BRAINSTORM CELL THERAPEUTICS INC.
Form S-1
July 10, 2014

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

BRAINSTORM CELL THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**20-8133057**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

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605 Third Avenue, 34th Floor

New York, NY 10158

(646) 666-3188

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

Liat Sossover

Chief Financial Officer

c/o Brainstorm Cell Therapeutics Inc.

605 Third Avenue, 34th Floor

New York, NY 10158

(646) 666-3188

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

Copies to:

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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 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 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 post-effective amendment filed pursuant to Rule 462(d) 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. ¨

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)	84,000,000	$ 0.36	(2)	$ 30,240,000	$ 3,895

(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 July 3, 2014 as reported on the Over-the-Counter Bulletin Board operated by the National Association of Securities Dealers Inc. 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 July 10, 2014

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.

84,000,000 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 42,000,000 shares of common stock purchased in a private placement; and
- the resale of up to 42,000,000 shares of common stock that are issuable on exercise of the warrants that were acquired in a private placement.

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.

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 warrants are exercisable at $0.348 per warrant at any time on or before the third anniversary of the date of issuance.

Our common stock is traded on the OTCQB Marketplace, operated by OTC Markets Group, under the symbol “BCLI”. On July 9, 2014, the last reported sales price for our common stock was $0.38 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 8 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 _____, 2014.

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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 provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under "Risk Factors" beginning on page 8 and our financial statements and notes thereto that appear elsewhere in this prospectus.

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). These diseases have 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 effectively treating neurodegenerative diseases.

Our approach is considered safe based on our use of autologous cells, which are considered to be free of the risk of rejection. Furthermore, MSC are known to be safe with no risk of tumor formation. The use of adult stem cells is also free of the controversy associated with the use of embryonic stem cells in some countries.

Our core technology was developed in collaboration with prominent neurologist 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 expert cell biologist 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 licensing company of Tel Aviv University, Israel.

On February 8, 2010, our Israeli Subsidiary entered into an agreement with Hadasit Medical Research Services and Development Ltd., a subsidiary of the Hadassah Medical Organization (Hadassah), pursuant to which Hadassah provides the Israeli Subsidiary with lab services.

On February 17, 2010, our Israeli Subsidiary entered into an agreement with Hadassah and Professor Dimitrios Karussis (the Clinical Trial Agreement). Under the Clinical Trial Agreement, Hadassah and our personnel agreed to conduct a clinical trial to evaluate the safety and tolerability of our NurOwn cells in patients with ALS, in accordance with a protocol developed jointly by us and Professor Karussis.

In February 2011, the U.S. Food and Drug Administration (FDA) granted Orphan Drug designation to NurOwn for the treatment of ALS.

In June 2011, we initiated a Phase I/II clinical trial for the treatment of ALS with NurOwn at the Hadassah University Medical Center in Jerusalem (HUMC) with Principal Investigator Professor Dimitrios Karussis, after receiving approval from the Israeli Ministry of Health (MoH).

In July 2011, we entered into a Memorandum of Understanding with Massachusetts General Hospital (MGH) and the University of Massachusetts Medical School (UMass) in anticipation of applying for FDA approval to begin ALS human clinical trials in the United States. In March 2014, we entered into a definitive agreement with MGH in order to launch a Phase II clinical trial in the second quarter of 2014, and we expect to enter into a definitive agreement with UMass for the same.

In July 2012, together with Professor Karussis, we submitted an interim safety evaluation report to the Israeli MoH for the first 12 of 24 patients in the Phase I/II clinical trial. The report confirmed that our NurOwn therapy is safe, did not cause any adverse side effects, and some of the patients showed promising indications of clinical improvement.

In January 2013, the Israeli MoH approved a Phase IIa combined (intramuscular and intrathecal) treatment, dose-escalating trial, which we are currently conducting at HUMC. According to the protocol for this safety and preliminary efficacy trial, 12 early-stage ALS patients received both intramuscular and intrathecal injections of NurOwn cells in three cohorts with increasing doses between February and August 2013. The patients were followed for six months after transplantation. Due to medical and technical considerations, two additional patients were enrolled in the trial in late 2013, in order to preserve the originally planned protocol design. These two patients were treated at the beginning of the second quarter of 2014. The complete and final statistical analysis of the Phase IIa data is expected to be available after 6 months of follow up with the patients.

In January 2013, we also announced that we had successfully completed a 12-week repeat dose toxicity study with our NurOwn cells in mice. These repeat doses were prepared from frozen cells, using a proprietary method recently developed by the Company. We believe that our cryopreservation, or freezing, method will enable long-term storage, and production of repeat patient doses of NurOwn without the need for additional bone marrow aspirations. We believe that the positive data from the toxicity study in mice will support our efforts to obtain approval for a future repeat dose clinical study in ALS patients. The study was conducted at Harlan Israel's laboratories, according to Good Laboratory Practice (GLP) standards. The study protocol was approved by Israel's National Council for Animal Experimentation.

In March 2013, Principal Investigator Professor Dimitrios Karussis of Hadassah presented some of the data from the Phase I/II trial at the American Academy of Neurology Annual Meeting. The trial results analyzed to date confirmed the safety of the NurOwn Treatment and also demonstrated initial signs of possible efficacy. There was a slower decline in overall clinical and respiratory function, as measured by the ALS Functional Rating Score (ALSFRS-R) and Forced Vital Capacity (FVC) score respectively, in the six patients that received an intrathecal injection of the cells, in the six months following treatment as compared to the three months preceding treatment.

On March 14, 2013, we entered into a Memorandum of Understanding with the Mayo Clinic (Mayo) in Rochester, Minnesota, to participate as an additional clinical site in the multi-center Phase II ALS clinical trial in the USA. The team there will be led by Professor Anthony J. Windebank, Head of the Regenerative Neurobiology Laboratory in the Department of Neurology. In January 2014, we announced that we had entered into a definitive agreement with Mayo to conduct the trial and manufacture NurOwn cells in their cell processing cleanroom facility.

Effective April 3, 2013, our Israeli Subsidiary entered into a manufacturing agreement with Dana-Farber Cancer Institute (Dana-Farber) under which Dana-Farber's Connell and O'Reilly Cell Manipulation Core Facility will produce NurOwn in its cGMP-compliant clean rooms for the MGH and UMass clinical sites during our upcoming Phase II

ALS clinical trial in the United States.

On May 21, 2013, we submitted a safety report to the hospital Helsinki Committee (IRB) for the first group of (four) patients in our ongoing Phase IIa ALS clinical trial at the Hadassah Medical Center in Jerusalem, Israel.

In June 2013, we entered into a Memorandum of Understanding (MOU) with PRC Clinical, a Contract Research Organization (CRO) based in the San Francisco Bay Area, in anticipation of our planned Phase II multi-center ALS clinical trial in the United States.

On July 17, 2013, we received Orphan Medicinal Product Designation for NurOwn for the treatment of ALS from the European Commission.

On August 1, 2013, we announced that we submitted a favorable safety report to the hospital Helsinki Committee (IRB) for the second group of (four) patients in our ongoing Phase IIa ALS clinical trial at the Hadassah Medical Center in Jerusalem, Israel. We announced that the treatment was well tolerated and no serious adverse events were observed, except for one SAE (Serious Adverse Event, death due to cardiopulmonary arrest) that was reported as non-treatment related.

In September 2013, we announced that we had completed treatment of the 12 patients in our ALS Phase IIa NurOwn dose-escalating clinical trial. We have been informed that one patient in the study expired due to a medical condition unrelated to the Clinical Trial.

In October 2013, we launched our activities in the US in preparation of our Phase II multi-center clinical trial, with the initiation of the NurOwn technology transfer process to the Dana Farber Cancer Institute (DFCI). This process was completed on March 31, 2014.

On December 10, 2013, we announced that Prof. Karussis had presented some of his preliminary findings from our ALS Phase IIa NurOwn dose-escalating clinical trial at the 24th International Symposium on ALS/MND in Milan, Italy. According to Prof. Karussis, the safety data are "impressively positive," with only minimal and transient (procedure related) adverse events, even though the patients in this study were injected both intrathecally and intramuscularly with up to double the dose of NurOwn cells given in the Phase I trial. In addition, a number of patients showed some initial indications of clinical improvement.

In December 2013, the Company submitted an Investigational New Drug (IND) application to the FDA.

On December 4, 2013, a Notice of Intention to Grant from the European Patent Office (EPO) was issued for the Company's patent application entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases" (European serial number EP06766101.7). 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, a Notice of Allowance was issued from the U.S. Patent Office for the same patent application as above, U.S. serial number 11/727,583.

On March 24, 2014, the Israeli Subsidiary entered into a clinical trial agreement with The General Hospital Corporation d/b/a Massachusetts General Hospital (MGH), to conduct a Phase II clinical trial of the Company’s

NurOwn in ALS, pending FDA and Institutional Review Board (IRB) approvals.

In March 2014, the U.S. Patent and Trademark Office granted the Company a key patent for its autologous stem cell technology. The patent covers the Company's stem cells induced to secrete elevated levels of neurotrophic factors for the treatment of neurodegenerative diseases.

On April 10, 2014, the Company announced that the U.S. Patent and Trademark Office granted the Company an additional patent for its autologous stem cell technology. The patent covers the production method of the Company's proprietary stem cells induced to secrete significantly elevated levels of neurotrophic factors for the treatment of neurodegenerative diseases.

On April 8, 2014, the FDA approved commencement of its Phase II clinical trial with NurOwn in patients with ALS. On June 6, 2014, the Company issued a press release announcing that its Phase II ALS clinical trial has now commenced with the enrollment of the first patient at MGH in Boston, Massachusetts. The Company’s Phase II trial is a randomized, double-blind, placebo controlled multi-center study designed to evaluate the safety and efficacy of transplantation of Autologous Mesenchymal Stem Cells Secreting Neurotrophic Factors (MSC-NTF or NurOwn) in 48 ALS patients. The trial is also being conducted at the UMass Memorial Hospital in Worcester, Massachusetts and the Mayo Clinic in Rochester, Minnesota.

On June 1, 2014, the interim results from our Phase IIa ALS trial conducted at Hadassah Medical Center in Jerusalem, Israel were presented at the Joint Congress of European Neurology by Principal Investigator Professor Dimitrios Karussis. The positive safety and preliminary efficacy results observed in this study are consistent with results observed in the Company's previous Phase I/II trial. Between these two studies, a total of 26 patients have been treated with NurOwn, the Company's stem cell therapy candidate for ALS. In all 26 patients who received NurOwn™ in the two trials, no treatment-related serious adverse events were observed. In the three month pre-treatment "run-in" period, 71% of the patients showed progression of disease with decline in neurological function. In contrast, in the three months post-transplantation with NurOwn, 63% of the patients who received intrathecal (IT), or combined IT and intramuscular (IM) administration, showed stabilization or improvement in neurological function, as measured by their revised ALS functional rating score (ALSFRS-R). Additionally, as Prof. Karussis discussed during his presentation, in both phases of the trial, 63% of the patients treated with NurOwn via IT or combined IT and IM administration were defined as "responders" (slower progression of disability or improvement in their neurological function) at 3 months post-treatment, based on both their ALSFRS-R score and Forced Vital Capacity (FVC), an indication of respiratory function. The six patients treated with NurOwn in the earlier Phase I/II trial via IM administration only, primarily exhibited a localized positive effect. Similarly, in the same Phase I/II trial, the IT transplanted patients also showed indications of neurotrophic and regenerative effects, as evidenced by an increase in Compound Muscle Action Potential (CMAP).

On June 6, 2014, the Company announced that the first patient had been enrolled in its Phase II ALS trial at MGH in Boston.

On June 6, 2014, the Company appointed Uri Yablonka as its Chief Operating Officer and director.

On June 9, 2014, the Company appointed Dr. Anthony (Tony) Fiorino as its Chief Executive Officer.

On June 10, 2014, the Company announced that it has initiated a study in a mouse model of autism at the Felsenstein Medical Research Center, Sackler Faculty of Medicine, Tel Aviv University, under the direction of Professor Daniel Offen. The study will explore the effects of the Company's MSC-NTF cells on mouse behavior. The study, which will be conducted using the BTBR mouse model for autism, will investigate repetitive behavior, increased cognitive flexibility and improved sociability in mice after administration of a single intracerebroventricular injection of the cells.

On June 27, 2014, the Company announced that its technology collaboration with Octane Biotech, Inc. reached an important milestone with the construction of an Alpha prototype of a customized bioreactor for NurOwn production. The proprietary bioreactor under development will, if successful, provide the Company with large-scale manufacturing capabilities, enabling it to achieve economies of scale in the manufacture of NurOwn.

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 with 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.

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 for:

- 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.

Transplantation site and method

Clinical Indication I: ALS (current) – Based on the approval of the Israeli MoH, we are currently conducting a Phase IIa dose-escalating trial to evaluate safety and preliminary efficacy of NurOwn in ALS patients. Following approval of our IND application by the FDA, we have launched a Phase II clinical trial in the USA.

Future Clinical 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.

Corporate Information

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 605 Third Avenue, 34th Floor, New York, New York 10158, and our telephone number is (646) 666-3188. We maintain an Internet website at *http://www.brainstorm-cell.com*. The information on our website is not incorporated into this prospectus.

The Private Placement

On June 13, 2014, we entered into a securities purchase agreement (the Securities Purchase Agreement) with a group of investors, including several healthcare-focused funds (the Investors) to effect a private placement (the Private Placement) of the Company's common stock, $0.00005 par value per share (Common Stock), and warrants to purchase Common Stock. On June 19, 2014, upon the closing of the Private Placement, we received gross proceeds of $10.5 million, resulting from the issuance and sale of 42,000,000 shares of Common Stock (the Shares) at a price per share of $0.25, a 15% discount to the 30 day volume-weighted average price of $0.294. The Investors also received warrants to purchase up to 42,000,000 shares of Common Stock at an exercise price of $0.348 per share (the Warrants). The Warrants were exercisable immediately upon closing of the Private Placement and have a term of three (3) years.

In connection with the Private Placement, we entered into a Registration Rights Agreement (the Registration Rights Agreement) at closing pursuant to which we will file a resale registration statement for the Shares and Common Stock underlying the Warrants within 30 days of the closing date (the Filing Deadline) and have it declared effective at the earlier of (i) the 90th calendar day after the closing date and (ii) the fifth business day after the date the Company is notified by the SEC that such Registration Statement will not be reviewed or will not be subject to further review (the Effectiveness Deadline). The Registration Rights Agreement contains penalties for failure to comply with the terms of the agreement, including monthly liquidated damages in an amount equal to 1.5% of the aggregate subscription amount for failure to meet the Effectiveness Deadline, up to a maximum of 12% of the aggregate subscription amount.

If at any time all of the Shares or shares of Common Stock underlying the Warrants are not covered by the initial Registration Statement, the Company agrees to file with the SEC one or more additional Registration Statements so as to cover all of the Shares and shares of Common Stock underlying the Warrants not covered by such initial Registration Statement, in each case, as soon as practicable, but in no event later than the applicable filing deadline for such additional Registration Statements as provided in the Registration Rights Agreement.

We are registering the shares of Common Stock covered by this prospectus in order to fulfill our contractual obligations to the Investors contained in the Registration Rights 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.

Offering by Selling Securityholders

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

- For resale by the Selling Securityholders, 42,000,000 shares of Common Stock purchased in the Private Placement; and

- For resale by the Selling Securityholders, 42,000,000 shares of Common Stock issuable upon exercise of the Warrants that were acquired in the Private Placement.

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 each Warrant is $0.348 per share. The Warrants are currently exercisable and expire on June 19, 2017. 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:	224,834,618 shares as of June 20, 2014.
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 OTCQB Marketplace 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 8 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 224,834,618 shares of Common Stock outstanding as of June 20, 2014, which excludes:

- 11,688,331 shares of Common Stock issuable upon exercise of outstanding stock options, at a weighted average exercise price of $0.23215 per share, under our equity incentive plans;
- 2,808,437 additional shares of Common Stock reserved for future issuance under our equity incentive plans; and
- 94,011,256 shares of Common Stock issuable upon exercise of outstanding warrants with exercise prices ranging from $0.00005 per share to $1.50 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 of the Private Placement will be sufficient to meet our obligations in the upcoming 12 months as we run a 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 accompanying financial statements, our auditors in their audit opinion have expressed concern with respect to our ability to continue as a going concern, as well as referred to Note 1 of our financial statements in this regard. 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 2015, 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 have not yet compared our NurOwn treatment candidate against placebo or any other active therapy control group. 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.

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, 2013 or December 31, 2012. 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 Phase IIa clinical trials 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. We do not expect to receive regulatory approval for any of our product candidates until at least 2015, 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 cell transplant 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 viableindication 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 two academic consultants who are not 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 Corp. holds equity participation rights and other rights that could affect our ability to raise funds.

Pursuant to the subscription agreement with ACCBT Corp., a company under the control of Mr. Chaim Lebovits, our President, we granted ACCBT Corp. 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 Corp. 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 Corp. at the same price and on the same terms as the other investors in the transaction. ACCBT Corp. will have 30 days from the date of our notice to ACCBT Corp. 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 Corp., including issuing shares, acquiring or divesting assets and making payment of cash compensation over $60,000 per year. Further, ACCBT Corp. 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 Corp. pursuant to which we granted piggyback registration rights to ACCBT Corp. In addition, we issued ACCBT warrants to purchase up to 30,250,000 shares of Common Stock, of which 30,250,000 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 10,083,333 of such warrants have an exercise price of $0.20 and the remainder have an exercise price of $0.29. ACCBT has waived its participation rights, registration 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 Corp. 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 Executive Officer, 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.

The trading price of our Common Stock entails additional regulatory requirements, which may negatively affect such trading price.

Our Common Stock is listed on the OTCQB Marketplace, an over-the-counter electronic quotation service. Because the trading price of our Common Stock is below $5.00 per share, trading in our Common Stock is subject to the requirements of certain “penny stock” rules promulgated under the Securities Exchange Act of 1934, as amended. These rules require additional disclosure by broker-dealers in connection with any trades generally involving any equity security not listed on either a securities exchange or NASDAQ that has a market price of less than $5.00 per share, subject to certain exceptions. Such rules require the delivery, before any penny stock transaction, of a disclosure schedule explaining the penny stock market and the risks associated therewith, and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors (generally institutions). For these types of transactions, the broker-dealer must determine the suitability of the penny stock for the purchaser and receive the purchaser's written consent to the transaction before sale. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our Common Stock. As a consequence, the market liquidity of our Common Stock could be severely affected or limited by these regulatory requirements.

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.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on management's beliefs and assumptions. In addition, other written or oral statements that constitute forward-looking statements are based on current expectations, estimates and projections about the industry and markets in which we operate and statements may be made by or on our behalf. Words such as "should," "could," "may," "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," variations of such words and expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements.

Forward looking statements include, but are not limited to, statements about:

- Statements as to the anticipated timing of clinical studies and other business developments;
- Statements as to the development of new products;
- Our expectations regarding federal, state and foreign regulatory requirements;
- Our expectations regarding grants from federal resources; and
- Statements regarding growth strategies, financial results, product development, competitive strengths, intellectual property rights, litigation, mergers and acquisitions, market acceptance or continued acceptance of our products, accounting estimates, financing activities and ongoing contractual obligations.

These statements reflect our views with respect to future events as of the date of this prospectus and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. You should read this prospectus and the documents referenced in this prospectus and filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. Our forward-looking statements do not reflect the potential impact of any future acquisitions, merger, dispositions, joint ventures or investments we may undertake. We qualify all of our forward-looking statements by these cautionary statements.

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EXCHANGE RATE INFORMATION

In this prospectus, references to "$" are to U.S. dollars, and references to "NIS" are to New Israeli Shekels. The exchange rate between the NIS and the U.S. dollar used in this prospectus varies depending on the date and context of the information contained herein.

The following table sets forth for each period indicated: (1) the low and high exchange rates during such period; (2) the exchange rates in effect at the end of the period; and (3) the average exchange rates for such period, for one U.S. dollar, expressed in NIS, as quoted by the Bank of Israel. The average exchange rate is calculated on the last business day of each month for the applicable period.

	Year ended December 31,				Quarter Ended	
					March 31,	June 30,
	2010	2011	2012	2013	2014	2014
Low	3.549	3.363	3.700	3.471	3.459	3.432
High	3.894	3.821	4.084	3.791	3.549	3.493
Period End	3.549	3.821	3.733	3.471	3.487	3.438
Average	3.733	3.578	3.858	3.609	3.497	3.465

As of July 9, 2014, the daily representative rate of exchange between the NIS and the U.S. dollar as published by the Bank of Israel was NIS 3.436 to $1.00.

USE OF PROCEEDS

We may receive gross proceeds of up to $14,616,000 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.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our Common Stock. We currently intend to retain any future earnings to finance the growth and development of our business. Therefore, we do not anticipate that we will declare

or pay any cash dividends on our Common Stock in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements, restrictions under any existing indebtedness and other factors the Board of Directors deems relevant.

DILUTION

Dilution represents the difference between the offering price of the Shares and the net tangible book value per share of our Common Stock immediately after completion of the Private Placement, assuming no value is attributed to the Warrants. Net tangible book value is the amount that results from subtracting total liabilities and intangible assets from total assets.

At March 31, 2014, the net tangible book value of our shares of Common Stock was $860,000 or approximately $0.005 per share. After giving effect to the Private Placement and attributing no value to the Warrants, and after deducting expenses payable by us, our as adjusted net tangible book value as of March 31, 2014 would have been approximately $10,604,000, or approximately $0.048 per share of Common Stock. This represents an immediate increase in net tangible book value of approximately $0.043 per share to existing stockholders and an immediate dilution of approximately $0.208 per share to new investors. The following table illustrates this per share dilution:

Private Placement price per Share		$0.25
Net tangible book value per share as of March 31, 2014	$ 0.005	
Increase per share attributable to new investors	0.043	
As adjusted net tangible book value per share after the Private Placement		0.048
Dilution per share to new investors		$ 0.202

Investors that acquire additional shares of Common Stock through the exercise of the Warrants may experience additional dilution depending on our net tangible book value at the time of exercise.

The information in the table above is based on 176,803,587 shares of our Common Stock outstanding as of March 31, 2014 and excludes as of that date:

- 51,191,451 shares of Common Stock reserved for future issuance under our equity incentive plans;
- 8,310,937 options outstanding under our equity incentive plans with a weighted average exercise price of $0.1705 per share;
- 68,871,843 shares of Common Stock issuable upon exercise of outstanding warrants with exercise prices ranging from $0.00005 per share to $1.50 per share; and

· shares of Common Stock issuable upon exercise of the Warrants.

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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 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).

DESCRIPTION OF CAPITAL STOCK

The following is a summary of all material characteristics of our capital stock as set forth in our certificate of incorporation and bylaws. The summary does not purport to be complete and is qualified in its entirety by reference to our certificate of incorporation and bylaws, and, to the extent applicable, to the provisions of the Delaware General Corporation Law.

Common stock

We are authorized to issue 800,000,000 shares of Common Stock, $0.00005 par value. As of June 20, 2014, there were 224,834,618 shares of our Common Stock issued and outstanding, held by approximately 64 record

holders.

The holders of Common Stock are entitled to one vote per share on all matters to be voted upon by stockholders, including the election of directors. The holders of Common Stock do not have any cumulative voting, conversion, redemption or preemptive rights. The holders of Common Stock are entitled to receive ratably dividends as may be declared from time to time by our Board of Directors out of funds legally available for that purpose. In the event of our liquidation, dissolution, or winding up, the holders of Common Stock are entitled to share ratably in our assets available for distribution to such holders. All issued and outstanding shares of Common Stock are fully paid and non-assessable.

Anti-Takeover Provisions of Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a "business combination," except under certain circumstances, with an "interested stockholder" for a period of three years following the date such person became an "interested stockholder" unless:

- before such person became an interested stockholder, the board of directors of the corporation approved either the business combination or the transaction that resulted in the interested stockholder becoming an interested stockholder;

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upon the consummation of the transaction that resulted in the interested stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares held by directors who also are officers of the corporation and shares held by employee stock plans; or

- at or following the time such person became an interested stockholder, the business combination is approved by the board of directors of the corporation and authorized at a meeting of stockholders by the affirmative vote of the holders of 66 2/3% of the outstanding voting stock of the corporation which is not owned by the interested stockholder.

The term “interested stockholder” generally is defined as a person who, together with affiliates and associates, owns, or, within the three years prior to the determination of interested stockholder status, owned, 15% or more of a corporation’s outstanding voting stock. The term “business combination” includes mergers, asset or stock sales and other similar transactions resulting in a financial benefit to an interested stockholder. Section 203 makes it more difficult for an “interested stockholder” to effect various business combinations with a corporation for a three-year period. The existence of this provision would be expected to have an anti-takeover effect with respect to transactions not approved in advance by our Board of Directors, including discouraging attempts that might result in a premium over the market price for the shares of Common Stock held by stockholders.

Registration Rights Agreement

Pursuant to the Registration Rights Agreement, we are required to file a resale registration statement for the Shares and Common Stock underlying the Warrants within 30 days of the closing date (the Filing Deadline) and have it declared effective at the earlier of (i) the 90th calendar day after the closing date and (ii) the fifth business day after the date the Company is notified by the SEC that such Registration Statement will not be reviewed or will not be subject to further review (the Effectiveness Deadline). The Registration Rights Agreement contains penalties for failure to comply with the terms of the agreement, including monthly liquidated damages in an amount equal to 1.5% of the aggregate subscription amount for failure to meet the Effectiveness Deadline, up to a maximum of 12% of the aggregate subscription amount.

If at any time all of the shares of Common Stock or shares of Common Stock underlying the Warrants are not covered by the initial Registration Statement, the Company agrees to file with the SEC one or more additional Registration Statements so as to cover all of the shares of Common Stock and shares of Common Stock underlying the Warrants not covered by such initial Registration Statement, in each case, as soon as practicable, but in no event later than the applicable filing deadline for such additional Registration Statements as provided in the Registration Rights Agreement.

The Company shall keep the Registration Statement 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 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.

Description of Warrants

After the closing of the Private Placement, there were Warrants to purchase up to 42,000,000 shares of Common Stock at an exercise price of $0.348 per share outstanding. The Warrants were exercisable immediately upon closing of the Private Placement and have a term of three (3) years.

The Warrants, at the option of the holder, may be exercised by cash payment of the exercise price to the Company. The Warrants may be exercised on a cashless basis commencing at the earlier of (i) one year after issuance or (ii) the completion of the then-applicable holding period required by Rule 144, if no registration statement registering the shares underlying the Warrants is then in effect. The exercise price and number of shares of Common Stock issuable on exercise of the Warrants may be adjusted in certain circumstances including stock dividends, recapitalizations,

reorganizations, mergers or consolidations.

No fractional shares will be issued upon exercise of the Warrants. If, upon exercise of the Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, at our election, either pay a cash adjustment or round up to the nearest whole number, the number of shares of Common Stock to be issued to the Warrant holder.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is American Stock Transfer & Trust Company LLC.

OTCQB Marketplace

Our Common Stock is traded on the OTCQB Marketplace operated by OTC Markets Group under the trading symbol "BCLI."

OUR BUSINESS

Company Overview

We are a biotechnology company developing novel adult stem cell therapies for debilitating neurodegenerative disorders such as ALS, MS and PD. These diseases have limited treatment options and as such represent unmet medical needs.

We believe that NurOwn, our proprietary process for the propagation of MSC and their differentiation into NTF secreting cells (MSC-NTF), and their transplantation at, or near, the site of damage, offers the hope of effectively treating neurodegenerative diseases.

Our approach is considered safe based on our use of autologous cells, which are considered to be free of the risk of rejection. Furthermore, MSC are known to be safe with no risk of tumor formation. The use of adult stem cells is also free of the controversy associated with the use of embryonic stem cells in some countries.

Our core technology was developed in collaboration with prominent neurologist 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 expert cell biologist Prof. Daniel Offen of the Felsenstein Medical Research Center of Tel Aviv University.

Our Israeli Subsidiary, holds rights to commercialize the technology, through a licensing agreement with Ramot, the technology licensing company of Tel Aviv University, Israel.

On February 8, 2010, our Israeli Subsidiary entered into an agreement with Hadassah, pursuant to which Hadassah provides the Israeli Subsidiary with lab services.

On February 17, 2010, our Israeli Subsidiary entered into the Clinical Trial Agreement. Under the Clinical Trial Agreement, Hadassah and our personnel agreed to conduct a clinical trial to evaluate the safety and tolerability of our NurOwn cells in patients with ALS, in accordance with a protocol developed jointly by us and Professor Karussis.

In February 2011, the U.S. FDA granted Orphan Drug designation to NurOwn for the treatment of ALS.

In June 2011, we initiated a Phase I/II clinical trial for the treatment of ALS with NurOwn at the HUMC with Principal Investigator Professor Dimitrios Karussis, after receiving approval from the Israeli MoH.

In July 2011, we entered into a Memorandum of Understanding with MGH and UMass in anticipation of applying for FDA approval to begin ALS human clinical trials in the United States. In March 2014, we entered into a definitive agreement with MGH and launched a Phase II clinical trial in the second quarter of 2014, and we expect to enter into a definitive agreement with UMass for the same.

In July 2012, together with Professor Karussis, we submitted an interim safety evaluation report to the Israeli MoH for the first 12 of 24 patients in the Phase I/II clinical trial. The report confirmed that our NurOwn therapy is safe, did not cause any adverse side effects, and some of the patients showed promising indications of clinical improvement.

In January 2013, the Israeli MoH approved a Phase IIa combined (intramuscular and intrathecal) treatment, dose-escalating trial, which we are currently conducting at HUMC. According to the protocol for this safety and preliminary efficacy trial, 12 early-stage ALS patients received both intramuscular and intrathecal injections of NurOwn cells in three cohorts with increasing doses between February and August 2013. The patients were followed for six months after transplantation. Due to medical and technical considerations, two additional patients were enrolled in the trial in late 2013, in order to preserve the originally planned protocol design. These two patients were treated at the beginning of the second quarter of 2014. The complete and final statistical analysis of the Phase IIa data is expected to be available after 6 months of follow up with the patients.

In January 2013, we also announced that we had successfully completed a 12-week repeat dose toxicity study with our NurOwn cells in mice. These repeat doses were prepared from frozen cells, using a proprietary method recently developed by the Company. We believe that our cryopreservation, or freezing, method will enable long-term storage, and production of repeat patient doses of NurOwn without the need for additional bone marrow aspirations. We believe that the positive data from the toxicity study in mice will support our efforts to obtain approval for a future repeat dose clinical study in ALS patients. The study was conducted at Harlan Israel's laboratories, according to GLP standards. The study protocol was approved by Israel's National Council for Animal Experimentation.

In March 2013, Principal Investigator Professor Dimitrios Karussis of Hadassah presented some of the data from the Phase I/II trial at the American Academy of Neurology Annual Meeting. The trial results analyzed to date confirmed the safety of the NurOwn Treatment and also demonstrated initial signs of possible efficacy. There was a slower decline in overall clinical and respiratory function, as measured by the ALSFRS-R and FVC score respectively, in the six patients that received an intrathecal injection of the cells, in the six months following treatment as compared to the three months preceding treatment.

On March 14, 2013, we entered into a Memorandum of Understanding with Mayo in Rochester, Minnesota, to participate as an additional clinical site in the multi-center Phase II ALS clinical trial in the USA. The team there will be led by Professor Anthony J. Windebank, Head of the Regenerative Neurobiology Laboratory in the Department of Neurology. In January 2014, we announced that we had entered into a definitive agreement with Mayo to conduct the trial and manufacture NurOwn cells in their cell processing cleanroom facility.

Effective April 3, 2013, our Israeli Subsidiary entered into a manufacturing agreement with Dana-Farber under which Dana-Farber's Connell and O'Reilly Cell Manipulation Core Facility will produce NurOwn in its cGMP-compliant clean rooms for the MGH and UMass clinical sites during our upcoming Phase II ALS clinical trial in the United States.

On May 21, 2013, we submitted a safety report to the hospital Helsinki Committee (IRB) for the first group of (four) patients in our ongoing Phase IIa ALS clinical trial at the Hadassah Medical Center in Jerusalem, Israel.

In June 2013, we entered into a MOU with PRC Clinical, a CRO based in the San Francisco Bay Area, in anticipation of our planned Phase II multi-center ALS clinical trial in the United States.

On July 17, 2013, we received Orphan Medicinal Product Designation for NurOwn for the treatment of ALS from the European Commission.

On August 1, 2013, we announced that we submitted a favorable safety report to the hospital Helsinki Committee (IRB) for the second group of (four) patients in our ongoing Phase IIa ALS clinical trial at the Hadassah Medical Center in Jerusalem, Israel. We announced that the treatment was well tolerated and no serious adverse events were observed, except for one SAE (death due to cardiopulmonary arrest) that was reported as non-treatment related.

In September 2013, we announced that we had completed treatment of the 12 patients in our ALS Phase IIa NurOwn dose-escalating clinical trial. We have been informed that one patient in the study expired due to a medical condition unrelated to the Clinical Trial.

In October 2013, we launched our activities in the US in preparation of our Phase II multi-center clinical trial, with the initiation of the NurOwn technology transfer process to the DFCI. This process was completed on March 31, 2014.

On December 10, 2013, we announced that Prof. Karussis had presented some of his preliminary findings from our ALS Phase IIa NurOwn dose-escalating clinical trial at the 24th International Symposium on ALS/MND in Milan, Italy. According to Prof. Karussis, the safety data are "impressively positive," with only minimal and transient (procedure related) adverse events, even though the patients in this study were injected both intrathecally and intramuscularly with up to double the dose of NurOwn cells given in the Phase I trial. In addition, a number of patients showed some initial indications of clinical improvement.

In December 2013, the Company submitted an IND application to the FDA.

On December 4, 2013, a Notice of Intention to Grant from the EPO was issued for the Company's patent application entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases" (European serial number EP06766101.7). 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, a Notice of Allowance was issued from the U.S. Patent Office for the same patent application as above, U.S. serial number 11/727,583.

On March 24, 2014, the Israeli Subsidiary entered into a clinical trial agreement with The General Hospital Corporation d/b/a MGH, to conduct a Phase II clinical trial of the Company’s NurOwn in ALS, pending FDA and IRB approvals.

In March 2014, the U.S. Patent and Trademark Office granted the Company a key patent for its autologous stem cell technology. The patent covers the Company's stem cells induced to secrete elevated levels of neurotrophic factors for the treatment of neurodegenerative diseases.

On April 10, 2014, the Company announced that the U.S. Patent and Trademark Office granted the Company an additional patent for its autologous stem cell technology. The patent covers the production method of the Company's proprietary stem cells induced to secrete significantly elevated levels of neurotrophic factors for the treatment of neurodegenerative diseases.

On April 8, 2014, the FDA approved commencement of its Phase II clinical trial with NurOwn in patients with ALS. On June 6, 2014, the Company issued a press release announcing that its Phase II ALS clinical trial has now commenced with the enrollment of the first patient at MGH in Boston, Massachusetts. The Company’s Phase II trial is a randomized, double-blind, placebo controlled multi-center study designed to evaluate the safety and efficacy of transplantation of Autologous Mesenchymal Stem Cells Secreting Neurotrophic Factors (MSC-NTF or NurOwn) in 48 ALS patients. The trial is also being conducted at the UMass Memorial Hospital in Worcester, Massachusetts and the Mayo Clinic in Rochester, Minnesota.

On June 1, 2014, the interim results from our Phase IIa ALS trial conducted at Hadassah Medical Center in Jerusalem, Israel were presented at the Joint Congress of European Neurology by Principal Investigator Professor Dimitrios Karussis. The positive safety and preliminary efficacy results observed in this study are consistent with results observed in the Company's previous Phase I/II trial. Between these two studies, a total of 26 patients have been treated with NurOwn, the Company’s stem cell therapy candidate for ALS. In all 26 patients who received NurOwn in the two trials, no treatment-related serious adverse events were observed. In the three month pre-treatment “run-in” period, 71% of the patients showed progression of disease with decline in neurological function. In contrast, in the three months

post-transplantation with NurOwn, 63% of the patients who received intrathecal (IT), or combined IT and intramuscular (IM) administration, showed stabilization or improvement in neurological function, as measured by their revised ALS functional rating score (ALSFRS-R). Additionally, as Prof. Karussis discussed during his presentation, in both phases of the trial, 63% of the patients treated with NurOwn via IT or combined IT and IM administration were defined as “responders” (slower progression of disability or improvement in their neurological function) at 3 months post-treatment, based on both their ALSFRS-R score and Forced Vital Capacity (FVC), an indication of respiratory function. The six patients treated with NurOwn in the earlier Phase I/II trial via IM administration only, primarily exhibited a localized positive effect. Similarly, in the same Phase I/II trial, the IT transplanted patients also showed indications of neurotrophic and regenerative effects, as evidenced by an increase in Compound Muscle Action Potential (CMAP).

On June 6, 2014, the Company announced that the first patient had been enrolled in its Phase II ALS trial at MGH in Boston.

On June 6, 2014, the Company appointed Uri Yablonka as its Chief Operating Officer and director.

On June 9, 2014, the Company appointed Dr. Anthony (Tony) Fiorino as its Chief Executive Officer.

On June 10, 2014, the Company announced that it has initiated a study in a mouse model of autism at the Felsenstein Medical Research Center, Sackler Faculty of Medicine, Tel Aviv University, under the direction of Professor Daniel Offen. The study will explore the effects of the Company's MSC-NTF cells on mouse behavior. The study, which will be conducted using the BTBR mouse model for autism, will investigate repetitive behavior, increased cognitive flexibility and improved sociability in mice after administration of a single intracerebroventricular injection of the cells.

On June 27, 2014, the Company announced that its technology collaboration with Octane Biotech, Inc. reached an important milestone with the construction of an Alpha prototype of a customized bioreactor for NurOwn production. The proprietary bioreactor under development will, if successful, provide the Company with large-scale manufacturing capabilities, enabling it to achieve economies of scale in the manufacture of NurOwn.

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 GDNF and BDNF, VEGF and 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 with 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.

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 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 for:

- 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.

Transplantation site and method

Clinical Indication I: ALS (current) – Based on the approval of the Israeli MoH, we are currently conducting a Phase IIa dose-escalating trial to evaluate safety and preliminary efficacy of NurOwn in ALS patients. Following approval of our IND application by the FDA, we have launched our Phase II clinical trial in the USA. We are considering whether to conduct further Phase II/III repeat dose clinical trials of NurOwn.

Future Clinical 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.

History

The Company was incorporated under the laws of the State of Washington on September 22, 2000, under the name Wizbang Technologies, Inc. and acquired the right to market and sell a digital data recorder product line in certain states in the U.S. Subsequently, the Company changed its name to Golden Hand Resources Inc. On July 12, 2004, the Company entered into a research and license agreement with Ramot to acquire certain stem cell technology and decided to discontinue all activities related to the sales of the digital data recorder product. In November 2004, the Company changed its name from Golden Hand Resources Inc. to Brainstorm Cell Therapeutics Inc. to better reflect its new line of business in development of novel cell therapies for neurodegenerative diseases. In October 2004, the Company formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics Ltd. in Israel. On December 18, 2006, the stockholders of the Company approved a proposal to change the state of incorporation of the Company from the State of Washington to the State of Delaware. The reincorporation was completed on December 21, 2006 through the merger of the Company into a newly formed, wholly-owned Delaware subsidiary of Brainstorm, also named Brainstorm Cell Therapeutics Inc. On February 19, 2013, the Israeli Subsidiary formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd. in the United Kingdom (the UK Subsidiary).

Other Recent Developments

Public Offerings

On August 16, 2013, the Company closed a public offering of an aggregate of 23,529,411 units at a public offering price of $0.17 per unit, with each unit consisting of one share of our Common Stock, and 0.75 of a warrant to

purchase one share of our Common Stock at an exercise price of $0.25 per whole share of Common Stock (the 2013 Public Offering). The warrants were immediately exercisable and will expire three years from the issuance date. No units were issued, however, and purchasers received only shares of Common Stock and warrants. The Common Stock and the warrants may be transferred separately immediately upon issuances. We do not intend to list the warrants on any securities exchange or other trading market and we do not expect that a public trading market will develop for the warrants. The net proceeds to the Company were approximately $3.3 million, assuming no exercise of the warrants and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us associated with the 2013 Public Offering.

On July 17, 2012, we raised approximately $5.7 million through a public offering (the 2012 Public Offering) of our Common Stock. We issued a total of 19,818,968 shares of our Common Stock at $0.29 per share and 14,864,228 warrants to purchase shares of Common Stock for every share purchased in the 2012 Public Offering, at an exercise price of $0.29 per share. The warrants are exercisable until the 30 month anniversary of the date of issuance. After deducting closing costs and fees, we received net proceeds of approximately $5 million.

Governmental Grants

In September 2011, we received notice from the Israeli Office of the Chief Scientist (OCS) of its commitment to grant the Company approximately $1.1 million in accordance with OCS guidelines and the relevant plan approved by the OCS (the Approved Plan).

In 2012, we received notices from the OCS of its commitment to grant the Company approximately $1,086,000 for the year ending June 30, 2013.

In December 2013, we were awarded an $800,000 non-dilutive grant from Israel's Office of the OCS for the year 2014.

In February 2014, we were awarded an additional $600,000 non-dilutive grant from the OCS for 2014.

With regards to any funding received from the OCS, we are obligated to pay royalties to the OCS, amounting to 3% to 3.5% of revenues (subject to the relevant regulations, as amended from time to time) derived from sales of the products funded with the OCS grant, depending on the origin of the products' production. Such royalty payments shall be up to an amount equal to 100% of the grant received. The grant is linked to the exchange rate of the U.S. dollar and bears interest of Libor per annum.

Any plan approved by the OCS research committee for grant funding is subject to Israel's Encouragement of Industrial Research and Development Law, 5744 – 1984 (R&D Law), which, among others, restricts the transfer of any know-how (as further defined therein) and the transfer of the manufacture of the outcome product of such Approved Plan outside of Israel.

The research committee may, in special cases, approve the transfer abroad of know-how or any right thereof, derived from research and development conducted under the Approved Plan in Israel, in exchange for receiving know-how from the party abroad; provided, however, that such exchange is towards joint and new research and development.

The research committee may, in special cases and on grounds to be recorded, approve a request to transfer outside of Israel, the manufacturing or the rights to manufacture a product developed within the framework of the Approved Plan; provided, however, that in exchange for such approval, the OCS shall be entitled to, *inter alia*, payment of increased royalties due to the transfer of such manufacturing rights.

Collaboration with Octane Biotech

On December 10, 2012, we signed a development agreement (the Octane Agreement) with Octane Biotech Inc. of Kingston, Ontario (Octane), to jointly collaborate towards developing proprietary bioreactor for scale up production of our NurOwn treatment. The customized bioreactor (the NurOwn Bioreactor) will enable us to enhance the efficiency of our NurOwn production process, significantly increasing our production capabilities by using a single clean room for multiple patients, reducing costs and time.

According to the Octane Agreement, in the event that the parties successfully complete the development of the NurOwn Bioreactor, the parties reserve the right to enter into an agreement for the supply of clinical products and/or provisions of services.

The Octane Agreement further dictates that Octane shall be prohibited from selling and/or transferring the NurOwn Bioreactor to any third party without our prior written consent.

The 3-year collaborative project with a total budget of 1,365,000 Canadian dollars is being supported by the Canada-Israel Industrial Research and Development Foundation which collaborates with the Israeli OCS. The Israeli OCS has confirmed its participation, in such project, of approximately U.S. $141,000 for the first year, which comprises 50% of our budget of approximately U.S. $282,000 for that period.

By the fourth quarter of 2013, Octane developed a first automation system prototype for culturing NurOwn cells, and for process development and optimization.

Development of Cryopreservation Method

In January 2013, we announced the development of a proprietary method for cryopreservation, or freezing, of cells, which will enable long-term storage, and production of repeat patient doses of NurOwn without the need for additional bone marrow aspirations. We believe that cryopreservation will enable us to create a personalized NurOwn stem cell bank for each patient, for ongoing, repeat treatments.

Orphan Drug Status by the European Medicine Agency (EMA)

On July 17, 2013, we received Orphan Medicinal Product Designation for our NurOwn for the treatment of ALS from the European Commission. Orphan designation grants a 10-year marketing exclusivity in the EU for the designated indication, as well as several other regulatory incentives.

Clinical Trial Update

On September 27, 2013, we announced that we had completed treatment of 12 patients in our ALS Phase IIa NurOwn dose-escalating clinical trial. We have been informed that one patient in the study expired due to a medical condition unrelated to the Clinical Trial. An interim safety summary for the first 12 patients in the study was submitted to the Hadassah Medical Center Ethical Committee about two months after transplantation of the 12th patient. One SAE (Serious Adverse Event, death due to cardiopulmonary arrest) was reported as non-treatment related. The majority of the other AE observed were procedure related and not treatment related. In the three months following this summary, one patient chose to undergo euthanasia and discontinued the study. Due to medical and technical considerations, two additional patients were enrolled in the trial in late 2013, in order to preserve the originally planned protocol design. These two patients were treated at the beginning of the second quarter of 2014. The complete and final statistical analysis of the Phase IIa data is expected to be available after 6 months of follow up with the patients.

On December 10, 2013, we announced that Prof. Karussis presented some of his preliminary findings from our ALS Phase IIa NurOwn dose-escalating clinical trial at the 24th International Symposium on ALS/MND in Milan, Italy. According to Prof. Karussis, the safety data are "impressively positive," with only minimal and transient adverse events, even though the patients in this study were injected both intrathecally and intramuscularly with up to double the dose of NurOwn cells given in the Phase I trial. In addition, a number of patients showed some initial indications of clinical improvement.

On March 24, 2014, the Israeli Subsidiary entered into a clinical trial agreement with MGH, to conduct a Phase II clinical trial of the Company's NurOwn in ALS, pending FDA and IRB approvals.

On June 1, 2014, the interim results from our Phase IIa ALS trial conducted at Hadassah Medical Center in Jerusalem, Israel were presented at the Joint Congress of European Neurology by Principal Investigator Professor Dimitrios Karussis. The positive safety and preliminary efficacy results observed in this study are consistent with results observed in the Company's previous Phase I/II trial. Between these two studies, a total of 26 patients have been treated with NurOwn, the Company's stem cell therapy candidate for ALS.

On June 6, 2014, we announced that our Phase II ALS clinical trial commenced with the enrollment of the first patient at MGH in Boston, Massachusetts. Our Phase II trial is a randomized, double-blind, placebo controlled multi-center study designed to evaluate the safety and efficacy of transplantation of Autologous Mesenchymal Stem Cells Secreting Neurotrophic Factors (MSC-NTF or NurOwn) in 48 ALS patients. The trial is also being conducted at the UMass Memorial Hospital in Worcester, Massachusetts and the Mayo Clinic in Rochester, Minnesota.

Chief Executive Officer

On July 28, 2013, Alon Natanson, Chief Executive Officer of the Company, informed us of his resignation from his position with the Company effective 90 days after the notice. Mr. Natanson continued to hold the title of Chief Executive Officer of the Company until October 28, 2013, the end of the 90 day notice period required by Mr. Natanson's employment agreement.

On August 1, 2013, the Company appointed Chaim Lebovits, the President of the Company, as its Principal Executive Officer, and to assume the duties and responsibilities of the Chief Executive Officer on an interim basis while we searched for a new Chief Executive Officer.

On June 9, 2014, the Company appointed Dr. Tony Fiorino as our Chief Executive Officer.

Our efforts are currently directed at:

- Completing a Phase IIa dose-escalating clinical trial of NurOwn for the treatment of ALS with 14 ALS patients in Israel;
- Conducting technology transfer of the NurOwn manufacturing process to the Mayo Clinic cell culture facility in Rochester and monitoring the activities at the Dana Farber Cell culture facility (DFCI) in Boston, having completed the technology transfer to this site;
- Fulfilling all requirements for IND approval;
- Obtaining IRB approval at the Mayo clinical site;
- Initiating a Phase II ALS clinical trial of NurOwn in the United States;
- Collaborating with Octane on development of a customized NurOwn bioreactor; and
- Completing pre-clinical studies of NurOwn for the treatment of MS.

Stem Cell Therapy

Our activities are within the stem cell therapy field. Stem cells are non-specialized cells with a potential for both self-renewal and differentiation into cell types with a specialized function, such as muscle, blood or brain cells. The cells have the ability to undergo asymmetric division such that one of the two daughter cells retains the properties of the stem cell, while the other begins to differentiate into a more specialized cell type. Stem cells are therefore central to normal human growth and development, and also are a potential source of new cells for the regeneration of diseased and damaged tissue. Stem cell therapy aims to restore diseased tissue function by the replacement and/or addition of healthy cells by stem cell transplants.

Currently, two principal platforms for cell therapy products are being explored: (i) embryonic stem cells (ESC), isolated from the inner mass of a few days old embryo; and (ii) adult stem cells, sourced from bone marrow, cord blood and various organs. Although ESCs are the easiest to grow and differentiate, their use in human therapy is limited by safety concerns associated with their tendency to develop teratomas (a form of tumor) and their potential to elicit an immune reaction. In addition, ESC has generated much political and ethical debate due to the derivation of ESCs from aborted fetuses.

Cell therapy using adult stem cells avoids many of these concerns. Mesenchymal stem cells (MSCs) are an example of adult stem cells. These “multi-potent” cells can produce more than one type of specialized cell of the body, such as bone, fat, cartilage, and other types of cells. They secrete factors that promote tissue repair, and decrease inflammatory and immune reactions. The bone marrow is an invaluable source of MSCs. Moreover, bone marrow may be obtained through a simple procedure of aspiration, from the patient himself, enabling autologous cell therapy, thus obviating the need for donor matching, circumventing immune rejection and other immunological mismatch risks, as well as avoiding the need for immunosuppressive therapy. We believe that autologous bone marrow-derived mesenchymal stem cells, which are capable of in-vitro growth and multipotential differentiation, are a preferable source of therapeutic stem cells.

Neurodegenerative Diseases

Studies of neurodegenerative diseases suggest that symptoms that arise in afflicted individuals are secondary to defects in neuron cell function and neural circuitry. To date, these diseases have been treated effectively with systemic drug delivery. Consequently, alternative approaches for treating neurodegenerative diseases have been attempted, such as transplantation of cells capable of replacing or supplementing the function of damaged neurons. For such cell replacement therapy to work, implanted cells must survive and integrate, both functionally and structurally, within the damaged tissue.

Amyotrophic Lateral Sclerosis (ALS)

ALS, often referred to as “Lou Gehrig's disease,” is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. The progressive degeneration of the motor neurons in ALS eventually leads to death. As motor neurons degenerate, they can no longer send impulses to the muscle fibers that normally result in muscle movement. With voluntary muscle action progressively affected, patients in the later stages of the disease may become completely paralyzed. However, in most cases, mental faculties are not affected.

Approximately 5,600 people in the U.S. are diagnosed with ALS each year. It is estimated that as many as 30,000 Americans have the disease at any given time. Estimated annual treatment costs for advanced stage patients can be as high as $200,000, representing an aggregate direct cost to the healthcare system of more than $6 billion per year (Source: Alliance for Regenerative Medicine).

Early symptoms of ALS often include increasing muscle weakness or stiffness, especially involving the arms and legs, speech, swallowing or breathing.

ALS is most often found in the 40 to 70 year age group with the same incidence as MS. There appear to be more MS sufferers because MS patients tend to live much longer, some for 30 years or more. The life expectancy of an ALS patient averages about two to five years from the time of diagnosis. However, up to 10% of ALS patients will survive more than ten years.

Treatment decisions are typically determined by the patient's symptoms and the stage of the disease. Some medications used for ALS patients include:

- Riluzole - the only medication approved by the FDA to slow the progress of ALS. While it does not reverse ALS, Riluzole has been shown to reduce nerve damage. Riluzole may extend the time before a patient needs a ventilator (a machine to assist breathing) and may prolong the patient's life by several months;
- Baclofen or Diazepam - used to control muscle spasms, stiffness or tightening (spasticity) that interfere with daily activities; and
- Trihexyphenidyl or Amitriptyline – used to treat patients who have excess saliva or secretions, and emotional changes.

Other medications may be prescribed to help reduce such symptoms as fatigue, pain, sleep disturbances, constipation, and excess saliva and phlegm.

Multiple Sclerosis (MS)

MS is a chronic neurodegenerative disorder that affects the brain and spinal cord. Nerve cells are normally insulated with a protective layer called myelin, which allows nerve signals to travel properly. In MS, the myelin is destroyed (demyelination), causing loss of function of the nerve cells and disrupting transmission of brain messages to various parts of the body. While generally thought to be an autoimmune disease, the exact cause of MS is unknown.

There are currently over 2.5 million people with MS worldwide, with roughly 800,000 of these in the U.S. and Europe. Over 10,000 new cases are diagnosed annually in the U.S., with the majority of these in women between the ages of 20 and 50. Annual treatment costs for MS can be as much as $34,000 a year per patient.

MS can cause blurred vision, slurred speech, tremors, numbness, extreme fatigue, and problems with memory and concentration. Most MS patients experience muscle weakness in their extremities and difficulty with coordination and balance. These symptoms may be severe enough to impair walking or even standing. In the worst cases, MS can produce partial or complete paralysis. MS is not considered a fatal disease, as the vast majority of people with MS live a normal life-span. But the unpredictability of the disease can present many challenges, including the possibility of facing increasing limitations.

Most people experience MS symptoms between the ages of 20 and 40. At least two to three times more women than men have been diagnosed with MS. MS occurs in most ethnic groups, including African-Americans, Asians and Latinos, but is more common in Caucasians of northern European ancestry.

Treatment of MS focuses on symptom management, treatment of attacks, and reduction of disease progression. Of the nine FDA-approved, disease modifying treatments introduced since 1993, three are interferon-based, two are immunomodulators, one is an immunosuppressant, one is an antineoplastic, one is a monoclonal antibody, and one's exact mechanism is unknown. (Source: National MS Society).

While disease-modifying treatments reduce the progression rate of the disease, they do not stop it. As multiple sclerosis progresses, the symptomatology tends to increase. Therefore, MS treatment management includes symptomatic treatments as well as rehabilitative and psychological approaches such as physical therapy, speech therapy, occupational therapy, support groups, an exercise program, a healthy lifestyle, good nutrition, rest and relaxation.

The variable clinical presentation of MS and the lack of established diagnostic laboratory tests lead to delays and difficulties in diagnosis. New diagnostic methods are being investigated as well as biomarkers for monitoring disease activity.

Parkinson's Disease (PD)

PD is a chronic, progressive disorder, affecting certain nerve cells, which reside in the Substantia Nigra of the brain and which produce dopamine, a neurotransmitter that directs and controls movement. In PD, these dopamine-producing nerve cells break down, causing dopamine levels to drop below the threshold levels and resulting in brain signals directing movement to become abnormal. The cause of the disease is unknown.

Over 6.3 million people worldwide suffer from PD, of whom about one million are in the United States. Most people are diagnosed with the disease between the ages of 55 and 65 and about 85% of people with PD are over the age of 65. Prevalence of PD is increasing in line with the general aging of the population. The market for pharmaceutical treatments for PD has been estimated to be $2.4 billion a year in the U.S., France, Germany, Italy, Spain, the United Kingdom and Japan. However, these costs are dwarfed when compared to the total economic burden of the disease, which has been estimated by the National Parkinson Foundation to exceed $14 billion annually in the U.S. alone, including costs of medical treatment, caring, facilities and other services, as well as loss of productivity of both patients and caregivers.

The symptoms of PD include shaking (tremor), stiff muscles (rigidity) and slow movement (Bradykinesia). A person with fully developed PD may also have a stooped posture, a blank stare or fixed facial expression, speech problems and difficulties with balance or walking. Although it can be highly debilitating, the disease is not life threatening and an average patient's life span is approximately 20 years from the onset of symptoms.

Treatment of PD primarily comprises dopamine replacement, either directly (levodopa), with dopamine mimetics or by inhibition of its breakdown. These treatments focus on treating the symptoms of the disease and are not a cure for PD.

Levodopa, which remains the standard and most potent PD medication available, has a propensity to cause serious motor response complications with long-term use. Moreover, effective drug dosage often requires gradual increase, leading to more adverse side effects and eventual resistance to its therapeutic action. This greatly limits patient benefit. Therefore, physicians and researchers have sought levodopa-sparing strategies in patients with early-stage disease to delay the need for levodopa.

PD is also treated by Deep Brain Stimulation (DBS), which consists of implanting electrodes deep into the brain to provide permanent electrical stimulation to specific areas of the brain and to cause a delay in the activity in those areas. However, DBS is problematic as it can cause uncontrollable and severe side effects such as bleeding in the brain, infection and depression. In addition, like drug therapy, DBS focuses on treating the symptoms of PD and does not provide a cure.

There is a greatly unsatisfied need for novel approaches towards management of PD, primarily to control levodopa-induced adverse side effects and motor dysfunction, as well as to delay the onset of disease-related dementia.

In addition to the symptomatic drug development approaches, there is an intense effort to develop cell and gene therapeutic "curative" approaches to restore the neural function in patients with PD, by (i) replacing the dysfunctional cells with dopamine producing cell transplant, or by (ii) providing growth factors and proteins, such as GDNF, that can maintain or preserve the patient's remaining dopaminergic cells, protecting them from further degeneration. Preclinical evaluation of cell therapeutic approaches based on transplantation of dopaminergic neurons differentiated *in-vitro* from ESC, have been successful in ameliorating PD in animal models, as has direct gene therapy with vectors harboring the GDNF gene. However, these approaches are limited, in the first case, by the safety and ethical considerations associated with use of ESC, and, in the second case, by the safety risks inherent to gene therapy. As a result, intensive efforts have been made to develop an adult stem-cell based treatment.

Company Business Strategy

Our Company is focused on advancing the NurOwn treatment, with the goal of obtaining FDA regulatory approval for uses as a treatment of ALS patients.

- Phase IIa dose-escalating safety and preliminary efficacy clinical trial in Israel;
- Phase II ALS safety and preliminary efficacy clinical trial in the United States; and
- Phase II/III repeat dose clinical efficacy trial.

Additional strategic goals of the Company:

- Development of a customized NurOwn bioreactor for optimization and scale-up of NurOwn production;
- Development of additional clinical indications, i.e. MS;
- Pursuing strategic partnerships with pharmaceutical companies as we progress towards advanced clinical development and commercialization.

Sales and Marketing

We intend to establish and maintain fully-equipped cGMP-certified Cell-Processing Centers in strategic locations to conduct NurOwn production and distribution over the broadest geographic area. Each Cell-Processing Center would receive an initial Bone Marrow sample of the patient, harvested at a medical center. The patient's MSC cells would be isolated and expanded, in order to produce an initial dose of NurOwn cells. A master cell bank for each individual patient would be maintained for production of subsequent, future NurOwn doses on a long-term basis. These doses would be produced as needed and transported to the medical centers, where they would then be transplanted back into the patient.

We intend to seek partnering opportunities with a strategic partner as we progress towards advanced clinical development and commercialization.

Intellectual Property

Patents:

On January 8, 2014 we announced that we received a Notice of Intention to Grant from the European Patent Office (EPO) for our patent application entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases" (European serial number EP 06766101.7) . 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 we were granted a U.S. Patent (No. 8,647,874) for the same patent application as above.

On March 4, 2014 we were granted a U.S. Patent (No. 8,663,987) for our “Mesenchymal Stem Cells for the Treatment of CNS Diseases” (serial number 12/994,761) patent application. This patent relates to our proprietary stem cells induced to secrete large quantities of neurotrophic factors for the treatment of neurodegenerative diseases.

We have pending patent applications in (1) the United States; (2) Europe; (3) Israel; and (4) Hong Kong, as follows:

A. 1. A United States Provisional patent application filed in early 2014.

2. United States Provisional patent application Serial No. 61/679,822, filed August 6, 2012, entitled "Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors.” This application has now been filed as International Application No.: PCT IL2013/050660.

This invention is directed to a method of generating MSCs which secrete neurotrophic factors (NTFs) comprising incubating a population of undifferentiated MSCs in a differentiating medium comprising basic fibroblast growth factor (bFGF), platelet derived growth factor (PDGF), heregulin and cAMP. The application also covers a method of treating a disease for which administration of neurotrophic factors is beneficial in a subject in need thereof, comprising administering to the subject a therapeutically effective amount of isolated population of MSCs which secretes neurotrophic factors made according to the above method. Also taught is a method of selecting MSCs which secrete NTFs from a mixed population of MSCs, comprising (a) analyzing the cells of said mixed population of cells for at least one of the following parameters: (i) cells which express CD44 below a predetermined threshold, or (ii) cells which express CD73 above a predetermined threshold; and (b) selecting cells which are positive for at least one of said parameters, thereby selecting the MSCs which secrete neurotrophic factors. The application teaches a pharmaceutical composition comprising the isolated population of MSCs as an active agent and a pharmaceutically acceptable carrier.

B. The Israeli Subsidiary is co-owner, with Ramot, in the invention entitled “Mesenchymal Stem Cells for the Treatment of CNS Diseases”, filed as a PCT application on May 26, 2009, currently pending as National Phase patent applications in the following countries:

- United States: Serial No. 14/164,286
- Europe: Serial No. 09754337.5
- Europe: Serial No. 13164650.7
- Israel: Serial No. 209604
- Hong Kong: Serial No. 11107062.5

·Hong Kong: Serial No. 13109415.3

This invention is directed to an isolated human cell comprising at least one mesenchymal stem cell phenotype and secreting brain-derived neurotrophic factor (BDNF), wherein a basal secretion of the BDNF is at least five times greater than a basal secretion of the BDNF in a mesenchymal stem cell. Also disclosed in this application is an isolated cell population comprising human mesenchymal stem cells, wherein at least 50% of the cells express glial fibrillary acidic protein (GFAP) and secrete at least one neurotrophic factor. Also taught is an isolated cell population comprising human cells wherein (i) at least N% of said human cells secreting BDNF, wherein a basal secretion of said BDNF is at least five times greater than a basal secretion of the BDNF in a mesenchymal stem cell; (ii) at least M% of said human cells comprise at least one mesenchymal stem cell phenotype; and (iii) at least one of the human cells secretes the BDNF and the mesenchymal stem cell phenotype; where M and N are each independently selected between 1 and 99. Methods of generating same and uses of same are also disclosed. The method of generating cells useful for treating a CNS disease or disorder comprises (a) incubating mesenchymal stem cells in a culture medium comprising platelet lysate to generate propagated mesenchymal stem cells; and (b) incubating said propagated mesenchymal stem cells in a differentiating medium, thereby generating cells useful for treating the CNS disease or disorder. Another method taught is that of generating cells secreting neurotrophic factors, comprising (i) incubating mesenchymal stem cells in a serum free medium comprising platelet lysate to generate propagated mesenchymal stem cells; and (ii) incubating the propagated mesenchymal stem cells in a differentiating medium comprising at least one differentiating agent, said at least one differentiating agent being selected from the group consisting of platelet derived growth factor (PDGF), human neuregulin 1-b1, FGF2, EGF, N2, IBMX and cAMP, thereby generating cells secreting neurotrophic factors. The European applications claim an isolated human cell comprising a cell being non-genetically manipulated, and characterized by: a) expressing tyrosine hydroxylase, nestin and H-NF and b) secreting BDNF, and c) not secreting nerve growth factor (NGF) wherein a basal secretion of said BDNF is at least five times greater than a basal secretion of said BDNF in a mesenchymal stem cell; an isolated cell population comprising cells generated from human bone marrow derived cells expressing CD73, CD90 and CD105 and not expressing CD14, CD19, CD34, CD45 and HLA-DR, wherein at least 50% of the cells of the cell population express GFAP and secrete BDNF; and a method of generating cells useful for treating a CNS disease or disorder, the method comprising: (1) incubating bone marrow derived cells expressing CD73, CD90 and CD105 and not expressing CD14, CD19, CD34, CD45 and HLA-DR in a culture medium comprising human platelet lysate to generate propagated cells; and (2) incubating said propagated cells in a medium comprising a differentiating agent, thereby generating cells useful for treating the CNS disease or disorder, wherein said differentiating agent is selected from the group consisting of PDGF, human neuregulin 1- 1, FGF2, EGF, N2, IBMX and cAMP.

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C. The Israeli Subsidiary is the licensee of the following patent applications owned by Ramot under terms set forth in the Second Ramot Agreement and the Assignment Agreement, as follows:

1. Invention entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases", filed as a PCT application on June 18, 2006, currently pending as National Phase patent applications in the following countries:

- Europe: Serial No. 06766101.7
- Europe: Serial No. 11000994.1
- Hong Kong: Serial No. 12112468.4
- United States: Serial No. 14/173,846

This invention is directed to an isolated human cell and populations thereof comprising at least one astrocytic phenotype and at least one mesenchymal stem cell phenotype, wherein the mesenchymal stem cell phenotype is not an astrocytic phenotype; an isolated human cell comprising at least one mesenchymal stem cell phenotype and at least one astrocytic structural phenotype, wherein the mesenchymal stem cell phenotype is not an astrocytic structural phenotype; or an isolated human cell comprising at least one mesenchymal stem cell phenotype and at least one astrocytic functional phenotype, wherein the mesenchymal stem cell phenotype is not an astrocytic functional phenotype. Also taught is a method of generating astrocyte-like cells expressing S100 beta, glial fibrillary acidic protein (GFAP), glutamine sythetase, GLAST, GLTI and glial derived neurotrophic factor (GDNF) comprising (a) culturing mesenchymal stem cells in a medium comprising human epidermal growth factor (hEGF) and human basic fibroblast growth factor (hbFGF); and (b) incubating the mesenchymal stem cells in a differentiating medium comprising platelet derived growth factor (PDGF) and human neuregulin 1-b1, thereby generating astrocyte-like cells. Another disclosed method of generating astrocyte-like cellse teaches (i) incubating mesenchymal stem cells in a medium comprising hEGF and hbFGF to generate cells predisposed to generate into astrocyte-like cells; and (ii) incubating the predisposed cells in a differentiating medium comprising PDGF and human neuregulin 1-b1, thereby generating astrocyte-like cells.

2. Invention entitled "Methods, nucleic acid constructs and cells for treating neurodegenerative disorders", filed on May 17, 2005 as United States patent application Serial No. 13/783,607. This invention is directed to a method of treating a neurodegenerative disorder by administering to an individual in need thereof cells capable of exogenously regulatable neurotransmitter synthesis. The cells are produced by incubating bone marrow stromal cells in a differentiating medium comprising docosahexaenoic acid or arachidonic acid and at least one differentiating agent.

Trademarks:

We own a pending United States application to register the trademark NUROWN (application no. 85154891, filed October 18, 2010) for use in connection with “compositions of cells derived from stem cells for medical purposes; stem cells for medical purposes.” The application was filed based on an intent-to-use the mark, but has not matured to registration yet.

The patent applications, as well as relevant know-how and research results are licensed from Ramot. We intend to work with Ramot to protect and enhance our mutual intellectual property rights by filing continuations and divisional patent applications. New discoveries arising in the course of research and development within the Company will be patented by us independently.

Research and License Agreement with Ramot

On July 12, 2004, we entered into a Research and License Agreement (the Original Ramot Agreement) with Ramot, the technology licensing company of Tel Aviv University, which agreement was amended on March 30, 2006 by the Amended Research and License Agreement (described below). Under the terms of the Original Ramot Agreement, Ramot granted to us a license to (i) the inventions, know-how and results made with respect to the above-mentioned stem cell technology developed by the team led by Prof. Melamed and Prof. Offen in the course of performance of the research, and the patents and pending patent applications owned by Ramot, and (ii) the results of further research to be performed by the same team on the development of the stem cell technology. Simultaneously with the execution of the Original Ramot Agreement, we entered into individual consulting agreements with Prof. Melamed and Prof. Offen pursuant to which all intellectual property developed by Prof. Melamed or Prof. Offen in the performance of services thereunder will be owned by Ramot and licensed to us under the Original Ramot Agreement.

On March 30, 2006 and May 23, 2006, we entered into an Amended Research and License Agreement and an Amendment Agreement to the Amended Research and License Agreement, respectively (the Amended Research and License Agreement) with Ramot. Under the Amended Research and License Agreement, the funding of further research relating to the licensed technology in an amount of $570,000 per year was reduced to $380,000 per year. Moreover, under the Amended Research and License Agreement, the initial period of time that we agreed to fund the research was extended from an initial period of two (2) years to an initial period of three (3) years. The Amended Research and License Agreement also extended the additional two-year period in the Original Ramot Agreement to an additional three-year period, if certain research milestones were met.

We entered into a Second Amended and Restated Research and License Agreement with Ramot on July 26, 2007, effective July 12, 2004 (the Second Ramot Agreement), which amended and replaced the Amended Research and License Agreement. The Second Ramot Agreement imposed on us development and commercialization obligations, milestone and other obligations. The license was granted in consideration for (i) royalty payments ranging from three percent (3%) to five percent (5%) of all net sales and (ii) potential payments concerning sublicenses ranging from twenty percent (20%) to twenty-five percent (25%) of sublicense receipts. In addition, in the event that the research period was extended for an additional three year period in accordance with the terms of the Second Ramot Agreement, then we had to make payments to Ramot for each year of the extended research period in the amount of $380,000. As of June 30, 2007, we owed Ramot an aggregate amount of $513,249 in overdue payments and patent fees under the Amended Research and License Agreement.

On August 1, 2007, we obtained a waiver and release from Ramot pursuant to which Ramot agreed to an amended payment schedule regarding our payment obligations under the Second Ramot Agreement and waived all claims against us resulting from our previous breaches, defaults and non-payment under the Amended Research and License Agreement.

After our failure to meet the amended payment schedule and subsequent negotiations, on December 24, 2009, we entered into a Letter Agreement and an amended agreement to the Second Ramot Agreement (collectively, the Letter Agreement) with Ramot, pursuant to which, among other things, Ramot agreed to: (i) release us from our obligation to fund three years of additional research (which would have totaled $1,140,000) and (ii) accept conversion of certain research payments due in the amount of $272,000 into 1,120,000 shares of our Common Stock. Pursuant to the Letter Agreement, we agreed, among other things, to: (i) reimburse Ramot for outstanding patent-related expenses; and (ii) abandon our rights in certain joint patent rights and patents of Ramot in certain countries.

As of February 2011, Ramot had sold the 1,120,000 shares of Common Stock of the Company for approximately $235,000 and we paid the remaining $5,000 due to Ramot. To date there is no additional debt to Ramot.

On December 20, 2011, we entered into an Assignment Agreement with our Israeli Subsidiary (the Assignment Agreement), with the consent of Ramot. Under the Assignment Agreement, we assigned and transferred all of our rights, interests, titles, liabilities and obligations (the Rights) under the Second Ramot Agreement to our Israeli Subsidiary, effective as of January 1, 2007 and our Israeli Subsidiary agreed to assume all such Rights. We agreed to be a guarantor of all obligations of our Israeli Subsidiary under the Second Ramot Agreement and Ramot can look to us to demand compliance with the Second Ramot Agreement.

In May 2012, we, the Israeli Subsidiary and Prof. Offen entered into a Consulting Agreement, effective as of January 1, 2012, which replaced the previous consulting agreement, dated July 31, 2004, pursuant to which all work product resulting from the provision of services will vest solely with the Israeli Subsidiary and if any work product resulting from the provision of services results in the creation or development of intellectual property it will be deemed a joint invention, and will be jointly owned by Ramot and the Israeli Subsidiary.

Government Regulation and Product Approval

Once fully developed, we intend to market our bone marrow derived differentiated neurothrophic-factor secreting cell products, NurOwn, for autologous transplantation in patients by neurologists in medical facilities in the U.S., Europe, Japan and the Pacific Rim. We plan to submit biologics license application (BLA) in the United States for the development of NurOwn for the treatment of ALS patients. We initiated the regulatory process with a Pre-IND meeting with the FDA in September 2012, and submitted our IND application in December 2013. We have retained expert regulatory consultants to assist us in our approach to the FDA.

In January 2013, the EMA Committee for Advanced Therapies classified NurOwn as an Advanced Therapy Medicinal Product.

Government authorities in the United States at the federal, state and local level extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates must receive final approval from the FDA before they may legally be marketed in the United States or by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. Biologics are subject to regulation by the FDA under the FDCA, the Public Health Service Act, or the PHSA, and related regulations and other federal, state and local laws and regulations. Biological products are therapies used to treat disease and health conditions. They include a wide variety of products including vaccines, blood and blood components, gene therapies, tissue and proteins. Unlike most prescription products made through chemical processes, biological products generally are made from human and/or animal materials. To be lawfully marketed in interstate commerce, a biologic product must be the subject of a BLA, issued by the FDA on the basis of a demonstration that the product is safe, pure and potent, and that the facility in which the product is manufactured meets standards to assure that it continues to be safe, pure and potent. The FDA has developed and is continuously updating the requirements with respect to cell and gene therapy products and has issued documents concerning the regulation of cellular and tissue-based products. Manufacturers of cell and tissue-based products must comply with the FDA's current good tissue practices, or cGTP, which are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of such products. The primary intent of the cGTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease.

The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, product detention, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a biological product or drug may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other regulations;
- Submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- Performance of adequate and well-controlled clinical trials according to Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed biological product or drug for its intended use;
- submission to the FDA of a new drug application, or NDA, for a new drug; or a biologic license application for a new biological product;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with Good Manufacturing Practices, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity; and
- FDA review and approval of the BLA or NDA.

The testing and approval process require substantial time, effort and financial resources and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing phase. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. Accordingly, we cannot assure you that submission of an IND will result in the FDA allowing clinical trials to begin or, once begun, issues will not arise that result in the suspension or termination of such trial.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent.

Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRBs for approval.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients having the specific disease.

- *Phase 2.* Phase 2 trials involve investigations in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and the optimal dosage and schedule.

- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Post-approval studies, also called Phase 4 trials, may be conducted after initial marketing approvals. These studies are used to obtain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected side effects. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During the development of a new drug or biologic, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. An SPA is intended to provide assurance that if the agreed upon clinical trial protocol is followed, the clinical trial endpoints are achieved, and there is a favorable risk-benefit profile, the data may serve as the primary basis for an efficacy claim in support of a BLA or an NDA. However, an SPA is not a guarantee of an approval of a product candidate or any permissible claims about the product candidate. In particular, SPAs are not binding on the FDA if previously unrecognized public health concerns arise during the performance of the clinical trial, other new scientific concerns regarding product candidate's safety or efficacy arise, or if the sponsoring company fails to comply with the agreed upon clinical trial protocol.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the biologic or drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or BLA, requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees which may be waived under certain

limited circumstances.

FDA Review of Biologics License Applications and New Drug Applications

The FDA reviews all BLAs and NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept a BLA or an NDA for filing. In this event, the BLA or NDA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete the initial review of a standard BLA or NDA and respond to the applicant and six months for a priority BLA or NDA. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs or NDAs. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure, and potent and the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the products continued safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements, and additionally, in the case of biologics in accordance with cGTP guidelines, and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of independent experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult and the FDA may refuse to approve a BLA an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information.

Even if such data and information is submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the BLA or NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the BLA or NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to conform the application to a condition suitable for approval. If a complete response letter is issued, the applicant may either resubmit the BLA or NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In

addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's or biologic's safety and effectiveness after BLA or NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA or BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. In addition to the potential for a period of exclusivity, we may be eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our drug or biological candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in the European Union.

In February 2011, we received Orphan Drug Designation for NurOwn for the treatment of ALS in the United States. In July 2013, we received Orphan Medicinal Product Designation for NurOwn for the treatment of ALS from the European Commission.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between (a) the effective date of an IND and the submission date of a BLA or an NDA plus (b) the time between the submission date of a BLA or an NDA and the approval of that application. Only one patent applicable to an approved drug or biologic is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of approval of the drug or biologic. The U.S. patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Biologics Price Competition and Innovation Act of 2009

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to create a new licensure framework for biosimilar products, which could ultimately subject our biological product candidates to competition. Under the BPCIA, a manufacturer may submit an application for licensure of a biological product that is "biosimilar to" or "interchangeable with" a referenced, branded biologic product. Previously, there had been no licensure pathway for such biosimilar or interchangeable products. For purposes of the BPCIA, a reference product is defined as the single biological product licensed under a full BLA against which a biological product is evaluated in an application submitted under a follow-on BLA.

The BPCIA also created a 12-year period of reference product exclusivity, which can be extended to 12.5 years with pediatric exclusivity. The 12-year exclusivity period begins on the date of first licensure of the reference product under the PHSA and during which the licensure of a follow-on application for a biosimilar or interchangeable product cannot be made effective. During the first four years (or four and one-half years with pediatric exclusivity) of the 12-year period, an application for a biosimilar or interchangeable version of the reference product cannot be submitted to the FDA. Under budget proposals submitted by President Obama, the Administration has requested that reference product exclusivity would decrease from twelve to seven years. Congress has not yet enacted such a change in the BPCIA, but could move to enact such a decrease in the reference product exclusivity period.

The BPCIA includes limits on obtaining 12-year reference product exclusivity for certain changes or modifications to the reference product. A separate 12-year reference product exclusivity period does not apply to:

- a BLA supplement for the product that is the reference product;
- a subsequent BLA filed by the same reference product sponsor or manufacturer (or a licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength; or
- a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

In February 2012, the FDA issued three draft guidance documents on biosimilar product development. The FDA is soliciting comments on the draft guidance documents which are described by the FDA as follows: (1) Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, which is intended to assist companies in demonstrating that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting an application, called a "351(k)" application, to the FDA. This draft guidance describes a risk-based "totality-of-the-evidence" approach that the FDA intends to use to evaluate the data and information submitted in support of a determination of biosimilarity of the proposed product to the reference product; (2) Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product, which provides an overview of analytical factors to consider when assessing biosimilarity between a proposed therapeutic protein product and a reference product for the purpose of submitting a 351(k) application; and (3) Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009, which provides answers to common questions from people interested in developing biosimilar products. We cannot predict when or whether these draft guidance documents will ever be finalized or what changes the agency may make in its approach to implementation of the BPCIA.

In addition to creating a 12-year period of reference product exclusivity, the BPCIA clarifies the interaction of that exclusivity with orphan drug exclusivity, such that, if a reference product has been designated for a rare disease or condition the licensure of a biosimilar or interchangeable version of a reference product for such disease or condition may only occur after the later of the expiration of any applicable seven-year orphan drug exclusivity or the 12-year reference product exclusivity (or seven and one-half years and 12.5 years with pediatric exclusivity).

Our biological product candidates, if approved, could be considered reference products entitled to 12-year exclusivity. Even if our products are considered to be reference products eligible for exclusivity, another company could market a competing version of any of our biological products if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

The BPCIA also sets forth a complex mechanism for resolving patent disputes that involves a step-wise exchange of information prior to the initiation of a patent infringement lawsuit against a biosimilar or interchangeable product sponsor. Unlike the Hatch-Waxman Act, the BPCIA provides no automatic stay on approval of a biosimilar product application, except an interchangeable product receives the lesser of one year of exclusivity after the date of first commercial marketing or 18 months of exclusivity after a final court decision or dismissal of a patent challenge or, if the applicant has not been sued, after approval. The BPCIA does not prevent a competitor from conducting its own clinical trials and submitting a full BLA on the same or similar product.

Post-Approval Requirements

Any drugs for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse effects with the product, reporting of changes in distributed products which would require field alert reports (FARs) for drugs and biological product deviation reports (BPDRs), providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require postmarketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies, or REMS, approved by the FDA. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of drugs and biologics must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Drug and biologic manufacturers and other entities involved in the manufacturing and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, GTP applicable to biologics, and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Discovery of previously unknown problems with a product subsequent to its approval may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to clinically evaluate or sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

Third Party Payor Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any of our biologic or drug candidates for which we obtain regulatory approval. In both the United States and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the Centers for Medicare and Medicaid Services, or CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who

are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payor has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payors.

The U.S. Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our product candidates profitably. For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the associated reconciliation bill, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law.

Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product candidates.

The cost of pharmaceuticals continues to generate substantial governmental and third party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third party payors also require pre-approval of coverage for new or innovative devices, biologics or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug or biological candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs and biologics, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. These regulations include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- the FDCA, which among other things, strictly regulates drug and biologic product marketing, prohibits manufacturers from marketing drug or biologic products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Compliance with Environmental, Health and Safety Laws

In addition to FDA regulations, we are also subject to evolving federal, state and local environmental, health and safety laws and regulations. In the past, compliance with environmental, health and safety laws and regulations has not had a material effect on our capital expenditures. We believe that we comply in all material respects with existing environmental, health and safety laws and regulations applicable to us. Compliance with environmental, health and safety laws and regulations in the future may require additional capital expenditures.

Competition

There are a number of clinical trials underway for potential treatments for ALS, of which only two are stem cell-based trials being conducted by other commercial entities. One is US-based Neuralstem (CUR), which is currently conducting a Phase II trial for its allogeneic, human (fetal) spinal cord derived neural stem cells. The other is Corestem, a Korean company, which is currently conducting two Phase I stem cell-based clinical trials. One is a recently launched Phase I trial with allogeneic bone marrow derived mesenchymal stem cells, and a previous trial, which is not actively recruiting, is with autologous, bone marrow-derived mesenchymal stem cells. There is little public information available about Corestem. Five non-stem cell-based companies are undergoing Phase I/II, Phase II or Phase III clinical trials for ALS. A number of academic institutions are also developing treatment candidates for ALS.

Employees

We currently have 16 employees, 14 of whom are full-time. None of our employees is represented by a labor union.

PROPERTIES

Our executive offices are located in premises at 605 Third Avenue, 34th Floor, New York, NY 10158, which we use, free of charge, pursuant to an oral agreement with Malcolm Taub, a member of our Board of Directors.

On December 1, 2004, our Israeli Subsidiary entered into a lease agreement (the Lease Agreement) for the lease of premises in 12 Basel Street, Petach Tikva, Israel, which include approximately 600 square meters of office and laboratory space. The original term of the lease was 36 months (the Lease Term), commencing on April 1, 2005, with two options to extend: one for an additional 24 months (the First Option); and one for an additional 36 months (the Second Option).

On November 11, 2012, the Israeli Subsidiary entered into an amendment to the Lease Agreement, pursuant to which the Lease Term (including the First Option and the Second Option) was extended by an additional five years, through March 31, 2018. After three years, we will have the right to cancel the agreement with 6 months' notice. Rent is paid on a monthly basis in the amount of NIS 40,000 (approximately U.S. $11,000).

We expanded our Petach Tikva facility in 2008 to include an animal research facility.

As part of the clinical trials with Hadassah, we pay $31,250 per month for rental and operation of a clean room at the Hadassah medical center GMP facilities in Jerusalem.

We believe that the current office and laboratory space is adequate to meet our needs or will be available in the U.S. to meet the needs of U.S. clinical trials.

LEGAL PROCEEDINGS

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

MARKET FOR OUR COMMON EQUITY

Market Information

Our Common Stock is traded on the OTCQB Marketplace under the symbol "BCLI." The following table contains information about the range of high and low sales prices for our Common Stock based upon reports of transactions on the OTCQB Marketplace.

Quarter Ended	High	Low
June 30, 2014	$0.38	$0.23
March 31, 2014	$0.37	$0.17
December 31, 2013	$0.23	$0.10
September 30, 2013	$0.26	$0.15
June 30, 2013	$0.25	$0.19
March 31, 2013	$0.27	$0.22
December 31, 2012	$0.27	$0.17
September 30, 2012	$0.38	$0.21
June 30, 2012	$0.30	$0.21
March 31, 2012	$0.34	$0.20

The source of these high and low prices was the OTCQB Marketplace. The high and low prices listed have been rounded up to the next highest two decimal places.

On July 9, 2014, the closing bid price of our Common Stock as reported by the OTCQB Marketplace was $0.38 per share.

Trades in our Common Stock may be subject to Rule 15g-9 of the Exchange Act, which imposes requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, broker/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction before the sale.

The Securities and Exchange Commission also has rules that regulate broker/dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than $5.00 (other than securities listed on certain national exchanges, provided that the current price and volume information with respect to

transactions in that security is provided by the applicable exchange or system). The penny stock rules require a broker/dealer, before effecting a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the Securities and Exchange Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing before effecting the transaction, and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for shares of Common Stock of the Company. As a result of these rules, investors may find it difficult to sell their shares.

Dividends

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

Record Holders

As of June 20, 2014, there were approximately 64 holders of record of our Common Stock.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Company Overview

We are a biotechnology company developing novel adult stem cell therapies for debilitating neurodegenerative disorders such as ALS, MS, and PD. These diseases have limited treatment options and as such represent unmet medical needs.

We believe that NurOwn, our proprietary process for the propagation of MSC and their differentiation into 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 approach is considered safe based on our use of autologous cells, which are free of the risk of rejection and tumor formation. It is also free of the controversy associated with the use of embryonic stem cells in some countries.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. We continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, our expected course of development, historical experience and other factors we believe are reasonable based on the circumstances, the results of which form our management's basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. There were no significant changes to our critical accounting policies during the quarter ended March 31, 2014. For a discussion of our significant accounting policies, please see Note 2 to our financial statements included in this prospectus, starting on page F-19.

Results of Operations

The Company has been a development stage company since its inception. For the period from inception (September 22, 2000) until March 31, 2014, the Company has not earned any revenues from operations. The Company does not expect to earn revenues from operations until 2017. In addition, the Company has incurred operating costs and other expenses of approximately $1,031,000 during the three months ended March 31, 2014, and approximately $50,989,000 for the period from inception (September 22, 2000) until March 31, 2014. Operating expenses incurred since inception were approximately $21,203,000 for general and administrative expenses and $29,786,000 for research and development costs.

Year ended December 31, 2013 vs. year ended December 31, 2012

Research and Development, net

Our business model calls for significant investments in research and development. Our research and development expenditures (i) in 2013 (before participation by the OCS) were $4,030,000, which included $51,000 in stock-based compensation and (ii) in 2012 (before participation by the OCS) were $2,688,000, which included $74,000 in stock-based compensation. Research and development expenses, net for the year ended December 31, 2013 and 2012 were $2,917,000 and $1,770,000, respectively. In addition, our grant from The Office of the Chief Scientist increased by $195,000 to $1,113,000 for the year ended December 31, 2013 from $918,000 for the year ended December 31, 2012.

The increase in research and development expenses is primarily due to (i) an increase of $966,000 for the year ended December 31, 2013, compared to zero for the year ended December 31, 2012 for costs of activities related to commencement of the US Clinical Trial including IND submission fees to PRC Clinical and FDA Consultant, purchase and validation of cleanroom equipment at DFCI and Mayo Clinic, adaptation of cleanroom facility at DFCI, and on-site technology transfer training to DFCI cleanroom personnel; (ii) an increase of $153,000 in costs associated with the clinical trials, conducted in accordance with GMP in Hadassah, for an aggregate amount of $1,432,000 for the year ended December 31, 2013, compared to $1,279,000 for the year ended December 31, 2012; (iii) an increase of $296,000 in payroll costs due to recruitment of two additional employees to conduct the clinical trials; and (iv) an increase of $111,000 for patents, travel and rent costs. This increase was offset by: (i) a decrease in stock-based compensation expenses, of $23,000 in the year ended December 31, 2013 to $51,000, compared to $74,000 for the year ended December 31, 2012; and (ii) a decrease of $161,000 for consultants and depreciation from $406,000 in the year ended December 31, 2012 to $245,000 in the year ended December 31, 2013.

General and Administrative

General and administrative expenses for the years ended December 31, 2013 and 2012 were $2,101,000 and $1,748,000, respectively. The increase in General and administrative expenses for the year ended December 31, 2013, is mainly due to: (i) an increase of $222,000 in stock-based compensation expenses, from $545,000 in the year ended December 31, 2012 to $767,000 in the year ended December 31, 2013;(ii) an increase of $140,000 in payroll costs due to recruitment of CEO during 2013; (iii) an increase of $107,000 for travel, rent and stock costs from $190,000 in the year ended December 31, 2012 to $297,000 in the year ended December 31, 2013. This increase was partially offset by a decrease of $116,000 in consultants, depreciation and PR costs from $573,000 in the year ended December 31, 2012 to $457,000 in the year ended December 31, 2013.

Financial Expenses

Financial income for the year ended December 31, 2013 was $144,000 compared to income of $93,000 for the year ended December 31, 2012.

The financial income for year ended December 31, 2013 is mainly due to income from revaluation of warrants of $174,000 and income from interest receivable from a bank deposit that were offset by conversion exchange rates and bank charges. The financial income for the year ended December 31, 2012, is primarily due to a one-time $192,000 financial income, from conversion of debt to a subcontractor to our Common Stock. The issuance of stock to the subcontractor was in an amount that was lower than the amount owed to the supplier. The value of the amount issued was based on the per share price on the date of the grant. In addition, the financial income is due to (i) an increase in financial income of $33,000 from conversion exchange; and (ii) an interest receivable from a bank deposit in the amount of $19,000.

Net Loss

Net loss for the year ended December 31, 2013 was $4,899,000, as compared to a net loss of $3,430,000 for the year ended December 31, 2012. Net loss per share for the year ended December 31, 2013 was $0.03, compared to net loss per share of $0.02 for the year ended December 31, 2012.

The increase in the net loss for the year ended December 31, 2013 is due to (i) an increase the progress of clinical trials conducted in GMP facilities in Hadassah and US Clinical Trial, and (ii) an increase in payroll costs, and (iii) an increase in stock-based compensation expenses. This increase was partially offset by an increase in OCS grants.

The weighted average number of shares of Common Stock used in computing basic and diluted net loss per share for the year ended December 31, 2013 was 161,071,968, compared to 137,596,391for the year ended December 31, 2012.

The increase in the weighted average number of shares of Common Stock used in computing basic for the year ended December 31, 2013 was due to: (i) the issuance of shares of Common Stock in the 2013 Public Offering, as described in more detail below and in the 2012 Public Offering, (ii) the exercise of options and warrants, and (iii) the issuance of shares to service providers.

Quarter ended March 31, 2014 vs. quarter ended March 31, 2013

Research and Development, net:

Research and development expenses, net for the three months ended March 31, 2014 and 2013 were $680,000 and $522,000, respectively. In addition, the Company's grant from The Office of the Chief Scientist increased by $6,000 to $286,000 for the three months ended March 31, 2014 from $280,000 for the three months ended March 31, 2013.

The increase in research and development expenses for the three months ended March 31, 2014 is primarily due to an increase of $328,000, associated with the clinical trials in the US, for the three months ended March 31, 2014, compared to zero for the three months ended March 31, 2013. This increase was partially offset by a decrease of $173,000 for the clinical trials in Israel.

General and Administrative:

General and administrative expenses for the three months ended March 31, 2014 and 2013 were $351,000 and $559,000, respectively. The decrease in general and administrative expenses for the three month period ended March 31, 2014 from the three month period ended March 31, 2013 is primarily due to: (i) a decrease of $122,000 in stock-based compensation expenses, from $226,000 in the three months ended March 31, 2013 to $104,000 in the three months ended March 31, 2014; (ii) a decrease of $38,000 in payroll costs from $130,000 in the three months ended March 31, 2013 to $92,000 in the three months ended March 31, 2014, and (iii) a decrease of $68,000 for IR and PR costs, travel and other costs, from $97,000 in the three months ended March 31, 2013 to $29,000 in the three months ended March 31, 2014. This decrease was partially offset by an increase of $20,000 for rent and consulting fees.

Financial Expenses:

Financial expense for the three months ended March 31, 2014 was $1,080,000, compared to a financial expense of $1,000 for the three months ended March 31, 2013.

The financial expense for the three months ended March 31, 2014 is mainly due to a financial expense of $1,071,000 that is due to revaluation of warrants issued to investors in the 2013 Public Offering (the 2013 Warrants). The 2013

Warrants contain anti-dilution provisions. Under generally accepted accounting principles, the anti-dilution provisions require the 2013 Warrants to be valued and classified as a warrant liability on the balance sheet, resulting in a reduction of stockholders' equity. This warrant liability will be revaluated every quarterly report. On April 25, 2014, the Company exchanged part of the 2013 Warrants, entitling the holders to purchase 11,662,059 shares of Common Stock, $0.00005 par value for 5,831,031 unregistered shares of Common Stock. The exchange was done to facilitate the Company's plans to uplist its stock to a national securities exchange such as NASDAQ. No such revaluation expense was recorded in the three months ended March 31, 2013. On March 24, 2014, ACCBT Corp. and ACC International Holdings Ltd. agreed to irrevocably waive all anti-dilution rights contained in all issued and outstanding warrants to purchase Company Common Stock held by ACCBT Corp. or ACC International Holdings Ltd.

The financial expense for the three months ended March 31, 2014 in the amount of $9,000 is due to conversion exchange rates and bank charges that were offset by an interest receivable from a bank deposit, compared to $1,000 for the three months ended March 31, 2013.

Net Loss:

Net loss for the three months ended on March 31, 2014 was $2,111,000, as compared to a net loss of $1,082,000 for the three months ended March 31, 2013. Net loss per share for the three months ended March 31, 2014 and 2013 was $0.01.

The weighted average number of shares of Common Stock used in computing basic and diluted net loss per share for the three months ended March 31, 2014 was 176,305,587, compared to 150,953,117 for the three months ended March 31, 2013.

The increase in the weighted average number of shares of Common Stock used in computing basic and diluted net loss per share for the three months ended March 31, 2014 was due to (i) the issuance of shares of Common Stock in the 2013 Public Offering, as described in more detail below, (ii) the exercise of options, and (iii) the issuance of shares to service providers and private investors.

Liquidity and Capital Resources

The Company has financed its operations since inception primarily through public and private sales of its Common Stock and warrants and the issuance of convertible promissory notes. At March 31, 2014, the Company had $3,853,000 in total current assets and $1,607,000 in total current liabilities.

Net cash used in operating activities was $391,000 for the three months ended March 31, 2014. Cash used for operating activities was primarily attributed to cost of clinical trials, rent of clean rooms and materials for clinical trials, payroll costs, rent, outside legal fee expenses and public relations expenses.

Net cash used in investing activities was $85,000 for the three months ended March 31, 2014.

There is no Net cash provided by financing activities for the three months ended March 31, 2014.

On August 16, 2013, the Company raised approximately $4.0 million through a public offering (the 2013 Public Offering) of its Common Stock. The Company issued a total of 23,529,411 units at a public offering price of $0.17 per unit, with each unit consisting of one share of Common Stock, and 0.75 of a warrant to purchase one share of our Common Stock at an exercise price of $0.25 per whole share of Common Stock. The warrants are exercisable until the three year anniversary of the date of issuance. After deducting closing costs and fees, the Company received net proceeds of approximately $3.3 million.

The Company’s other material cash needs for the next 12 months will include payments of (i) costs of the clinical trials in the US and Israel; (ii) employee salaries; (iii) patents; (iv) construction fees for facilities to be used in the

Company’s research and development and (v) fees to Company consultants and legal advisors.

Company's operations are very capital intensive and will require substantial capital raisings. If the Company is not able to raise substantial additional capital, it may not be able to continue to function as a going concern and may have to cease operations. Even if the Company obtains funding sufficient to fund its operations in the short term, it would still be required to raise a substantial amount of capital in the future in order to reach profitability and to complete the commercialization of the Company’s products. The Company’s ability to fund these future capital requirements will depend on many factors, including the following:

- our ability to obtain funding from third parties, including any future collaborative partners;
- the scope, rate of progress and cost of our clinical trials and other research and development programs;
- the time and costs required to gain regulatory approvals;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of filing, prosecuting, defending and enforcing patents, patent applications, patent claims, trademarks and other intellectual property rights;
- the effect of competition and market developments; and
- future pre-clinical and clinical trial results.

Off Balance Sheet Arrangements

We have no off balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Subsequent Events

Warrant Exchange

On April 25, 2014, the Company entered into agreements with holders of warrants originally issued in the Company's 2013 Public Offering (the 2013 Warrants) to exchange outstanding 2013 Warrants entitling the holder to purchase an aggregate of 11,662,059 shares of Common Stock for an aggregate of 5,831,031 unregistered shares of Common Stock. Each share of Common Stock issuable pursuant to the 2013 Warrants (the Warrant Shares) was exchanged for shares of unregistered Common Stock equal to one-half (0.5) of the number of Warrant Shares (the Exchange Shares), provided that in the event the number of Exchange Shares resulted in a fractional number it was rounded up to the nearest whole share. The 2013 Warrants were cancelled and of no further force and effect.

The offer and sale of the Exchange Shares were made in reliance upon the exemption from registration provided for by Rule 506 of Regulation D promulgated under the Securities Act. No form of general solicitation or general advertising was used by the Company, or any representative of the Company, in connection with the offer or sale of the Exchange Shares. No underwriters were involved with the issuance of the Exchange Shares and no commissions were paid in connection with the exchange. Each of the investors represented to the Company that they are an accredited investor. This prospectus shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall the Exchange Shares be offered or sold absent registration or an applicable exemption from the registration requirements under the Securities Act and any applicable state securities laws.

The Company believes that the exchange will help facilitate the Company's plans to uplist its stock to a national securities exchange such as NASDAQ. The 2013 Warrants contain anti-dilution provisions. Under generally accepted accounting principles, the anti-dilution provisions require the 2013 Warrants to be valued and classified as a warrant liability on the balance sheet, resulting in a reduction of stockholders' equity. NASDAQ requires as part of its initial listing standards that the Company have a minimum of $5 million of stockholders' equity, which the exchange is anticipated to help facilitate.

Warrant Redemption

On May 27, 2014 (the Effective Date), the Company entered into agreements with certain holders of 2013 Warrants to repurchase outstanding 2013 Warrants entitling the holders to purchase an aggregate of approximately five (5) million shares of Common Stock for an aggregate of approximately $600,000 (the Redemption). On the Effective Date, each share of Common Stock issuable pursuant to the 2013 Warrants was repurchased for $0.12 cash payment by the Company per Warrant share. As of the Effective Date, all 2013 Warrants participating in the Redemption were cancelled and of no further force and effect. In connection with the Redemption, certain holders of 2013 Warrants which did not participate in the Redemption and whose 2013 Warrants will therefore remain outstanding after the Effective Date, have waived anti-dilution provisions of their 2013 Warrants (the Waiver). Following the Redemption and the Waiver, there remain outstanding 2013 Warrants exercisable for an aggregate of 435,000 shares of Common Stock which continue to have anti-dilution provisions.

The Company believes that the Redemption and the Waiver will help facilitate the Company’s plans to uplist its stock to a national securities exchange such as NASDAQ. The 2013 Warrants contained anti-dilution provisions. Under generally accepted accounting principles, the anti-dilution provisions required the 2013 Warrants to be valued and classified as a warrant liability on the balance sheet, resulting in a reduction of stockholders’ equity. NASDAQ requires as part of its initial listing standards that the Company have a minimum of $5 million of stockholders’ equity, which the Redemption and Waiver is anticipated to help facilitate.

Warrant Amendment Agreement with ACCBT

On May 25, 2014, the Company entered into a Warrant Amendment Agreement (the Amendment) with ACCBT Corp. and ACC International Holdings Ltd. (together, 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 anti-dilution rights. ACCBT and the Company are party to a Subscription Agreement, dated as of July 2, 2007, a related Registration Rights Agreement and warrants to purchase up to an aggregate of 30,250,000 shares of Common Stock, and related documents (all of the foregoing documents together as amended to date, the ACCBT Documents). Pursuant to the Amendment, the ACCBT Documents were amended to reflect the extension of the warrants' expiration date.

Chairman of the Board

On April 22, 2014, Prof. Abraham Israeli, a director and Chairman of the Board of Directors of the Company and a consultant to the Company, informed the Company of his resignation from the Company effective April 25, 2014. Prof. Israeli had served the Company since April 13, 2010.

Effective upon Prof. Israeli's resignation, Dr. Irit Arbel, a co-founder and member of the Board of Directors of the Company, succeeded Prof. Israeli as Chairman of the Board of Directors of the Company.

Hadasit Agreement

On April 25, 2014, the Agreement by and among the Company, Prof. Abraham Israeli and Hadasit Medical Research Services and Development Ltd. (Hadasit), dated April 13, 2010 and amended December 31, 2011 (as amended, the Hadasit Agreement) was terminated pursuant to notice given by Hadasit and Prof. Israeli, in connection with Prof. Israeli's resignation from the Company. The Hadasit Agreement provided terms for Prof. Israeli's service as the Company's Clinical Trials Advisor and a member of the Company's Board of Directors, both of which ceased on April 25, 2014. As a result of the termination of the Hadasit Agreement Prof. Israeli and Hadasit will no longer receive annual grants to purchase shares of Common Stock, and any outstanding and unvested grants made pursuant to the Hadasit Agreement will cease to vest, and the grants shall be valid until and may be exercised only on or before October 25, 2014.

Commencement of Phase II Clinical Trial

On April 8, 2014, the Company announced that the FDA has approved commencement of its Phase II clinical trial with NurOwn in patients with ALS. On June 6, 2014, the Company issued a press release announcing that its Phase II ALS clinical trial has now commenced with the enrollment of the first patient at MGH in Boston, Massachusetts. The Company's Phase II trial is a randomized, double-blind, placebo controlled multi-center study designed to evaluate the safety and efficacy of transplantation of Autologous Mesenchymal Stem Cells Secreting Neurotrophic Factors (MSC-NTF or NurOwn) in 48 ALS patients. The trial is also being conducted at the UMass Memorial Hospital in Worcester, Massachusetts and the Mayo Clinic in Rochester, Minnesota.

Uri Yablonka, Chief Operating Officer and Director

On June 6, 2014, the Company appointed Uri Yablonka as its Chief Operating Officer and director, effective June 6, 2014. On June 6, 2014, the Israeli Subsidiary and Uri Yablonka entered into an employment agreement which sets forth the terms of Mr. Yablonka's employment (the Employment Agreement). Pursuant to the Employment Agreement, Uri Yablonka will be paid a monthly salary of NIS31,900 (approximately $9,200 based on current currency exchange rates). Mr. Yablonka will also receive other benefits that are generally made available to the Company's employees, including pension and education fund benefits. The Company will provide Mr. Yablonka with a Company car and cellular phone, and a gross-up payment for any taxes relating thereto. Mr. Yablonka also was granted a stock option (the Initial Grant) on June 6, 2014 (the Grant Date) under the Company's Amended and Restated 2004 Global Share Option Plan (the Global Plan) for the purchase of 500,000 shares of the Company's Common Stock, which was fully vested and exercisable upon grant. The exercise price for the Initial Grant is $0.18 per share.

In addition, the Company agreed to grant Mr. Yablonka a stock option under the Global Plan (or the applicable successor option plan) for the purchase of up to 200,000 shares of Common Stock (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like) of the Company (the Additional Options and each an Additional Option) on the first business day after each annual meeting of stockholders (or special meeting in lieu thereof) of the Company beginning with the 2014 annual meeting, and provided that Mr. Yablonka remains an employee of the Company on each such date. The exercise price per share of the Common Stock subject to each Additional Option shall be equal to $0.05 (subject to appropriate adjustment in the case of stock splits, reverse stock splits and the like, or changes to the Israeli Annual Option Award under the Company's Director Compensation Plan as amended from time to time). Each Additional Option will vest and become exercisable on each monthly anniversary date as to 1/12th the number of shares subject to the option over a period of twelve months from the date of grant such that each Additional Option will be fully vested and exercisable on the first anniversary of the date of grant, provided that Mr. Yablonka remains an employee of the Company on each such vesting date.

Tony Fiorino, Chief Executive Officer

On June 9, 2014, the Company appointed Tony Fiorino, M.D., Ph.D. as its Chief Executive Officer, effective June 9, 2014. On June 9, 2014, the Company and Dr. Fiorino entered into an employment agreement which sets forth the terms of Dr. Fiorino's employment (the Agreement). Pursuant to the Agreement, Dr. Fiorino will be paid an annual salary of $275,000, to be increased annually by no less than $7,500 per year. Dr. Fiorino will also receive other benefits that are generally made available to the Company's employees. Dr. Fiorino also was granted a stock option (the Fiorino Grant) on June 9, 2014 (the Grant Date) for the purchase of 5,700,000 shares of the Company's Common Stock (the Shares), which shall vest and become exercisable as to 25% of the Shares on the first anniversary of the Grant Date (the Initial Vesting Date) and the remainder of the Shares shall vest and become exercisable in equal monthly installments on each of the 36 monthly anniversaries following the Initial Vesting Date. The exercise price for the Fiorino Grant is $0.30 per share.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

We have not had any changes in or disagreements with accountants on accounting and financial disclosure during our two most recent fiscal years and the subsequent interim periods.

MANAGEMENT

Executive Officers and Directors

The following table lists our current executive officers and directors. Our executive officers are elected annually by our Board of Directors and serve at the discretion of the Board of Directors. Each current director is serving a term that will expire at our Company's next annual meeting. There are no family relationships among any of our directors or executive officers.

Name	Age	Position
Anthony Fiorino	46	Chief Executive Officer
Chaim Lebovits	43	President
Liat Sossover	46	Chief Financial Officer
Uri Yablonka	37	Chief Operating Officer and Director
Dr. Irit Arbel	54	Chairperson and Director
Mordechai Friedman	61	Director
Alon Pinkas	52	Director
Chen Schor	41	Director
Dr. Robert Shorr	60	Director
Malcolm Taub	68	Director

Dr. Tony Fiorino joined the Company on June 9, 2014 as Chief Executive Officer. Dr. Fiorino is an experienced biotechnology executive, entrepreneur and investor with expertise in clinical drug development, biotechnology finance and portfolio management. Dr. Fiorino joined BrainStorm from Greywall Asset Management, where he was a Managing Director and served as a biopharmaceuticals analyst from January 2013, when the fund launched, through May 2014. In March 2008, Dr. Fiorino founded a start-up biotechnology company, EnzymeRx, and served as President and Chief Executive Officer. At EnzymeRx, Dr. Fiorino successfully developed pegylated uricase through phase II studies and led its sale to 3SBio. After closing this transaction in November 2010, Dr. Fiorino served as a consultant to several biotechnology and pharmaceutical companies until joining Greywall. Before founding EnzymeRx, Dr. Fiorino was a biotechnology analyst and portfolio manager for healthcare hedge funds at Pequot Capital and Sands Point Partners and at Citigroup Asset Management, and a sell-side pharmaceuticals equity research analyst at JP Morgan. Dr. Fiorino received his MD and PhD from the Albert Einstein College of Medicine and a BS in Biology from the Massachusetts Institute of Technology, and trained in medicine and dermatology at the Hospital of the University of Pennsylvania.

Chaim Lebovits joined the Company in July 2007 as President. Mr. Lebovits controls ACC HOLDINGS INTERNATIONAL, and its subsidiaries ACC Resources, specializing in the mining, oil and energy industries, and ACC BioTech, which is focused on biotechnology. He has been at the forefront of mining and natural resource management in the African region for over a decade and has spent years leading the exploration and development of

resources in West Africa and Israel and served as a member of the board of directors of several companies in the industry. Mr. Lebovits has also held senior positions for the worldwide Chabad Lubavitch organization, the largest Jewish organization in the world today.

Liat Sossover joined the Company in June 2010 as our Chief Financial Officer. From 2001 until June 2010, Ms. Sossover served as the Vice President of Finance of ForeScout Technologies, an international high tech company in the network security solutions field. In such role, Ms. Sossover managed all financial and accounting aspects. Prior to that, Ms. Sossover served as VP of Finance and Secretary of Maximal Innovative Intelligence, a high tech company in the field of business intelligence solutions, which was acquired by Microsoft. She has held positions as Chief Financial Officer at Real Time Synthesized Entertainment Technology Ltd (RT-Set), currently known as Vizrt Ltd., a publicly traded company in Norway. Vizrt provides real-time 3D graphics and asset management tools for the broadcast industry. Ms. Sossover served as Financial Controller for BVR Systems (1998), Ltd., currently known as RVB Holdings Ltd., a company that is traded on Nasdaq, which develops, manufactures and markets simulation systems for military applications, which was later was acquired by Elbit Systems. Ms. Sossover holds an MBA from Edinburgh University, and a Bachelor's degree in Accounting & Economics from Ben Gurion University.

Uri Yablonka joined the Company on June 6, 2014 as Chief Operating Officer and as a member of the Board of Directors. Prior to joining the Company, Mr. Yablonka served since December 2010 as owner and General Manager of Uri Yablonka Ltd., a business consulting firm. He also served since January 2011 as Vice President, Business Development at ACC International Holdings Ltd. (Holdings). Holdings is also an affiliate of ACCBT Corp. Prior to serving with Holdings, Mr. Yablonka served as Senior Partner of PM-PR Media Consulting Ltd. From 2008 to January 2011, Mr. Yablonka was Senior Partner at PM-PR Media Consulting Ltd., where he led public relations and strategy consulting for a wide range of governmental and private organizations. From 2002 to 2008, he served as a correspondent at the Maariv Daily News Paper, including extensive service as a Diplomatic Correspondent. The Company believes that Mr. Yablonka's skills and experience provide the variety and depth of knowledge, judgment and vision necessary for the effective oversight of the Company. His experience in business consulting and development and media experience are expected to be valuable to the Company in its current stage of growth and beyond, and his governmental experience can provide valuable insight into issues faced by companies in regulated industries such as the Company. The Company believes that these skills and experiences qualify Mr. Yablonka to serve as a director of the Company.

Dr. Irit Arbel, one of BrainStorm's co-founders, joined the Company in May 2004 as a member of the Board of Directors and served as President of the Company for six months. Currently, Dr. Arbel is the Chairperson of the Board and the Chair of the Governance, Nominating and Compensation Committee (the GNC Committee). Dr. Arbel serves as Executive Vice President, Research and Development at Savicell Diagnostic Ltd. since July 2012. Savicell Diagnostic Ltd. is a biotechnology company and is a wholly-owned subsidiary of Online Disruptive Technologies, Inc. From 2009 through 2011, Dr. Arbel served as Chairperson of Real Aesthetics Ltd., a company specializing in cellulite ultrasound treatment, and BRH Medical, developer of medical devices for wound healing. She was also Director of M&A at RFB Investment House, a private investment firm focusing on early stage technology related companies. Previously, Dr. Arbel was President and Chief Executive Officer of Pluristem Life Systems, a biotechnology company, and prior to that, Israeli Sales Manager of Merck, Sharp & Dohme, a pharmaceutical company. Dr. Arbel earned her Post Doctorate degree in 1997 in Neurobiology, after performing research in the area of Multiple Sclerosis. Dr. Arbel also holds a Chemical Engineering degree from the Technion, Israel's Institute of Technology. We believe that Dr. Arbel possesses specific attributes that qualify her to serve on our Board of Directors including Dr. Arbel's extensive experience in the biotechnology field and significant leadership skills as a chief executive officer. Dr. Arbel previously served as our President, which service has given her a deep knowledge of the Company and its business and directly relevant management experience.

Mordechai Friedman joined the Company on April 4, 2011 as a member of the Board of Directors and as Chair of the Audit Committee of the Board. Mr. Friedman currently serves as Chairman of IPM Beer Tuvia Ltd. and Vice-Chairman of Triple-M Power Plants Ltd. From 2013 to 2014, Mr. Friedman served as Chief Executive Officer of Israel Financial Levers Ltd, an Israeli real estate company traded on Tel-Aviv Stock Exchange. From 2007 through 2010, Mr. Friedman served as the Chairman of the Board of The Israel Electric Corp., an electric utility company. From 2005 to 2007, Mr. Friedman served as Deputy Chairman of Brightman Almagor Zohar CPAs, the Israel Member Firm of Deloitte Touché Tohmatsu. Mr. Friedman has been a partner and director in several business ventures and companies in Israel and abroad in the transportation, consumer business, telecommunication and energy industries. Mr. Friedman currently serves as a director in the following public companies: (traded on Tel-Aviv Stock Exchange): (i) Elco Holdings Ltd. (Chairman of the Board); and (ii) Carmel Olefins Ltd. Mr. Friedman holds a B.A. in Economics and Accounting from Tel Aviv University. We believe that Mr. Friedman possesses specific attributes that qualify him to serve on our Board of Directors including Mr. Friedman's considerable experience in accounting

and valuable leadership skills as a chief executive officer.

Alon Pinkas joined the Company on December 13, 2010 as a member of the Board of Directors. Mr. Pinkas served as the Israeli Consul General to New York from 2000 to 2004 and is an internationally respected foreign affairs analyst. Mr. Pinkas currently serves as an Adviser at Tigris Financial Group, a financial services company, and the Rhodium Group, an advisory firm, and as a director for Ormat Industries Limited, B.G.I. Investments (1961) Ltd. and Agri-Invest Ltd. Mr. Pinkas has a B.S. in Political Science from The Hebrew University of Jerusalem and a Masters Degree in Politics from Georgetown University. We believe that Mr. Pinkas possesses specific attributes that qualify him to serve on our Board of Directors including Mr. Pinkas' considerable experience in foreign affairs. Mr. Pinkas also has substantial leadership and government experience from his service as the consul general of Israel to New York and as chief of staff to Ministers of Foreign Affairs of Israel.

Chen Schor joined the Company as a member of the Board of Directors on August 22, 2011. Mr. Schor is a global industry leader with vast experience in biotechnology, medical devices, business development and private equity. Mr. Schor led multiple licensing and M&A transactions valued at over $2 billion with companies such as GlaxoSmithKline, Amgen, Pfizer, Bayer, Merck-Serono and OncoGeneX Pharmaceuticals, and raised significant funds from reputable investors. Mr. Schor has a broad range of experience in multiple therapeutic areas including Neurology, Respiratory, Oncology, Auto-Immune, Genetic Diseases, and Women's Health. In addition to leading the global business development at Teva Pharmaceuticals, Mr. Schor played a key role in building early stage companies to regulatory approvals, IPOs and M&As. From March 2009 until September 2011, Mr. Schor served as Vice President of Business Development, global branded products at Teva Pharmaceuticals. Prior to joining Teva, Mr. Schor was Chief Business Officer at Epix Pharmaceuticals, Inc. (formerly known as Predix Pharmaceuticals, Inc.) from December 2003 until March 2009, leading the formation of more than $1.5 billion collaborations with GlaxoSmithKline, Amgen and additional pharmaceutical companies. Prior to joining Epix, Mr. Schor was a Partner at Yozma Venture Capital from September 1998 until December 2003, managing the fund's investments in biotechnology and medical device companies. Mr. Schor previously held positions at Arthur Anderson and BDO Consulting, an advisory firm. Mr. Schor holds an M.B.A., a B.A. in Biology, a B.A. in Economics and is a Certified Public Accountant. We believe that Mr. Schor possesses specific attributes that qualify him to serve on our Board of Directors including Mr. Schor's extensive experience in biotechnology and significant leadership skills from his service as a partner of a venture capital firm.

Dr. Robert Shorr joined the Company in March 2005 as a member of the Board of Directors. Since 1999, Dr. Shorr has served as Chief Executive Officer and Chief Science Officer of Cornerstone Pharmaceuticals, a biotechnology company. He has also been a member of the Department of Biomedical Engineering at SUNY Stony Brook, where he also serves as Director of Business Development for the university's Center for Advanced Technology. He has served as trustee at the Tissue Engineering Charities, Imperial College, London. From 1999 until 2005, Dr. Shorr was Vice-President of Science and Technology (CSO) of United Therapeutics, a NASDAQ listed biotechnology company. Prior to 1998, he was Vice President, Research and Development at Enzon, Inc., a NASDAQ listed pharmaceuticals company, and AT Biochem, a pharmaceuticals company, of which he was also founder. Dr. Shorr also served on the Board of Directors of Biological Delivery Systems Inc., a NASDAQ listed company. Dr. Shorr holds both a Ph.D. and a D.I.C. from the University of London, Imperial College of Science and Technology as well as a B.Sc. from SUNY Buffalo. We believe that Dr. Shorr possesses specific attributes that qualify him to serve on our Board of Directors including Dr. Shorr's extensive experience in biotechnology and valuable leadership skills as a chief executive officer.

Malcolm Taub joined the Company in March 2009 as a member of the Board of Directors. He is a member of the GNC Committee of the Board of Directors. He has recently served as a member of the Company's Deal Committee. Since October 2010, Mr. Taub has been a Partner at Davidoff Hutcher & Citron LLP, a full service law and government relations firm. He serves on the management committee of that firm. From 2001 to September 30, 2010, Mr. Taub was the Managing Member of Malcolm S. Taub LLP, a law firm which practiced in the areas of commercial litigation, among other practice areas. Mr. Taub also works on art transactions, in the capacity as an attorney and a consultant. Mr. Taub has acted as a consultant to the New York Stock Exchange in its Market Surveillance Department. Mr. Taub acts as a Trustee of The Gateway Schools of New York. Mr. Taub has served as an adjunct professor at Long Island University, Manhattan Marymount College and New York University Real Estate Institute. Mr. Taub holds a B.A. from Brooklyn College and a J.D. from Brooklyn Law School. Mr. Taub formerly served on the Board of Directors of Safer Shot, Inc. (formerly known as Monumental Marketing Inc.). We believe that Mr. Taub possesses specific attributes that qualify him to serve on our Board of Directors including Mr. Taub's vast law experience and his demonstrated leadership skills as a managing member of a law firm, as well as his service on the Boards of not-for-profit corporations.

Independence of the Board of Directors

The Board of Directors has determined that each of Dr. Arbel, Mr. Friedman, Mr. Pinkas, Dr. Shorr and Mr. Taub satisfies the criteria for being an “independent director” under the standards of the Nasdaq Stock Market, Inc. (NASDAQ) and has no material relationship with the Company other than by virtue of service on the Board of Directors. Mr. Schor and Mr. Yablonka are not considered “independent directors.”

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

Consulting Agreement with Mr. Schor

On August 22, 2011, we entered into an agreement with Chen Schor, which was amended and restated on November 11, 2011 to clarify vesting terms (as amended and restated, the Executive Director Agreement) pursuant to which we pay $15,000 per quarter to Mr. Schor for his services as an Executive Board Member. In accordance with the terms of the Executive Director Agree