

BRAINSTORM CELL THERAPEUTICS INC.  
Form S-1/A  
August 06, 2013

**Registration No. 333-186516**

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**Amendment No. 5**

**to**

**FORM S-1**

**REGISTRATION STATEMENT**

**UNDER**

**THE SECURITIES ACT OF 1933**

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**BRAINSTORM CELL THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

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

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**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)

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**Approximate date of commencement of proposed sale to the public:** promptly 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:

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   
(Do not check if a smaller reporting company)

#### **CALCULATION OF REGISTRATION FEE**

<b>Title of Each Class of Securities to be Registered</b>	<b>Proposed Maximum Aggregate Offering Price (1)</b>	<b>Amount of Registration Fee (2)</b>
Common stock, \$0.00005 par value		
Warrants to purchase shares of common stock (1)		

Common stock issuable upon exercise of the warrants

Total	\$ 4,000,000.00	\$ 545.60	*
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Pursuant to Rule 416 under the Securities Act, this Registration Statement shall also cover any additional shares of (1) common stock which become issuable by reason of any change in the amount of securities being offered or issued to prevent dilution resulting from stock splits, stock dividends, or similar transactions.

- (2) Calculated pursuant to Rule 457(o) of the rules and regulations under the Securities Act of 1933.

\*Previously paid.

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**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.**

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**Subject to Completion, Dated August 6, 2013**

*The information in this prospectus is not complete and may be changed. We may not sell these securities 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.**

**16,000,000 Units**

**Each Unit Consisting of One Share of Common Stock**

**and**

**0.75 of a Warrant to Purchase One Share of Common Stock**

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We are offering 16,000,000 units, each of which consists of one share of our common stock, par value \$0.00005 per share, and 0.75 of a warrant to purchase one share of our common stock at an exercise price of \$[\*] per share. The warrants will be immediately exercisable and will expire 30 months after the issuance date. No units will be issued, however, and purchasers will receive only shares of common stock and warrants. The common stock and the warrants may be transferred separately immediately upon issuances.

Our common stock is traded on the OTCQB Marketplace, operated by OTC Markets Group, under the symbol "BCLI". On August 2, 2013, the last reported sales price for our common stock was \$0.25 per share. 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.

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*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 5 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.*

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	Per Unit	Total
Public offering price	\$	\$
Underwriting discounts and commissions (1)	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) We estimate the total expenses of this offering will be approximately \$220,000. We have also agreed to reimburse the underwriters for certain expenses. See “Underwriting” on page 22 of this prospectus for a description of these arrangements.

**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 underwriters expect to deliver the units against payment on or about 2013.

Roth Capital Partners Maxim Group LLC

The date of this prospectus is \_\_\_\_\_, 2013.

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## ABOUT THIS PROSPECTUS

**You should rely only on the information contained in this prospectus and any related free writing prospectus that we may provide to you in connection with this offering. We have not, and the underwriters have not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.**



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 5 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 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.

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), 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. This memorandum of understanding expired on July 7, 2012. Pending submission of an Investigational New Drug (IND) application to the FDA and subsequent approval, we are planning to enter into an agreement with these institutions in order to launch a Phase II clinical trial in late 2013, which we expect to complete during the first half of 2015.

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 acceleration to a Phase IIa combined treatment, dose-escalating trial, which we are currently conducting at HUMC. In this safety and preliminary efficacy trial, 12 early-stage ALS patients will receive both intramuscular and intrathecal injections of NurOwn cells in three cohorts with increasing doses. The patients will be followed for six months after transplantation.

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 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 of the FDA. The study protocol was approved by Israel's National Council for Animal Experimentation.

On February 21, 2013, Brainstorm Cell Therapeutics UK Ltd., a wholly-owned U.K. subsidiary of the Israeli Subsidiary (the UK Subsidiary), filed a request for Orphan Medicinal Product Designation by the European Medicine Agency (EMA) for our autologous bone marrow-derived mesenchymal stem cells secreting neurotropic factors.

In March 2013, principal investigator Professor Dimitrios Karussis of Hadassah presented some of the final 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 in Rochester, Minnesota, to participate as an additional clinical site in the Phase II ALS clinical trial planned for later this year. The team there will be led by Professor Anthony J. Windebank, Head of the Regenerative Neurobiology Laboratory in the Department of Neurology. This Memorandum of Understanding is due to expire on March 14, 2014.

On April 3, 2013, we 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.

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 our 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 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. We plan to release the preliminary efficacy data at the conclusion of the trial.

## **Our Proprietary Technology**

Our NurOwn technology is based on a novel differentiation protocol that differentiates 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), both of which are critical for the growth, survival, and differentiation of developing neurons.

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, optimized processes for induction of differentiation of human bone marrow derived mesenchymal stem cells into differentiated cells that produce NTF (MSC-NTF) are conducted in full compliance with current Good Manufacturing Practices (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, it 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. Pending submission of an IND application to the FDA and subsequent approval, we are planning to launch a Phase II clinical trial in the USA in late-2013, which we expect to complete during the first half of 2015. If this trial is successful, we intend to conduct further Phase II and Phase III clinical trials of NurOwn.

**Clinical Indication II: MS (future)** – Based on positive proof-of-concept results obtained at Tel Aviv University with MSC-NTF cells for MS, we are currently conducting pre-clinical studies for this disease.

**Proposed Reverse Stock Split**

On February 28, 2013, our Board of Directors approved, subject to stockholder approval, a resolution authorizing our Board of Directors to effect a reverse stock split of our common stock by a ratio of between 1-for-10 and 1-for-20, inclusive, with our Board of Directors retaining the discretion as to whether to implement the reverse stock split and which exchange ratio to implement. On April 18, 2013, our stockholders approved this resolution. In connection with this offering, we have agreed that for a period of 90 days from the date hereof, we will not effect or make any public announcement that it intends to effect any reverse split, combination or other recapitalization of our Common Stock which would reduce the outstanding shares of Common Stock without the prior written consent of the Underwriters.

**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 Offering

**Securities we are offering:** 16,000,000 units, each 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 \$[ \* ] per share. The warrants will be immediately exercisable and will expire 30 months after the issuance date.

**Public offering price:** \$[ \* ] per unit.

**Common stock outstanding before this offering:** 152,714,176 shares.

**Common stock included in the units:** 16,000,000 shares.

**Common stock to be outstanding after this offering:** 168,714,176 shares.

**Use of proceeds:** We estimate that the net proceeds to us from the sale of the units offered by this prospectus will be approximately \$3,521,000, assuming the sale by us of 16,000,000 units at an assumed public offering price of \$0.25 per unit (the closing sale price of our common stock on August 2, 2013) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this offering for the clinical development of NurOwn treatment, including the completion of our Phase II clinical trial, and for working capital and other general corporate purposes. For a more complete description of our intended use of proceeds from this offering, see "Use of Proceeds."

**Market Symbol and Listing:** Our common stock is quoted on the OTCQB Marketplace under the symbol "BCLI". There is no established trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other trading market.

**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 5 for a discussion of factors to consider before deciding to invest in our securities.

The number of shares of our common stock outstanding after this offering is based on 152,714,176 shares outstanding as of July 30, 2013 and excludes as of that date:



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9,378,331 shares of common stock issuable upon exercise of outstanding stock options, at a weighted average exercise price of \$0.23 per share, under our equity incentive plans;

- 5,138,437 additional shares of common stock reserved for future issuance under our equity incentive plans; and

51,224,785 shares of common stock issuable upon exercise of outstanding warrants with exercise prices ranging from \$0.00005 per share to \$1.00 per share.

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

## **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 this offering will be insufficient to meet our obligations in the upcoming 12 months, as we commence and pursue clinical trials in the United States, and that additional capital will be required in order to finance the Company's planned operations or the Company will reduce its costs, including curtailing its current plan to accelerate pursuit of U.S. clinical trials, in order to continue operating for the next 12 months.

Assuming 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 have issued a going concern opinion on our financial statements, expressing substantial doubt that we can continue to operate as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

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

The therapeutic treatment development and regulatory approval process is expensive, uncertain and time-consuming. The timing of any future regulatory approval, if any, for our NurOwn treatment candidate cannot be accurately predicted. We do not expect to receive regulatory approval for any of our product candidates until at least 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.

***We are currently searching for a new Chief Executive Officer. If we were to be unable to hire and retain an experienced and qualified CEO, we may experience difficulty executing our business strategy.***

Our future success depends in a large part upon the continued service of key members of our senior management team. Alon Natanson, our Chief Executive Officer, has announced his resignation from the Company effective October 26, 2013. Chaim Lebovits, our President, has assumed the duties and responsibilities of the Chief Executive Officer on an interim basis while we search for a new Chief Executive Officer. Identifying and hiring an experienced and qualified Chief Executive Officer may be difficult for a small, development stage, biotech company such as ours. In particular, we expect that the CEO we hire will be critical to the overall management of the Company as well as the development of our technology, our culture and our strategic direction. If we are unable to hire and retain an experienced CEO or if we lose any other key members of our management or personnel we may not be able to execute our business strategy.

***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 has 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.

***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, 2012 or December 31, 2011 nor through March 31, 2013. Our ability to operate successfully is materially uncertain and our operations are subject to significant risks inherent in a developing business enterprise. We are currently in the process of introducing the Company to strategic partners. In the upcoming three years, the Company will focus on clinical trials. We are unable at this time to foresee when we will generate revenues from strategic partnerships or otherwise. Furthermore, we expect to incur substantial and increasing operating losses for the next several years as we increase our spending to execute our development programs. These losses are expected to have an adverse impact on our working capital, total assets and stockholders' equity, and we may never achieve profitability.

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

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our stem cell therapy creates significant challenges with regard to product development and optimization, manufacturing, government regulations, and market acceptance. For example, the FDA has relatively limited experience with stem cell therapies. None have been approved by them for commercial sale, and the pathway to

regulatory approval for our cell therapy product candidates may accordingly be more complex and lengthy. As a result, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

***We are faced with uncertainties related to our research.***

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

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

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

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

Our intended cell therapeutic treatment methods for ALS involve a new approach that has not yet been proven to work in humans. We are currently conducting 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. 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 and institutions 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, or 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 viable indication or profitable market opportunities.

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

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

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

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

We rely upon the patent applications filed by Ramot, the technology licensing company of Tel Aviv University, and the license granted to us by Ramot, all in accordance with the Second Ramot Agreement dated as of July 26, 2007. We further agreed under the Second Ramot Agreement that Ramot, in consultation with us, is responsible for obtaining patent protection for technology owned by Ramot and licensed to us. No assurance can be given that any of our pending or future patent applications will be approved, that the scope of any patent protection granted will exclude competitors or provide us with competitive advantages, that any of the patents that may be issued to us will be held valid if subsequently challenged, or that other parties will not claim rights to or ownership of our patents or other proprietary rights that we hold license to. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or products or design around any patents that have been or may be issued to us or any future licensors. Since patent applications in the United States and in Europe are not disclosed until applications are published, there can be no assurance that others did not first file applications for products covered by our pending patent applications, nor can we be certain that we will not infringe any patents that

may be issued to others. Also, we have abandoned our rights to certain patents of Ramot in certain countries in connection with the Letter Agreement by and between us and Ramot dated December 24, 2009, which may limit our ability to fully market our proposed products.

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

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

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

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

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

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

We currently have relationships with 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 investing in our securities**

#### *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 full-ratchet anti-dilution provisions and 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 and with regard to this offering.

***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 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 small 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.

## **Risks related to this offering**

***U.S. holders of warrants may not be able to exercise their warrants without compliance with applicable state securities laws and the value of your warrants may be significantly reduced.***

Because our common stock is not listed on a national securities exchange, the exercise of the warrants by U.S. holders may not be exempt from state securities laws. As a result, depending on the state of residence of a holder of the warrants, a U.S. holder may not be able to exercise its warrants unless we comply with any state securities law requirements necessary to permit such exercise or an exemption applies. Although we plan to use our reasonable efforts to assure that U.S. holders will be able to exercise their warrants under applicable state securities laws if no exemption exists, there is no assurance that we will be able to do so. As a result, your ability to exercise your warrants may be limited. The value of the warrants may be significantly reduced if U.S. holders are not able to exercise their warrants under applicable state securities laws.

***A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock.***

A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. If there are more shares of common stock offered for sale than buyers are willing to purchase, then the market price of our common stock may decline to a market price at which buyers are willing to purchase the offered shares of common stock and sellers remain willing to sell the shares. All of the securities issued in the offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended (the Securities Act).

***The Company has a right to effect a Reverse Stock Split.***

On April 18, 2013, our stockholders approved a proposal which authorizes our Board of Directors, in its discretion, to effect a reverse stock split of our common stock by a ratio of between 1-for-10 and 1-for-20, inclusive. The proposed reverse stock split is intended to allow us to meet the minimum share price requirement of The NASDAQ Capital Market's initial listing requirements. We have applied to list our common stock on The NASDAQ Capital Market; however, if we effect a reverse split it could potentially negatively impact the price per share of our Common Stock.

In connection with this offering, we have agreed that for a period of 90 days from the date of the Underwriting Agreement, the Company will not effect or make any public announcement that it intends to effect any reverse split,



combination or other recapitalization of its Common Stock which would reduce the outstanding shares of Common Stock without the prior written consent of the Underwriters.

***We may use these proceeds in ways with which you may not agree.***

We have considerable discretion in the application of the proceeds of this offering. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used in a manner agreeable to you. You must rely on our judgment regarding the application of the net proceeds of this offering. The net proceeds may be used for corporate purposes that do not improve our profitability or increase the price of our shares. The net proceeds may also be placed in investments that do not produce income or that lose value.

***You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.***

Since the public offering price per unit is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on a public offering price of \$0.25 per unit (the closing sale price of our common stock on August 2, 2013) and attributing no value to the warrants, if you purchase units in this offering, you will suffer immediate and substantial dilution of approximately \$0.208 per share in the net tangible book value of the shares of common stock included in the units. See the section entitled "Dilution" in this prospectus for a more detailed discussion of the dilution you will incur if you purchase units in this offering.

***The warrants may not have any value.***

The warrants have an exercise price of \$[\*] per share and expire 30 months after the date of issuance. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

***There is no public market for the warrants being sold in this offering.***

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. We do not intend to apply for listing of any such warrants on any securities exchange or other trading market. Without an active market, the liquidity of the warrants will be limited.

***Holders of our warrants will have no rights as common stockholders until they acquire our common stock.***

Until you acquire shares of our common stock upon exercise of your warrants, you will have no rights with respect to our common stock. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

## 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.

**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, 2013	Quarter Ended June 30, 2013
	2009	2010	2011	2012	2013	2013
Low	3.690	3.549	3.363	3.700	3.637	3.556
High	4.256	3.894	3.821	4.084	3.791	3.707
Period End	3.775	3.549	3.821	3.733	3.648	3.618
Average	3.933	3.733	3.578	3.858	3.709	3.626

As of July 30, 2013, the daily representative rate of exchange between the NIS and the U.S. dollar as published by the Bank of Israel was NIS 3.569 to \$1.00.

**USE OF PROCEEDS**

We estimate that the net proceeds to us from the sale of the units offered by this prospectus will be approximately \$3,521,000, assuming the sale by us of 16,000,000 units at an assumed public offering price of \$0.25 per unit (the closing sale price of our common stock on August 2, 2013) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. This amount does not include the proceeds which we may receive in connection with the exercise of the warrants. We intend to use the net proceeds of this offering for the clinical development of NurOwn treatment, including the completion of our Phase II clinical trial, and for working capital and other general corporate purposes.

A \$0.05 increase (decrease) in the assumed public offering price of \$0.25 per unit would increase (decrease) the net proceeds from this offering by approximately \$748,000, assuming that the number of units we are offering, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of units we are offering. Each increase (decrease) of 3,200,000 units in the number of units we are offering would increase (decrease) the net proceeds to us from this offering by approximately \$748,000, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The net proceeds from this offering will not be sufficient to complete clinical trials and other studies required for the approval of our NurOwn treatment for any indication by the FDA, and we will need significant additional funds in the future. See the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operation.”

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Accordingly, we will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the proceeds of this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

## **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