BRAINSTORM CELL THERAPEUTICS INC.
Form S-3
January 26, 2015

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

BRAINSTORM CELL THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**20-7273918**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

3 University Plaza Drive, Suite 320

Hackensack, NJ 07601

(201) 488-0460

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Tony Fiorino, MD, PhD

Chief Executive Officer

c/o Brainstorm Cell Therapeutics Inc.

3 University Plaza Drive, Suite 320

Hackensack, NJ 07601

(201) 488-0460

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Thomas B. Rosedale, Esq.

BRL Law Group LLC

425 Boylston Street, 3rd Floor

Boston, MA 02116

(617) 399-6931 (telephone number)

(617) 399-6930 (facsimile number)

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: þ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company þ

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Amount to be Registered**	**Proposed Maximum Offering Price Per Share**		**Proposed Maximum Aggregate Offering Price**	**Amount of Registration Fee**
Common Stock, $.00005 par value per Share(1)	3,858,201	$ 3.91	(2)	$ 15,085,566	$ 1,753

(1) Pursuant to Rule 416 under the Securities Act, this registration statement also covers such indeterminate number of additional shares of Common Stock as may be issuable with respect to the shares being registered hereunder as a result of any stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee, and based on the average of the high and low prices of the Common Stock on the Nasdaq Capital Market on January 22, 2015 in accordance with Rule 457(c) under the Securities Act of 1933.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Subject to Completion, Dated January 26, 2015

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

BRAINSTORM CELL
THERAPEUTICS INC.

3**,858,201 Shares of Common Stock**

This prospectus relates to the following offerings by certain of our stockholders and warrantholders, which we refer to as "Selling Securityholders":

- the resale of up to 3,820,001 shares of common stock that are issuable on exercise of the warrants that were acquired pursuant to a warrant exercise agreement (the "New Warrants"); and
- the resale of up to 38,200 shares of common stock that are issuable on exercise of a warrant issued pursuant to an engagement letter (the "Agent Warrant").

We will not receive any proceeds from the sale of these securities, although we will receive the exercise price for any warrants that are exercised. We are registering securities for resale by the Selling Securityholders, but that does not necessarily mean that they will sell any of the securities. Any securities sold by the Selling Securityholders will be offered at market or privately negotiated prices.

The exercise price of the New Warrants and the Agent Warrant is $6.50 per share. The New Warrants are currently exercisable and expire on June 19, 2018. The Agent Warrant is exercisable six months after the effective date of this registration statement until June 19, 2018. Holders of the warrants may currently purchase one share of common stock for each warrant exercised. The exercise price and number of shares of common stock issuable upon exercise of the

warrants is subject to further adjustment in certain circumstances.

Our common stock is traded on the Nasdaq Capital Market under the symbol “BCLI”. On January 23, 2015, the last reported sales price for our common stock was $3.80 per share.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading “Risk Factors” beginning on page 7 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2015.

TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY	1
RISK FACTORS	7
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	23
USE OF PROCEEDS	24
SELLING SECURITYHOLDERS	25
PLAN OF DISTRIBUTION	26
LEGAL MATTERS	27
EXPERTS	27
WHERE YOU CAN FIND MORE INFORMATION	27
INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE	27

ABOUT THIS PROSPECTUS

You should rely only on the information contained in this document or to which we have referred you. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information contained in this document may only be accurate on the date of this document.

As used herein, “we,” “us,” “our” or the “Company” refers to Brainstorm Cell Therapeutics Inc. and all of its consolidated subsidiaries.

PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under "Risk Factors." All share amounts and stock prices relating to our common stock contained in this prospectus give effect to a 1-for-15 reverse split of our shares of common stock, which was effected on September 15, 2014.

Company Overview

We are a biotechnology company developing novel adult stem cell therapies for debilitating neurodegenerative disorders such as Amyotrophic Lateral Sclerosis ("ALS", also known as Lou Gehrig's disease), Multiple Sclerosis ("MS"), and Parkinson's disease ("PD") among others. These diseases for the most part have no or limited treatment options and as such represent unmet medical needs. We believe that NurOwn, our proprietary process for the propagation of Mesenchymal Stem Cells ("MSC") and their differentiation into neurotrophic factor-("NTF") secreting cells ("MSC-NTF"), and their transplantation at, or near, the site of damage, offers the hope of more effectively treating neurodegenerative diseases. Our core technology was developed in collaboration with Prof. Eldad Melamed, former head of Neurology of the Rabin Medical Center and member of the Scientific Committee of the Michael J. Fox Foundation for Parkinson's Research and Prof. Daniel Offen of the Felsenstein Medical Research Center of Tel Aviv University. Our wholly-owned Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. (the "Israeli Subsidiary"), holds rights to commercialize the technology, through a licensing agreement with Ramot at Tel Aviv University Ltd. ("Ramot"), the technology transfer company of Tel Aviv University, Israel. We currently employ 14 employees in Israel and one in the United States.

Our Proprietary Technology

Our NurOwn technology is based on a novel differentiation protocol which induces differentiation of the bone marrow-derived mesenchymal stem cells into neuron-supporting cells, MSC-NTF cells, capable of releasing several neurotrophic factors, including Glial-derived neurotrophic factor ("GDNF") and Brain-derived neurotrophic factor ("BDNF"), Vascular endothelial growth factor ("VEGF") and Hepatocyte growth factor ("HGF") which are critical for the growth, survival and differentiation of developing neurons. GDNF is one of the most potent survival factors known for peripheral neurons. VEGF and HGF have been reported to have important neuro-protective effects in ALS.

Our approach to treatment of neurodegenerative diseases with autologous adult stem cells includes a multi-step process beginning with harvesting of undifferentiated stem cells from the patient's own bone marrow, and concluding

with transplantation of differentiated, neurotrophic factor-secreting mesenchymal stem cells (MSC-NTF) into the same patient – intrathecally and/or intramuscularly. Intrathecal (injection into the cerebrospinal fluid) transplantation consists of injection by a standard lumbar puncture; there is no need for a laminectomy – an invasive, orthopedic spine operation to remove a portion of the vertebral bone, as required by other technologies. Intramuscular (injection directly into muscle) transplantation is performed via a standard injection procedure as well.

1

Our proprietary, production process for induction of differentiation of human bone marrow derived mesenchymal stem cells into differentiated cells that produce NTF (MSC-NTF) for clinical use is conducted in full compliance with current Good Manufacturing Practice ("cGMP").

Our proprietary technology is licensed to and developed by our Israeli Subsidiary.

The NurOwn Transplantation Process

- Bone marrow aspiration from patient;
- Isolation and expansion of the mesenchymal stem cells;
- Differentiation of the expanded stem cells into neurotrophic-factor secreting (MSC-NTF) cells; and
- Autologous transplantation into the patient's spinal cord or muscle tissue.

Differentiation before Transplantation

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

The specialized cells secrete neurotrophic factors that may lead to:

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

Autologous (Self-transplantation)

The NurOwn approach is autologous, or self-transplanted, using the patient's own stem cells. In autologous transplantation there is no risk of rejection and no need for treatment with immunosuppressive agents, which can cause severe and/or long-term side effects. In addition, the use of adult stem cells is free of controversy associated with the use of embryonic stem cells in some countries.

The ALS Program

NurOwn is in clinical development for the treatment of ALS. It has been granted Fast Track designation by the FDA for this indication, and has been granted Orphan Status in both the United States and in Europe. We have completed two clinical trials of NurOwn in patients with ALS at Hadassah Medical Center ("Hadassah") in collaboration with Professor Dimitrios Karussis, who served as the principal investigator on these studies. We also have an agreement with Hadasit Medical Research Services and Development Ltd., a subsidiary of the Hadassah Medical Organization, pursuant to which Hadassah provides the Israeli Subsidiary with lab services relating to studies of NurOwn. The first study, a phase 1/2 safety and efficacy study of NurOwn in ALS patients, was initiated in June 2011 after receiving approval from the Israeli Ministry of Health ("MoH"). In March 2013, Professor Karussis presented some of the data from this trial at the American Academy of Neurology Annual Meeting. The trial results demonstrated the safety of NurOwn as well as signs of efficacy on both the ALS Functional Rating Score ("ALSFRS-R") and Forced Vital Capacity ("FVC") Further analyses of this study were presented by Professor Karussis in December 2013 at the 24th International Symposium on ALS/MND.

In January 2013, the Israeli MoH approved the second study, phase 2a combined (intramuscular and intrathecal) treatment, dose-escalating trial, which we also conducted at Hadassah in collaboration with Prof. Karussis. The last follow-up visits in this study occurred in September 2014. In June 2014, Professor Karussis presented interim data from this study at the Joint Congress of European Neurology in Istanbul, Turkey. On January 5, 2015, the Company presented final top line data from this study in a press release and investor conference call. The Company expects to present additional results from this study at one or more medical conferences and to publish the results in a medical journal in 2015.

In December 2013, the Company submitted an Investigational New Drug ("IND") application to the US Food and Drug Administration (the "FDA") for NurOwn in ALS, and on April 28, 2014, the FDA approved commencement of the Company's randomized, double-blind, placebo controlled multi-center phase 2 clinical trial of NurOwn in ALS patients. On June 6, 2014, the Company announced that this clinical trial has commenced with the enrollment of the first patient at Massachusetts General Hospital ("MGH") in Boston, Massachusetts. The trial is also being conducted at the University of Massachusetts Memorial ("UMass") Hospital in Worcester, Massachusetts and the Mayo Clinic in Rochester, Minnesota. For this study, NurOwn production occurs at the Connell and O'Reilly Cell Manipulation Core Facility at the Dana Farber Cancer Institute in Boston, Massachusetts, and at the Human Cellular Therapy Lab at the Mayo Clinic. This study is designed to enroll 48 patients randomized in a 3:1 ratio to receive NurOwn or placebo. Results from this trial are not expected until 2016.

Future Development

Future development of NurOwn in ALS will require additional clinical trials, including the administration of repeated doses to ALS patients enrolled in those trials. The design and timing of subsequent clinical trials in ALS is currently under review by the Company. In addition, the Company is reviewing the potential clinical development of NurOwn in other neurodegenerative disorders, such as Parkinson's disease, Huntington's disease, and multiple sclerosis, and continues to conduct preclinical research in additional areas, including autism.

In addition, the Company is engaged in a number of research initiatives to improve the scale and efficiency of NurOwn production and to improve the stability of NurOwn, which is currently produced in clean room facilities close to the clinical trial sites, where the cells are administered to patients. We are also engaged in collaboration with Octane Biotech Inc., a Canadian firm that focuses on culture systems for cell and tissue therapy, to develop a NurOwn bioreactor. On June 27, 2014, the Company announced that this collaboration has successfully developed a sophisticated Alpha prototype of the NurOwn Bioreactor, utilizing a customized disposable cartridge that is dedicated to the intricacies of the Company's NurOwn process. Based on this first working prototype, the Company and Octane are advancing to the next stage of development with a goal of eventually qualifying a bioreactor for full clinical use.

Intellectual Property

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

On March 4, 2014, the USPTO granted the Company patent US 8,663,987 (“Mesenchymal stem cells for the treatment of CNS diseases”) for its autologous stem cell technology. A divisional patent application therefrom was issued as US Patent 8,900,574 on December 2, 2014.

Recent Developments

A reverse stock split of the Company’s shares of common stock, par value $0.00005 per share (the “Common Stock”) by a ratio of 1-for-15 was effected on September 15, 2014 at 11:59 p.m. pursuant to an amendment to the Company’s Certificate of Incorporation approved by the stockholders of the Company on August 14, 2014.

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

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

Common Stock at an exercise price of $6.50. Please see “The Transactions—Warrant Exercise Agreement” for further information.

Corporate Information

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 3 University Plaza Drive, Suite 320, Hackensack, NJ 07601, and our telephone number is (201) 488-0460. We maintain an Internet website at *http://www.brainstorm-cell.com*. The information on our website is not incorporated into this prospectus.

The Transactions

Warrant Exercise Agreement

On January 8, 2015, we entered into a Warrant Exercise Agreement (the "Warrant Exercise Agreement") with holders of warrants to purchase an aggregate of approximately 2.5 million shares of our Common Stock, at an exercise price of $5.22 per share (the "2014 Warrants"). The 2014 Warrants were originally issued in a private placement to accredited investors (the "Investors") that was consummated on June 13, 2014. The Investors agreed to exercise their 2014 Warrants in full and we agreed to issue new warrants to the Investors to purchase up to an aggregate of approximately 3.8 million unregistered shares of Common Stock at an exercise price of $6.50 (the "New Warrants"). The New Warrants are immediately exercisable and expire on June 19, 2018. We received an aggregate of approximately $13 million in proceeds from the exercises of the 2014 Warrants.

Under the Warrant Exercise Agreement, we agreed that we would file a resale registration statement for the Common Stock underlying the New Warrants within 30 days following the signing of the Warrant Exercise Agreement. We agreed to have the registration statement declared effective within 120 days following the signing of the agreement and to use commercially reasonable efforts to keep the registration statement effective until all securities covered by the registration statement have been sold or may be sold without restriction under Rule 144 under the Securities Act. If the Company does not comply with the registration rights provisions in the Warrant Exercise Agreement, the Investors will have the option of cashless exercise of the New Warrants as their sole remedy.

We are registering the shares of Common Stock underlying the New Warrants in order to fulfill our contractual obligations to the Investors contained in the Warrant Exercise Agreement. Registration of the shares of Common Stock covered by this prospectus does not necessarily mean that all or any portion of such shares will be offered for sale by the Selling Securityholders.

Agent Warrant

On January 6, 2015, we entered into an Engagement Letter with Maxim Group LLC (the "Engagement Letter") whereby Maxim Group LLC acted as solicitation agent for the Warrant Exercise Agreement. Pursuant to the Engagement Letter, we issued a warrant to purchase 38,200 shares of our Common Stock at an exercise price of $6.50 to Maxim Partners LLC (the "Agent Warrant"). The Agent Warrant expires on June 19, 2018. The Engagement Letter granted the same registration rights for the shares of Common Stock underlying the Agent Warrant as was granted to the Investors for the shares of Common Stock underlying the New Warrants. Once registered, the Agent Warrant may not be transferred, assigned (except to any successor, officer or member of Maxim Partners LLC) or hypothecated for a period of six months following the effective date of the registration statement.

We are registering the shares of Common Stock underlying the Agent Warrant in order to fulfill our contractual obligations contained in the Engagement Letter. Registration of the shares of Common Stock covered by this prospectus does not necessarily mean that all or any portion of such shares will be offered for sale by the Selling Securityholder.

Offering by Selling Securityholders

We are registering the following securities issued in connection with the transactions as described above under "The Transactions":

- For resale by the Selling Securityholders, 3,820,001 shares of Common Stock issuable upon exercise of the New Warrants that were acquired pursuant to the Warrant Exercise Agreement; and

- For resale by a Selling Securityholder, 38,200 shares of Common Stock issuable upon exercise of the Agent Warrant that was issued pursuant to the Engagement Letter.

As of the date of this prospectus, each warrant is exercisable to purchase one share of Common Stock. The exercise price and number of shares of Common Stock issuable upon exercise of the warrants are subject to further adjustment in certain circumstances.

The exercise price of the New Warrants and the Agent Warrant is $6.50 per share. The New Warrants are currently exercisable and expire on June 19, 2018. The Agent Warrant is exercisable six months after the effective date of this registration statement until June 19, 2018. There is a possibility that the warrants will never be exercised when in-the-money or otherwise, and that warrant holders will never receive shares or payment of cash in settlement of the warrants.

Common stock outstanding:	17,993,546 shares as of January 12, 2015.
Use of proceeds:	We will not receive any of the proceeds from the sale of the securities being registered on behalf of the Selling Securityholders hereunder. We will receive the exercise price upon the exercise of any Warrant. To the extent we receive cash upon any exercise of the Warrants, we expect to use that cash for general corporate and working capital purposes.
Market Symbol:	Our Common Stock is quoted on the Nasdaq Capital Market under the symbol "BCLI".
Risk Factors:	Investing in our securities involves substantial risks. You should carefully review and consider the "Risk Factors" section of this prospectus beginning on page 7 for a discussion of factors to consider before deciding to invest in our securities.

We will bear the expenses of registering these securities. The Selling Securityholders will pay the cost of any brokerage commissions and discounts, and all expenses incurred by them in connection with the resale of the securities. See "Plan of Distribution."

We had 17,993,546 shares of Common Stock outstanding as of January 12, 2015, which excludes:

- 792,111 shares of Common Stock issuable upon exercise of outstanding stock options, at a weighted average exercise price of $3.45 per share, under our equity incentive plans;
- 665,896 additional shares of Common Stock reserved for future issuance under our equity incentive plans; and
- 6,760,232 shares of Common Stock issuable upon exercise of outstanding warrants with exercise prices ranging from $0.00075 per share to $15.00 per share.

Except as otherwise indicated herein, all information in this prospectus assumes or gives effect to no exercise of the Warrants.

RISK FACTORS

You should carefully consider and evaluate all of the information in this prospectus, including the risk factors listed below. Risks and uncertainties in addition to those we describe below, that may not be presently known to us, or that we currently believe are immaterial, may also harm our business and operations. If any of these risks occur, our business, results of operations and financial condition could be harmed, the price of our Common Stock could decline, and future events and circumstances could differ significantly from those anticipated in the forward-looking statements contained in this prospectus.

Risks related to our business

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

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

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

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

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

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

As described in Note 1 of our 2013 financial statements incorporated herein by reference, our auditors in their audit opinion have expressed concern with respect to our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

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

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

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

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

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

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

Agreements we and our Israeli Subsidiary have with Ramot impose on us royalty payment obligations. If we fail to comply with these obligations, Ramot may have the right to terminate the license under certain circumstances. If Ramot elects to terminate our license, we would need to change our business strategy and we may be forced to cease our operations. We currently do not owe Ramot any overdue payments. Royalties are due upon commencement of revenues by the Company.

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

As a development stage company, we are in the early stages of executing our business plan. We had no revenues for the fiscal years ended December 31, 2014 or December 31, 2013. Our ability to operate successfully is materially uncertain and our operations are subject to significant risks inherent in a developing business enterprise. We are currently in the process of introducing the Company to strategic partners. In the upcoming three years, the Company will focus on clinical trials. We are unable at this time to foresee when we will generate revenues from strategic partnerships or otherwise. Furthermore, we expect to incur substantial and increasing operating losses for the next

several years as we increase our spending to execute our development programs. These losses are expected to have an adverse impact on our working capital, total assets and stockholders' equity, and we may never achieve profitability.

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

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

We are faced with uncertainties related to our research.

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

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

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

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

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

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

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

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

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

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

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

Our limited experience in conducting and managing clinical trials and the application process necessary to obtain regulatory approvals might prevent us from successfully designing or implementing a preclinical study or clinical trial. Cell-based therapy products, in general, may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their approval by regulators or commercial use. Many companies in the industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials. If our clinical trials are unsuccessful, or if we do not complete our clinical trials, we may not receive regulatory approval for or be able to commercialize our product candidates.

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

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

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

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

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

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

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

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

- The FDA or similar foreign regulatory authorities may find that our product candidates are not sufficiently safe or effective or may find our processes or facilities unsatisfactory;
- Officials at the Israeli MoH, the FDA or similar foreign regulatory authorities may interpret data from preclinical studies and clinical trials differently than we do;
- Our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the Israeli MoH, the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and/or clinical trials or to abandon one or more of our development programs;
- The Israeli MoH, the FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations;
- There may be delays or failure in obtaining approval of our clinical trial protocols from the Israeli MoH, the FDA or other regulatory authorities or obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;
- We, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects;
- We may experience difficulties in managing multiple clinical sites;
- Enrollment in our clinical trials for our product candidates may occur more slowly than we anticipate, or we may experience high drop-out rates of subjects in our clinical trials, resulting in significant delays; and
- We may be unable to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates for use in clinical trials.

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

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

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

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

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

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

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

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

Even if our NurOwn treatment candidate is approved for sale, physicians and the medical community may not ultimately use it or may use it only in applications more restricted than we anticipate. Our NurOwn treatment candidate, if successfully developed, will compete with a number of traditional products manufactured and marketed by major pharmaceutical and biotechnology companies. Our NurOwn treatment candidate may also compete with new products currently under development by such companies and others. Physicians will prescribe a treatment only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently available and in use. Physicians also will prescribe a product based on their

traditional preferences. Many other factors influence the adoption of new products, including patient perceptions and preferences, marketing and distribution restrictions, adverse publicity, product pricing, views of thought leaders in the medical community and reimbursement by government and private payers. Any of these factors could have a material adverse effect on our business, financial condition, and results of operations.

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

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

We are subject to environmental, health and safety laws.

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

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

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

A key aspect of our business strategy is to establish strategic relationships in order, to expand or complement our research and development or commercialization capabilities, and to reduce the cost of research and development. There can be no assurance that we will enter into such relationships, that the arrangements will be on favorable terms or that such relationships will be successful. If we are ultimately successful in executing our strategy of securing collaborations with companies that would undertake advanced clinical development and commercialization of our products, we may not have day-to-day control over their activities. Any such collaborator may adhere to criteria for determining whether to proceed with a clinical development program under circumstances where we might have

continued such a program. Potential collaborators may have significant discretion in determining the efforts and amount of resources that they dedicate to our collaborations or may be unwilling or unable to fulfill their obligations to us, including their development and commercialization. Potential collaborators may underfund or not commit sufficient resources to the testing, marketing, distribution or other development of our products. They may also not properly maintain or defend our intellectual property rights or they may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability. Potential collaboration partners may have the right to terminate the collaboration on relatively short notice and if they do so or if they fail to perform or satisfy their obligations to us, the development or commercialization of products would be delayed and our ability to realize any potential milestone payments and royalty revenue would be adversely affected.

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

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

·train, manage and motivate a growing employee base;

- accurately forecast demand for our treatment; and
- expand existing operational, financial and management information systems.

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

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

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

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

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

Furthermore, we must supply all necessary documentation, including product characterization and process validation, to regulatory authorities in support of our BLA on a timely basis and must adhere to cGMP regulations and current

Good Tissue Practices (GTP) enforced by the regulatory authority through its facilities inspection program. We have not fully characterized our NurOwn treatment candidate and have not validated our manufacturing process. If the FDA determines that the products used in our clinical trials are not sufficiently characterized, we may be required to repeat all or a portion of our clinical trials. If our facilities cannot pass a pre-approval plant inspection, the regulatory approval of the treatment candidates will not be granted.

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

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

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

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

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

loss or destruction of, or damage to, patient-specific materials or our NurOwn treatment candidate stored at clinical and future commercial sites due to improper handling or holding by clinicians, hospitals or physicians.

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

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

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

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

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

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

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

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

The pharmaceutical industry is characterized by rapidly changing markets, technology, emerging industry standards and frequent introduction of new products. The introduction of new products embodying new technologies, including new manufacturing processes, and the emergence of new industry standards may render our technologies obsolete, less competitive or less marketable. Advances in other treatment methods or in disease prevention techniques could significantly reduce or entirely eliminate the need for our stem cell services, planned products and therapeutic efforts. Additionally, technological or medical developments may materially alter the commercial viability of our technology

or services, and require us to incur significant costs to replace or modify equipment in which we have a substantial investment. In either event, we may experience a material adverse effect on our business, results of operations and financial condition.

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

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

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

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

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

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

We rely upon the patent applications filed by Ramot, the technology licensing company of Tel Aviv University, and the license granted to us by Ramot, all in accordance with the Second Ramot Agreement dated as of July 26, 2007. We further agreed under the Second Ramot Agreement that Ramot, in consultation with us, is responsible for

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

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

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

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

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

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

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

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

the proprietary rights to such information, we may expend significant resources in such disputes and we may not win those disputes.

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

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

- Reducing reimbursement rates;
- Challenging the prices charged for medical products and services;

- Limiting services covered;
- Decreasing utilization of services;
- Negotiating prospective or discounted contract pricing;
- Adopting capitation strategies; and
- Seeking competitive bids.

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

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

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

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

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

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

associated with the use of embryonic stem cells if the public fails to appreciate the distinction between adult and embryonic stem cells. Delays in achieving public acceptance may materially and adversely affect the results of our operations and profitability.

We are exposed to fluctuations in currency exchange rates.

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

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

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

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

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

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

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

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

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

Risks related to our Common Stock

The price of our stock is expected to be volatile.

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

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

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

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

Pursuant to the Subscription Agreement with ACCBT Corp. (“ACCBT”), a company under the control of Mr. Chaim Lebovits, our President, we granted ACCBT the right to acquire additional shares of our Common Stock whenever we issue additional shares of Common Stock or other securities of the Company, or options or rights to purchase shares of the Company or other securities directly or indirectly convertible into or exercisable for shares of the Company (including shares of any newly created class or series). This participation right could limit our ability to enter into equity financings and to raise funds from third parties. ACCBT is entitled to purchase its pro rata share of any additional securities we offer, so that its percentage ownership of the Company remains the same after any such issuance of additional securities. Such additional securities will be offered to ACCBT at the same price and on the same terms as the other investors in the transaction. ACCBT will have 30 days from the date of our notice to ACCBT of any intended transaction, to decide whether it wishes to exercise its participation rights in the transaction. We also are prohibited from taking certain corporate actions without the consent of ACCBT, including issuing shares, acquiring or divesting assets and making payment of cash compensation over $60,000 per year. Further, ACCBT also has the right to appoint a majority of our Board of Directors. In connection with the Subscription Agreement, we entered into a registration rights agreement with ACCBT pursuant to which we granted piggyback registration rights to ACCBT. In addition, we issued ACCBT warrants to purchase up to 2,016,666 shares of Common Stock, of which 2,016,666 warrants are presently outstanding. The outstanding warrants contain cashless exercise provisions, which permit the cashless exercise of up to 50% of the underlying shares of Common Stock, and 672,222 of such warrants

have an exercise price of $3.00 and the remainder have an exercise price of $4.35. Concurrently with this registration statement, we are registering 1,920,461 shares of Common Stock and 2,016,666 shares of Common Stock underlying the ACCBT warrants on a separate registration statement pursuant to ACCBT's registration rights. ACCBT has waived its participation rights and anti-dilution rights with respect to issuances that were made prior to the date hereof. In March 2014, we entered an agreement with ACCBT according to which ACCBT waived certain anti-dilution rights. On May 25, 2014, the Company entered into a Warrant Amendment Agreement with ACCBT, pursuant to which the expiration date of each warrant held by ACCBT was extended until November 5, 2017, in consideration of ACCBT having provided a series of waivers of their rights, including the anti-dilution rights waiver.

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

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

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

As a public company in the United States, we are subject to the reporting obligations under the U.S. securities laws. The Securities and Exchange Commission, or 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 shareholders, or otherwise harm our reputation. If material weaknesses are identified in the future, it could be costly to remediate such material weaknesses, which may adversely affect our results of operations. In addition, our auditor is not required to attest to the effectiveness of our internal controls over financial reporting due to our status of qualifying as a smaller reporting company. As a result, current and potential investors could lose confidence in our financial reporting, which could harm our business and have an adverse effect on our share price.

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

The Delaware General Corporation Law contain provisions that may have the effect of making more difficult or delaying attempts by others to obtain control of our Company, even when these attempts may be in the best interests of stockholders. Delaware law imposes conditions on certain business combination transactions with "interested stockholders." These provisions and others that could be adopted in the future could deter unsolicited takeovers or delay or prevent changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests.

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

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

22

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes and incorporates forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical facts, included or incorporated in this prospectus regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included or incorporated in this prospectus, particularly under the heading “Risk Factors,” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. Except as otherwise required by law, we do not assume any obligation to update any forward-looking statements.

USE OF PROCEEDS

We may receive gross proceeds of up to $25,078,307 from the exercise of the warrants. We will retain discretion over the use of the net proceeds we may receive from this offering, but we currently intend to use such proceeds, if any, for general corporate and for working capital purposes.

SELLING SECURITYHOLDERS

Below is information with respect to the beneficial ownership of our securities by the Selling Securityholders as of January 12, 2015. Except as described below, the Selling Securityholders do not have, or have had, any position, office or other material relationship with us or any of our affiliates beyond their investment in, or receipt of, our securities. Beneficial ownership has been determined in accordance with the rules of the SEC, and includes voting or investment power with respect to the securities. Our registration of these securities does not necessarily mean that the Selling Securityholders will sell any or all of the securities covered by this prospectus.

We are registering 3,858,201 shares of Common Stock underlying the warrants, issued to the Selling Securityholders, in each case, for resale from time to time by the Selling Securityholders identified in this prospectus.

The information set forth in the following table regarding the beneficial ownership after resale of securities assumes that the Selling Securityholder will purchase the maximum number of shares of Common Stock provided for by the warrants and will sell all of the shares of Common Stock owned by that Selling Securityholder covered by this prospectus. There is no assurance that any of the warrants will be exercised.

	Securities Beneficially Owned Prior to the Offering		Securities Offered Hereby		Securities Beneficially Owned After this Offering		Percentage of Common Stock Owned After this Offering
Name	Common Stock	Warrants	Common Stock	Common Stock underlying Warrants	Common Stock	Warrants	
AIGH Investment Partners LP	397,867 (1)	400,001	—	400,001	397,867	—	2.2
Dr. Joshua A. Hirsch	53,334	20,001	—	20,001	53,334	—	*
Perceptive Life Sciences Master Fund Ltd.	210,057	520,500	—	520,500	210,057	—	1.2
Titan Perc, Ltd.	106,000	79,500	—	79,500	106,000	—	*
HFR HE Sphera Global Healthcare Master Trust	—	25,200	—	25,200	—	—	—
Sphera Global Healthcare Master Fund	—	574,800	—	574,800	—	—	—
Sabby Healthcare Volatility Master	926,036	1,200,000	—	1,200,000	926,036	—	5.1

Fund, Ltd.							
Sabby Volatility Warrant Master Fund, Ltd.	666,666	999,999	—	999,999	666,666	—	3.7
Maxim Partners LLC	—	122,200	—	38,200	—	84,000	—

* Less than 1%

(1) Consists of 312,867 shares of Common Stock owned by AIGH Investment Partners LP and 85,000 shares of Common Stock owned by AIGH Investment Partners LLC.

PLAN OF DISTRIBUTION

Each Selling Securityholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal Trading Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Securityholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Securityholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Securityholders may also sell securities under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Securityholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Securityholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Securityholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Securityholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Securityholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Securityholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Securityholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Securityholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because Selling Securityholders may be deemed to be “underwriters” within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. The Selling Securityholders have advised us that there is no underwriter or coordinating broker acting in connection with the proposed sale of the resale securities by the Selling Securityholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the Selling Securityholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information requirement under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have

been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Securityholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of securities of the Common Stock by the Selling Securityholders or any other person. We will make copies of this prospectus available to the Selling Securityholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

LEGAL MATTERS

Validity of the securities offered by this prospectus will be passed upon for us by BRL Law Group LLC, Boston, Massachusetts. As of December 31, 2014, Thomas B. Rosedale, the Managing Member of BRL Law Group LLC, beneficially owned 47,088 shares of our Common Stock.

EXPERTS

The consolidated financial statements as of and for the years ended December 31, 2013 and 2012, incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K filed on March 27, 2014 for the year ended December 31, 2013, have been audited by Brightman Almagor Zohar & Co., a member of Deloitte Touche Tohmatsu Limited, an independent registered public accounting firm, as stated in their report (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph regarding the Company's ability to continue as a going concern), which is incorporated herein by reference, and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports and other information with the SEC. These filings contain important information that does not appear in this prospectus. For further information about us, you may read and copy any reports, statements and other information filed by us at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549-0102. You may obtain further information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our SEC filings are also available on the SEC Internet site at http://www.sec.gov, which contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission. The registration statement contains more information than this prospectus regarding us and our Common Stock, including certain exhibits and schedules. You can obtain a copy of the registration statement from the Securities and Exchange Commission at the address listed above or from the SEC's Internet site.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The Securities and Exchange Commission requires us to "incorporate by reference" into this prospectus certain information we file with them, which means that we can disclose important information to you by referring you to those documents. The information we incorporate herein by reference is considered to be part of this prospectus and information that we file later with the Securities and Exchange Commission automatically will update and supersede such information. We incorporate herein by reference the documents listed below and any future filings we make with the Securities and Exchange Commission under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, prior to the termination of the offering of the securities covered by this prospectus, as amended:

(1) Our Annual Report on Form 10-K for the fiscal year ended December 31, 2013;

(2) Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2014, June 30, 2014 and September 30, 2014;

(3) Our Current Reports on Form 8-K dated March 24, 2014, April 25, 2014, May 25, 2014 (filed on May 30, 2014), June 1, 2014 (filed on June 2, 2014), June 5, 2014 (filed on June 10, 2014), June 6, 2014, June 6, 2014 (filed on June 9, 2014), June 9, 2014 (filed on June 10, 2014), June 10, 2014, June 13, 2014, June 19, 2014, July 9, 2014 (filed on July 10, 2014), August 14, 2014 (filed on August 15, 2014), September 15, 2014 (filed on September 16, 2014), October 30, 2014 (filed on November 4, 2014), January 8, 2015 and January 14, 2015 (filed on January 15, 2015);

(4) The description of our Common Stock contained in our Registration Statement on Form 8-A filed with the Securities and Exchange Commission on September 24, 2014, including any amendments or reports filed for the purpose of updating that description; and

(5) All of our filings pursuant to the Exchange Act after the date of filing the initial registration statement and prior to effectiveness of the registration statement.

You may request, orally or in writing, a copy of these filings (including exhibits to such filings that we have specifically incorporated by reference in such filings), at no cost, by contacting our executive offices at the following address:

Brainstorm Cell Therapeutics Inc.
3 University Plaza Drive, Suite 320
Hackensack, NJ 07601
Attention: Chief Executive Officer
(201) 488-0460

You should rely only on the information contained in this prospectus, including information incorporated by reference as described above, or any prospectus supplement or that we have specifically referred you to. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus

or any prospectus supplement is accurate as of any date other than the date on the front of those documents or that any document incorporated by reference is accurate as of any date other than its filing date. You should not consider this prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

Any statement contained in a document incorporated or deemed to be incorporated herein by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein or any other subsequently filed document that is deemed to be incorporated herein by reference modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the various costs and expenses, other than underwriting discounts, payable by us in connection with the sale of the securities being registered. All such costs and expenses shall be borne by us. Except for the SEC registration fee, all the amounts shown are estimates.

	Amount to be paid
SEC registration fee	$ 1,753
Legal fees and expenses	5,000
Accounting fees and expenses	5,000
Transfer Agent and Registrar fees	5,000
Printing fees and expenses	4,000
Miscellaneous expenses	1,247
Total	$ 22,000

Item 15. Indemnification of Directors and Officers

Section 145(a) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement

of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or other adjudicating court shall deem proper.

Section 145(g) of the Delaware General Corporation Law provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify the person against such liability under Section 145 of the Delaware General Corporation Law.

The Certificate of Incorporation and the Bylaws of our Company provide that our Company will indemnify, to the fullest extent permitted by the Delaware General Corporation Law, each person who is or was a director or officer of our Company. Pursuant to Delaware law, this includes elimination of liability for monetary damages for breach of the directors' fiduciary duty of care to our Company and its stockholders. These provisions do not eliminate the directors' duty of care and, in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under Delaware law. In addition, each director will continue to be subject to liability for breach of the director's duty of loyalty to our Company, for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for any transaction from which the director derived an improper personal benefit, and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or state or federal environmental laws.

Our Company maintains a policy of directors' and officers' liability insurance that insures its directors and officers against the cost of defense, settlement or payment of a judgment under some circumstances.

Item 16. Exhibits and Financial Statement Schedules

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of November 28, 2006, by and between Brainstorm Cell Therapeutics Inc., a Washington corporation, and Brainstorm Cell Therapeutics Inc., a Delaware corporation, is incorporated herein by reference to Appendix A of the Company's Definitive Schedule 14A dated November 20, 2006 (File No. 333-61610).
4.1	Certificate of Incorporation of Brainstorm Cell Therapeutics Inc. is incorporated herein by reference to Appendix B of the Company's Definitive Schedule 14A dated November 20, 2006 (File No. 333-61610).
4.2	ByLaws of Brainstorm Cell Therapeutics Inc. is incorporated herein by reference to Appendix C of the Company's Definitive Schedule 14A dated November 20, 2006 (File No. 333-61610).
4.3	Amendment No. 1 to ByLaws of Brainstorm Cell Therapeutics Inc., dated as of March 21, 2007, is incorporated herein by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K dated March 27, 2007 (File No. 333-61610).
4.4	Certificate of Amendment of Certificate of Incorporation of Brainstorm Cell Therapeutics Inc. dated September 15, 2014, is incorporated herein by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K dated September 15, 2014 (File No. 000-54365).
4.5	Specimen Certificate of Common Stock of Brainstorm Cell Therapeutics Inc., is incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K dated September 15, 2014 (File No. 000-54365).
5.1	Opinion of BRL Law Group LLC.

10.1 Form of Warrant is incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 8, 2015 (File No. 001-36641).

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

10.3 Warrant Exercise Agreement is incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 8, 2015 (File No. 001-36641).

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

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

23.3 Consent of BRL Law Group LLC (included in Exhibit 5.1).

24.1 Power of Attorney (included on signature page).

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and

included in the registration statement as of the date it is first used after effectiveness. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, such undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(7) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the indemnification provisions described herein, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Petach Tikva, ISRAEL, on the 21st day of January, 2015.

BRAINSTORM CELL THERAPEUTICS INC.

By: /s/ Anthony Fiorino
Anthony Fiorino
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Anthony Fiorino, Chaim Lebovits and Liat Sossover, jointly and severally, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign the Registration Statement on Form S-3 of BrainStorm Cell Therapeutics Inc. and any or all amendments (including post-effective amendments) thereto and any new registration statement with respect to the offering contemplated thereby filed pursuant to Rule 462(b) of the Securities Act, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Anthony Fiorino Anthony Fiorino	Chief Executive Officer (Principal Executive Officer)	January 21, 2015
/s/ Liat Sossover Liat Sossover	Chief Financial Officer (Principal Financial and Accounting Officer)	January 21, 2015

/s/ Irit Arbel Irit Arbel	Director	January 22, 2015
/s/ Mordechai Friedman Mordechai Friedman	Director	January 22, 2015
Alon Pinkas	Director	January __, 2015
/s/ Chen Schor Chen Schor	Director	January 22, 2015
/s/ Robert Shorr Robert Shorr	Director	January 22, 2015
/s/ Malcolm Taub Malcolm Taub	Director	January 22, 2015
/s/ Uri Yablonka Uri Yablonka	Director	January 21, 2015