BRAINSTORM CELL THERAPEUTICS INC.
Form 424B3
August 16, 2013

Filed Pursuant to Rule 424(b)(3)

Registration Statement No. 333-179331

Prospectus Supplement No. 3

(to Prospectus dated July 19, 2012, as supplemented by Prospectus Supplement No. 1 dated August 16, 2013 and Prospectus Supplement No. 2 dated August 16, 2013)

BRAINSTORM CELL THERAPEUTICS INC.

19,818,972 Shares of Common Stock

Warrants to Purchase 14,864,229 Shares of Common Stock

and

14,864,229 Shares of Common Stock Underlying Warrants

This prospectus supplement, together with the prospectus listed above, is to be used by certain holders of the above-referenced securities or by their pledgees, donees, transferees or other successors-in-interest in connection with the offer and sale of such securities.

This prospectus supplement updates and should be read in conjunction with the prospectus dated July 19, 2012 (as supplemented to date), which is to be delivered with this prospectus supplement. Such documents contain information that should be considered when making your investment decision. To the extent there is a discrepancy between the information contained herein and the information in the prospectus, the information contained herein supersedes and replaces such conflicting information.

This prospectus supplement consists of Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “Commission”) on March 14, 2013 (the “Form 10-K”).

Our common stock is traded on the OTCQB Marketplace, operated by OTC Markets Group, under the symbol "BCLI". On August 14, 2013, the last reported sales price for our common stock was $0.20 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 the Company's securities involves risks. See "Risk Factors" beginning on page 4 of the Prospectus, as supplemented or amended by the prospectus supplements filed to date, to read about factors you should consider.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus Supplement No. 3 is August 16, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

x ANNUAL REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012

¨ TRANSITION REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 000-54365

BRAINSTORM CELL THERAPEUTICS INC.

(Exact Name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	20-8133057 (I.R.S. Employer Identification No.)
605 Third Avenue, 34th Floor New York NY	10158

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (646) 666-3188

Securities registered under Section 12(b) of the Act: None

Securities registered under Section 12(g) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.00005 par value	**OTC Markets Group**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.¨

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. (Check one):

Large accelerated filer ¨	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes¨ No x

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the issuer as of June 30, 2012 (the last business day of the registrant’s most recently completed second fiscal quarter), was $26,708,644.

As of March 8, 2013, the number of shares outstanding of the registrant's common stock, $0.00005 par value per share, was 151,260,480.

DOCUMENTS INCORPORATED BY REFERENCE

None.

BRAINSTORM CELL THERAPEUTICS, INC.

ANNUAL REPORT ON FORM 10-K

YEAR ENDED DECEMBER 31, 2012

TABLE OF CONTENTS

ITEM		**Page**
	PART I	
1.	Business	3
1A.	Risk Factors	16
1B.	Unresolved Staff Comments	28
2.	Properties	28
3.	Legal Proceedings	29
4.	Mine Safety Disclosures	29
	PART II	
5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	29
6.	Selected Financial Data	31
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	31
7A.	Quantitative and Qualitative Disclosures About Market Risk	34
8.	Financial Statements and Supplementary Data	35
9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	78
9A.	Controls and Procedures	78
9B.	Other Information	79
	PART III	
10.	Directors, Executive Officers and Corporate Governance	80

11.	Executive Compensation	85
12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	90
13.	Certain Relationships and Related Transactions, and Director Independence	92
14.	Principal Accounting Fees and Services	96
	PART IV	
15.	Exhibits, Financial Statement Schedules	97

PART I

SPECIAL NOTE

Unless otherwise specified in this annual report on Form 10-K, all references to currency, monetary values and dollars set forth herein shall mean United States (U.S.) dollars.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains numerous statements, descriptions, forecasts and projections, regarding Brainstorm Cell Therapeutics Inc. and its potential future business operations and performance. These statements, descriptions, forecasts and projections constitute "forward-looking statements," and as such involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance and achievements to be materially different from any results, levels of activity, performance and achievements expressed or implied by any such "forward-looking statements." Some of these are described under "Risk Factors" in this annual report. In some cases you can identify such "forward-looking statements" by the use of words like "may," "will," "should," "could," "expects," "hopes," "anticipates," "believes," "intends," "plans," "estimates," "predicts," "likely," "potential," or "continue" or the negative of any of these terms or similar words. These "forward-looking statements" are based on certain assumptions that we have made as of the date hereof. To the extent these assumptions are not valid, the associated "forward-looking statements" and projections will not be correct. Although we believe that the expectations reflected in these "forward-looking statements" are reasonable, we cannot guarantee any future results, levels of activity, performance or achievements. It is routine for our internal projections and expectations to change as the year or each quarter in the year progresses, and therefore it should be clearly understood that the internal projections and beliefs upon which we base our expectations may change prior to the end of each quarter or the year. Although these expectations may change, we may not inform you if they do and we undertake no obligation to do so. We caution investors that our business and financial performance are subject to substantial risks and uncertainties. In evaluating our business, prospective investors should carefully consider the information set forth under the caption "Risk Factors" in addition to the other information set forth herein and elsewhere in our other public filings with the Securities and Exchange Commission ("SEC").

Item 1. BUSINESS.

Company Overview

Brainstorm Cell Therapeutics Inc. ("we," "us," "our" or the "Company") is a biotechnology company developing innovative adult stem cell therapies for highly 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 devastating diseases have limited treatment options and as such represent highly unmet medical needs.

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 overcoming 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 transfer company of Tel Aviv University, Israel.

On February 17, 2010, our Israeli Subsidiary entered into a series of agreements with Hadasit Medical Research Services and Development Ltd., a subsidiary of the Hadassah Medical Organization ("Hadassah") and Professor Dimitrios Karousis (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 Hadassah.

In February 2011, the U.S. Food and Drug Administration ("FDA") granted Orphan Drug designation to NurOwn, our autologous adult stem cell product candidate 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 and the University of Massachusetts Medical School in anticipation of applying for FDA approval to begin ALS human clinical trials in the United States. Pending submission of an Investigational New Drug ("IND") application to the FDA and subsequent approval, we are planning to launch a Phase II clinical trial at these institutions in mid-2013.

In July 2012, we submitted an interim safety report to the 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 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 three to 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 recently developed by the Company. 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 the Israeli MoH.

On February 21, 2013, our wholly-owned U.K. subsidiary, Brainstorm Cell Therapeutics UK Ltd. (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.

Our Approach

Our NurOwn technology is based on a novel differentiation protocol which 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").

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.

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 current Good Manufacturing Practice ("cGMP") compliance.

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.

This approach is based on pre-clinical data documented by our research team, led by Prof. Melamed and Prof. Offen.

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. It is considered safe, with 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

Intrathecal 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 transplantation is performed via a standard injection procedure as well.

Clinical Indication I: ALS (current) – Based on the fast-track 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 mid-2013. Following the successful completion of these, we hope to progress to repeat dosing and Phase III trials.

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.

History

The Company was incorporated under the laws of the State of Washington on September 22, 2000, under the name Wizbang Technologies, Inc. and acquired the right to market and sell a digital data recorder product line in certain states in the U.S. Subsequently, the Company changed its name to Golden Hand Resources Inc. On July 8, 2004, the Company entered into the licensing agreement with Ramot to acquire certain stem cell technology and decided to discontinue all activities related to the sales of the digital data recorder product. In November 2004, the Company changed its name from Golden Hand Resources Inc. to Brainstorm Cell Therapeutics Inc. to better reflect its new line of business in development of novel cell therapies for neurodegenerative diseases. On October 25, 2004, the Company formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics Ltd. in Israel. On December 18, 2006, the stockholders of the Company approved a proposal to change the state of incorporation of the Company from the State of Washington to the State of Delaware. The reincorporation was completed on December 21, 2006 through the merger of the Company into a newly formed, wholly-owned Delaware subsidiary of Brainstorm, also named Brainstorm Cell Therapeutics Inc. On February 19, 2013, the Israeli Subsidiary formed its wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd. in the United Kingdom.

Other Recent Developments

Public Offering

On July 17, 2012, we raised approximately $5.7 million through a public offering (“Public Offering”) of our common stock. We issued a total of 19,818,968 shares of our common stock at $0.29 per share and 14,864,228 warrants to purchase 0.75 shares of common stock for every share purchased in the Public Offering, at an exercise price of $0.29 per share. The warrants are exercisable until the 30 month anniversary of the date of issuance. After deducting closing costs and fees, we received net proceeds of approximately $5 million.

MS Pre-Clinical Trials

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.

Governmental Grants

In September 2011, we received notice from the Israeli Office of the Chief Scientist ("OCS") of its commitment to grant the Company approximately $1.1 million in accordance with OCS guidelines. As of February 5, 2013, approximately $450,000 has been received. We are obligated to pay royalties to the OCS, amounting to 3% to 3.5% of revenues derived from sales of the products funded with the OCS grant, up to an amount equal to 100% of the grant received.

In December 2012, the OCS awarded us a 3 million NIS (approximately U.S. $786,000) grant for the fiscal year ending December 31, 2013.

Collaboration with Octane Biotech

In December 2012, we signed an agreement with Octane Biotech of Kingston, Ontario, to jointly develop a proprietary bioreactor for production of its NurOwn cell therapy candidate. The customized bioreactor will enable us to optimize our NurOwn production process, significantly increasing our production capabilities by using a single clean room for multiple patients, reducing costs and time. The 3-year collaborative project with a total budget of 1,365,000 Canadian dollars, is being supported by the Canada Israel Industrial Research and Development Foundation. The Israeli OCS has confirmed its participation of 530,000 NIS (approximately U.S. $141,000) for the first year, which comprises 50% of the Company's budget of 1,060,000 NIS (approximately U.S. $282,000) for that period. The collaborative project is currently underway.

Development of Cryopreservation Method

In our fourth quarter of 2012, we announced the development of a proprietary method for cryopreservation, or freezing, of cells, which will enable long-term storage, and production of repeat patient doses of NurOwn without the need for additional bone marrow aspirations. We believe that cryopreservation will enable us to create a personalized NurOwn stem cell bank for each patient, for ongoing, repeat treatments.

Our efforts are currently directed at:

- Conducting a Phase IIa dose-escalating clinical trial with 12 ALS patients in Israel;
- Submitting an IND to the FDA;
- Initiating a Phase II ALS clinical trial in the United States;
- Collaborating with Octane Biotech on development of a customized NurOwn bioreactor; and
- Completing pre-clinical studies on MS.

Stem Cell Therapy

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

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

Cell therapy using adult stem cells does not suffer from the same concerns. Bone marrow is the tissue where differentiation of stem cells into blood cells (haematopoiesis) occurs. In addition, it harbors stem cells capable of differentiation into mesenchymal (muscle, bone, fat and other) tissues. Such mesenchymal stem cells have also been shown capable of differentiating into nerve, skin and other cells. In fact, bone marrow transplants have been safely and successfully performed for many years, primarily for treating leukemia, immune deficiency diseases, severe blood cell diseases, lymphoma and multiple myeloma.

Moreover, bone marrow may be obtained through a simple procedure of aspiration, from the patient himself, enabling autologous cell therapy, thus obviating the need for donor matching, circumventing immune rejection and other immunological mismatch risks, as well as avoiding the need for immunosuppressive therapy. We believe bone marrow, in particular autologous bone marrow, capable of *in-vitro* growth and multipotential differentiation, presents a preferable source of therapeutic stem cells.

Neurodegenerative Diseases

Studies of neurodegenerative diseases suggest that symptoms that arise in afflicted individuals are secondary to defects in neuron cell function and neural circuitry and, to date, cannot be treated effectively with systemic drug delivery. Consequently, alternative approaches for treating neurodegenerative diseases have been attempted, such as transplantation of cells capable of replacing or supplementing the function of damaged neurons. For such cell replacement therapy to work, implanted cells must survive and integrate, both functionally and structurally, within the damaged tissue.

Amyotrophic Lateral Sclerosis (ALS)

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

Approximately 5,600 people in the U.S. are diagnosed with ALS each year. It is estimated that as many as 30,000 Americans and 100,000 people across the western world may have the disease at any given time. Estimated annual treatment costs for advanced stage patients can be as high as $200,000, representing an aggregate direct cost to the healthcare system of more than $6 billion per year (Source: Alliance for Regenerative Medicine).

Description

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

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

Current Treatments

The physician bases medication decisions on the patient's symptoms and the stage of the disease. Some medications used for ALS patients include:

- Riluzole - the only medication approved by the FDA to slow the progress of ALS. While it does not reverse ALS, Riluzole has been shown to reduce nerve damage. Riluzole may extend the time before a patient needs a ventilator (a machine to assist breathing) and may prolong the patient's life by several months;

- Baclofen or Diazepam - these medications may be used to control muscle spasms, stiffness or tightening (spasticity) that interfere with daily activities; and

- Trihexyphenidyl or Amitriptyline - these medications may help patients who have excess saliva or secretions, and emotional changes.

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

Multiple Sclerosis (MS)

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

There are currently over 2.5 million people with MS worldwide, with roughly 800,000 of these in the U.S. and Europe. 10,000 new cases are diagnosed annually in the U.S., with the majority of these in women between the ages of 20 and 50. Annual treatment costs for MS can be as much as $30,000 a year per patient.

Description

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

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

Current Treatments

Treatment of MS generally falls into two categories: those that address symptom management, and those that change the course of the disease by modifying the number and severity of attacks and the progression of disability. Of the six FDA-approved, disease modifying treatments introduced since 1993, three are interferon-beta based, two are immunomodulators, and one is an immunosuppressant.

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

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

Parkinson’s Disease (PD)

Background

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

Over 6.3 million people worldwide suffer from PD, of whom about one million are in the United States. In over 85% of cases, PD occurs in people over the age of 65. Prevalence of PD is increasing in line with the general aging of the population. We believe the markets for pharmaceutical treatments for PD have a combined value of approximately $3.754 billion per year. However, these costs are dwarfed when compared to the total economic burden of the disease, which has been estimated by the National Institute of Neurological Disease to exceed $6 billion annually in the U.S. alone, including costs of medical treatment, caring, facilities and other services, as well as loss of productivity of both patients and caregivers.

Description

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

Current Treatments

Current drug therapy for PD primarily comprises dopamine replacement, either directly (levodopa), with dopamine mimetics or by inhibition of its breakdown. Thus, the current drugs focus on treating the symptoms of the disease and do not presume to provide a cure.

Levodopa, which remains the standard and most potent PD medication available, has a propensity to cause serious motor response complications with long-term use. Moreover, effective drug dosage often requires gradual increase, leading to more adverse side effects and eventual resistance to their therapeutic action. This greatly limits patient benefit. Therefore, physicians and researchers are continuously seeking levodopa-sparing strategies in patients with early-stage disease to delay the need for levodopa, as well as in patients with late stage disease who no longer respond to therapy.

Prescription drugs to treat PD currently generate sales of over $3.351 billion worldwide and the market is expected to grow to approximately $3.754 billion by 2015, driven by the increase in size of the elderly population and the introduction of new PD therapies that carry a higher price tag than the generic levodopa.

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

There is a greatly unsatisfied need for novel approaches towards management of PD. These include development of neurotrophic agents for neuroprotection and/or neurorestoration, controlling levodopa-induced adverse side effects, developing compounds targeting nondopaminergic systems (e.g., glutamate antagonists) controlling the motor dysfunction such as gait, freezing, and postural imbalance, treating and delaying the onset of disease-related dementia and providing simplified dosing regimens.

In addition to the symptomatic drug development approaches, there is an intense effort to develop cell and gene therapeutic “curative” approaches to restore the neural function in patients with PD, by (i) replacing the dysfunctional cells with dopamine producing cell transplant, or by (ii) providing growth factors and proteins, such as GDNF, that can maintain or preserve the patient’s remaining dopaminergic cells, protecting them from further degeneration. Preclinical evaluation of cell therapeutic approaches based on transplantation of dopaminergic neurons differentiated *in-vitro* from ESC, have been successful in ameliorating the Parkinsonian behavior of animal models, as has direct gene therapy with vectors harboring the GDNF gene. However, these approaches are limited, in the first case, by the

safety and ethical considerations associated with use of ESC, and, in the second case, by the safety risks inherent to gene therapy.

In fact, PD is the first neurodegenerative disease for which cell transplantation has been attempted in humans, first with adrenal medullary cells and, later, with tissue grafts from fetal brains. About 300 such fetal transplants have already been performed and some benefits have been observed, mainly in younger patients. However, this approach is not only impractical but greatly limited by the ethical issues influencing the availability of human fetuses. The above considerations have led to intensive efforts to define and develop appropriate cells from adult stem cells.

Company Business Strategy

Our primary efforts are currently focused on advancing the NurOwn clinical development program, with the goal of obtaining FDA regulatory approval for treatment of ALS patients. The following roadmap describes the clinical trials that we anticipate will be required in order to reach this goal:

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

Given the Orphan Drug Status of NurOwn, we anticipate that the regulatory process will be expedited.

Additional strategic goals of the Company:

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

Company Business Model

Our commercialization strategy calls for NurOwn to be adopted by medical centers throughout the United States and Europe. Aiming to restrict access to our proprietary technology, we will establish and maintain fully-equipped cGMP certified Cell-Processing Centers in strategic locations to support NurOwn production and distribution over the broadest geographic area. Each Cell-Processing Center would receive an initial tissue sample of the patient, harvested at a medical center. The patient's MSC cells would be isolated and expanded, in order to produce an initial dose of NurOwn cells. A master cell bank for each individual patient would be maintained for production of subsequent, future NurOwn doses on a long-term basis. These doses would be produced as needed and transported to the medical centers, where they would then be transplanted back into the patient.

We will seek cooperation with a major strategic partner as we progress towards advanced clinical development and commercialization.

We believe there is a substantial market opportunity and cooperation with strategic partners that would facilitate a more rapid and broad market penetration, by leveraging the partner's market credibility and the proven ability to provide service and support across a large and geographically spread target market. Such partners will also have established distribution channels and the ability to gain relatively fast access to the target markets.

Potential strategic partners include major pharmaceutical companies seeking new product opportunities in the neurodegenerative disease area.

We cannot guarantee that we will succeed in finding strategic partners that are willing to enter into collaborations for our potential products at the appropriate stage of development, on economic terms that are attractive to us or at all.

Our business model calls for significant investments in research and development. Our research and development expenditures (i) in 2011 (before participation by the OCS) were $2,077,000, which included $316,000 in stock-based compensation and (ii) in 2010 (before participation by the OCS) were $1,385,000, which included $325,000 in stock-based compensation.

Intellectual Property

Patents:

We have filed for patents in (1) the United States; (2) Europe; (3) Israel; and (4) Hong Kong, resulting in the following:

In the United States, we co-own, with Ramot, pending patent application no. 12/994,761, filed on November 25, 2010, entitled “Mesenchymal Stem Cells for the Treatment of CNS Diseases.”

In Europe, we co-own, with Ramot, pending patent application no. 09754337.5, filed on May 26, 2009, entitled “Mesenchymal Stem Cells for the Treatment of CNS Diseases.”

In Israel, we co-own, with Ramot, pending patent application no. 209604, filed on May 26, 2009, entitled “Mesenchymal Stem Cells for the Treatment of CNS Diseases.”

In Hong Kong, we co-own, with Ramot, pending patent application no. 11107062.5, filed on May 26, 2009, entitled "Mesenchymal Stem Cells for the Treatment of CNS Diseases."

We have also taken a license to several patents and patent applications from Ramot, resulting in the following:

We are a licensee of United States patent application no. 11/130,197, filed May 17, 2005, entitled "Methods, nucleic acid constructs and cells for treating neurodegenerative disorders."

We are a licensee of European patent application no. 06766101.7, filed on June 18, 2006, entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases."

We are a licensee of European patent application no. 11000994.1, filed on June 18, 2006, entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases."

We are a licensee of Hong Kong patent application no. 12112468.4, filed on June 18, 2006, entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases."

We are a licensee of United States patent application no. 11/727,583, filed on March 27, 2007, entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases."

We are the sole owners of United States Provisional patent application 61/679,822, filed August 6, 2012, entitled "Methods of Generating Mesenchymal Stem Cells Which Secrete Neurotrophic Factors."

Trademarks:

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

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

Research and License Agreement with Ramot

On July 8, 2004, we entered into a Research and License Agreement (the "Original Ramot Agreement") with Ramot, the technology licensing company of Tel Aviv University, which agreement was amended on March 30, 2006 by the Amended Research and License Agreement (described below). Under the terms of the Original Ramot Agreement, Ramot granted to us a license to (i) the know-how and patent applications on the above-mentioned stem cell technology developed by the team led by Prof. Melamed and Prof. Offen, and (ii) the results of further research to be performed by the same team on the development of the stem cell technology. Simultaneously with the execution of the Original Ramot Agreement, we entered into individual consulting agreements with Prof. Melamed and Prof. Offen pursuant to which all intellectual property developed by Prof. Melamed or Prof. Offen in the performance of services thereunder will be owned by Ramot and licensed to us under the Original Ramot Agreement.

On March 30, 2006, we entered into an Amended Research and License Agreement (the "Amended Research and License Agreement") with Ramot. Under the Amended Research and License Agreement, the funding of further research relating to the licensed technology in an amount of $570,000 per year was reduced to $380,000 per year. Moreover, under the Amended Research and License Agreement, the initial period of time that we agreed to fund the research was extended from an initial period of two (2) years to an initial period of three (3) years. The Amended Research and License Agreement also extended the additional two-year period in the Original Ramot Agreement to an additional three-year period, if certain research milestones were met. In addition, the Amended Research and License Agreement reduced (i) certain royalties payments from five percent (5%) to three percent (3%) of all net sales in cases of third party royalties and (ii) potential payments concerning sublicenses from 30% to 20-25% of sublicense receipts.

We entered into a Second Amended and Restated Research and License Agreement with Ramot on July 26, 2007. Like the Original Ramot Agreement, the amended license agreement imposed on us development and commercialization obligations, milestone and royalty payment obligations and other obligations.

In addition, in the event that the "research period", as defined in the amended license agreement, was extended for an additional three year period in accordance with the terms of the amended license agreement, then we had to make payments to Ramot during the first year of the extended research period in an aggregate amount of $380,000.

On December 24, 2009, we entered into a Letter Agreement (the "Letter Agreement") with Ramot, pursuant to which, among other things, Ramot agreed to: (i) release us from our obligation to fund three years of additional research (which would have totaled $1,140,000); and (ii) accept 1,120,000 shares of our common stock in lieu of $272,000 in past-due amounts. Pursuant to the Letter Agreement, we agreed, among other things, to: (i) reimburse Ramot for outstanding patent-related expenses; and (ii) abandon our rights in certain patents of Ramot in certain countries.

Through March 2011, Ramot sold the 1,120,000 shares of common stock of the Company for $235,000 and we paid the remaining $5,000 due to Ramot. There is no additional liability owed to Ramot.

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

Government Regulations and Supervision

Once fully developed, we intend to market our bone marrow derived differentiated neurothrophic-factor secreting cell products, NurOwn, for autologous transplantation in patients by neurosurgeons in medical facilities in the U.S., Europe, Japan and the Pacific Rim. Accordingly, we believe our research and development activities and the manufacturing and marketing of our technology are subject to the laws and regulations of governmental authorities in the United States and other countries in which our technology and products will be marketed. Specifically, in the U.S., the FDA, among other agencies, regulates new biological product approvals ("BLA") to establish safety and efficacy, as well as appropriate production of these products. Governments in other countries have similar requirements for testing and marketing.

As we are currently in the research and development stage of our technology and NurOwn cell product, we have initiated the process of seeking regulatory approval from the FDA. We have retained/recruited expert regulatory consultants and employees to assist us in our approaches to the FDA. In our efforts to obtain regulatory approval, we have had a successful pre-IND meeting with the FDA. We are also engaging a regulatory consultant to assist us with the regulatory authorities in Israel.

In February 2011, the FDA granted Orphan Drug designation to our NurOwn autologous adult stem cell product candidate for the treatment of ALS. Orphan Drug status entitles us to seven years of marketing exclusivity for NurOwn upon regulatory approval, as well as the opportunity to apply for grant funding from the FDA of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA's application user fee.

In January 2013, the European Medicine Agency ("EMA") Committee for Advanced Therapies, classified NurOwn as an Advanced Therapy Medicinal Product.

In January 2013, we also submitted an application for Orphan Medicinal Product Designation for our NurOwn cell product to the EMA. A reply is expected in May 2013.

Regulatory Process in the United States

Regulatory approval of new biological products is a lengthy procedure leading from development of a new product through pre-clinical animal testing and clinical studies in humans. This process is regulated by the FDA, may take a number of years, and requires the expenditure of significant resources. The Orphan Drug designation we have recently been granted by the FDA will no doubt assist us through the regulatory process. However, there can be no assurance that our technology will ultimately receive regulatory approval. We summarize below our understanding of the regulatory approval requirements that may be applicable to us if we pursue the process of seeking an approval from the FDA.

The Federal Food, Drug, and Cosmetic Act and other federal statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, use, reporting, advertising and promotion of our future products. Non-compliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

The FDA has developed and is continuously updating the requirements with respect to cell and gene therapy products and has issued documents concerning the regulation of cellular and tissue-based products, as new biological products. In order to file for a BLA, we will be required to develop our stem cell product in accordance with the regulatory guidelines for cell therapy and manufacture the cell products under GMP. GMP, or Good Manufacturing Practice, is a standard set of guidelines for pharmaceutical and bio-pharmaceutical production operations and facilities by the FDA and other health regulatory authorities, which apply caution in allowing any biologically active material to be administered into the human body.

Although there can be no assurance that the FDA will not choose to change its regulations, current regulation proposes that cell products which are manipulated, allogeneic, or as in our case, autologous but intended for a different purpose than the natural source cells (NurOwn are bone marrow derived and are intended for transplantation into the spinal cord, brain or into the muscles) must be regulated through a "tiered approach intended to regulate human cellular and tissue based products only to the extent necessary to protect public health". Thus the FDA requires: (i) preclinical

laboratory and animal testing; (ii) submission of an IND exemption which must be in effect prior to the initiation of human clinical studies; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to the FDA of a BLA; and (v) review and approval of the BLA as well as inspections of the manufacturing facility for GMP compliance, prior to commercial marketing of the product.

Generally, in seeking an approval from the FDA for sale of a new medical product, an applicant must submit proof of safety and efficacy. Such proof entails extensive pre-clinical studies in the lab and in animals and, if approved by the agency, in humans. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive and may take several years to complete. There can be no assurance that the FDA will act favorably or in a timely manner in reviewing submitted applications, and an applicant may encounter significant difficulties or costs in its efforts to obtain FDA approvals. This, in turn, could delay or preclude the applicant from marketing any products it may develop.

The FDA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. For patented technologies, delays imposed by the governmental approval process may materially reduce the period during which an applicant will have the exclusive right to exploit such technologies.

In order to conduct clinical trials of the proposed product, the manufacturer or distributor of the product will have to file an IND submission with the FDA for its approval to commence human clinical trials. The submission must be supported by data, typically including the results of pre-clinical and laboratory testing.

Following submission of the IND, the FDA has 30 days to review the application and raise safety and other clinical trial issues. If an applicant is not notified of objections within that period, clinical trials may be initiated at a specified number of investigational sites with the number of patients, as applied. Clinical trials which are to be conducted in accordance with Good Clinical Practice ("GCP") guidelines are typically conducted in three sequential phases. Phase I represents the initial administration of the drug or biologic to a small group of humans, either healthy volunteers or patients, to test for safety and other relevant factors.

Phase II involves studies in a small number of patients to explore the efficacy of the product, to ascertain dose tolerance and the optimal dose range and to gather additional data relating to safety and potential adverse effects. Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, multi-center Phase III studies are initiated to establish safety and efficacy in an expanded patient population and multiple clinical study sites. The FDA reviews both the clinical plans and the results of the trials and may request an applicant to discontinue the trials at any time if there are significant safety issues.

In addition, the manufacturer of our cell therapy product, whether it is performed in-house or by a contract manufacturer, should be registered as a biologic product manufacturer with the FDA product approval process. The FDA may inspect the production facilities on a routine basis for compliance with the GMP and Good Tissue Practice ("GTP") guidelines for cell therapy products. The regulations of the FDA require that we, and/or any contract manufacturer, design, manufacture and service products and maintain documents in the prescribed manner with respect to manufacturing, testing, distribution, storage, design control and service activities. The FDA may prohibit a company from promoting an approved product for unapproved applications and reviews product labeling for accuracy.

Compliance with Environmental, Health and Safety Laws

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

Competition

We face significant competition in our efforts to develop our products and services, including: (i) cell therapies competing with NurOwn and its applications and (ii) other treatments or procedures to cure or slow the effects of ALS, PD and other neurodegenerative diseases. There are a number of companies developing cell therapies for ALS, among them are companies that are involved in the controversial fetal cell transplant or ESC-derived cell therapy, as well as 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, which we intend to target. We believe that as an autologous bone marrow derived product that has shown proof of concept *in-vitro* and in animal studies, as well as clinical safety and possible indications of clinical benefit in a Phase I/II clinical trial in 12 ALS patients, NurOwn has a first mover advantage in the adult stem cell space and such space has competitive advantages over the fetal cell or ESC-derived cell space as it has a long safety record and does not have the same ethical limitations.

Employees

We currently have 17 scientific and administrative employees, 15 of whom are full-time. None of our employees is represented by a labor union and we believe that we have good relationships with our employees.

WHERE YOU CAN FIND MORE INFORMATION

We maintain a website at www.brainstorm-cell.com. We make available through our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission. We also similarly make available, free of charge through our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act. We are not including the information contained at www.brainstorm-cell.com or at any other Internet address as part of, or incorporating it by reference into, this Annual Report on Form 10-K.

Item 1A. RISK FACTORS

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. Forward looking statements in this report and those made from time to time by us through our senior management are made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward looking statements concerning the expected future revenues, earnings or financial results or concerning project plans, performance, or development of products and services, as well as other estimates related to future operations are necessarily only estimates of future results and there can be no assurance that actual results will not materially differ from expectations. Forward-looking statements represent management's current expectations and are inherently uncertain. We do not undertake any obligation to update forward-looking statements. If any of the following risks actually occurs, our financial condition and operating results could be materially adversely affected.

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.

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

Agreements we and our Israeli Subsidiary have with Ramot impose on us royalty payment obligations. If we fail to comply with these obligations, Ramot may have the right to terminate the license. 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. 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.

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

Except for bone marrow transplants for neoplastic disease, the field of stem cell therapy remains largely untested in the clinical setting. 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 I/II 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.

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. We believe that there will be many different applications for products successfully derived from our technologies and that the anticipated market for products under development will continue to expand. No assurance, however, can be given that these beliefs will prove to be correct due to competition from existing or new products and the yet to be established commercial viability of our products. 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. As there are no real experts who can forecast this market with accuracy, there is limited data from which the future use of our services may be forecasted. 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. Specifically, the limited number of centers experienced with cell therapy product candidates heightens our dependence on such research institutions. 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.

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 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 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 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 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 MoH or the FDA.

Even if a product candidate is approved by the 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.

We are subject to environmental, health and safety laws.

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

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

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

A key aspect of our business strategy is to establish strategic relationships in order, to expand or complement our research and development or commercialization capabilities, and to reduce the cost of research and development. There can be no assurance that we will enter into such relationships, that the arrangements will be on favorable terms or that such relationships will be successful. If we are ultimately successful in executing our strategy of securing collaborations with companies that would undertake advanced clinical development and commercialization of our products, we may not have day-to-day control over their activities. Any such collaborator may adhere to criteria for determining whether to proceed with a clinical development program under circumstances where we might have continued such a program. Potential collaborators may have significant discretion in determining the efforts and amount of resources that they dedicate to our collaborations or may be unwilling or unable to fulfill their obligations to us, including their development and commercialization. Potential collaborators may underfund or not commit sufficient resources to the testing, marketing, distribution or other development of our products. They may also not properly maintain or defend our intellectual property rights or they may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability. Potential collaboration partners may have the right to terminate the collaboration on relatively short notice and if they do so or if they fail to perform or satisfy their obligations to us, the development or commercialization of products would be delayed and our ability to realize any potential milestone payments and royalty revenue would be adversely affected.

We 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.

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 application filed by Ramot and the license granted to us and our Israeli Subsidiary by Ramot under the Research and License Agreement (the “Original Ramot Agreement”), dated as of July 8, 2004, with Ramot, the technology licensing company of Tel Aviv University. We agreed under the Original 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. 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 inrelation 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 Original Ramot Agreement are located in Israel. Accordingly, political, economic and military conditions in Israel may affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Acts of random terrorism periodically occur which could affect our operations or personnel. Ongoing or revived hostilities or other factors related to Israel could harm our operations and research and development process and could impede our ability to execute our plan of operations.

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

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

Risks related to our common stock

The price of our stock is expected to be volatile.

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

There is no guarantee that our shares will be listed on the NASDAQ Capital Market.

We have applied for listing of our common stock on the NASDAQ Capital Market. Such listing, however, is not guaranteed. If the application is not approved, our common stock will continue to be traded on the OTCQB Bulletin Board subject to continued compliance with the OTCQB Bulletin Board's requirements for continued quotation. Even if such listing is approved, we may not be able to meet the requirements for continued listing, and there may not be any broker interested in making a market for our stock. Therefore, it may be difficult to sell your shares of common stock if you desire or need to sell them. It is possible that an active and liquid trading market in our securities may never develop or, if one does develop, there is no assurance that the market will continue.

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.

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

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

As a public company in the United States, we are subject to the reporting obligations under the U.S. securities laws. The Securities and Exchange Commission, or the SEC, as required under Section 404 of the Sarbanes-Oxley Act of 2002, has adopted rules requiring every public company to include a report of management on the effectiveness of such company’s internal control over financial reporting in its annual report. Our consolidated financial statements for the year ended December 31, 2012 provided that our management has performed an evaluation of the effectiveness of

our disclosure controls and internal control over financial reporting for the periods covered by Forms 10-K and 10-Q, and concluded that our disclosure controls and procedures were not effective as of December 31, 2012 as a result of the material weaknesses in our internal control over financial reporting. The material weaknesses identified in our internal control over financial reporting are related to both the inadequate supervisory review structure and insufficient personnel with appropriate levels of accounting knowledge and experience to address the high volume of U.S. GAAP accounting issues and to prepare and review financial statements and related disclosures under U.S. GAAP. In response to the material weaknesses described above, we plan to develop and take several measures designed to remediate the material weaknesses in our internal control over financial reporting. The measures we intend to take in the future may not be sufficient to remediate the material weaknesses noted by our management and our independent registered public accounting firm and to avoid potential future material weaknesses. We may require more resources and incur more costs than currently expected to remediate our identified material weaknesses or any additional significant deficiencies or material weaknesses that may be identified, which may adversely affect our results of operations. If either of the material weaknesses is not remedied or 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. 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our executive offices are located in premises at 605 Third Avenue, 34th Floor, New York, NY 10158.

On December 1, 2004, our Israeli subsidiary, Brainstorm Cell Therapeutics Ltd., entered into a lease agreement for the lease of premises in 12 Basel Street, Petach Tikva, Israel, which include approximately 600 square meters of office and laboratory space. The original term of the lease was 36 months, commencing on April 1, 2005, with two options to extend: one for an additional 24 months (the "First Option"); and one for an additional 36 months (the "Second Option"). We are currently in the Second Option period, which will expire on March 31, 2013, and rent is paid on a quarterly basis in the amount of NIS 32,200 (approximately U.S. $8,600) per month.

On November 11, 2012, the Israeli Subsidiary extended the lease agreement by five more years, through March 31, 2018. After three years, we will have the right to cancel the agreement with 6 months' notice. The monthly rent will increase by 5% in April 2013.

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

As part of the clinical trials with Hadassah, we pay $67,000 per month for rental and operation of two clean room facilities at Hadassah facilities in Jerusalem.

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

Item 3. LEGAL PROCEEDINGS

On April 17, 2008, Chapman, Spira & Carson, LLC ("CSC") filed a breach of contract complaint in the Supreme Court of the State of New York (the "Court") against the Company. The complaint alleged that the Company improperly terminated its contract with CSC. The complaint sought, among other things, the following relief: (i) 400,000 shares of the common stock of the Company and (ii) warrants to purchase 250,000 shares of the common stock of the Company at an exercise price of $0.30 per share. Further, the complaint alleged that CSC performed its obligations under the contract and suffered compensatory damages in an amount up to approximately $672,500.

On October 24, 2012, the Company reached an understanding with CSC according to which the Company will pay CSC $125,000 in full satisfaction of CSC's claims against the Company, out of which $80,000 has already been paid to CSC and a $45,000 accrual was included in the financial statements accordingly.

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

Item 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

Item 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is currently traded on the OTCQB under the symbol “BCLI”. The following table contains information about the range of high and low sales prices for our common stock based upon reports of transactions on the OTCQB.

Quarter Ended	High	Low
December 31, 2012	$0.27	$0.17
September 30, 2012	$0.38	$0.21
June 30, 2012	$0.30	$0.21
March 31, 2012	$0.34	$0.20
December 31, 2011	$0.40	$0.20
September 30, 2011	$0.56	$0.27
June 30, 2011	$0.60	$0.25
March 31, 2011	$0.43	$0.18

The source of these high and low prices was the OTCQB. These quotations reflect inter-dealer prices, without retail mark-up, markdown or commissions and may not represent actual transactions. The high and low prices listed have been rounded up to the next highest two decimal places.

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

The Securities and Exchange Commission also has rules that regulate broker/dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than $5.00 (other than securities listed on certain national exchanges, provided that the current price and volume information with respect to transactions in that security is provided by the applicable exchange or system). The penny stock rules require a broker/dealer, before effecting a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the Securities and Exchange Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing before effecting the transaction, and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for shares of common stock of the Company. As a result of these rules, investors may find it difficult to sell their shares.

Dividends

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

Record Holders

As of March 11, 2013, there were approximately 68 holders of record of our common stock.

Equity Compensation Plans

Information regarding our equity compensation plans and the securities authorized under the plans is included in Item 12 below.

Recent Sales of Unregistered Securities

On January 16, 2013, we issued 72,000 and 144,000 shares of common stock to Dani Offen and Eldad Melamed, respectively, for consulting services. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On February 4, 2013, we issued 126,111 shares of common stock to Aaron Lasry in accordance with a settlement agreement with Mr. Lasry. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On February 7, 2013, we issued 833,334 shares of common stock at a purchase price of $0.30 per share (for a total purchase price of $250,000) and a 32-month warrant to purchase up to 833,334 shares of our common stock with an exercise price equal to $0.50 per share to E.E.B Investments and Holdings (2009) Ltd. and pursuant to a Securities Purchase Agreement with E.E.B Investments and Holdings (2009) Ltd. dated February 7, 2013. These securities were issued without registration pursuant to the exemption afforded by Regulation S promulgated under the Securities Act. No underwriters were involved with the issuance of these securities and no commissions were paid in connection with this transaction.

Item 6. SELECTED FINANCIAL DATA

Not required.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Company Overview

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

NurOwn, our proprietary process for the propagation of MSC and their differentiation into NTF secreting cells (MSC-NTF), and their transplantation at, or near, the site of damage, offers the hope of overcoming 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 Israeli Subsidiary holds rights to commercialize the technology, through a licensing agreement with Ramot, the technology transfer company of Tel Aviv University, Israel.

On February 17, 2010, our Israeli Subsidiary entered into the Clinical Trial Agreement with Hadassah. 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 Hadassah.

In February 2011, the FDA granted Orphan Drug designation to NurOwn, our autologous adult stem cell product candidate for the treatment of ALS.

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

In July 2011, we entered into a Memorandum of Understanding with Massachusetts General Hospital and the University of Massachusetts Medical School in anticipation of applying for FDA approval to begin ALS human clinical trials in the United States. Pending submission of an IND application to the FDA and subsequent approval, we are planning to launch a Phase II clinical trial at these institutions in mid-2013.

In July 2012, we submitted an interim safety report to the 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 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 three to 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 recently developed by the Company. Our cryopreservation, or freezing, method will enable long-term storage, and production of repeat patient doses of NurOwn without the need for additional bone marrow aspirations. We believe that the positive data from the toxicity study in mice will support our efforts to obtain approval for a future repeat dose clinical study in ALS patients. The study was conducted at Harlan Israel's laboratories, according to GLP standards of the FDA. The study protocol was approved by the Israeli MoH.

On February 21, 2013, the UK Subsidiary filed a request for Orphan Medicinal Product Designation by the EMA for our autologous bone marrow-derived mesenchymal stem cells secreting neurotropic factors.

Results of Operations

The Company has been a development stage company since its inception. For the period from inception (September 22, 2000) until December 31, 2012, the Company did not generate any revenues from operations. The Company does not expect to generate revenues from operations until 2013. In addition, the Company incurred operating costs and expenses of approximately $3,518,000 during the year ending December 31, 2012, and approximately $44,940,000 for the period from inception (September 22, 2000) through December 31, 2012. Operating expenses incurred since inception were approximately $18,751,000 for general and administrative expenses and $26,189,000 for research and development costs.

Research and Development, net

Research and development expenses, net for the year ended December 31, 2012 and 2011 were $1,770,000 and $1,689,000, respectively. In addition, our grant from The Office of the Chief Scientist increased by $530,000 to $918,000 for the year ended December 31, 2012 from $388,000 for the year ended December 31, 2011.

The increase in research and development expenses is primarily due to: (i) an increase of $500,000 in costs associated with the clinical trials, conducted in accordance with GMP in Hadassah, for an aggregate amount of $1,300,000 for

the year ended December 31, 2012, compared to $800,000 for the year ended December 31, 2011; (ii) an increase of $180,000 in payroll costs due to recruitment of three additional employees to conduct the clinical trials; and (iii) an increase of $170,000 for consulting and travel costs. This increase was offset by: (i) a decrease in stock-based compensation expenses, of $240,000 in the year ended December 31, 2011 to $74,000 in the year ended December 31, 2012; and (ii) an increase of $530,000 in CSO grants from $388,000 in the year ended December 31, 2011 to $918,000 in the year ended December 31, 2012.

General and Administrative

General and administrative expenses for the years ended December 31, 2012 and 2011 were $1,748,000 and $2,205,000, respectively. The decrease in General and administrative expenses for the year ended December 31, 2012, is mainly due to a decrease of $530,000 in stock-based compensation expenses, from $1,075,000 in the year ended December 31, 2011 to $545,000 in the year ended December 31, 2012; this decrease was partially offset by an increase of $74,000 in payroll costs from $366,000 in the year ended December 31, 2011 to $440,000 in the year ended December 31, 2012.

Financial Expenses

Financial income for the year ended December 31, 2012 was $93,000 compared to financial expense of $151,000 for the year ended December 31, 2011.

The increase in financial income for the year ended December 31, 2012, is primarily due to a one-time $192,000 financial expense included in the year ended December 31, 2011, from conversion of debt to a subcontractor to our common stock. The issuance of stock to the subcontractor was in an amount that was lower than the amount owed to the supplier. The value of the amount issued was based on the per share price on the date of the grant. In addition, the increase in financial income is due to (i) an increase in financial income of $33,000 from conversion exchange, compared to $41,000 for the year ended December 31, 2011; and (ii) an interest receivable from a bank deposit in the amount of $19,000 (no such income was received in the year ended December 31, 2011).

Net Loss

Net loss for the year ended December 31, 2012 was $3,430,000, as compared to a net loss of $3,918,000 for the year ended December 31, 2011. Net loss per share for the year ended December 31, 2012 was $0.02, compared to net loss per share of $0.03 for the year ended December 31, 2011.

The decrease in the net loss for the year ended December 31, 2012 is due to (i) a decrease in stock-based compensation expenses, and (ii) an increase in CSO grants. This decrease was partially offset by an increase the progress of clinical trials conducted in GMP facilities in Hadassah.

The weighted average number of shares of common stock used in computing basic and diluted net loss per share for the year ended December 31, 2012 was 137,596,391, compared to 120,117,724 for the year ended December 31, 2011.

The increase in the weighted average number of shares of common stock used in computing basic for the year ended December 31, 2012 was due to (i) the issuance of shares of common stock in a public offering in July 2012, as described in more detail below, (ii) the exercise of options and warrants, and (iii) the issuance of shares to service providers.

Liquidity and Capital Resources

We have financed our operations since inception primarily through public and private sales of our common stock and warrants and the issuance of convertible promissory notes. As of December 31, 2012, we had $4,874,000 in total current assets and $1,139,000 in total current liabilities.

Net cash used in operating activities was $2,935,000 for the year ended December 31, 2012. Cash used for operating activities in the year ended December 31, 2012 was primarily attributed to cost of clinical trials, rent of clean rooms and materials for clinical trials, payroll costs, rent, outside legal fee expenses and public relations expenses.

Net cash used in investing activities was $2,840,000 for the year ended December 31, 2012.

Net cash provided by financing activities was $5,169,000 for the year ended December 31, 2012 and is primarily attributable to the Public Offering, as discussed below.

On July 17, 2012, the Company raised approximately $5.7 million through a public offering (“Public Offering”) of its common stock. The Company issued a total of 19,818,968 shares of its common stock at $0.29 per share and 14,864,228 warrants to purchase 0.75 shares of common stock for every share purchased in the Public Offering, at an exercise price of $0.29 per share. The warrants are exercisable until the 30 month anniversary of the date of issuance. After deducting closing costs and fees, the Company received net proceeds of approximately $5 million.

Our material cash needs for the next 12 months include the payments due under an agreement with Hadassah to conduct clinical trials in ALS patients, under which we must pay to Hadassah an amount of (i) up to $32,225 per patient (up to $773,400 in the aggregate) and (ii) $65,000 per month for rent and operation of the GMP facilities in anticipation of Hadassah's clinical trials.

Our other material cash needs for the next 12 months will include payments of (i) employee salaries, (ii) patents, (iii) construction fees for facilities to be used in our research and development and (iv) fees to our consultants and legal advisors.

The Company believes it has sufficient funds to meet its obligations in the upcoming 12 months. However, future operations are very capital intensive and will require substantial capital raisings. If we are not able to raise substantial additional capital, we may not be able to continue to function as a going concern and we may have to cease operations. Even if we obtain funding sufficient to continue functioning as a going concern, we will be required to raise a substantial amount of capital in the future in order to reach profitability and to complete the commercialization of our products. Our ability to fund these future capital requirements will depend on many factors, including the following:

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

Off Balance Sheet Arrangements

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

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not required.

34

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2012

U.S. DOLLARS IN THOUSANDS

(Except share data)

35

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2012

U.S. DOLLARS IN THOUSANDS

(Except share data)

INDEX

	Page
Report of Independent Registered Public Accounting Firm	37-38
Consolidated Balance Sheets	39
Consolidated Statements of Operations	40
Statements of Changes in Stockholders' Equity (Deficiency)	41-50
Consolidated Statements of Cash Flows	50
Notes to Consolidated Financial Statements	52-77

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

BRAINSTORM CELL THERAPEUTICS Inc. (A Development Stage Company)

We have audited the accompanying consolidated balance sheet of BRAINSTORM CELL THERAPEUTICS Inc. and subsidiary (a development stage company) (the "Company") as of December 31, 2012 and 2011, and the related consolidated statement of income, stockholders' equity (deficiency), and cash flows for each of the two years in the period ended December 31, 2012 and for the period from April 1, 2004 to December 31, 2012. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on the financial statements based on our audits.

The financial statements for the period from April 1, 2004 through December 31, 2007, were audited by other auditors. The consolidated financial statements for the period from April 1, 2004 through December 31, 2007 included a net loss of $32,325,000. Our opinion on the consolidated statements of operations, changes in stockholders' deficiency and cash flows for the period from April 1, 2004 through December 31, 2012, insofar as it relates to amounts for prior periods through December 31, 2007, is based solely on the report of other auditors. The other auditors report dated April 13, 2008 expressed an unqualified opinion, and included an explanatory paragraph concerning an uncertainty about the Company's ability to continue as a going concern, and regarding the status of the Company research and development license agreement with Ramot.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditor, such consolidated financial statements present fairly, in all material respects, the financial position of BRAINSTORM CELL THERAPEUTICS Inc. and subsidiary as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2012 and for the period from April 1, 2004 to December 31, 2012, in conformity with

accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company is a development stage enterprise engaged in development innovative stem cell therapeutic products based on technologies enabling the *in-vitro* differentiation of bone marrow stem cells into neural-like cells, based on the acquired technology and research to be conducted and funded by the Company as discussed in Note 1 to the financial statements. The Company's operating losses since inception through December 31, 2012 raise substantial doubts about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of' these uncertainties.

/s/ Brightman Almagor Zohar & Co.

Brightman Almagor Zohar & Co.

Certified Public Accountants

A Member Firm of Deloitte Touche Tohmatsu

Tel Aviv, Israel

March 13, 2013

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of

BRAINSTORM CELL THERAPEUTICS INC.

(A development stage company)

We have audited the accompanying consolidated balance sheet of Brainstorm Cell Therapeutics Inc. (a development stage company) ("the Company") and its subsidiary as of December 31, 2007, and the related consolidated statements of operations, statements of changes in stockholders' equity (deficiency) and the consolidated statements of cash flows for the year ended December 31, 2007, for the nine months ended December 31, 2006 and 2005 and for the period from March 31, 2004 through December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits and the report of the other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its subsidiary as of December 31, 2007, and the consolidated results of their operations and cash flows for the year ended December 31, 2007, for the nine months ended December 31, 2006 and 2005 and for the period from March 31, 2004 through December 31, 2007, in conformity with U.S generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, in 2007, the Company adopted Financial Accounting Standard Board Statement No. 123(R), "Share-Based Payment".

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1h, the Company has incurred operating losses and has a negative cash flow from operating activities and has a working capital deficiency. As for the Company research and development license agreement with Ramot, see Note 3. These conditions raise substantial doubt about the Company's ability to continue to operate as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Kost Forer Gabbay & Kasierer
Tel-Aviv, Israel KOST FORER GABBAY & KASIERER
April 13, 2008 A Member of Ernst & Young Global

38

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

(Except share data)

	December 31,	
	2012	2011
ASSETS	U.S. $ in thousands	
Current Assets:		
Cash and cash equivalents	1,317	1,923
Short-term deposit	2,769	-
Accounts receivable (Note 5)	742	312
Prepaid expenses	46	69
Total current assets	4,874	2,304
Long-Term Assets:		
Prepaid expenses	17	17
Severance pay fund	172	109
Total long-term assets	189	126
Property And Equipment, Net (Note 6)	247	314
Total assets	5,310	2,744
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Trade payables	358	244
Accrued expenses	605	750
Other accounts payable	176	141
Total current liabilities	1,139	1,135
Accrued Severance Pay	189	121

Total liabilities	1,328	1,256
Stockholders' Equity:		
Stock capital: (Note 8)	7	6
Common stock $0.00005 par value - Authorized: 800,000,000 shares at		
December 31, 2012 and December 31, 2011; Issued and outstanding:		
150,085,035 and 126,444,309 shares		
Additional paid-in-capital	51,483	45,560
Deficit accumulated during the development stage	(47,508)	(44,078)
Total stockholders' equity	3,982	1,488
Total liabilities and stockholders' Equity	5,310	2,744

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands

(Except share data)

	Year ended December 31,		Period from September 22, 2000 (inception date) through December 31,
	2012	2011	2012(*)
	U.S. $ in thousands		
Operating costs and expenses:			
Research and development, net (Note 9)	1,770	1,689	26,189
General and administrative	1,748	2,205	18,751
Total operating costs and expenses	3,518	3,894	44,940
Financial expense (income), net	(93)	151	2,454
Other income	-	(132)	(132)
Operating loss	3,425	3,913	47,262
Taxes on income (Note 10)	5	5	82
Loss from continuing operations	3,430	3,918	47,344
Net loss from discontinued operations	-	-	164
Net loss	3,430	3,918	47,508
Basic and diluted net loss per share from continuing operations	0.02	0.03	-

Weighted average number of shares outstanding used in computing basic and diluted net loss per share	137,596,391	120,117,724	-

(*) Out of which, $163, relating to the period from inception to March 31 2004, is unaudited.

The accompanying notes are an integral part of the consolidated financial statements

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Deferred Stock - based	Deficit accumulated during the development	Total stockholders' equity
	Number	**Amount**	**capital**	**compensation**	**stage**	**(deficiency)**
Balance as of September 22, 2000 (date of inception) (unaudited)	-	$ -	$ -	$ -	$ -	$ -
Stock issued on September 22, 2000 for cash at $0.00188 per share	8,500,000	1	16	-	-	17
Stock issued on June 30, 2001 for cash at $0.0375 per share	1,600,000	*	60	-	-	60
Contribution of capital	-	-	8	-	-	8
Net loss	-	-	-	-	(17)	(17)
Balance as of March 31, 2001 (unaudited)	10,100,000	$ 1	$ 84	$ -	$ (17)	$ 68
Contribution of capital	-	-	11			