BRAINSTORM CELL THERAPEUTICS INC.
Form 424B1
August 13, 2013

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Registration No. 333-186516

PROSPECTUS

BRAINSTORM CELL THERAPEUTICS INC.

23,529,411 Units

Each Unit Consisting of One Share of Common Stock

and

0.75 of a Warrant to Purchase One Share of Common Stock

We are offering 23,529,411 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 $0.25 per share. The warrants will be immediately exercisable and will expire on the third anniversary of 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 12, 2013, the last reported sales price for our common stock was $0.21 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.

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.

	Per Unit	Total

Public offering price	$0.17	$4,000,000
Underwriting discounts and commissions (1)	$0.01105	$260,000
Proceeds, before expenses, to us	$0.15895	$3,740,000

(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 August 16, 2013.

Roth Capital Partners Maxim Group LLC

The date of this prospectus is August 13, 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:	23,529,411 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 $0.25 per share. The warrants will be immediately exercisable and will expire on the third anniversary of the issuance date.
Public offering price:	$0.17 per unit.
Common stock outstanding before this offering:	152,714,176 shares.
Common stock included in the units:	23,529,411 shares.
Common stock to be outstanding after this offering:	176,243,587 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 $3.5 million after deducting the 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:

- 9,371,664 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 excercise 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 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.

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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

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- 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.