

BRAINSTORM CELL THERAPEUTICS INC

Form S-1

February 03, 2012

Registration No. 333 - _____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BRAINSTORM CELL THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

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

605 Third Avenue, 34th Floor
New York, NY 10158
(646) 666-3188

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Liat Sossover
Chief Financial Officer
c/o Brainstorm Cell Therapeutics Inc.
605 Third Avenue, 34th Floor
New York, NY 10158
(646) 666-3188

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: promptly after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

(Do not check if a smaller reporting company)

 CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee (3)
Common stock, \$0.00005 par value		
Warrants to purchase shares of common stock (2)		
Common stock issuable upon exercise of the warrants		
Total	\$ 10,000,000.00	\$ 1,146.00

(1) Pursuant to Rule 416 under the Securities Act, this Registration Statement shall also cover any additional shares of common stock which become issuable by reason of any stock dividend, stock split or other similar transaction effected without the receipt of consideration that results in an increase in the number of the outstanding shares of common stock of the registrant.

(2) The securities registered also include such indeterminate number of shares of common stock as may be issued upon exercise of warrants pursuant to the anti-dilution provisions of the warrants.

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

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Subject to Completion, Dated _____, 2012

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

BRAINSTORM CELL THERAPEUTICS INC.

[_____] Shares of Common Stock
Warrants to Purchase up to [_____] Shares of Common Stock
and
[] Shares of Common Stock Underlying Warrants

We are offering [_____] shares of our common stock and warrants. Each investor investing \$[_____] or more will receive [] warrants to purchase an aggregate of up to [_____] shares of common stock at a price of \$[_____] per share. We are not required to sell any specific dollar amount or number of shares of common stock or warrants, but will use our best efforts to sell all of the shares of common stock and warrants being offered. The offering expires on the earlier of (i) the date upon which all of the shares of common stock and warrants being offered have been sold, or (ii) _____, 2012.

Our common stock is traded on the OTCQB Bulletin Board under the symbol "BCLI". On February 2, 2012 the last reported sales price for our common stock was \$0.23 per share.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 4 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

	Per Share	Total
Public Offering Price	\$	\$
Underwriting Discounts and Commissions	\$	\$
Offering Proceeds before expenses	\$	\$

We estimate the total expenses of this offering will be approximately \$[]. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering set forth above. We have no current arrangements nor have we entered into any agreements with any underwriters, broker-dealers or selling agents for the sale of the securities, but we plan on entering into such arrangements and agreements. If we can engage one or more underwriters, broker-dealers or selling agents and enter into any such arrangement(s), the securities will be sold through such licensed underwriter(s), broker-dealer(s) and/or selling agent(s). See "Plan of Distribution" beginning on page 18 of this prospectus for more information on this offering.

This offering will terminate on _____, 2012, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you. All costs associated with the registration will be borne by us. As there is no minimum purchase requirement, no

funds are required to be escrowed and all net proceeds will be available to us at closing for use as set forth in “Use of Proceeds” beginning on page 16.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The shares of Common Stock may be sold directly by us to investors or through our underwriters, broker-dealers or selling agents. See "Plan of Distribution".

The date of this prospectus is _____, 2011.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in or incorporated by reference in this prospectus and any applicable prospectus supplement. We have not authorized anyone to provide you with different or additional information. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of securities described in this prospectus. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have previously filed with the Securities and Exchange Commission (“SEC”) and incorporated by reference, is accurate as of the date on the front of those documents only. Our business, financial condition, results of operations and prospects may have changed since those dates.

As used herein, “we,” “us,” “our” or the “Company” refers to Brainstorm Cell Therapeutics Inc.

PROSPECTUS SUMMARY

This summary may not contain all of the information that may be important to you. You should read the entire prospectus, including the financial data and related notes, and risk factors.

Company Overview

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

Our core technology was developed in collaboration with prominent neurologist, Prof. Eldad Melamed, former head of Neurology of the Rabin Medical Center and member of the Scientific Committee of the Michael J. Fox Foundation for Parkinson's Research, and expert Cell biologist Prof. Daniel Offen, of the Felsenstein Medical Research Center of Tel Aviv University.

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

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

Our wholly-owned Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. (the "Israeli Subsidiary") holds exclusive worldwide rights to commercialize the technology, through a licensing agreement with Ramot at Tel Aviv University Ltd. ("Ramot"), the technology transfer company of Tel Aviv University, Israel.

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

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

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

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

Our efforts are directed at:

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

- Setting up a centralized facility to provide the therapeutic products and services for transplantation in patients in the US and in Europe, as part of the clinical development program; and
 - Submitting an Investigational New Drug application (“IND”) to the FDA.

Our Approach

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

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

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

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

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

The therapeutic modality will comprise the following:

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

- Autologous transplantation into the patient into the site of damage.

Corporate Information

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 605 Third Avenue, 34th Floor, New York, New York 10158, and our telephone number is (646) 666-3188. We maintain an Internet website at <http://www.brainstorm-cell.com>. The information on our website is not incorporated into this prospectus.

The Offering

Securities Offered [] shares of common stock
Warrants to purchase up to [] shares of common stock
[] shares of common stock issuable upon exercise of the warrants

Common stock outstanding as of December 31, 2011 126,444,309 shares

Common stock to be outstanding after the offering assuming the sale of all shares covered hereby and assuming no exercise of the warrants for the shares covered by this prospectus [] shares

Common stock to be outstanding after the offering assuming the sale of all shares covered hereby and assuming the exercise of all warrants for the shares covered by this prospectus [] shares

Use of proceeds We estimate that we will receive up to \$[] in net proceeds from the sale of the securities in this offering, based on a price of [\$] per unit, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will use the proceeds from the sale of the securities for initiation of clinical trials in the United States, research and development, working capital needs, capital expenditures and other general corporate purposes. See "Use of Proceeds" for more information.

Risk factors The shares of common stock offered hereby involve a high degree of risk. See "Risk Factors" beginning on page 4.

Dividend policy We currently intend to retain any future earnings to fund the development and growth of our business. Therefore, we do not currently anticipate paying cash dividends on our common stock.

Trading Symbol Our common stock currently trades on the OTCQB Bulletin Board under the symbol "BCLI."

RISK FACTORS

You should carefully consider and evaluate all of the information in this prospectus, including the risk factors listed below. Risks and uncertainties in addition to those we describe below, that may not be presently known to us, or that we currently believe are immaterial, may also harm our business and operations. If any of these risks occur, our business, results of operations and financial condition could be harmed, the price of our common stock could decline, and future events and circumstances could differ significantly from those anticipated in the forward-looking statements contained in this prospectus.

Risks related to our business

We need to raise additional capital. If we are unable to raise additional capital on favorable terms and in a timely manner, we will not be able to execute our business plan and we could be forced to restrict or cease our operations. We will need to raise additional funds to meet our anticipated expenses so that we can execute our business plan. We expect to incur substantial and increasing net losses for the foreseeable future as we increase our spending to execute our development programs. Our auditors have expressed in their audit report that there is substantial doubt regarding our ability to continue as a going concern.

The amount of financing required will depend on many factors including our financial requirements to fund our research and clinical trials, and our ability to secure partnerships and achieve partnership milestones as well as to fund other working capital requirements. Our ability to access the capital markets or to enlist partners is mainly dependent on the progress of our research and development and regulatory approval of our products.

Assuming we raise additional funds through the issuance of equity, equity-related or debt securities, these securities may have rights, preferences or privileges (including registrations rights) senior to those of the rights of our common stock and our stockholders will experience additional dilution.

Our business in the foreseeable future will be based on technology licensed from Ramot and if this license were to be terminated upon failure to make required royalty payments in the future, we would need to change our business strategy and we may be forced to cease our operations. Agreements we and our Israeli Subsidiary have with Ramot impose on us royalty payment obligations. If we fail to comply with these obligations, Ramot may have the right to terminate the license. If Ramot elects to terminate our license, we would need to change our business strategy and we may be forced to cease our operations. We currently do not owe Ramot any overdue payments.

Our company has a history of losses and we expect to incur losses for the foreseeable future. As a development stage company, we are in the early stages of executing our business plan. We had no revenues for the fiscal years ended December 31, 2010 or December 31, 2009. Our ability to operate successfully is materially uncertain and our operations are subject to significant risks inherent in a developing business enterprise. We are currently in the process of introducing the Company to strategic partners. In the upcoming three years, the Company will focus on clinical trials. We are unable at this time to foresee when we will generate revenues from strategic partnerships or otherwise. Furthermore, we expect to incur substantial and increasing operating losses for the next several years as we increase our spending to execute our development programs. These losses are expected to have an adverse impact on our working capital, total assets and stockholders' equity, and we may never achieve profitability.

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

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our stem cell therapy creates significant challenges with regard to product development and optimization, manufacturing, government regulations, and market acceptance. For example, the FDA has relatively limited

experience with stem cell therapies. None have been approved by them for commercial sale, and the pathway to regulatory approval for our cell therapy product candidates may accordingly be more complex and lengthy. As a result, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

We are faced with uncertainties related to our research.

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

The field of stem cell therapy is relatively new and our development efforts may not yield an effective treatment of human diseases. Except for bone marrow transplants for neoplastic disease, the field of stem cell therapy remains largely untested in the clinical setting. Our intended cell therapeutic treatment methods for ALS involve a new approach that has not yet been proven to work in humans. We are currently conducting Phase I/II clinical trials for ALS, which, together with other stem cell therapies, may ultimately prove ineffective in treatment of human diseases. If we cannot successfully implement our NurOwn™ stem cell therapy in human testing, we would need to change our business strategy and we may be forced to change our operations.

A significant global market for our services has yet to emerge.

Very few companies have been successful in their efforts to develop and commercialize a stem cell product. We believe that there will be many different applications for products successfully derived from our technologies and that the anticipated market for products under development will continue to expand. No assurance, however, can be given that these beliefs will prove to be correct due to competition from existing or new products and the yet to be established commercial viability of our products. Stem cell products in general may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their approval or commercial use. The demand for stem cell processing and the number of people who may use cell or tissue-based therapies is difficult to forecast. As there are no real experts who can forecast this market with accuracy, there is limited data from which the future use of our services may be forecasted. Physicians, patients, formularies, third party payers or the medical community in general may not accept or utilize any products that the Company or its collaborative partners may develop. Our success is dependent on the establishment of a large global market for our products and services and our ability to capture a share of this market.

We have limited experience in conducting and managing clinical trials and the application process necessary to obtain regulatory approvals. Our limited experience in conducting and managing clinical trials and the application process necessary to obtain regulatory approvals might prevent us from successfully designing or implementing a preclinical study or clinical trial. Cell-based therapy products, in general, may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their approval by regulators or commercial use. Many companies in the industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials. If our clinical trials are unsuccessful, or if we do not complete our clinical trials, we may not receive regulatory approval for

or be able to commercialize our product candidates.

If we do not succeed in conducting and managing our preclinical development activities or clinical trials, or in obtaining regulatory approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which will materially harm our business.

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Our ability to generate revenues from any of our product candidates will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and implement our commercialization strategy. We may, and anticipate that we will need to, transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not succeed in such a transition.

We may not be able to secure and maintain research institutions to conduct our clinical trials.

We rely on research institutions to conduct our clinical trials. Specifically, the limited number of centers experienced with cell therapy product candidates heightens our dependence on such research institutions. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreements with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. Furthermore, we may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

We are subject to a strict regulatory environment. If we fail to obtain and maintain required regulatory approvals for our potential cell therapy products, our ability to commercialize our potential cell therapy products will be severely limited.

None of our product candidates have received regulatory approval for commercial sale.

Numerous statutes and regulations govern human testing and the manufacture and sale of human therapeutic products in the United States and other countries where we intend to market our products. Such legislation and regulation bears upon, among other things, the approval of protocols and human testing, the approval of manufacturing facilities, testing procedures and controlled research, review and approval of manufacturing, preclinical and clinical data prior to marketing approval including adherence to GMP during production and storage as well as regulation of marketing activities including advertising and labeling.

The completion of the clinical testing of our product candidates and the obtaining of required approvals are expected to take several years and require the expenditure of substantial resources. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent regulatory approval and/or commercialization of our product candidates, including the following:

- The FDA or similar foreign regulatory authorities may find that our product candidates are not sufficiently safe or effective or may find our processes or facilities unsatisfactory;
- Officials at the MOH, the FDA or similar foreign regulatory authorities may interpret data from preclinical studies and clinical trials differently than we do;
- Our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the MOH, the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and/or clinical trials or to abandon one or more of our development programs;
- The MOH, the FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations;
- There may be delays or failure in obtaining approval of our clinical trial protocols from the MOH, the FDA or other regulatory authorities or obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;
- We, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects;
- We may experience difficulties in managing multiple clinical sites;

- Enrollment in our clinical trials for our product candidates may occur more slowly than we anticipate, or we may experience high drop-out rates of subjects in our clinical trials, resulting in significant delays; and
- We may be unable to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates for use in clinical trials.

Investors should be aware of the risks, problems, delays, expenses and difficulties which may be encountered by us in light of the extensive regulatory environment in which our business operates. In particular, our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval may be delayed or denied by the MOH or the FDA.

Even if a product candidate is approved by the MOH, the FDA or any other regulatory authority, we may not obtain approval for an indication whose market is large enough to recoup our investment in that product candidate. We may never obtain the required regulatory approvals for any of our product candidates. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market.

Even if regulatory approvals are obtained for our product candidates, we will be subject to ongoing government regulation. If we or one or more of our partners or collaborators fail to comply with applicable current and future laws and government regulations, our business and financial results could be adversely affected.

The healthcare industry is one of the most highly regulated industries in the United States. The federal government, individual state and local governments and private accreditation organizations all oversee and monitor the activities of individuals and businesses engaged in the delivery of health care products and services. Even if regulatory authorities approve any of our human therapeutic product candidates, current laws, rules and regulations that could directly or indirectly affect our ability and the ability of our strategic partners and customers to operate each of their businesses could include, without limitation, the following:

• State and local licensing, registration and regulation of laboratories, the collection, processing and storage of human cells and tissue, and the development and manufacture of pharmaceuticals and biologics;

- The federal Clinical Laboratory Improvement Act and amendments of 1988;

• Laws and regulations administered by the FDA, including the Federal Food Drug and Cosmetic Act and related laws and regulations;

- The Public Health Service Act and related laws and regulations;

• Laws and regulations administered by the United States Department of Health and Human Services, including the Office for Human Research Protections;

- State laws and regulations governing human subject research;
- Occupational Safety and Health requirements; and
- State and local laws and regulations dealing with the handling and disposal of medical waste.

Compliance with such regulation may be expensive and consume substantial financial and management resources. If we, or any future marketing collaborators or contract manufacturers, fail to comply with applicable regulatory requirements, we may be subject to sanctions including fines, product recalls or seizures, injunctions, total or partial suspension of production, civil penalties, withdrawal of regulatory approvals and criminal prosecution. Any of these sanctions could delay or prevent the promotion, marketing or sale of our products.

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

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

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

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

We face competition in our efforts to develop cell therapies for ALS and other neurodegenerative diseases.

We face competition in our efforts to develop cell therapies and other treatment or procedures to cure or slow the effects of ALS and other neurodegenerative diseases. Among our competitors are companies that are involved in the fetal cell transplant or embryonic stem cell derived cell therapy and companies developing adult stem cells. Other companies are developing traditional chemical compounds, new biological drugs, cloned human proteins and other treatments, which are likely to impact the markets that we intend to target. Some of our competitors possess longer operating histories and greater financial, managerial, scientific and technical resources than we do and some possess greater name recognition and established customer bases. Some also have significantly more experience in preclinical testing, human clinical trials, product manufacturing, the regulatory approval process and marketing and distribution than we do.

The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies having greater financial resources and discovery technological capabilities, thus intensifying competition in these industries. This trend may also result in fewer potential collaborators or licensees for our therapeutic product candidates. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or collaborators as a result of such consolidation.

There is a scarcity of experienced professionals in the field of cell therapy and we may not be able to retain key personnel or hire new key personnel needed to implement our business strategy and develop our products and businesses. If we are unable to retain or hire key personnel, we may be unable to continue to grow our business or to implement our business strategy, and our business may be materially and adversely affected.

Given the specialized nature of cell therapy and the fact that it is a young field, there is an inherent scarcity of experienced personnel in the field. Our success depends on a significant extent to the continued services of certain highly qualified scientific and management personnel. We face competition for qualified personnel from numerous industry sources, and there can be no assurance that we will be able to attract and retain qualified personnel on acceptable terms. The loss of service of any of our key personnel could have a material adverse effect on our operations or financial condition. In the event of the loss of services of such personnel, no assurance can be given that we will be able to obtain the services of adequate replacement personnel. We do not have key person life insurance on all of our key personnel. The future success of the Company also depends upon our ability to attract and retain additional qualified personnel (including medical, scientific, technical, commercial, business and administrative personnel) necessary to support our anticipated growth, develop our business, and maintain appropriate licensure, on acceptable terms. There can be no assurance that we will be successful in attracting or retaining personnel required by us to continue and grow our operations. The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees, as needed, could result in our inability to continue to grow our business or to implement our business strategy, or may have a material adverse effect on our business, financial condition and results of operations.

Technological and medical developments or improvements in conventional therapies could render the use of stem cells and our services and planned products obsolete.

The pharmaceutical industry is characterized by rapidly changing markets, technology, emerging industry standards and frequent introduction of new products. The introduction of new products embodying new technologies, including new manufacturing processes, and the emergence of new industry standards may render our technologies obsolete, less competitive or less marketable. Advances in other treatment methods or in disease prevention techniques could significantly reduce or entirely eliminate the need for our stem cell services, planned products and therapeutic efforts. Additionally, technological or medical developments may materially alter the commercial viability of our technology or services, and require us to incur significant costs to replace or modify equipment in which we have a substantial investment. In either event, we may experience a material adverse effect on our business, results of operations and financial condition.

If Ramot is unable to obtain patents on the patent applications and technology exclusively licensed to our Israeli Subsidiary or if patents are obtained but do not provide meaningful protection, we may not be able to successfully market our proposed products. We rely upon the patent application filed by Ramot and the license granted to us and our Israeli Subsidiary by Ramot under the Research and License Agreement (the "Original Ramot Agreement"), dated as of July 8, 2004, with Ramot, the technology licensing company of Tel Aviv University. We agreed under the Original Ramot Agreement to seek comprehensive patent protection for all inventions licensed to us under the Original Ramot Agreement. No assurance can be given that any of our pending or future patent applications will be approved, that the scope of any patent protection granted will exclude competitors or provide us with competitive advantages, that any of the patents that may be issued to us will be held valid if subsequently challenged, or that other parties will not claim rights to or ownership of our patents or other proprietary rights that we hold. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or products or design around any patents that have been or may be issued to us or any future licensors. Since patent applications in the United States and in Europe are not disclosed until applications are published, there can be no assurance that others did not first file applications for products covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others.

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

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

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

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

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

As a result of our reliance on consultants, we may not be able to protect the confidentiality of our technology, which, if disseminated, could negatively impact our plan of operations. We currently have relationships with two academic consultants who are not employed by us, and we may enter into additional relationships of such nature in the future. We have limited control over the activities of these consultants and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, in connection with every relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results of operations. To the extent that our scientific consultants develop inventions or processes independently that may be applicable to our proposed products, disputes may arise as to the ownership of the proprietary rights to such information, we may expend significant resources in such disputes and we may not win those disputes.

It is uncertain to what extent the government, private health insurers and third-party payers will approve coverage or provide reimbursement for the therapies and products to which our services relate. Availability for such reimbursement may be further limited by an increasing uninsured population and reductions in Medicare and Medicaid funding in the United States.

Our ability to successfully commercialize our human therapeutic products will depend significantly on our ability to obtain acceptable prices and the availability of reimbursement to the patient from third-party payers, such as government and private insurance plans. While we have not commenced discussions with any such parties, these third-party payers frequently require companies to provide predetermined discounts from list prices, and they are increasingly challenging the prices charged for pharmaceuticals and other medical products. Our human therapeutic products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us to sell our products on a competitive basis. Further, as cost containment pressures are increasing in the health care industry, government and private payers adopt strategies designed to limit the amount of reimbursement paid to health care providers. Such cost containment measures may include:

- Reducing reimbursement rates;
- Challenging the prices charged for medical products and services;
- Limiting services covered;
- Decreasing utilization of services;

- Negotiating prospective or discounted contract pricing;
 - Adopting capitation strategies; and
 - Seeking competitive bids.

Similarly, the trend toward managed health care and bundled pricing for health care services in the United States could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our therapies.

We may not be able to negotiate favorable reimbursement rates for our human therapeutic products. If we fail to obtain acceptable prices or an adequate level of reimbursement for our products, the sales of our products would be adversely affected or there may be no commercially viable market for our products.

Unintended consequences of recently adopted health reform legislation in the U.S. may adversely affect our business.

The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the U.S., comprehensive programs are under consideration that seek to, among other things, increase access to healthcare for the uninsured and control the escalation of healthcare expenditures within the economy. On March 23, 2010, health reform legislation was approved by Congress and has been signed into law. While we do not believe this legislation will have a direct impact on our business, the legislation has only recently been enacted and requires the adoption of implementing regulations, which may have unintended consequences or indirectly impact our business. For instance, the scope and implications of the recent amendments pursuant to the Fraud Enforcement and Recovery Act of 2009 have yet to be fully determined or adjudicated and as a result it is difficult to predict how future enforcement initiatives may impact our business. Also, in some instances our clients may be health insurers that will be subject to limitations on their administrative expenses and new federal review of “unreasonable” rate increases which could impact the prices they pay for our services. If the legislation causes such unintended consequences or indirect impact, it could have a material adverse effect on our business, financial condition and results of operations.

Ethical and other concerns surrounding the use of stem cell therapy may negatively impact the public perception of our stem cell services, thereby suppressing demand for our services.

Although our stem cell business pertains to adult stem cells only, and does not involve the more controversial use of embryonic stem cells, the use of adult human stem cells for therapy could give rise to similar ethical, legal and social issues as those associated with embryonic stem cells, which could adversely affect its acceptance by consumers and medical practitioners. Additionally, it is possible that our business could be negatively impacted by any stigma associated with the use of embryonic stem cells if the public fails to appreciate the distinction between adult and embryonic stem cells. Delays in achieving public acceptance may materially and adversely affect the results of our operations and profitability.

We are exposed to fluctuations in currency exchange rates.

A significant portion of our business, particularly our research and development, is conducted outside the United States. Therefore, we are exposed to currency exchange fluctuations in other currencies such as the New Israeli Shekels (“NIS”) and the Euro. Moreover, a portion of our expenses in Israel and Europe are paid in NIS and Euros, respectively, which subjects us to the risks of foreign currency fluctuations. Our primary expenses paid in NIS are employee salaries, fees for consultants and subcontractors and lease payments on our Israeli facilities.

The dollar cost of our operations in Israel will increase to the extent increases in the rate of inflation in Israel are not offset by a devaluation of the NIS in relation to the dollar, which would harm our results of operations.

Since a considerable portion of our expenses such as employees' salaries are linked to an extent to the rate of inflation in Israel, the dollar cost of our operations is influenced by the extent to which any increase in the rate of inflation in Israel is or is not offset by the devaluation of the NIS in relation to the dollar. As a result, we are exposed to the risk that the NIS, after adjustment for inflation in Israel, will appreciate in relation to the dollar. In that event, the dollar

cost of our operations in Israel will increase and our dollar-measured results of operations will be adversely affected. During the past few years inflation-adjusted NIS appreciated against the dollar, which raised the dollar cost of our Israeli operations. We cannot predict whether the NIS will appreciate against the dollar or vice versa in the future. Any increase in the rate of inflation in Israel, unless the increase is offset on a timely basis by a devaluation of the NIS in relation to the dollar, will increase labor and other costs, which will increase the dollar cost of our operations in Israel and harm our results of operations.

We may be subject to significant product liability claims and litigation which could adversely affect our future earnings and financial condition.

Our business exposes us to potential product liability risks inherent in the testing, processing and marketing of stem cell therapy products. Specifically, the conduct of clinical trials in humans involves the potential risk that the use of our stem cell therapy products will result in adverse effects. Such liability claims may be expensive to defend and result in large judgments against us. We currently maintain liability insurance for our clinical trials; however such liability insurance may not be adequate to fully cover any liabilities that arise from clinical trials of our stem cell therapy products. We also maintain errors and omissions, directors and officers, workers' compensation and other insurance appropriate to our business activities. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our own limited resources, which could have a material adverse effect on our financial condition, results of operations and business. Additionally, liability or alleged liability could harm our business by diverting the attention and resources of our management and damaging our reputation and that of our subsidiaries.

Political, economic and military instability in Israel may impede our ability to execute our plan of operations.

Our principal operations and the research and development facilities of the scientific team funded by us under the Original Ramot Agreement are located in Israel. Accordingly, political, economic and military conditions in Israel may affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Acts of random terrorism periodically occur which could affect our operations or personnel. Ongoing or revived hostilities or other factors related to Israel could harm our operations and research and development process and could impede our ability to execute our plan of operations.

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

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

Risks related to our common stock

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

Your percentage ownership will be diluted by future issuances of our securities. In order to meet our financing needs, we may issue additional significant amounts of our common stock and warrants to purchase shares of our common stock. The precise terms of any future financings will be determined by us and potential investors and such future

financings may also significantly dilute your percentage ownership in the Company.

ACCBT Corp. holds equity participation rights 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 Chief Executive Officer, Chief Financial Officer, and some of our directors are foreign citizens and do not reside in the U.S. It may be difficult for courts in the U.S. to obtain jurisdiction over our foreign assets or these persons and as a result, it may be difficult or impossible for you to enforce judgments rendered against us or our directors or executive officers in U.S. courts. Thus, should any situation arise in the future in which you have a cause of action against these persons or entities, you are at greater risk in investing in our Company rather than a domestic company because of greater potential difficulties in bringing lawsuits or, if successful, collecting judgments against these persons or entities as opposed to domestic persons or entities.

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

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

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

Delaware law could discourage a change in control, or an acquisition of us by a third party, even if the acquisition would be favorable to you, and thereby adversely affect existing stockholders.

The Delaware General Corporation Law contain provisions that may have the effect of making more difficult or delaying attempts by others to obtain control of our Company, even when these attempts may be in the best interests of stockholders. Delaware law imposes conditions on certain business combination transactions with “interested stockholders.” These provisions and others that could be adopted in the future could deter unsolicited takeovers or delay or prevent changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests.

We do not expect to pay dividends in the foreseeable future, and accordingly you must rely on stock appreciation for any return on your investment.

We have paid no cash dividends on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the continued development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Further, any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors, including contractual restrictions to which we may be subject, and will be at the discretion of our Board of Directors.

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

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

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains or incorporates forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are management's beliefs and assumptions. In addition, other written or oral statements that constitute forward-looking statements are based on current expectations, estimates and projections about the industry and markets in which we operate and statements may be made by or on our behalf. Words such as "should," "could," "may," "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," variations of such words and expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements.

We describe material risks, uncertainties and assumptions that could affect our business, including our financial condition and results of operations, under "Risk Factors" and may update our descriptions of such risks, uncertainties and assumptions in any prospectus supplement. We base our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecast by our forward-looking statements. Accordingly, you should be careful about relying on any forward-looking statements. Forward looking statements include, but are not limited to, statements about:

- Statements as to the anticipated timing of clinical studies and other business developments;
 - Statements as to the development of new products;
 - Our expectations regarding federal, state and foreign regulatory requirements;
 - Our expectations regarding grants from federal resources; and
- Statements regarding growth strategies, financial results, product development, competitive strengths, intellectual property rights, litigation, mergers and acquisitions, market acceptance or continued acceptance of our products, accounting estimates, financing activities and ongoing contractual obligations.

Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this prospectus, whether as a result of new information, future events, changes in assumptions, or otherwise.

EXCHANGE RATE INFORMATION

In this prospectus, references to “\$” are to U.S. dollars, and references to “NIS” are to New Israeli Shekels. The exchange rate between the NIS and the U.S. dollar used in this prospectus varies depending on the date and context of the information contained herein.

The following table sets forth for each period indicated: (1) the low and high exchange rates during such period; (2) the exchange rates in effect at the end of the period; and (3) the average exchange rates for such period, for one U.S. dollar, expressed in NIS, as quoted by the Bank of Israel. The average exchange rate is calculated on the last business day of each month for the applicable period.

	Year ended December 31,			
	2008	2009	2010	2011
Low	3.230	3.690	3.549	3.363
High	4.022	4.256	3.894	3.821
Period End	3.802	3.775	3.549	3.821
Average	3.588	3.933	3.733	3.578

As of February 2, 2012, the daily representative rate of exchange between the NIS and the U.S. dollar as published by the Bank of Israel was NIS 3.727 to \$1.00.

USE OF PROCEEDS

We estimate that we will receive up to \$[] in net proceeds from the sale of the securities in this offering, based on a price of \$[] per unit and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will use the proceeds from the sale of the securities for initiation of clinical trials in the United States, research and development, working capital needs, capital expenditures and other general corporate purposes.

Pending any ultimate use of any portion of the proceeds from this offering, we intend to invest the proceeds in a variety of capital preservation investments, including short-term, interest-bearing instruments such as United States government securities and municipal bonds.

If a warrant holder exercises his warrants, we will also receive proceeds from the exercise of warrants. We cannot predict when, or if, the warrants will be exercised. It is possible that the warrants may expire and may never be exercised.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to finance the growth and development of our business. Therefore, we do not anticipate that we will declare or pay any cash dividends on our common stock in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements, restrictions under any existing indebtedness and other factors the Board of Directors deems relevant.

DILUTION

Dilution represents the difference between the offering price and the net tangible book value per share immediately after completion of this offering. Net tangible book value is the amount that results from subtracting total liabilities and intangible assets from total assets. Dilution of the value of the shares you purchase is a result of the lower book value of the shares held by our existing stockholders.

At _____, 2012, the net tangible book value of our shares of common stock was \$[_____] or approximately \$[_____] per share based upon 126,444,309 shares outstanding. After giving effect to our sale of [_____] shares of common stock at a public offering price of \$[_____] per share, and after deducting underwriting discounts and commissions and estimated offering expenses, our pro forma net tangible book value as of _____, 2012 would have been \$[_____] or \$[_____] per share. This represents an immediate increase in net tangible book value of \$[_____] per share to existing stockholders and an immediate dilution in net tangible book value of \$[_____] per share to purchasers of securities in this offering, as illustrated in the following table:

Assumed initial public offering price per share	\$
Pro forma net tangible book value per share as of _____, 2012	\$
Increase per share attributable to new investors	
Pro forma as adjusted net tangible book value per share after this offering	
Dilution per share to new investors in this offering	\$

The above discussion does not include the following:

4,380,769 shares of common stock reserved for future issuance under our equity incentive plans. As of December 31, 2011, there were 4,938,821 options outstanding under such plans with a weighted average exercise price of \$0.16840 per share;

60,166,366 shares of common stock issuable upon exercise of outstanding warrants as of December 31, 2011, with exercise prices ranging from \$0.00005 per share to \$2.50 per share;

[_____] shares of common stock issuable upon exercise of warrants at an exercise price of \$[_____] per share sold as part of this offering.

PLAN OF DISTRIBUTION

As of the date of this prospectus, we have not entered into any arrangements with any underwriter, broker-dealer or selling agent for the sale of the securities. We intend to engage one or more underwriters, broker-dealers or selling agents to sell the securities. We intend to compensate underwriters, broker-dealers or selling agents that sell securities in this offering with a cash commission to be agreed upon between us and any underwriters which we shall disclose prior to effectiveness. The offering will be presented by us primarily through mail, telephone, electronic transmission and direct meetings in those states in which we have registered the securities.

DESCRIPTION OF SECURITIES

The descriptions of the securities contained in this prospectus summarizes all the material terms and provisions of the various types of securities that we may offer.

Common stock

We are authorized to issue 800,000,000 shares of common stock, \$0.00005 par value. As of December 31, 2011, there were 126,444,309 shares of our common stock issued and outstanding, held by approximately 97 record holders. In addition, as of December 31, 2011, there were warrants and options outstanding to purchase approximately 65,105,187 shares of our common stock.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by stockholders, including the election of directors. The holders of common stock do not have any cumulative voting, conversion, redemption or preemptive rights. The holders of common stock are entitled to receive ratably dividends as may be declared from time to time by our Board of Directors out of funds legally available for that purpose. In the event of our liquidation, dissolution, or winding up, the holders of common stock are entitled to share ratably in our assets available for distribution to such holders. All issued and outstanding shares of common stock are fully paid and non-assessable.

Anti-Takeover Provisions of Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a “business combination,” except under certain circumstances, with an “interested stockholder” for a period of three years following the date such person became an “interested stockholder” unless:

- before such person became an interested stockholder, the board of directors of the corporation approved either the business combination or the transaction that resulted in the interested stockholder becoming an interested stockholder;
- upon the consummation of the transaction that resulted in the interested stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares held by directors who also are officers of the corporation and shares held by employee stock plans; or
- at or following the time such person became an interested stockholder, the business combination is approved by the board of directors of the corporation and authorized at a meeting of stockholders by the affirmative vote of the holders of 66 2/3% of the outstanding voting stock of the corporation which is not owned by the interested stockholder.

The term “interested stockholder” generally is defined as a person who, together with affiliates and associates, owns, or, within the three years prior to the determination of interested stockholder status, owned, 15% or more of a corporation’s outstanding voting stock. The term “business combination” includes mergers, asset or stock sales and other similar transactions resulting in a financial benefit to an interested stockholder. Section 203 makes it more difficult for an “interested stockholder” to effect various business combinations with a corporation for a three-year period. The existence of this provision would be expected to have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Warrants

In connection with this offering, we will issue [] warrant for each share of common stock purchased or issued. Each warrant entitles the holder to purchase one share of common stock at an exercise price of \$[] per share. After the expiration of the [] exercise period, warrant holders will have no further rights to exercise such warrants.

The warrants may be exercised only for full shares of common stock. We will not issue fractional shares of common stock or cash in lieu of fractional shares of common stock. Warrant holders do not have any voting or other rights as a stockholder of our Company. The exercise price and the number of shares of common stock purchasable upon the exercise of each warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company LLC.

OTC Bulletin Board Listing

Our common stock is currently traded on the OTCQB operated by the OTC Markets Group (“OTCQB”) under the trading symbol “BCLI.”

OUR BUSINESS

Company Overview

We are a biotechnology company developing innovative stem cell therapeutic products based on technologies enabling the in-vitro differentiation of bone marrow stem cells into neural-like cells. We aim to become a leader in adult stem cell transplantation for neurodegenerative diseases. Our technology entails exploiting the patient's own bone marrow stem cells to generate glial-like cells that may provide an effective treatment for ALS, PD, MS and Spinal Cord Injury.

Our core technology was developed in collaboration with prominent neurologist, Prof. Eldad Melamed, former head of Neurology of the Rabin Medical Center and member of the Scientific Committee of the Michael J. Fox Foundation for Parkinson's Research, and expert Cell biologist Prof. Daniel Offen, of the Felsenstein Medical Research Center of Tel Aviv University.

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

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

Our Israeli Subsidiary holds exclusive worldwide rights to commercialize the technology, through a licensing agreement with Ramot, the technology transfer company of Tel Aviv University, Israel.

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

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

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

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

Our efforts are directed at:

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

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

- Submitting an IND to the FDA.

Our Approach

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

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

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

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

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

The therapeutic modality will comprise the following:

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

History

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

Recent Developments

In February 2011, the FDA's Office of Orphan Products Developments granted Orphan Drug designation for the Company's NurOwn™ autologous adult stem cell product candidate for the treatment of ALS. In July 2011, we entered into a Memorandum of Understanding with Massachusetts General Hospital and the University of Massachusetts Medical School in anticipation of applying for FDA approval to begin ALS human clinical trials in the United States.

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

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

On February 17, 2010, our wholly owned Israeli subsidiary entered into a series of agreements with Hadasit Medical Research Services and Development Ltd., a subsidiary of the Hadassah Medical Organization ("Hadassah") and Professor Dimitrios Karousis (the "Clinical Trial Agreement"). Under the Clinical Trial Agreement, Hadassah and our personnel will conduct a clinical trial to evaluate the safety and tolerability of our treatment using mesenchymal bone marrow stem cells secreting neurotrophic factors (MSC-NTF) in patients with ALS, in accordance with a protocol developed jointly by us and Hadassah. The trial is expected to include between 24 and 26 patients.

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

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

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

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

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

Stem Cell Therapy

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

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

Cell therapy using adult stem cells does not suffer from the same concerns. Bone marrow is the tissue where differentiation of stem cells into blood cells (haematopoiesis) occurs. In addition, it harbors stem cells capable of differentiation into mesenchymal (muscle, bone, fat and other) tissues. Such mesenchymal stem cells have also been shown capable of differentiating into nerve, skin and other cells. In fact, bone marrow transplants have been safely and successfully performed for many years, primarily for treating leukemia, immune deficiency diseases, severe blood cell diseases, lymphoma and multiple myeloma. Moreover, bone marrow may be obtained through a simple procedure of aspiration, from the patient himself, enabling autologous cell therapy, thus obviating the need for donor matching, circumventing immune rejection and other immunological mismatch risks, as well as avoiding the need for immunosuppressive therapy. We believe bone marrow, in particular autologous bone marrow, capable of in-vitro growth and multipotential differentiation, presents a preferable source of therapeutic stem cells.

Neurodegenerative Diseases

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

Amyotrophic Lateral Sclerosis (ALS)

ALS, often referred to as “Lou Gehrig's disease,” is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. The progressive degeneration of the motor neurons in ALS eventually leads to death. As

motor neurons degenerate, they can no longer send impulses to the muscle fibers that normally result in muscle movement. With voluntary muscle action progressively affected, patients in the later stages of the disease may become completely paralyzed. However, in most cases, mental faculties are not affected.

Approximately 6,000 people in the U.S. are diagnosed with ALS each year. It is estimated that as many as 30,000 Americans and 100,000 people across the western world may have the disease at any given time. Consequently, the total estimated cost of treating ALS patients is approximately \$1.25 billion per year in the U.S. and \$3 billion per year in the western world.

Description

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

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

Current Treatments

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

- Riluzole - the only medication approved by the FDA to slow the progress of ALS. While it does not reverse ALS, Riluzole has been shown to reduce nerve damage. Riluzole may extend the time before a patient needs a ventilator (a machine to assist breathing) and may prolong the patient's life by several months;
- Baclofen or Diazepam - these medications may be used to control muscle spasms, stiffness or tightening (spasticity) that interfere with daily activities; and
- Trihexyphenidyl or Amitriptyline - these medications may help patients who have excess saliva or secretions, and emotional changes.

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

Parkinson's Disease (PD)

Background

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

Over four million people suffer from PD in the western world, of whom about 1.5 million are in the United States. In over 85% of cases, PD occurs in people over the age of 65. Prevalence of PD is increasing in line with the general aging of the population. We believe the markets for pharmaceutical treatments for PD have a combined value of approximately \$4 billion per year. However, these costs are dwarfed when compared to the total economic burden of the disease, which has been estimated by the National Institute of Neurological Disease ("NINDS") to exceed \$26 billion annually in the U.S. alone, including costs of medical treatment, caring, facilities and other services, as well as loss of productivity of both patients and caregivers.

Description

The classic symptoms of PD are shaking (tremor), stiff muscles (rigidity) and slow movement (Bradykinesia). A person with fully developed PD may also have a stooped posture, a blank stare or fixed facial expression, speech problems and difficulties with balance or walking. Although highly debilitating, the disease is not life threatening and an average patient's life span is approximately 15 years.

Current Treatments

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

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

Prescription drugs to treat PD currently generate sales of over \$1 billion and the market is expected to grow to approximately \$4 billion by 2011, driven by the increase in size of the elderly population and the introduction of new PD therapies that carry a higher price tag than the generic levodopa.

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

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

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

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

Company Business Strategy

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

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

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

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

Company Business Model

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

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

Our approach will be optimized by working with a major partner. We believe there is a substantial market opportunity and cooperation with strategic partners would facilitate a more rapid and broad market penetration, by leveraging the partner's market credibility and the proven ability to provide service and support across a large and geographically spread target market.

Potential strategic partners include:

- Private Medical Center Chains - interested in expanding their service offerings and being associated with an innovative technology, thereby enhancing their professional standing and revenue potential; and
- Major Pharmaceutical and/or Medical Device Companies - seeking new product opportunities and/or wishing to maintain interest in the market, which may shift away from drugs towards surgical treatment.

We cannot guarantee that we will succeed in finding strategic partners that are willing to enter into collaborations for our potential products at the appropriate stage of development, on economic terms that are attractive to us or at all. We have entered into a Memorandum of Understanding with the Massachusetts General Hospital and the University of Massachusetts Medical School in anticipation of applying for FDA approval to begin ALS human clinical trials in the United States.

Our business model calls for significant investments in research and development. Our research and development expenditures (i) in 2010 (before participation by the Israeli Office of Chief Scientist) were \$1,385,000, which included \$325,000 in stock-based compensation and (ii) 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.

Intellectual Property

We have filed the following patent applications:

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

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

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

WO2009/144718 MESENCHYMAL STEM CELLS FOR THE TREATMENT OF CNS DISEASES
National phase filings in the U.S., Europe and Israel. Substantive examination is ongoing in Europe.

The patent applications, as well as relevant know-how and research results are licensed from Ramot. We intend to work with Ramot to protect and enhance our mutual intellectual property rights by filing continuations and new patent applications on any improvements and any new discoveries arising in the course of research and development.

Research and License Agreement with Ramot

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

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

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

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

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

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

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

Government Regulations and Supervision

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

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

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

Regulatory Process in the United States

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

the FDA.

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

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

Although there can be no assurance that the FDA will not choose to change its regulations, current regulation proposes that cell products which are manipulated, allogeneic, or as in our case, autologous but intended for a different purpose than the natural source cells (NurOwn™ are bone marrow derived and are intended for transplantation into the spinal cord, brain or into the muscles) must be regulated through a "tiered approach intended to regulate human cellular and tissue based products only to the extent necessary to protect public health". Thus the FDA requires: (i) preclinical laboratory and animal testing; (ii) submission of an IND exemption which must be in effect prior to the initiation of human clinical studies; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to the FDA of a BLA; and (v) review and approval of the BLA as well as inspections of the manufacturing facility for GMP compliance, prior to commercial marketing of the product.

Generally, in seeking an approval from the FDA for sale of a new medical product, an applicant must submit proof of safety and efficacy. Such proof entails extensive pre-clinical studies in the lab and in animals and, if approved by the agency, in humans. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive and may take several years to complete. There can be no assurance that the FDA will act favorably or in a timely manner in reviewing submitted applications, and an applicant may encounter significant difficulties or costs in its efforts to obtain FDA approvals. This, in turn, could delay or preclude the applicant from marketing any products it may develop. The FDA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. For patented technologies, delays imposed by the governmental approval process may materially reduce the period during which an applicant will have the exclusive right to exploit such technologies.

In order to conduct clinical trials of the proposed product, the manufacturer or distributor of the product will have to file an IND submission with the FDA for its approval to commence human clinical trials. The submission must be supported by data, typically including the results of pre-clinical and laboratory testing. Following submission of the IND, the FDA has 30 days to review the application and raise safety and other clinical trial issues. If an applicant is not notified of objections within that period, clinical trials may be initiated at a specified number of investigational sites with the number of patients, as applied. Clinical trials which are to be conducted in accordance with Good Clinical Practice ("GCP") guidelines are typically conducted in three sequential phases. Phase I represents the initial administration of the drug or biologic to a small group of humans, either healthy volunteers or patients, to test for safety and other relevant factors. Phase II involves studies in a small number of patients to explore the efficacy of the product, to ascertain dose tolerance and the optimal dose range and to gather additional data relating to safety and potential adverse affects. Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, multi-center Phase III studies are initiated to establish safety and efficacy in an expanded patient population and multiple clinical study sites. The FDA reviews both the clinical plans and the results of the trials and may request an applicant to discontinue the trials at any time if there are significant safety issues.

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

Compliance with Environmental, Health and Safety Laws

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

Competition

We face significant competition in our efforts to develop our products and services, including: (i) cell therapies competing with NurOwn™ and its applications and (ii) other treatments or procedures to cure or slow the effects of ALS, PD and other neurodegenerative diseases. There are a number of companies developing cell therapies for ALS, among them are companies that are involved in the controversial fetal cell transplant or ESC-derived cell therapy, as well as companies developing adult stem cells. Other companies are developing traditional chemical compounds, new biological drugs, cloned human proteins and other treatments, which are likely to impact the markets, which we intend to target. We believe that as an autologous bone marrow derived product that has shown proof of concept in-vitro and in animal studies, NurOwn™ has a first mover advantage in the adult stem cell space and such space has competitive advantages over the fetal cell or ESC-derived cell space as it has a long safety record and does not have the same ethical limitations.

Employees

We currently have 11 scientific and administrative employees, 8 of whom are full-time. None of our employees is represented by a labor union and we believe that we have good relationships with our employees.

PROPERTIES

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

On December 1, 2004, our Israeli subsidiary, Brainstorm Cell Therapeutics Ltd. entered into a lease agreement for the lease of premises in 12 Basel Street, Petach Tikva, Israel, which include approximately 600 square meters of office and laboratory space. The original term of the lease was 36 months, 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 32,200 per month.

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

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

We believe that the current office space is adequate to meet our needs.

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 the Company improperly terminated its contract with CSC. The complaint seeks, among other things, the following relief: (i) 400,000 shares of the common stock of the Company and (ii) warrants to purchase 250,000 shares of the common stock of the Company at an exercise price of \$0.30 per share. Further, the complaint alleges that CSC performed its obligations under the contract and has suffered compensatory damages in an amount up to approximately \$672,500. CSC also seeks costs and attorneys’ fees. On June 5, 2008, the Company filed an answer with the Court. The Company believes that it has

substantial defenses to the claims made by CSC and has vigorously defended this action over this period of time. 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.

MARKET FOR OUR COMMON EQUITY

Market Information

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

Quarter Ended	High	Low
December 30, 2011	\$ 0.40	\$ 0.20
September 30, 2011	\$ 0.56	\$ 0.27
June 30, 2011	\$ 0.60	\$ 0.25
March 31, 2011	\$ 0.43	\$ 0.18
December 31, 2010	\$ 0.30	\$ 0.18
September 30, 2010	\$ 0.26	\$ 0.16
June 30, 2010	\$ 0.34	\$ 0.19
March 31, 2010	\$ 0.47	\$ 0.21

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

On February 2, 2012, the closing bid price of our common stock as reported by the OTCQB was \$0.23 per share.