BRAINSTORM CELL THERAPEUTICS INC
Form 10-K
March 25, 2010

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, 2009

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 333-61610

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.)
110 East 59th Street New York, NY (Address of principal executive offices)	10022 (Zip Code)

Registrant's telephone number, including area code: 212-557-9000

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	Over-the-Counter Bulletin Board

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 ¨ 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, 2009 (the last business day of the registrant's most recently completed second fiscal quarter), was $2,607,465.

As of March 24, 2010, the number of shares outstanding of the registrant's common stock, $0.00005 par value per share, was 87,707,647.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement (the "Definitive Proxy Statement") to be filed with the Securities and Exchange Commission relative to the registrant's 2010 Annual Meeting of Stockholders are incorporated by reference into Part III of this annual report.

BRAINSTORM CELL THERAPEUTICS, INC.
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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,” “hop “anticipates,” “believes,” “intends,” “plans,” “estimates,” “predicts,” “likely,” “potential,” or “continue” or the negative of any 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.

Item 1. Description of Business.

Company Overview

Brainstorm Cell Therapeutics Inc. (“Brainstorm” or the “Company”) is a leading company developing stem cell therapeutic products based on breakthrough technologies enabling the in-vitro differentiation of bone marrow stem cells to neural-like cells. We aim to become a leader in adult stem cell transplantation for neurodegenerative diseases. Our focus is on utilizing the patient’s own bone marrow stem cells to generate neuron-like cells that may provide an effective treatment initially for ALS, PD and Multiple Sclerosis.

Our core technology was developed in collaboration with prominent neurologist, Prof. Eldad Melamed, the 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.

The Company’s team is among the first to demonstrate creation of neurotrophic-factor secreting cells (glial cells) from in-vitro differentiated bone marrow cells that produce neurotrophic factors (“NTF”) including GDNF, BDNF, NGF and IGF-1.

The team is also among the first to have successfully demonstrated release of neurotrophic factors from in-vitro differentiated bone marrow cells. Moreover, in research conducted by this team, implantation of these differentiated

cells into brains of animal models that had been induced to Parkinsonian behavior markedly improved their symptoms.

Our aim is to provide neural stem cell transplants that maintain, preserve and restore the damaged and remaining dopaminergic cells in the patient's brain, protecting them from further degeneration.

The Company holds exclusive worldwide rights to commercialize the technology, through a licensing agreement with Ramot, the technology transfer company of Tel Aviv University.
We are currently in the developmental stage of our technology and products and we intend to begin the process of seeking regulatory approval from regulatory agencies in the U.S and Europe.

In Israel, we have obtained Institutional Review Board (IRB) approval for a Phase I/II clinical study in ALS patients at the Hadassah Medical Center, and are currently awaiting final approval of the Israeli Ministry of Health.

In parallel, our efforts are directed at:

- Finalizing a GMP compliant production process;
- Demonstrating safety and efficacy in animals and in human ALS patients; and
- Setting up centralized facilities to provide the therapeutic products and services for transplantation in patients.

As a result of limited cash resources and the desire to take a faster path to clinical trials, in the fourth quarter of 2008 the Company determined to focus all of its efforts on ALS, and we are currently not allocating resources towards PD or other neurodegenerative diseases.

Our Approach

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

NurOwn program 1 - 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.

NurOwn program 2 - Neurotrophic-factors ("NTF") secreting cells - human bone marrow derived NTF secreting cells for treatment of PD, ALS and Multiple Sclerosis. In-vitro differentiation of the expanded human bone marrow derived mesenchymal stem cells in a proprietary medium leads 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.

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We already optimized the proprietary processes for induction of differentiation of human bone marrow derived mesenchymal stem cells into differentiated cells that produce dopamine and/or NTFs for transplantation into PD and ALS patients. The optimization and process development will be conducted in Good Manufacturing Practice ("GMP"). Once the optimization of the process is completed, we intend to evaluate the safety and efficacy of our various cell transplants in animal models. Based on the results in animals, we intend to use the differentiated cell products for conducting clinical trials to assess the efficacy of the cell therapies in ALS and PD patients.

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

We believe that 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 neuronal-like dopamine producing cells and/or neurotrophic-factor secreting cells; and
- Autologous transplantation into the patient.

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 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 opened 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

Hadassah

On February 17, 2010, a wholly owned Israeli subsidiary of the Company entered into a series of agreements with Hadasit Medical Research Services and Development Ltd., a subsidiary of the Hadassah Medical Organization ("Hadassah"). Under the agreements, Hadassah and BrainStorm personnel will conduct a clinical trial to evaluate the safety and tolerability of BrainStorm's treatment using mesenchymal bone marrow stem cells secreting neurotrophic factors (MSC-NTF) in patients with ALS, in accordance with a protocol developed jointly by BrainStorm and Hadassah. The trial is scheduled to include 26 patients.

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Intellectual property generated through the study will be owned by BrainStorm. Hadassah will be entitled to use the intellectual property generated through the study for non-commercial purposes. All existing intellectual property of Brainstorm and Hadassah shall be retained by them.

Investment of $1,500,000

On February 17, 2010, the Company entered into Securities Purchase Agreements with three individual investors (collectively, the "Investors"), pursuant to which the Company agreed to issue to the Investors an aggregate of 6,000,000 shares of common stock and two-year warrants to purchase 3,000,000 shares of common stock with an exercise price of $0.50 in exchange for $1,500,000.

On March 2, 2010, the transaction involving the sale of the shares of common stock and warrants was completed, and the 6,000,000 shares of common stock and warrants or purchase 3,000,000 shares of common stock were issued in exchange for the investment of $1,500,000 in the Company.

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, 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 Multiple Sclerosis (“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 help breathe) 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

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 $2.3 billion by 2010, 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.

Business Strategy

Our efforts are currently focused on the development of the technology to convert the process from the lab stage to the clinical stage, with the following main objectives:

- Developing the cell differentiation process according to health regulation guidelines;
- Demonstrating safety and efficacy, first in animals and then in patients; and
- Setting up centralized facilities to provide NurOwn therapeutic products and services for transplantation in patients.

We intend to enter into strategic partnerships as we progress towards advanced clinical development and commercialization with companies responsible for 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.

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, PD, and other neurodegenerative diseases. Our intended procedure for the replacement of the degenerated neurons with healthy functional cells derived by differentiation of bone marrow, 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 the 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.

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We cannot assure you 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 2009 (before Ramot reserve accrual and participation by the Israeli Office of Chief Scientist) were $1,069,000, which included $289,000 in stock-based compensation and (ii) in 2008 were $2,097,000, which included $219,000 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 Europe and the United States. Substantive examinations have been initiated in the U.S. and Europe. A patent was granted in Singapore.

WO2006/134602 ISOLATED CELLS AND POPULATIONS COMPRISING SAME FOR THE TREATMENT OF CNS DISEASES. National phase filings in the U.S., Australia, Europe, Israel and China. Substantive examinations have been initiated in some jurisdictions, including Israel and Europe. A patent was granted in South Africa.

A joint Brainstorm-Ramot patent application as PCT:

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

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 Dr. 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 Dr. Offen pursuant to which all intellectual property developed by Prof. Melamed or Dr. Offen in the performance of services thereunder will be owned by Ramot and licensed to us under the Original Ramot Agreement.

Under the Original Ramot Agreement, we agreed to fund further research relating to the licensed technology in an amount of $570,000 per year for an initial period of two years, and for an additional two-year period if certain research milestones were met.

In consideration for the license, we originally agreed to pay Ramot:

- An up-front license fee payment of $100,000;
- An amount equal to 5% of all net sales of products; and
- An amount equal to 30% of all sublicense receipts.

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. As of June 30, 2007, we owed Ramot an aggregate of $513,249 in overdue payments and patent fees under the Amended Research and License Agreement. On August 1, 2007, we obtained a waiver and release from Ramot pursuant to which Ramot agreed to an amended payment schedule regarding our payment obligations under the amended license agreement and waived all claims against us resulting from our previous breaches, defaults and non-payment under the Amended Research and License Agreement.

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 the Company from it's obligation to fund three years of additional research (which would have totaled $1,140,000); (ii) accept shares of common stock of the Company in lieu of $272,000 is past-due amounts. Pursuant to the Letter Agreement, the Company agreed, among other things, to: (i) reimburse Ramot for outstanding patent-related expenses; (ii) abandon its rights in certain patents of Ramot.

Government Regulations and Supervision

Once fully developed, we intend to market our bone marrow derived differentiated neurothrophic-factor secreting cell products, NurOwnTM, 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 NurOwnTM cell product, we have initiated the process of seeking regulatory approval from the FDA and other regulatory agencies. 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 pre Investigational New Drug ("IND") meeting with the FDA and we are planning to retain such expert regulatory consultants to assist the Company in its approach to the EMEA in order to get regulatory approval in Europe. We have also engaged a regulatory consultant to assist us with the regulatory authorities in Israel.

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 takes a number of years, is regulated by the FDA and requires the expenditure of significant resources. 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 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 effective 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 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.

Competition

We face significant competition in our efforts to develop our products and services, including: (i) cell therapies competing with NurOwnTM and its applications and (ii) other treatments or procedures to cure or slow the effects of PD and other neurodegenerative diseases. There are a number of companies developing cell therapies. 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, NurOwnTM 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 eight scientific and administrative employees, six of whom are full-time. None of our employees is represented by a labor union and we believe that we have good relations 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.stockeryale.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.

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.

Pursuant to a subscription agreement, as amended, we have with ACCBT Corp., we expected to issue and sell additional shares and warrants to ACCBT for aggregate consideration of up to $5,000,000. As of December 31, 2009, ACCBT had invested up to $4,509,000 in the Company pursuant to the subscription agreement, as amended.

In recent months, we have entered into subscription agreements and/or securities purchase agreements with various investors and have raised an aggregate of $1,750,000. However, we will still need to secure additional funds to effect our plan of operations.

We may not be able to raise additional funds on favorable terms, or at all. If we are unable to obtain additional funds on favorable terms and in a timely fashion, we will be unable to execute our business plan and we will be forced to restrict or cease our operations.

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 for any reason, including failure to make required payments, we would need to change our business strategy and we may be forced to cease our operations. Agreements we have with Ramot impose on us development and commercialization obligations, milestone and royalty payment obligations and other obligations. Under these agreements, we are obligated to pay certain fees to Ramot. 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.

Disruption in financial and currency markets could have a negative effect on our business. As has been widely reported, financial markets in the U.S., Europe, Asia and elsewhere have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken unprecedented actions intended to address extreme market conditions that include severely restricted credit and declines in real estate values. While currently these conditions have not impaired our ability to operate our business, there can be no assurance that there will not be a further deterioration in financial markets and confidence in major economies, which can then lead to challenges in the operation of our business. These economic developments affect businesses such as ours in a number of ways, including our ability to obtain the financing that is necessary to continue operating our business. We are unable to predict the likely duration and severity of the current disruption in financial markets and adverse economic conditions and the effects they will have on our business and financial condition.

Our company has a history of losses and we expect to incur losses for the foreseeable future. We had no revenues for the fiscal years ended December 31, 2009 or December 31, 2008. As a development stage company, we are in the early stages of executing our business plan. Our ability to operate successfully is materially uncertain and our operations are subject to significant risks inherent in a developing business enterprise. Most notably, we do not expect that any therapies resulting from our or our collaborators' research and development efforts will be commercially available for a significant number of years, if at all. We also do not expect to generate revenues from strategic partnerships or otherwise for at least the next 12 months, and likely longer. 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.

The field of stem cell therapy is 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 and PD involve a new approach that has never been proven to work in human testing. We are still conducting experimental testing in animals for our treatment and are going to conduct clinical trials, which, together with other stem cell therapies, may ultimately prove ineffective in treatment of human diseases. If we cannot successfully implement our stem cell therapy in human testing, we would need to change our business strategy and we may be forced to cease our operations.

Our ability to commercialize the products we intend to develop will depend upon our ability to prove the efficacy and safety of these products according to government regulations. Our present and proposed activities are subject to extensive and rigorous regulation by governmental authorities in the U.S. and other countries. To clinically test, produce and market our proposed future products for human use, we must satisfy mandatory procedural and safety and efficacy requirements established by the FDA and comparable state and foreign regulatory agencies. Typically, such rules require that products be approved by the government agency as safe and effective for their intended use prior to being marketed. The approval process is expensive, time consuming and subject to unanticipated delays. It takes years to complete the testing of a product, and failure can occur at any stage of testing. Our product candidates may not be approved. In addition, our product approvals could be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the product's marketing approval.

We may not be able to obtain regulatory approval of potential products, or may experience delays in obtaining such approvals, and we may consequently never generate revenues from product sales because of any of the following risks inherent in the regulation of our business:

- We may not be successful in obtaining the approval to perform clinical studies, including the approval the Israeli Ministry of Health to conduct clinical trials on ALS patients, an investigational new drug application, or IND, with

respect to a proposed product;

- Preclinical or clinical trials may not demonstrate the safety and efficacy of proposed products satisfactory to the FDA or foreign regulatory authorities; or

- Completion of clinical trials may be delayed, or costs of clinical trials may exceed anticipated amounts (for example, negative or inconclusive results from a preclinical test or clinical trial or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated, additional tests to be conducted or a program to be terminated, even if other studies or trials relating to the program are successful).

We may not be able to succeed in our business model of seeking to enter into collaborations at appropriate stages of development. We intend to enter into strategic partnerships as we progress towards advanced clinical development and commercialization with companies responsible for such activities. We intend to provide strategic partners with services required to process the NurOwn products for the clinical trials. It may be difficult for us to find third parties 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. If we are not able to continue to enter into acceptable collaborations, we could fail in our strategy of generating an early inflow of up-front and milestone payments and to enhance our capacities in regulatory and clinical infrastructure while minimizing expenditure and risk and we could be required to undertake and fund further development, clinical trials, manufacturing and marketing activities solely at our own expense.

We may be dependent upon a company with which we enter into collaborations to conduct clinical trials and to commercialize our potential products. 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 significant competition in our efforts to develop cell therapies for ALS, PD and other neurodegenerative diseases. We face significant competition in our efforts to develop cell therapies and other treatment or procedures to cure or slow the effects of ALS, PD 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. Many 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. Many also have significantly more experience in preclinical testing, human clinical trials, product manufacturing, the regulatory approval process and marketing and distribution than we do.

If Ramot is unable to obtain patents on the patent applications and technology exclusively licensed to us 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 as filed by Ramot and the license granted to us by Ramot under the Original Ramot Agreement. We agreed under the Original Ramot Agreement to seek comprehensive patent protection for all inventions licensed to us under the Original Ramot Agreement. However, we cannot be sure that any patents will be issued to Ramot as a result of its domestic or future foreign patent applications or that any issued patents will

withstand challenges by others.

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.

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.

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

Your percentage ownership will be diluted by future offerings of our securities, upon the conversion of outstanding convertible promissory notes into shares of common stock and by options, warrants or shares we grant to management, employees, directors and consultants. If we issue all of the shares and warrants to ACCBT Corp. as provided for in the subscription agreement, it will have a significant dilutive effect on your percentage ownership in the Company. In addition, in order to meet our financing needs described above, 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.

In November 2004 and February 2005, the Company’s Board of Directors adopted and ratified the Global Plan and the U.S. Plan (the “Global Plan” and “U.S. Plan” respectively and the “Plans” together), and further approved the reservation of 9,143,462 shares of our common stock for issuance under the Plans (the “Shares”). Our shareholders approved the Plans and the issuance of the Shares in a special meeting of shareholders that was held on March 28, 2005.

On April 28, 2008, the Board approved the amendment and restatement of the Plans to increase the number of shares available for issuance under the Plans by an additional 5,000,000 shares. Our shareholders approved the amendment and restatement of the Plans on June 5, 2008. We have made and intend to make further option grants under the Plans or otherwise issue warrants or shares of our common stock to individuals under the Plans. For example, as of March 16, 2010:

- under our Global Plan we have granted and not canceled a total of 9,546,778 options with various exercise prices and expiration dates, to officers, directors, services providers, consultants and employees.

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- under our U.S. Plan we have issued an additional 830,000 shares of restricted stock and options for grants to Scientific Advisory Board members, service providers, consultants and directors.

Such issuances will, if and when made (and if options or warrants are subsequently exercised), dilute your percentage ownership in the Company.

As of March 16, 2010, all of our outstanding convertible notes had been converted or repaid.

ACCBT Corp. holds equity participation 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.

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 President, 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.

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. Since October 2000, terrorist violence in Israel increased significantly and until they were recently revived, negotiations between Israel and Palestinian representatives had effectively ceased. 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.

Investors may face significant restrictions on the resale of our stock due to the way in which stock trades are handled by broker-dealers. Brokers may be less willing to execute transactions in securities subject to “penny stock” rules. This may make it more difficult for investors to dispose of shares of our common stock and cause a decline in the market value of our stock. Because of large broker-dealer spreads, investors may be unable to sell the stock immediately back to the broker-dealer at the same price the broker-dealer sold the stock to the investor. In some cases, the stock may fall quickly in value. Investors may be unable to reap any profit from any sale of the stock, if they can sell it at all. The market among broker-dealers may not be active. Investors in penny stocks often are unable to sell stock back to the dealer that sold them the stock. The mark-ups or commissions charged by the broker-dealers may be greater than any profit a seller may make.

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 Bulletin Board, an over-the-counter electronic quotation service, which stock currently trades below $5.00 per share. We anticipate the trading price of our common stock will 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 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 non-NASDAQ equity security 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

The address of our principal executive offices is 110 East 59 th Street, New York, NY 10022, where we have a license to use office space and receive general office services. We have paid rent in the past, but are currently not required to do so.

On December 1, 2004, our Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. (the “Subsidiary”) 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, 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 and rent is paid on a quarterly basis in the amount of NIS 31,035 (approximately $8,200) per month.

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

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 alleges that CSC performed its obligations to the Company under a consulting agreement entered into between the parties and that the Company failed to provide CSC with the compensation outlined in the consulting agreement. The complaint seeks compensatory damages in an amount up to approximately $896,667, as well as costs and attorneys’ fees. On June 5, 2008, the Company filed an answer with the Court. The Company believes CSC’s claims are without merit. We intend to vigorously defend our actions. We cannot predict the scope, timing or outcome of this matter. We cannot predict what impact, if any, this matter may have on our business, financial condition, results of operations and cash flow.

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. REMOVED AND RESERVED

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is currently traded on the OTC Bulletin Board operated by the NASD (OTC BB) under the symbol "BCLI". The following table sets forth for the periods indicated the high and low sales prices for our common stock as reported on the OTC BB.

Quarter Ended	High	Low
December 31, 2009	$ 0.44	$ 0.18
September 30, 2009	$ 0.49	$ 0.05
June 30, 2009	$ 0.10	$ 0.06
March 31, 2009	$ 0.22	$ 0.05
December 31, 2008	$ 0.19	$ 0.06
September 30, 2008	$ 0.32	$ 0.15
June 30, 2008	$ 0.51	$ 0.24
March 31, 2008	$ 0.73	$ 0.32

We believe that a number of factors may cause the market price of our common stock to fluctuate significantly. These factors are described in Item 7 below.

Dividends

We have not paid or declared any cash or other dividends on our common stock within the last two 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 16, 2010, there were approximately 84 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 October 1, 2009, the Company issued 150,000 shares of the Company's common stock to ERS Associates Ltd. for public relations and investor relations work performed by ERS Associates Ltd. for the Company.

On January 6, 2010, the Company issued 60,000 shares of the Company's common stock to Landoy Risk Management Ltd. in full satisfaction of the $15,000 owed by the Company to Landoy Risk Management Ltd. The amount payable by the Company to Landoy Risk Management Ltd. was converted into our common stock at a conversion price of $0.25.

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On January 27, 2010, upon conversion of a $150,000 8% Convertible Promissory Note, dated as of March 5, 2007, issued by the Company to Eliyahu Weinstein, the Company issued 1,016,109 shares of the Company's common stock to Tayside Trading Ltd. ("Tayside"), Mr. Weinstein's assignee, upon receipt of Tayside's written notice of his election to convert all of the outstanding principal and interest amount of the note into shares of the Company's common stock. The conversion price was $0.1875.

On February 19, 2010, upon conversion of a $135,000 4% Convertible Promissory Note, dated as of December 13, 2009, issued by the Company to Thomas B. Rosedale, the Company issued 402,385 shares of the Company's common stock to Thomas B. Rosedale upon receipt of written notice of his election to convert all of the outstanding principal and interest amount of the note into shares of the Company's common stock. The conversion price was $0.338.

On January 5, 2010, the Company issued 50,000 shares of common stock to its public relations advisors for six months of services performed for the Company. The issuance of such shares was in accordance with an agreement with the public relations advisors that entitles them to a monthly grant of 8,333 shares of the Company's common stock.

The issuances of the securities described in this Item 5 were effected without registration in reliance upon Regulation D promulgated under Securities Act of 1933, as amended. No underwriters were involved with the issuance of such securities and no commissions were paid in connection with such transaction.

Item 6. SELECTED FINANCIAL DATA

Not required.

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

Company Overview

The Company is a leading company developing stem cell therapeutic products based on breakthrough technologies enabling the in-vitro differentiation of bone marrow stem cells to neural-like cells. We aim to become a leader in adult stem cell transplantation for neurodegenerative diseases. Our technology is based on the use of the patient's own bone marrow stem cells to generate astrocyte-like cells secreting Neurotrophic factors that may provide an effective treatment initially for ALS, PD and Multiple Sclerosis.

Our core technology was developed in collaboration with prominent neurologist, Prof. Eldad Melamed, the 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.

The Company's team is among the first to demonstrate the in-vitro differentiation of bone marrow cells into glial-like cells secreting neurotrophic-factor ("NTF") including GDNF, BDNF, NGF and IGF-1.

The team is also among the first to have successfully demonstrated release of neurotrophic factors from in-vitro differentiated bone marrow cells. Moreover, in research conducted by this team, implantation of these differentiated cells into the brains of animal models that had been induced to Parkinsonian behavior markedly improved their Parkinsonian symptoms.

Our aim is to provide neural stem cell transplants that maintain, preserve and restore the damaged and remaining dopaminergic cells in the patient's brain, protecting them from further degeneration.

The Company holds exclusive worldwide rights to commercialize the technology, through a licensing agreement with Ramot, the technology transfer company of Tel Aviv University.

On February 17, 2010, the Company entered into an agreement with Hadasit Medical Research Services and Development Ltd., a subsidiary of the Hadassah Medical Organization ("Hadassah") to conduct clinical trials to evaluate the safety and tolerability of the Company's treatment using mesenchymal bone marrow stem cells secreting neurotrophic factors in up to 26 ALS patients at the Hadassah Medical Center.
Hadassah's Institutional Review approved the commencement of such clinical trials, pending approval by the Israel's Ministry of Health Review Board.

We are going to begin the process of seeking regulatory approval from regulatory agencies in the U.S and Europe. Our efforts are directed at the development of the technology from the lab to the clinic with the following main objectives:

- Developing the cell differentiation process according to Food and Drug Administration ("FDA") and the European agency for evaluation of medical product ("EMEA") guidelines;
- Demonstrating safety and efficacy in animals and in human patients; and
- Setting up centralized facilities to provide the therapeutic products and services for transplantation in patients.

As a result of limited cash resources and the desire to take a faster path to clinical trials, in the fourth quarter of 2008 the Company determined to focus all of its efforts on ALS, and we are currently not allocating resources towards PD or other neurodegenerative diseases.

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, 2009, the Company did not earn any revenues from operations. The Company does not expect to earn revenues from operations until 2013. In addition, the Company incurred operating costs and expenses of approximately $1,750,000 during the year ending December 31, 2009, and approximately $34,939,000 for the period from inception (September 22, 2000) through December 31, 2009. Operating expenses incurred since inception were approximately $13,254,000 for general and administrative expenses and $21,685,000 for research and development costs.

Research and Development, net:

Research and development expenses, net for the year ended December 31, 2009 and 2008 were $181,000 and $1,639,000, respectively. In addition, the Company grant from The Office of the Chief Scientist decreased by $330,000 to $128,000 for the year ended December 31, 2009 from $458,000 for the year ended December 31, 2008.

The decrease in research and development expenses, net for the year ended December 31, 2009 is primarily due to: (i) the Settlement Agreement with Ramot, under which Ramot released the Company from it's obligation to fund the extended research period; the Company reversed an amount equal to $760,000 that accumulated in the past years for the extended research period; (ii) the decrease in salary expenses due to the downsizing of the employee base in connection with the Company's financial condition; and (iii) the reduction in development activities as the Company decided to delay development activities in PD and other neurodegenerative diseases and focus solely on ALS.

General and Administrative

General and administrative expenses for the years ended December 31, 2009 and 2008 were $1,569,000 and $1,629,000, respectively. General and administrative expenses for the year ended December 31, 2009 consisted of $895,000 in stock-based compensation expenses and $674,000 in salary, legal, audit, public and investor relations and other expenses. General and administrative expenses for the year ended December 31, 2008 consisted of $509,000 in stock-based compensation expenses and $1,120,000 in salary, legal, audit, public and investor relations and other expenses.

The decrease in general and administrative expenses, excluding stock-based compensation expenses, for the year ended December 31, 2009 is primarily due to a reduction in Company activities in fiscal 2009 due to the Company's financial condition.

Financial Expenses

Financial expenses decreased by $173,000 to $31,000 for the year ended December 31, 2009 from $204,000 for the year ended December 31, 2008.

The decrease in financial expenses for the year ended December 31, 2009 is primarily to a decrease in amortization of the discount on short-term convertible loans that were recognized in the first half of 2008 and the exchange differentials derived from the changes in the exchange rate between the New Israeli Shekel to U.S. dollar.

Net Loss

Net loss for the year ended December 31, 2009 was $1,781,000, as compared to a net loss of $3,472,000 for the year ended December 31, 2008. Net loss per share for the year ended December 31, 2009 was $0.03, as compared to a net loss per share of $0.07 for the year ended December 31, 2008.

The decrease in the net loss for the year ended December 31, 2009 is due to a (i) reduction in Company activities, (ii) downsizing of employees and (iii) amortization of discount on short-term convertible loans.

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, 2009 was 61,151,011, compared to 49,040,500 for the year ended December 31, 2008.

The increase in 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, 2009 was due to (i) the issuance of shares in a private placement, (ii) the conversion of convertible loans, (iii) the exercise of warrants and (iv) the issuance of shares to service providers.

Liquidity and Capital Resources

The Company has financed its operations since inception primarily through private sales of its common stock and warrants and the issuance of convertible promissory notes. At December 31, 2009, we had $87,000 in total current assets and $2,388,000 in total current liabilities.

Net cash used in operating activities was $744,000 for the year ended December 31, 2009. Cash used for operating activities in the year ended December 31, 2009 was primarily for (i) payment of salaries and fees to our employees, consultants, subcontractors and services providers, (ii) purchase of laboratory materials and (iii) Company operations.

Net cash used in investing activities was $39,000 for the year ended December 31, 2009. Cash used for investing activities in the year ended December 31, 2009 was primarily for cancellation of restricted cash.

Net cash provided by financing activities was $704,000 for the year ended December 31, 2009 and is primarily attributable to funds received from ACCBT under the Subscription Agreement and the amendment of the Subscription Agreement.

Our material cash needs for the next 12 months include the payments due under the following:

1. An agreement with a lender under which we must pay approximately $120,000 over the next year; and
2. An agreement with Hadassah to conduct clinical trials in ALS patients, under which we must pay to Hadassah an amount of (i) up to $38,190 per patient (up to $992,880 in the aggregate) and (ii) $31,250 per month for rent and operations.

Our other material cash needs for the next 12 months will include payments of/to (i) employee salaries, (ii) lease of clean room for cell differentiation for Hadassah's clinical trials (iii) conduct clinical trials in the Hadassah Medical Center, (iv) patents, (v) construction fees for facilities to be used in our research and development and (vi) fees to our consultants and legal advisors.

On July 2, 2007, we entered into a subscription agreement with ACCBT Corp., pursuant to which we agreed to sell and issue (i) up to 27,500,000 shares of our common stock for an aggregate subscription price of up to $5.0 million, and (ii) for no additional consideration, warrants to purchase up to 30,250,000 shares of our common stock. Subject to certain closing conditions, separate closings of the purchase and sale of the shares and the warrants were scheduled to take place from August 30, 2007 through November 15, 2008.

On August 18, 2009, we entered into an amendment to the subscription agreement with ACCBT Corp. (the "Amendment"). Pursuant to the Amendment: (i) ACCBT Corp. agreed to invest the remaining amount (approximately $1,000,000) under the subscription agreement at a price per share of $0.12 (instead of a price per share of $0.1818) in monthly installments of not less than $50,000 beginning in August 2009; (ii) the exercise price of the final 10,083,334 warrants decreased from $0.36 to $0.29; (iii) the expiration date of all warrants extended from November 5, 2011 to November 5, 2013; and (iv) the purchase price per share of all 27,500,000 shares purchased pursuant to the subscription agreement decreased from $0.1818 to $0.12, which repricing applied retroactively to all shares purchased by ACCBT Corp. prior to the Amendment.

On January 25, 2010, we entered into a Subscription Agreement with Reytalon Ltd, pursuant to which the Company issued 1,250,000 shares of common stock of the Company to Reytalon Ltd at a purchase price of $0.20 per share for total gross proceeds of $250,000 paid to the Company and a warrant to purchase up to an additional 1,250,000 shares of the Company's common stock at an exercise price of $0.50 per share and which is exercisable until January 24, 2012.

On February 17, 2010, we entered into Securities Purchase Agreements with three individual investors, pursuant to which the Company agreed to issue to the Investors an aggregate of 6,000,000 shares of common stock and two-year warrants to purchase 3,000,000 shares of common stock with an exercise price of $0.50 in exchange for $1,500,000. On March 2, 2010, the transaction was completed and the Company received the $1,500,000 investment.

We will need to raise additional capital in order to meet our anticipated expenses. 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:

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- 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;
- 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.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2009

U.S. DOLLARS IN THOUSANDS
(Except share data)

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2009

U.S. DOLLARS IN THOUSANDS
(Except share data)

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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, 2009 and 2008, and the related consolidated statement of income, stockholders' deficiency, and cash flows for each of the two years in the period ended December 2009 and for the period from September 22, 2000 (date of inception) to December 31, 2009. 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 September 22, 2000 (inception) through December 31, 2007, were audited by other auditors. The consolidated financial statements for the period from September 22, 2000 (inception) through December 31, 2007 included a net loss of $32,488,000. Our opinion on the consolidated statements of operations, changes in stockholders' deficiency and cash flows for the period from September 22, 2000 (inception) through December 31, 2009, 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, 2009 and 2008, and the results of their operations and their cash flows for each of the two years in the period ended December 2009 and for the period from September 22, 2000 (date of inception) to December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

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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 of novel cell therapies for neurodegenerative diseases, particularly Parkinson's disease, 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 working capital deficiency and operating losses since inception through December 31, 2009 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 25, 2010

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share data)

	December 31	
	2009	2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	1	2
Restricted cash (Note 10b)	-	36
Accounts receivable and prepaid expenses (Note 5)	86	21
Total current assets	87	59
LONG-TERM INVESTMENTS:		
Prepaid expenses	7	11
Severance pay fund	88	62
Total long-term investments	95	73
PROPERTY AND EQUIPMENT, NET (Note 6)	575	743
Total assets	757	875
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
CURRENT LIABILITIES:		
Short term Credit from bank	46	72
Trade payables	600	744
Other accounts payable and accrued expenses (Note 7)	1,418	1,672
Short- term convertible note (Note 8 and 15g)	135	-
Short-term convertible loans (Note 9b and 15b)	189	172
Short-term loans (Note 9h)	-	199
Total current liabilities	2,388	2,859
ACCRUED SEVERANCE PAY	112	92
Total liabilities	2,500	2,951
COMMITMENTS AND CONTINGENCIES (Note 10)	-	-
STOCKHOLDERS' DEFICIENCY:		
Stock capital: (Note 11)	4	3
Common stock of $ 0.00005 par value - Authorized: 800,000,000 shares at December 31, 2009 and 2008; Issued and outstanding: 76,309,152 and 55,241,418 shares at December 31, 2009 and 2008, respectively		

Additional paid-in-capital	35,994	33,881
Deficit accumulated during the development stage	(37,741)	(35,960)

