net deferred tax asset before valuation allowance	50,788	42,683
Valuation allowance	(50,788)	(42,683)
Net deferred tax asset	—	—

As of December 31, 2023, the Company has provided a full valuation allowance of $50,788 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, 2023, the Company has an accumulated tax loss carryforward of approximately $182,489. 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 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.

BRAINSTORM CELL THERAPEUTICS INC.

U.S. dollars in thousands
(Except share data and exercise prices)
Notes to Consolidated Financial Statements

NOTE 13 - TAXES ON INCOME (Cont.)

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

	Year ended December 31,	
	2023	2022
	U.S. $ in thousands	
United States	(8,837)	(9,989)
Israel	(8,355)	(14,288)
	(17,192)	(24,277)

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 2023 and 2022.

NOTE 15 - SUBSEQUENT EVENTS

A. On February 14, 2024, February 15, 2024 and March 21, 2024, three purported shareholders of the Company filed derivative action complaints against the Company. For more details, please refer to Note 7D.

B. From January 1, 2024 through April 1, 2024, the Company has raised aggregate gross proceeds of approximately $2.6 million under the ATM Distribution Agreement.

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 Interim 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, 2023 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 Interim 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, 2023. 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 Framework (2013 Framework).

Based on our assessment, management concluded that, as of December 31, 2023, 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.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not Applicable.

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 next annual meeting. There are no family relationships among any of our directors or executive officers.

Name	Age	Position
Chaim Lebovits	53	President and Co-Chief Executive Officer
Dr. Stacy Lindborg, PhD	53	Co-Chief Executive Officer
Alla Patlis, CPA, MBA	37	Interim Chief Financial Officer and Controller
Uri Yablonka	47	Executive Vice President, Chief Business Officer, Secretary and Director
Dr. Jacob Frenkel, PhD, MA	81	Chairperson and Director
Dr. Irit Arbel, PhD	64	Director
Dr. Anthony Polverino, PhD	61	Director
Dr. Menghisteab Bairu	63	Director
Nir Naor	49	Director

Chaim Lebovits has served as our Chief Executive Officer since September of 2015, and has been serving as our President and Co-Chief Executive Officer since January 2023. 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. Stacy Lindborg has been serving as our Co-Chief Executive Officer since January 2023. Prior to this, from June 2020 to January 2023, Dr. Lindborg served as our Executive Vice President and Chief Development Officer. She currently serves on the board of directors of Imunon, Inc. (formerly Celsion Corporation), a publicly-traded clinical stage biotechnology company. Dr. Lindborg previously served at Biogen Inc. ("Biogen") 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. Prior to her role at Biogen, Dr. Lindborg worked at Eli Lilly & Company, where she held positions of increasing responsibility. In her role as the Head of R&D strategy, 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. Additionally, she was Leader of Zyprexa Product Management in which she was responsible for R&D, Commercial and Manufacturing plans. Dr. Lindborg holds a Ph.D. in statistics from Baylor University.

Ms. Alla Patlis joined the Company in December 2012 as Controller. From May 2015 to July 2015, November 2016 to November 2017, July 2019 to September 2019 and September 2021 to present, the Company appointed Ms. Patlis as its Interim Chief Financial Officer during the search for a new Chief Financial Officer, and she currently serves in that capacity. Prior to joining the Company, from 2010 to December 2012, Ms. Patlis was Audit Senior of technology, media and telecommunications industries at Brightman Almagor Zohar & Co. (Certified Public Accountants, A Member of Deloitte Touche Tohmatsu Limited). Ms. Patlis holds an MBA and a Bachelor's degree in Accounting & Economics from Tel Aviv University.

Uri Yablonka joined the Company in June 2014 as Chief Operating Officer and as a member of the Board. In March 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, beginning in 2010, Mr. Yablonka served as owner and General Manager of Uri Yablonka Ltd., a business consulting firm. From January 2011 to May 2014, he served as Vice President, Business Development at ACC International Holdings Ltd. ("ACC International"), an affiliate of ACCBT Corp. Prior to his role in ACC International, Mr. Yablonka served as Senior Partner of PM-PR Media Consulting Ltd. from 2008 to January 2011, 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. Mr. Yablonka holds an LL.B from Ono Academic College and an LL.M from Bar-Ilan University, and is a member of the Israeli Bar Association. 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.

Dr. Jacob Frenkel joined the Company in March 2020 as a director and Chairperson. Dr. Frenkel is Chairman Emeritus of the Board of Trustees of the Group of Thirty ("G-30"), 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. From 2001 to 2011, he served as Chairman and Chief Executive Officer of the G-30, and from 2012 to 2022 as Chairman of the Board of Trustees of the G-30. From 2004 to 2009, he served 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 is Chairman Emeritus 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 him 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. She previously served as Chief Executive Officer of Neurochords Corp ("Neurochords"), a biotechnology firm developing graphene-based scaffolds for nerve reconstruction in the acute spinal cord and peripheral nerve injury, from August 2018 to 2020. 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, a 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, Inc., 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 has given her a deep knowledge of the Company and its business and directly relevant management experience.

Dr. Menghisteab Bairu joined the Company in October 2021 as a director. Currently, Dr. Bairu serves as co-founder, President and Chief Executive Officer of Bio Usawa, Inc., a private company that develops and manufactures quality, affordable monoclonal antibodies. In addition to his role at Bio Usawa, Dr. Bairu serves as the founder, chairman and Chief Executive Officer of Proxenia Venture Partners, which focuses on companies in late preclinical and early-stage clinical development in biotechnology. Dr. Bairu has also served as Chairman and Chief Executive Officer of Bairex, an international medical education and market research organization focused on Africa and the Middle East since December 2018. Dr. Bairu also served as Executive Chairman of Treos Bio Limited from 2016 to 2019, a start-up company that uses computational biology to develop precision cancer immunotherapies tailored to patients' genetics. In addition, he is Founder and Chairman Emeritus of Serenus Biotherapeutics, Inc., an emerging market focused specialty biopharmaceutical company, and has served on its board since 2013. Dr. Bairu received his M.D. from Università degli Studi di Milano and currently serves as Adjunct Professor at the University of California, San Francisco School of Medicine, where he lectures on global clinical trials' design, development, and conduct. We believe that Dr. Bairu possesses specific attributes that qualify him to serve on our Board including his valuable leadership skills and his deep knowledge of pharmaceutical product development.

Dr. Anthony Polverino joined the Company on February 5, 2018 as a director. Dr. Polverino is currently an independent consultant to corporate executives and board members. Dr. Polverino was an Executive Vice President Early Development and Chief Scientific Officer of Zymeworks Inc. ("Zymeworks"), from September of 2018 to January 2022, and where he was 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, Inc. ("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. ("Amgen"), 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. 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 that Dr. Polverino possesses specific attributes that qualify him to serve on our Board including his deep knowledge of the pharmaceutical industry.

Nir Naor joined the Company in June 2023 as a director and as Chair of the Audit Committee. Mr. Naor has been serving in a finance advisory capacity to a number of private companies. Mr. Naor serves as Chief Financial Officer of Axogen since December 2023. Mr. Naor served as Chief Financial Officer of QuVa Pharma from February 2023 to September 2023. Mr. Naor previously served as the Chief Financial Officer of HMNC Brain Health from December 2021 to October 2022 and as the Chief Financial Officer of Arbor Pharmaceuticals from January 2021 to September 2021. Prior to this, Mr. Naor served as the Chief Financial Officer, U.S. and the Americas, of Molnlycke, from October 2017 to January 2021. Prior to this, Mr. Naor served as Chief Financial Officer, U.S., of UCB from July 2016 to July 2017. Previously, Mr. Naor held various senior leadership finance roles in the biopharmaceutical industry. Previously, Mr. Naor worked as an investment banker and as a commercial lawyer in Israel. Mr. Naor is a Certified Public Accountant (Israel, inactive) and a Chartered Financial Analyst, and holds an MBA from IMD Business School in Switzerland and an MBA from Tel Aviv University in Israel, an L.L.M. from Hamburg University in Germany, and an L.L.B. in Law and a Bachelor degree in Accounting from Tel Aviv University in Israel. We believe that Mr. Naor possesses specific attributes that qualify him to serve on our Board, including his substantial experience in corporate finance and the biopharmaceutical industry.

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, Menghisteab Bairu and Polverino), financial markets and accounting (Dr. Frenkel, Mr. Naor), business consulting and development (Dr. Polverino and Mr. Yablonka), media (Mr. Yablonka) and law (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), executive officer (Drs. Polverino and Mr. Yablonka), 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 and Mr. Naor). 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 Dr. 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, a former director of the Company, received 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 did not receive annual director awards under the Director Compensation Plan, but when Dr. Almenoff served as a member of the Audit Committee of the Board she was entitled to committee compensation under the Director Compensation Plan. Dr. Almenoff stepped down as a director of the Company upon the conclusion of the Company's annual general meeting held in December 2023.

Pursuant to an October 28, 2021 resolution of the Board, Dr. Bairu receives the following compensation for his service on the Board: an annual cash award in the amount of $30,000, paid in biannual installments. Dr. Bairu will not receive annual director awards under the Director Compensation Plan, but in the event that Dr. Bairu serves as a member of any committee of the Board he will be entitled to committee compensation under the Director Compensation Plan.

Uri Yablonka serves as the Company's Executive Vice President, 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. Naor (Chair), Dr. Arbel and Dr. Bairu, each of whom is independent within the meaning of The Nasdaq Marketplace Rules and Rule 10A-3 under the Exchange Act. The Board of Directors has determined that Dr. Arbel is an "audit committee financial expert" as defined in Item 407(d)(5) of Regulation S-K. Prior to the appointment of Mr. Naor to the Audit Committee Chair in June 2023, the Audit Committee consisted of Mr. Malcolm Taub (Chair) from January 2023 to June 2023, Dr. Almenoff from January 2023 to December 2023 and Dr. Arbel. The Audit Committee held four meetings during the fiscal year ended December 31, 2023.

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. Naor, each of whom is independent as defined under applicable Nasdaq listing standards. Prior to the appointment of Mr. Naor to the GNC Committee in June 2023, the GNC Committee consisted of Dr. Arbel (Chair), Dr. Polverino and Mr. Malcolm Taub from January 2023 to June 2023. The GNC Committee held one meeting during the fiscal year ended December 31, 2023.

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 2023, 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, 2023 all Reporting Persons complied with the applicable requirements of Section 16(a) of the Exchange Act. 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/documents-charters*. 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, 2023 and 2022 earned by our Chief Executive Officer, Former President & Former Chief Medical Officer, and Co-Chief Executive 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 ($) (1)	Bonus ($)	Stock Awards ($) (2)	All Other Compensation ($)	Total ($)
Chaim Lebovits (*),Co-Chief Executive Officer & President	2023	441,667	250,000 (3)	250,012	187,116 (4)	1,128,795
	2022	500,000	250,000 (5)	127,547	240,419	1,117,966
Ralph Kern, Former President & Former Chief Medical Officer	2023	29,514	125,000 (6)	671,444 (7)	7,234 (8)	833,192
	2022	500,000	150,000 (9)	106,220	56,339	812,559
Stacy Lindborg, Co-Chief Executive Officer (10)	2023	475,000	200,000 (11)	256,650	76,075	1,007,725
	2022	469,000	164,150 (12)	143,150	75,243	851,543
Uri Yablonka (*), Executive Vice President, Chief Business Officer, Secretary and Director	2023	164,780	—	—	82,275 (13)	247,055
Alla Patlis (*), Interim Chief Financial Officer and Controller	2023	98,251	—	15,864	32,668 (14)	146,783

(*) Mr. Lebovits, Mr. Yablonka and Ms. Patlis were paid in NIS; the amounts above are the U.S. dollar equivalent. The conversion rate used was the average of the 2023 and 2022 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 reflect the base salary earned for services in the applicable year. In November 2023, the Company reduced each executive officer's base salary by 30% as part of a strategic realignment of the Company.

(2) The amounts shown in the "Stock 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 Named Executive Officer during fiscal 2023 and fiscal 2022. 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.

(3) During 2023, 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 2023.

(4) For 2023, includes (i) $68,404 in management insurance (which includes pension, disability insurance and severance pay), (ii) $34,728 towards such employee's education fund, (iii) $10,794 for Israeli social security and (iv) $33,980 for use of a Company car. Also includes $39,210 in the form of a tax gross-up for these benefits.

(5) During 2022, 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 2022.

(6) During 2023, the Company paid Dr. Kern a payment of $125,000 as prorated annual bonus compensation as part of his separation agreement.

(7) Amounts reported for Mr. Kern include a payment of $250,000, which was paid to him in the form of non-restricted shares and an award of 150,000 non-restricted shares, payable pursuant to Dr. Kern's separation agreement.

(8) Amounts reported for Mr. Kern include (i) a matching 401(k) plan contribution, (ii) medical, dental and vision insurance, and (iii) life, long-term and short-term disability insurance.

(9) During 2022, 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 2022.

(10) Ms. Lindborg's employment with the Company began on June 1, 2020. Ms. Lindborg served as EVP, Chief Development Officer through January 3, 2023, when she was promoted to Co-Chief Executive Officer.

(11) During 2023, the Company agreed to pay Dr. Lindborg a discretionary cash bonus payment of $200,000 in recognition of her contributions to the Company's performance in fiscal year 2023.

(12) During 2022, the Company paid Dr. Lindborg a discretionary cash bonus payment of $164,150 in recognition of her contributions to the Company's performance in fiscal year 2022.

(13) For 2023, includes (i) $26,573 in management insurance (which includes pension, disability insurance and severance pay), (ii) $12,434 towards such employee's education fund, (iii) $10,794 for Israeli social security and (iv) $15,672 for use of a Company car. Also includes $16,802 in the form of a tax gross-up for these benefits.

(14) For 2023, includes (i) $15,846 in management insurance (which includes pension, disability insurance and severance pay), (ii) $7,414 towards such employee's education fund, (iii) $7,071 for Israeli social security. Also includes $2,337 in the form of a tax gross-up for these benefits.

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 Sarah Company, without the payment of any consideration to Mr. Lebovits.

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 set forth the terms of Dr. Kern's employment, which was amended on March 3, 2017 (as amended, the "Kern Employment Agreement"), which governed the compensation terms and conditions of Dr. Kern's employment.

On January 3, 2023, the Company and Dr. Kern entered into a separation agreement (the "Kern Separation Agreement"). Effective as of January 3, 2023, the Kern Separation Agreement terminated the Kern Employment Agreement. The Kern Separation Agreement provides, among other things, that Dr. Kern shall be eligible to receive, in exchange for agreeing and complying with the terms of the Kern Separation Agreement, including the release it contains, (i) a payment of $250,000, payable within 90 days of January 20, 2023 (the "Kern Separation Date"), (ii) a grant of 150,000 non-restricted shares of Common Stock, which shall be granted 90 days after the Kern Separation Date, and (iii) a payment of $125,000 as prorated annual bonus compensation, payable within 30 days of the Kern Separation Date. In addition, all unvested equity and/or equity-based awards that would have vested during the six months following the Kern Separation Date shall vest immediately upon the Kern Separation Date and be treated as described in the preceding sentence.

Effective as of the Kern Separation Date, Dr. Kern became a member of the Company's Scientific Advisory Board, which advises the management team on scientific matters such as research, clinical trials and drug development. In connection with Dr. Kern's appointment to the Scientific Advisory Board, the Company and Dr. Kern entered into a consulting agreement (the "Kern Consulting Agreement"), effective as of the Kern Separation Date. Pursuant to the Kern Consulting Agreement, Dr. Kern will provide scientific advisory board consulting services to the Company for $450 per hour for up to ten hours each month, for an initial term of two years, unless earlier terminated in accordance with the terms of the Kern Consulting Agreement.

Stacy Lindborg

Dr. Stacy Lindborg, PhD, the Company's Co-Chief Executive Officer, is party to a May 26, 2020 employment agreement with the Company, as amended on January 10, 2021, September 21, 2022 and January 3, 2023 (as amended, the "Lindborg Employment Agreement"). Pursuant to the Lindborg Employment Agreement, Dr. Lindborg initially received an annual base compensation of $375,000, which was increased to $469,000 in January 2021 and $500,000 in January 2023. Dr. Lindborg's base salary is subject to an annual increase of 5% effective each January 1. Dr. Lindborg is eligible to receive an annual cash bonus equal to 450 of her base salary, subject to satisfaction of pre-established performance goals.

Pursuant to the Lindborg Employment Agreement, Dr. Lindborg also received a one-time grant of an option (the "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 vested and became exercisable on February 28, 2021 (the "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 she remains continuously employed by the Company through each applicable vesting date. The Option has a ten (10) year term. Any unvested shares underlying the Option as of the date of Dr. Lindborg's employment termination shall automatically terminate.

Pursuant to the Lindborg Employment Agreement, at the first GNC Committee meeting that occurs on or after each anniversary of Dr. Lindborg's start date, Dr. Lindborg is entitled to receive a grant of up to 35,000 shares of restricted stock. 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. Lindborg remains continuously employed by the Company from the date of grant through each applicable vesting date. In addition, pursuant to the Lindborg Employment Agreement, Dr. Lindborg is entitled to receive a one-time bonus in the form of an equity grant of up to 250,000 shares of restricted stock, which shall vest as to twenty-five percent (25)% of the award on each of the first, second, third and fourth anniversary of the date of grant, provided Dr. Lindborg 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 Lindborg Employment Agreement) of the Company. In the event of Dr. Lindborg'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. Lindborg.

Pursuant to the Lindborg Employment Agreement, in the event that the Company terminates the Lindborg Employment Agreement or the Executive's employment without cause or if Dr. Lindborg terminates the Agreement or employment with good reason, the Company shall pay Dr. Lindborg an amount equal to six months of the Base Salary, subject to delivery and execution of a full and general waiver and release to the Company. If within six months of a Change in Control Dr. Lindborg's employment is terminated by the Company other than for cause or due to disability or death, the Company shall provide an amount equal to 12 months of the Base Salary, any portion of bonus compensation that Dr. Lindborg would otherwise be entitled to receive, and accelerated vesting of the equity grant as described above, subject to delivery and execution of a full and general waiver and release to the Company.

Uri Yablonka

Uri Yablonka, the Company's Executive Vice President, Chief Business Officer and director, is party to a June 6, 2014 employment agreement with the Subsidiary, which was amended July 26, 2017 and June 23, 2020. Pursuant to the agreement, Uri Yablonka is paid an annual salary of 640,000 NIS. 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 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 for the purchase of up to 13,333 shares of Common Stock (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like) of the Company on the first business day after each annual meeting of stockholders (or special meeting in lieu thereof) of the Company beginning with the 2014 annual meeting, and provided that Mr. Yablonka remains an employee of the Company on each such date. The exercise price per share of the Common Stock subject to each additional option shall be equal to $0.75 (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like, or changes to the Israeli Annual Option Award under the Company's Director Compensation Plan as amended from time to time). Each additional option vests and becomes exercisable on each monthly anniversary date as to 1/12th the number of shares subject to the option, over a period of twelve months from the date of grant, such that each additional option will be fully vested and exercisable on the first anniversary of the date of grant, provided that Mr. Yablonka remains an employee of the Company on each such vesting date. In the event the Company terminates Mr. Yablonka's employment, he will be entitled to receive three months' salary.

Alla Patlis

Alla Patlis, the Company's Controller, is party to a December 23, 2012 employment agreement with the Israeli Subsidiary, which was amended on March 1, 2015, April 1, 2019, May 1, 2020, and August 1, 2022 (as amended, the "Patlis Employment Agreement"). Pursuant to the Patlis Employment Agreement, Ms. Patlis initially received a monthly gross salary of 15,000 NIS, along with benefits that are generally made available to the Company's employees – including an insurance policy and education fund. Ms. Patlis's monthly gross salary has increased four times since 2012: first, in March 2015 to 20,000 NIS; then, in April 2019 to 23,950 NIS; again, in May 2020 to 26,500 NIS; and, finally, in August 2022 to 31,800 NIS.

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, 2023. All equity awards in the following table were granted pursuant to the 2014 Global Share Option Plan (solely to participants who are residents of Israel) (the "2014 Global Plan") or the 2014 Stock Incentive Plan (the "2014 U.S. Plan" and together with the 2014 Global Plan, the "2014 Plans"). 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, 2023

	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)	2,105
					15,593 (3)	4,210
					23,389 (4)	6,315
					31,185 (5)	8,420
Stacy Lindborg	100,000	—	7.67	01/06/2030	26,250 (6)	7,088
					35,000 (7)	9,450
Uri Yablonka	33,333	—	2.70	06/06/2024	—	—
	13,333	—	0.75	08/15/2024	—	—
	13,333	—	0.75	08/27/2025	—	—
	13,333	—	0.75	06/22/2026	—	—
	13,333	—	0.75	11/10/2027	—	—
	13,333	—	0.75	11/30/2028	—	—
	13,333	—	0.75	12/12/2029	—	—
	13,333	—	0.75	12/10/2031	—	—
	13,333	—	0.75	12/15/2031	—	—
Alla Patlis	7,200	2,400 (8)	9.51	10/21/2030	—	—
	2,400	7,200 (9)	4.09	09/15/2032	—	—
	—	12,000 (10)	1.73	08/01/2033	—	—

(*) Mr. Ralph Kern was excluded from the table because he did not hold unexercised options or unvested shares as of 12/31/23.

(1) Based on the fair market value of our Common Stock on December 31, 2023 ($0.27 per share).

(2) 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.

(3) Restricted stock award vests 25% on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (July 26, 2021), 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, 2022), 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, 2023), 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 (June 1, 2022), provided that Stacy Lindborg 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 (August 2, 2023), provided that Stacy Lindborg remains continuously employed by the Company from the date of grant through each applicable vesting date.

(8) The shares subject to this stock option vest in installments of 2,400 shares on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (October 22, 2020), provided that Alla Patlis remains continuously employed by the Company from the date of grant through each applicable vesting date.

(9) The shares subject to this stock option vest in installments of 2,400 shares on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (September 16, 2022), provided that Alla Patlis remains continuously employed by the Company from the date of grant through each applicable vesting date.

(10) The shares subject to this stock option vest in installments of 3,000 shares on each of the 1st, 2nd, 3rd and 4th anniversary of date of grant (August 2, 2023), provided that Alla Patlis remains continuously employed by the Company from the date of grant through each applicable vesting date.

Stock Incentive Plans

During the fiscal year ended December 31, 2023, 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, 2023 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 2023

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($) (1)	Total ($)
Dr. Jacob Frenkel	—	—	— (2)	—
Dr. Irit Arbel	—	—	— (3)	—
Dr. June S. Almenoff (4)	30,000	—	—	30,000
Dr. Anthony Polverino(5)	12,500	—	—	—
Dr. Menghisteab Bairu (6)	—	—	—	—
Nir Naor(7)	—	—	—	—

(1) We did not grant any restricted stock awards nor grant any stock options to our non-employee directors in 2023.

(2) At December 31, 2023, Dr. Frenkel held unexercised options (vested and unvested) to purchase 150,000 shares of Common Stock and no unvested shares of restricted Common Stock. Stock and no unvested shares of restricted Common Stock.

(3) At December 31, 2023, Dr. Arbel held unexercised options (vested and unvested) to purchase 227,998 shares of Common Stock and no unvested shares of restricted Common Stock.

(4) At December 31, 2023, Dr. Almenoff held no unvested shares of restricted Common Stock and no unexercised options to purchase shares of Common Stock.

(5) At December 31, 2023, Dr. Polverino held no unvested shares of restricted Common Stock and no unexercised options to purchase shares of Common Stock.

(6) As of December 31, 2023, Dr. Bairu held no unvested shares of restricted common stock or unexercised option to purchase shares of Common Stock.

(7) At December 31, 2023, Nir Naor held no unvested shares of restricted Common Stock and no unexercised options to purchase 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. 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. All awards granted to non-U.S. directors shall be made under the 2014 Global Plan, and all awards granted to U.S. directors shall be made under the 2014 U.S. Plan. 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, 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 Dr. June S. Almenoff, Dr. Menghisteab Bairu, and Dr. Anthony Polverino are not entitled to 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. Dr. Almenoff, Dr. Menghisteab Bairu and Dr. Polverino's director compensation is further discussed below.

Pursuant to a February 26, 2017 resolution of the Board, Dr. Almenoff, a former director of the Company, received 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 did not receive annual director awards under the Director Compensation Plan, but when Dr. Almenoff served as a member of the Audit Committee of the Board she was entitled to committee compensation under the Director Compensation Plan. Dr. Almenoff stepped down as a director of the Company upon the conclusion of the Company's annual general meeting held in December 2023.

Pursuant to an October 28, 2021 resolution of the Board, Dr. Bairu receives the following compensation for his service on the Board: an annual cash award in the amount of $30,000, paid in biannual installments. Dr. Bairu will not receive annual director awards under the Director Compensation Plan, but in the event that Dr. Bairu serves as a member of any committee of the Board he will be entitled to committee compensation under the Director Compensation Plan.

Pursuant to resolution 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.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information as of March 1, 2024 (unless otherwise indicated) with respect to the beneficial ownership of our Common Stock by the following: (i) each of our current directors; (ii) the Named Executive Officers; and (iii) all of the current executive officers and directors as a group. As of March 1, 2024, to the knowledge of the Company, no shareholder of the Company beneficially owns more than five percent (5)% of the outstanding shares of our Common Stock.

For purposes of the following table, beneficial ownership is determined in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as otherwise noted in the footnotes to the table, we believe that each person or entity named in the table has sole voting and investment power with respect to all shares of our Common Stock shown as beneficially owned by that person or entity (or shares such power with his or her spouse). Under the SEC's rules, shares of our Common Stock issuable under options that are exercisable on or within 60 days after March 1, 2024 ("Presently Exercisable Options") or under warrants that are exercisable on or within 60 days after March 1, 2024 ("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 68,136,301 shares of Common Stock outstanding as of March 1, 2024, 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) #	%
Directors and Named Executive Officers in 2023		
Chaim Lebovits	2,663,761 (1)	3.9 %
Dr. Stacy Lindborg	281,500 (2)	*
Uri Yablonka	157,540 (3)	*
Alla Patlis	9,600 (4)	*
Ralph Kern	—	0
Dr. June Almenoff	13,175 (5)	*
Dr. Irit Arbel	383,831 (6)	*
Dr. Anthony Polverino	25,960 (7)	*
Nir Naor	—	0
Dr. Jacob Frenkel	206,667 (8)	*
Dr. Menghisteab Bairu	—	0
All current directors and executive officers as a group (11 persons)	**3,742,034 (9)**	**5.4 %**

* Less than 1%.

(1) Consists of (i)1,933,794 shares of Common Stock owned by ACCBT Corp. acquired through an investment into the Company and (ii) 67,053 shares of Common Stock owned by ACC International Holdings Ltd., (iii) 369,619 shares of Common Stock issuable to Chaim Lebovits upon the exercise of Presently Exercisable Options and (iv) 293,295 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) Dr. Lindborg's employment with the Company commenced on June 1, 2020. Consists of 181,500 shares of restricted stock and 100,000 issuable upon the exercise of Presently Exercisable Options.

(3) Consists of 139,997 of shares of Common Stock issuable upon the exercise of Presently Exercisable Options and 17,543 shares of restricted stock.

(4) Consists of 9,600 shares of Common Stock issuable upon the exercise of Presently Exercisable Options.

(5) Consists of 7,175 shares owned by Meadowlark Management LLC and 6,000 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.

(6) Consists of 227,998 shares of Common Stock issuable upon the exercise of Presently Exercisable Options and 155,833 shares of restricted stock. Dr. Arbel's address is 6 Hadishon Street, Jerusalem, Israel.

(7) Consists of 25,960 shares of restricted stock.

(8) Prof. Frenkel joined the board of directors of the Company on March 31, 2020. Consists of 56,667 shares of Common Stock owned prior to joining the board and 150,000 issuable upon the exercise of Presently Exercisable Options.

(9) Includes 997,214 shares of Common Stock issuable upon the exercise of Presently Exercisable Options.

Equity Compensation Plan Information

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2023:

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	1,605,783 (2)	$ 3.2671 (3)	2,108,070 (3)
Equity compensation plans not approved by security holders	—	—	—
Total	1,605,783	$ 3.2671	2,108,070 (1)

(1) Includes 1,605,783 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 3,713,853 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. Polverino, Mr. Abbhi and Mr. Naor satisfy the criteria for being an "independent director" under the standards of the Nasdaq and have no material relationships 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

Our independent public accounting firm is Brightman Almagor Zohar & Co., a Firm in the Deloitte Global Network ("Deloitte"), PCAOB Auditor ID 1197. The following table presents fees for professional audit services rendered by Deloitte for the audit of our financial statements for the fiscal years ended December 31, 2023 and 2022 and fees billed for other services rendered by Deloitte during those periods.

	December 31,	
	2023	2022
Audit Fees (1)	$ 100,000	$ 90,750
Audit-Related Fees (2)	$ 60,000	$ 60,000
Tax Fees (3)	$ 12,000	$ 12,000
Total Fees	$ 172,000	$ 162,750

(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 No. 000-54365	September 16, 2014
4.2	Description of the Company's Securities.		Form 10-K	Exhibit 4.2 File No.001-36641	March 30, 2023
4.3	Form of Common Warrant		Form 8-K	Exhibit 4.1 File No. 001-36641	July 19, 2023

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 30, 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	Amendment No. 3 to the Brainstorm Cell Therapeutics Inc. 2014 Stock Incentive Plan.		Schedule 14A	Appendix A File No. 001-36641	October 1, 2020
10.18*	Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.		Form 8-K	Exhibit 10.2 File No. 000-54365	August 15, 2014
10.19*	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
10.20*	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
10.21	Amendment No. 3 to the Brainstorm Cell Therapeutics Inc. 2014 Global Share Option Plan.		Schedule 14A	Appendix B File No. 001-36641	October 1, 2020
10.21*	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
10.22*	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
10.23*	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
10.24*	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
10.25	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

10.26	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
10.27	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
10.28	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
10.29	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
10.30	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
10.31	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
10.32	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
10.33	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
10.34	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
10.35*	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 No. 001-36641	June 7, 2018
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*	Brainstorm Cell Therapeutics Inc. Second Amended and Restated Director Compensation Plan.		Form 8-K	Exhibit 10.1 File No. 001-36641	July 10, 2014
10.51*	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
10.52*	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
10.53*	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

10.54	Brainstorm Cell Therapeutics Inc. Fourth Amendment to the Second Amended and Restated Director Compensation Plan.		Form 10-K	Exhibit 10.54 File No. 001-36641	March 28, 2022
10.55	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
10.56	Distribution Agreement, dated June 11, 2019, by and between Brainstorm Cell Therapeutics Inc. and Raymond James & Associates, Inc.		Form 8-K	Exhibit 1.1 File No. 001-36641	June 11, 2019
10.57	Form of Warrant		Form 8-K	Exhibit 4.1 File No. 001-36641	August 2, 2019
10.58	Warrant Exercise Agreement		Form 8-K	Exhibit 10.1 File No. 001-36641	August 2, 2019
10.59*	Offer letter, dated April 1, 2020, by and between Brainstorm Cell Therapeutics Inc. and David Setboun		Form 8-K	Exhibit 10.1 File No. 001-36641	April 3, 2020
10.60*	Offer letter, dated May 26, 2020, by and between Brainstorm Cell Therapeutics Inc. and Stacy Lindborg		Form 10-K	Exhibit 10.63 File No. 001-36641	February 4, 2021
10.61*	Third Amendment to Employment Agreement dated June 23, 2020 between the Company and Chaim Lebovits.		Form 10-Q	Exhibit 10.1 File No. 001-36641	August 5, 2020
10.62*	Amendment to Employment Agreement dated June 23, 2020 between the Company and Uri Yablonka.		Form 10-Q	Exhibit 10.2 File No. 001-36641	August 5, 2020
10.63	Distribution Agreement, dated August 9, 2021, by and among Brainstorm Cell Therapeutics, Inc., SVB Leerink LLC and Raymond James & Associates, Inc.		Form S-3	Exhibit 1.2 File No. 001-36641	August 9, 2021
10.64*	Amendment No. 2 to Offer Letter Agreement dated September 18, 2022 between Brainstorm Cell Therapeutics Inc. and Dr. Stacy Lindborg		Form 8-K	Exhibit 10.1 File No. 001-36641	September 22, 2022
10.65*	Amendment No. 3 to Offer Letter Agreement dated January 3, 2023 between Brainstorm Cell Therapeutics Inc. and Dr. Stacy Lindborg		Form 8-K	Exhibit 10.1 File No. 001-36641	January 4, 2023
10.66*	Separation Agreement, effective January 20, 2023, between Brainstorm Cell Therapeutics Inc. and Dr. Ralph Kern		Form 8-K	Exhibit 10.2 File No. 001-36641	January 4, 2023

10.67	Form of Securities Purchase Agreement		Form 8-K	Exhibit 10.1 File No. 001-36641	July 19, 2023
10.68	Placement Agency Agreement, dated as of July 17, 2023 by and between Brainstorm Cell Therapeutics Inc. and the placement agency party thereto		Form 8-K	Exhibit 10.2 File No. 001-36641	July 19, 2023
10.69*	Employment Agreement, dated as of December 23, 2012 by and between Brainstorm Cell Therapeutics Ltd. and Alla Patlis	‡#			
10.70*	Amendment No. 1 to Employment Agreement, effective as of March 1, 2015 by and between Brainstorm Cell Therapeutics Ltd. and Alla Patlis	‡#			
10.71*	Amendment No. 2 to Employment Agreement, effective as of April 1, 2019 by and between Brainstorm Cell Therapeutics Ltd. and Alla Patlis	‡#			
10.72*	Amendment No. 3 to Employment Agreement, effective as of May 1, 2020 by and between Brainstorm Cell Therapeutics Ltd. and Alla Patlis	‡#			
10.73*	Amendment No. 4 to Employment Agreement, effective as of August 1, 2022 by and between Brainstorm Cell Therapeutics Ltd. and Alla Patlis	‡#			
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.	‡‡			
97.1	Brainstorm Cell Therapeutics Inc. Compensation Recovery Policy	‡			
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.				
#	Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K.				

Item 16. FORM 10-K SUMMARY.

Not required.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BRAINSTORM CELL THERAPEUTICS INC.

Date: April 1, 2024

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)*	*April 1, 2024*
/s/ Alla Patlis *Alla Patlis*	*Interim Chief Financial Officer and Controller* *(Principal Financial and Accounting Officer)*	*April 1, 2024*
/s/ Irit Arbel *Irit Arbel*	*Director*	*April 1, 2024*
/s/ Nir Naor *Nir Naor*	*Director*	*April 1, 2024*
/s/ Jacob Frenkel *Jacob Frenkel*	*Director*	*April 1, 2024*
/s/ Anthony Polverino *Anthony Polverino*	*Director*	*April 1, 2024*
/s/ *Uri Yablonka* *Uri Yablonka*	*Director*	*April 1, 2024*
/s/ Menghisteab Bairu *Menghisteab Bairu*	*Director*	*April 1, 2024*