BRAINSTORM CELL THERAPEUTICS INC.
Form 424B1
February 10, 2015

Filed Pursuant to Rule 424(b)(1)

Registration No. 333-201705

PROSPECTUS

**BRAINSTORM CELL
THERAPEUTICS INC.**

3**,937,127 Shares of Common Stock**

This prospectus relates to resales from time to time by the selling securityholder or by its pledgees, donees, transferees or other successors in interest of:

- 1,920,461 shares of common stock issued and sold by us pursuant to a subscription agreement; and
- 2,016,666 shares of common stock that are issuable on exercise of the warrants that were acquired pursuant to a subscription agreement (the "ACCBT Warrants").

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 securityholder, but that does not necessarily mean that it will sell any of the securities. Any securities sold by the selling securityholder will be offered at market or privately negotiated prices.

672,222 of the ACCBT Warrants have an exercise price of $3.00 per share and the remainder have an exercise price of $4.35. The ACCBT Warrants are currently exercisable and expire on November 5, 2017. As of the date of this prospectus, each ACCBT 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 ACCBT Warrants is subject to further adjustment in certain circumstances.

Our common stock is traded on the Nasdaq Capital Market under the symbol “BCLI”. On February 9, 2015, the last reported sales price for our common stock was $3.90 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 February 10, 2015.

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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.

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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.

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.

Subscription Agreement With ACCBT Corp.

On July 2, 2007, we entered into a Subscription Agreement (the "Subscription Agreement") with ACCBT Corp. ("ACCBT"), a company under the control of Mr. Chaim Lebovits, our President, pursuant to which we agreed to sell (i) up to 1,833,333 shares of our Common Stock for an aggregate subscription price of up to $5.0 million (the "Subscription Shares"), and (ii) for no additional consideration, warrants to purchase up to 2,016,666 shares of our Common Stock (the "ACCBT Warrants"). Subject to certain closing conditions, separate closings of the purchase and sale of the shares and the warrants were scheduled to take place from August 30, 2007 through November 15, 2008. The warrants originally had the following exercise prices: (i) warrants for the first 672,222 shares of our Common Stock had an exercise price of $3.00; (ii) warrants for the next 672,222 shares of our Common Stock had an exercise price of $4.35; and (iii) warrants for the final 672,223 shares of our Common Stock had an exercise price of $5.40. Each warrant issued pursuant to the Subscription Agreement was to expire on November 5, 2011.

Pursuant to the terms of the Subscription Agreement, as amended, and a related registration rights agreement, ACCBT has the following rights for so long as ACCBT or its affiliates hold at least 5% of our issued and outstanding share capital:

- Board Appointment Right : ACCBT has the right to appoint 50.1% (any fractions to be rounded up to the nearest whole number) of the members of our Board of Directors and any of our committees and the Board of Directors of our subsidiary.

- Preemptive Right : ACCBT has the right to receive thirty day notice of, and to purchase a pro rata portion (or greater under certain circumstances where offered shares are not purchased by other subscribers) of, securities issued by us, including options and rights to purchase shares. This preemptive right does not include issuances under our equity incentive plans.

- Consent Right : ACCBT's written consent is required for certain corporate actions, including issuance of shares (other than existing warrants and issuances under our incentive plans), amendment of our charter or bylaws, repurchase of shares, declaration or payment of dividends or distributions, related party transactions, non-ordinary course transactions involving $25,000 or more, liquidation or dissolution, the creation, acquisition or disposition of a subsidiary or entry into a joint venture or strategic alliance, a material change to our business, merger, change of control, sale of the Company, any acquisition, and any payment of cash compensation over $60,000 per year.

In addition, ACCBT is entitled to demand and piggyback registration rights, whereby ACCBT may request, upon 15 days' written notice, that we file, or include within a registration statement to be filed, with the Securities and Exchange Commission for ACCBT's resale of the Subscription Shares, as adjusted, and the shares of our Common Stock issuable upon exercise of the ACCBT Warrants.

On August 18, 2009, we entered into an amendment to the Subscription Agreement (the "Amendment"), dated as of July 31, 2009, with ACCBT. Under the terms of the Subscription Agreement, ACCBT was no longer obligated to invest any further amounts in the Company. Pursuant to the Amendment, ACCBT agreed to invest the remaining amount outstanding under the Subscription Agreement up to $5.0 million in the Company, and, in return, we agreed to amend the Subscription Agreement to, among other things: (i) decrease the purchase price per share of the Subscription Shares that ACCBT previously purchased or will purchase pursuant to the terms of the Subscription Agreement, as amended, from $2.73 to $1.80 (the "Repricing"); (ii) adjust the number of shares of Common Stock issuable under the Subscription Agreement in accordance with the Repricing; (iii) extend the expiration date of all warrants; (iv) amend the exercise price of certain of the warrants from $5.40 to $4.35; and (v) revise the investment schedule of the purchase and sale of the Subscription Shares. Pursuant to the Amendment, the Repricing retroactively applied to all Subscription Shares purchased by ACCBT prior to the Amendment.

As of the date of this prospectus, ACCBT has purchased all of the Subscription Shares.

Warrants to purchase up to 2,016,666 shares of Common Stock were issued to ACCBT, all of which are presently outstanding. The outstanding ACCBT 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 ACCBT Warrants have an exercise price of $3.00 and the remainder have an exercise price of $4.35.

On May 25, 2014, the Company entered into a Warrant Amendment Agreement with ACCBT, pursuant to which the expiration date of each ACCBT Warrant was extended until November 5, 2017, in consideration of ACCBT having provided a series of waivers of their rights, including anti-dilution rights. Pursuant to the amendment, the ACCBT documents were amended to reflect the extension of the warrants' expiration date.

We are registering the Subscription Shares and the shares of Common Stock underlying the ACCBT Warrants pursuant to ACCBT's registration rights. 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 ACCBT.

Offering by Selling Securityholder

We are registering the following securities issued in connection with the Subscription Agreement as described above:

- For resale by the Selling Securityholder, 1,920,461 shares of Common Stock issued and sold by us pursuant to the Subscription Agreement with ACCBT; and

- For resale by the Selling Securityholder, 2,016,666 shares of Common Stock issuable upon exercise of the ACCBT Warrants that were issued pursuant to the Subscription Agreement.

As of the date of this prospectus, each ACCBT 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 ACCBT Warrants are subject to further adjustment in certain circumstances.

672,222 of the ACCBT Warrants have an exercise price of $3.00 per share and the remainder have an exercise price of $4.35. The ACCBT Warrants are currently exercisable and expire on November 5, 2017. There is a possibility that the ACCBT Warrants will never be exercised when in-the-money or otherwise, and that ACCBT 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 Securityholder hereunder. We will receive the exercise price upon the exercise of any ACCBT Warrant. To the extent we receive cash upon any exercise of the ACCBT 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 Securityholder 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 ACCBT 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 certain June 2014 warrants pursuant to a January 8, 2015 Warrant Exercise Agreement 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
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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 h