BRAINSTORM CELL THERAPEUTICS INC
Form 10-K
March 15, 2012

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, 2011

¨ 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

(Address of principal executive offices) 10158
(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 ¨ Smaller reporting company x
(Do not check if a smaller reporting company)

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, 2011 (the last business day of the registrant’s most recently completed second fiscal quarter), was $43,398,267.

As of March 9, 2012, the number of shares outstanding of the registrant's common stock, $0.00005 par value per share, was 126,569,309.

DOCUMENTS INCORPORATED BY REFERENCE

None.

BRAINSTORM CELL THERAPEUTICS, INC.

ANNUAL REPORT ON FORM 10-K

YEAR ENDED DECEMBER 31, 2011

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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," "h "anticipates," "believes," "intends," "plans," "estimates," "predicts," "likely," "potential," or "continue" or the negative o 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 stem cell therapeutic products based on technologies enabling the *in-vitro* differentiation of bone marrow stem cells

into neural-like cells. We aim to become a leader in adult stem cell transplantation for neurodegenerative diseases. Our technology entails exploiting the patient's own bone marrow stem cells to generate glial-like cells that may provide an effective treatment for Amyotrophic Lateral Sclerosis ("ALS"), Parkinson's Disease ("PD"), Multiple Sclerosis ("MS") and Spinal Cord Injury.

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 team demonstrated formation of neurotrophic-factor secreting cells (glial-like cells) from *in-vitro* differentiated bone marrow cells that produce neurotrophic factors ("NTF") including Glial Derived Neurotrophic factor ("GDNF"), Brain Derived Neurotrophic factor ("BDNF") and additional factors**.** Moreover, in research conducted by our team, implantation of these differentiated cells into brains of animal models that had been induced to Parkinsonian behavior markedly improved their condition.

Our aim is to provide neural-supporting stem cell transplants that are expected to maintain, preserve and possibly restore the damaged neurons, protecting them from further degeneration.

Our wholly-owned Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. (the "Israeli Subsidiary") holds exclusive worldwide 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.

As a result of limited cash resources and the desire to take a faster path to clinical trials, since the fourth quarter of 2008 we have focused all of our efforts on ALS, and are currently not allocating resources towards PD, MS or other neurodegenerative diseases. Other indications are currently being evaluated.

We are currently in the clinical stage of development of our technology and we intend to begin the process of seeking regulatory approval from regulatory agencies in the U.S.

In June 2011, we initiated a Phase I/II clinical study for ALS patients using our autologous NurOwn™ stem cell therapy, after receiving final approval from the Israel Ministry of Health ("MOH").

In February 2011, the U.S. Food and Drug Administration ("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.

Our efforts are directed at:

- Operating a Good Manufacturing Practice ("GMP") compliant production process;
- Demonstrating Safety Tolerability and Therapeutic effect of transplantation of Autologous cultured Bone Marrow Stromal Cells secreting Neurothrophic factors (MSC-NTF) in a Phase I/II Clinical trial in human ALS patients;
- Setting up a centralized facility to provide the therapeutic products and services for transplantation in patients in the US, as part of the clinical development program; and
- Submitting an Investigational New Drug application ("IND") to the FDA.

Our Approach

Our research team led by Prof. Melamed and Prof. Offen has shown that human bone marrow mesenchymal stem cells can be expanded and induced to differentiate into two types of brain cells, neuron-like and astrocyte-like cells, each having different therapeutic potential, as follows:

NurOwn™ program one - NTF secreting cells (MSC-NTF) - human bone marrow derived NTF secreting cells for treatment of, ALS, PD and MS. In-vitro differentiation of the expanded human bone marrow derived mesenchymal stem cells in a proprietary medium led to the generation of neurotrophic-factors secreting cells. The in-vitro differentiated cells were shown to express and secrete GDNF, as well as other NTFs, into the growth medium. GDNF is a neurotrophic-factor, previously shown to protect, preserve and even restore neuronal function, particularly dopaminergic cells in PD, but also neuron function in other neurodegenerative pathologies such as ALS and Huntington's disease. Unfortunately, therapeutic application of GDNF is hampered by its poor brain penetration and stability. Attempting to infuse the protein directly to the brain is impractical and the alternative, using GDNF gene therapy, suffers from the limitations and risks of using viral vectors. Our preliminary results show that our NTF secreting cells, when transplanted into a 6-OHDA lesion PD rat model, show significant efficacy. Within weeks of the transplantation, there was an improvement of more than 50% in the animals' characteristic disease symptoms.

We have optimized the proprietary processes for induction of differentiation of human bone marrow derived mesenchymal stem cells into differentiated cells that produce NTF (MSC-NTF). The optimization and process development is conducted in GMP compliance.

NurOwn™ program two - Dopaminergic neuron-like cells - human bone marrow derived dopamine producing neural cells for restorative treatment in PD. Human bone marrow mesenchymal stem cells were isolated and expanded. Subsequent differentiation of the cell cultures in a proprietary differentiation medium generated cells with neuronal-like morphology and showing protein markers specific to neuronal cells. Moreover, the *in-vitro* differentiated cells were shown to express enzymes and proteins required for dopamine metabolism, particularly the enzyme tyrosine hydroxylase. Most importantly, the cells produce and release dopamine *in-vitro*. Further research consisting of implanting these cells in an animal model of PD (6-OHDA induced lesions), showed the differentiated cells exhibit long-term engraftment, survival and function *in vivo*. Most importantly, such implantation resulted in marked attenuation of their symptoms, essentially reversing their Parkinsonian movements.

Our technology is based on the NurOwn™ products - an autologous cell therapeutic modality, comprising the extraction of the patient bone marrow, which is then processed into the appropriate neuronal-like cells and re-implanted into the patient's muscles, spinal cord or brain. This approach is taken in order to increase patient safety and minimize any chance of immune reaction or cell rejection.

The therapeutic modality will comprise the following:

- Bone marrow aspiration from patient;
- Isolation and expansion of the mesenchymal stem cells;
- Differentiation of the expanded stem cells into neurotrophic-factor secreting cells; and
- Autologous transplantation into the patient into the site of damage.

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. On November 22, 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.

Recent Developments

In February 2011, the FDA's Office of Orphan Products Developments granted Orphan Drug designation for the Company's NurOwn™ autologous adult stem cell product candidate for the treatment of ALS. 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.

Between February 22, 2011 and March 1, 2011, we entered into Securities Purchase Agreements with institutional and individual investors pursuant to which we issued and sold 12,815,000 units comprised of shares of common stock and warrants for the purchase of common stock in exchange for $3,588,200 ($0.28 per unit). Each unit includes (i) one share of common stock, (ii) a warrant to purchase one-half of one share of our common stock until the first anniversary of the closing date at a purchase price of $0.28 per share and (iii) a warrant to purchase one share of our common stock until the second anniversary of the closing date at a purchase price of $0.50 per share. The warrants may only be exercised by the payment of the exercise price in cash. The warrants, if exercised in full, will result in additional cash proceeds to the Company of approximately $8.2 million.

In June 2011, we initiated a Phase I/II clinical study for ALS patients using our autologous NurOwn™ stem cell therapy, after receiving final approval from the Israel MOH.

On February 17, 2010, our wholly owned 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 will conduct a clinical trial to evaluate the safety and tolerability of our treatment using mesenchymal bone marrow stem cells secreting neurotrophic factors (MSC-NTF) in patients with ALS, in accordance with a protocol developed jointly by us and Hadassah. The trial is expected to include between 24 and 26 patients.

Intellectual property generated through the study will be owned by us. Hadassah will be entitled to use the intellectual property generated through the study for non-commercial purposes. All existing intellectual property of the Company and Hadassah shall be retained by each respective party.

In connection with the study, we agreed to pay Hadassah $38,190 per patient totaling up to $992,880, as well as $31,250 per month for rental and operation of clean room facilities according to GMP standards at Hadassah facilities in Jerusalem in order to apply the cell growth and differentiation process in accordance with our methods.

On June 27, 2011, our wholly owned Israeli subsidiary entered into the Amendment (the "Amendment") to the Clinical Trial Agreement. The Amendment amended the Clinical Trial Agreement to, among other things: (i) decrease the total payment due to Hadassah from $992,880 to $773,400 and (ii) change the termination provisions so only we may terminate the agreement upon 60 days' notice.

On September 22, 2011, our wholly owned Israeli subsidiary entered into an additional Amendment to the Clinical Trial Agreement ("Amendment 2") to rent an additional clean room starting December 1, 2011.

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. We are obligated to pay royalties to the OCS, amounting to 3% to 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.

On March 12, 2012, we announced plans to initiate a preclinical study assessing the efficiency of our NurOwn™ stem cell technology in patients with MS. Positive proof-of-concept results for MS have been confirmed in a set of *in-vitro* and *in-vivo* experiments, and we are working to advance MS into preclinical development in our second quarter in 2012.

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 6,000 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. Consequently, the total estimated cost of treating ALS patients is approximately $1.25 billion per year in the U.S. and $3 billion per year in the western world.

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.

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 four million people suffer from PD in the western world, of whom about 1.5 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 $4 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 ("NINDS") to exceed $26 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 15 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 (“MRCs”) 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 $1 billion and the market is expected to grow to approximately $4 billion by 2011, 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 glial derived neurotrophic factor ("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 efforts are currently focused on the development of the technology to upscale the process from the lab stage to the clinical stage, with the following main objectives:

- Operating a GMP compliant production process;
- Demonstrating Safety Tolerability and Therapeutic effect of transplantation of Autologous cultured Bone Marrow Stromal Cells secreting Neurothrophic factors (MSC-NTF) in a Phase I/II Clinical trial in human ALS patients;

- Setting up a centralized facility to provide the therapeutic products and services for transplantation in patients in the US, as part of the clinical development program; and
- Submitting an IND to the FDA

We intend to develop the NurOwn™ therapeutic technology to reach clinical proof of concept and proceed to commercialization with companies experienced in advanced clinical development and commercialization. This approach is intended to generate an early inflow of up-front and milestone payments and to enhance our capacities in regulatory and clinical infrastructure while minimizing expenditure and risk.

We have received interim safety data for the first ALS patients in our Phase I/II clinical study at the Hadassah Medical Center, in the first quarter of 2012. This clinical study is expected to be complete within an additional 12 to 15 months. Initial steps have been made for conducting FDA approved clinical trials in the US. The study is intended to evaluate safety and efficacy of our' cell therapy. We are currently considering developing our autologous cell therapy for the treatment of an additional Central Nervous System indication. Our clinical development timeline is subject to a number of risks as described in the section entitled “Risk Factors.”

Company Business Model

Our objective is to have the proprietary procedure adopted by many medical centers, throughout the U.S., Europe, Israel and East Asia for the treatment of ALS, MS, PD, and other neurodegenerative diseases. Our intended procedure for supporting the degenerated neurons with healthy cells secreting Neurotrophic factors derived by differentiation of bone marrow cells, may be among the earliest successes of stem cell technologies and could be the starting point for a massive market potential in the area of autologous transplantation. A central laboratory would be responsible for processing bone marrow extracted from patients, enabling the production of the cells required for transplantation. Transplantation would be carried out by the medical centers, with revenues shared with us on an agreed basis.

We will consider seeking cooperation with a major strategic marketing partner, having established distribution channels and the ability to gain relatively fast access to the target markets.

Our approach will be optimized by working with a major partner. We believe there is a substantial market opportunity and cooperation with strategic partners 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.

Potential strategic partners include:

- Private Medical Center Chains - interested in expanding their service offerings and being associated with an innovative technology, thereby enhancing their professional standing and revenue potential; and

- Major Pharmaceutical and/or Medical Device Companies - seeking new product opportunities and/or wishing to maintain interest in the market, which may shift away from drugs towards surgical treatment.

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. We have entered into a Memorandum of Understanding with the 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.

Our business model calls for significant investments in research and development. Our research and development expenditures (i) in 2011 (before participation by the Israeli Office of Chief Scientist) were $2,077,000, which included

$388,000 in stock-based compensation and (ii) in 2010 (before participation by the Israeli Office of Chief Scientist) were $1,385,000, which included $340,000 in stock-based compensation.

Intellectual Property

We have filed the following patent applications:

WO2004/046348 METHODS, NUCLEIC ACID CONSTRUCTS AND CELLS FOR TREATING NEURODEGENERATIVE DISORDERS. National phase filings in the United States. Substantive examination is ongoing in the U.S.

WO2006/134602 ISOLATED CELLS AND POPULATIONS COMPRISING SAME FOR THE TREATMENT OF CNS DISEASES. National phase filings in the U.S. and Europe. Substantive examination is ongoing in the U.S. and Europe. A divisional application has been submitted in Europe.

A joint Brainstorm-Ramot patent application was submitted as PCT:

WO2009/144718 MESENCHYMAL STEM CELLS FOR THE TREATMENT OF CNS DISEASES

National phase filings in the U.S., Europe and Israel. Substantive examination is ongoing in Europe.

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 new patent applications on any improvements and any new discoveries arising in the course of research and development.

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 an exclusive 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.

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 debt 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 will request a pre-Investigational New Drug ("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.

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 affects. 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, 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 13 scientific and administrative employees, 8 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, 2011 or December 31, 2010. 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