

BioRestorative Therapies, Inc.  
Form 10-K  
April 16, 2012

**United States Securities and Exchange Commission**

**Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

**x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2011**

**..TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT  
OF 1934  
FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_**

Commission File Number **0-54402**

**BIORESTORATIVE THERAPIES, INC.**

(Exact name of registrant as specified in its charter)

Nevada 91-1835664  
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

555 Heritage Drive, Jupiter, Florida 33458  
(Address of principal executive offices) (Zip Code)

**(561) 904-6070**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class Name of each exchange on which registered

None                      Not applicable

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, par value \$0.001 per share**

(Title of Class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated  (Do not check if a smaller reporting company)

Smaller reporting company

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

As of June 30, 2011, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$9,563,385 based on the closing sale price as reported on the OTC Markets. As of April 10, 2012, there were 647,991,911 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None

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## **PART I**

### **Forward-Looking Statements**

This Annual Report contains forward-looking statements as that term is defined in the federal securities laws. The events described in forward-looking statements contained in this Annual Report may not occur. Generally these statements relate to business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions to be made by us, or projections involving anticipated revenues, earnings or other aspects of our operating results. The words “may,” “will,” “expect,” “believe,” “anticipate,” “project,” “plan,” “intend,” “estimate,” and “continue,” and their opposites and similar expressions are intended to identify forward-looking statements. We caution you that these statements are not guarantees of future performance or events and are subject to a number of uncertainties, risks and other influences, many of which are beyond our control, that may influence the accuracy of the statements and the projections upon which the statements are based. Factors which may affect our results include, but are not limited to, the risks and uncertainties discussed in Item 7 of this Annual Report under “Factors That May Affect Future Results and Financial Condition”.

Any one or more of these uncertainties, risks and other influences could materially affect our results of operations and whether forward-looking statements made by us ultimately prove to be accurate. Our actual results, performance and achievements could differ materially from those expressed or implied in these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether from new information, future events or otherwise.

**ITEM 1.**

**BUSINESS.**

**(a)**

**Business Development**

**General**

As used in this Annual Report on Form 10-K (the “Annual Report”), references to the “Company”, “we”, “us”, or “our” refer to BioRestorative Therapies, Inc. and its subsidiaries.

We are a development stage enterprise. Our primary activities have been the development of our business plan, negotiating strategic alliances and other agreements, and raising capital. We have not generated any revenues from our operations.

We were incorporated in Nevada on June 13, 1997 under the name “Columbia River Resources Inc.” We changed our name to “Traxxec Inc.” on August 11, 2008 and to “Stem Cell Assurance, Inc.” on June 29, 2009. On August 15, 2011, we changed our name to “BioRestorative Therapies, Inc.”

During the year ended December 31, 2011, we raised an aggregate of \$2,962,500 in debt financing, including \$2,050,000 through Stem Cell Cayman Ltd., our Cayman Islands subsidiary. As of December 31, 2011, our outstanding debt of \$3,190,000, together with interest at rates ranging between 10% and 15% per annum, was due between November 2011 and November 2012. Subsequent to December 31, 2011 and through April 10, 2012, we have received aggregate debt and equity financing of \$1,600,500 and \$650,000, respectively, the due date for the repayment of \$1,610,000 of debt has been extended, \$175,000 of debt has been converted to equity and we have repaid \$50,000 of debt.

See Item 7 (“Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources – Availability of Additional Funds”).

**(b)**

**Business**

**Overview**

Every human being has stem cells in his or her body. These cells exist from the early stages of human development until the end of a person's life. Throughout our lives, our body continues to produce stem cells that regenerate to produce differentiated cells that make up various aspects of the body such as skin, blood, muscle and nerves. These are generally referred to as adult stem cells (non-embryonic). These cells are important for the purpose of medical therapies aiming to replace lost or damaged cells or tissues or to otherwise treat disorders.

Our goal is to become a medical center of excellence using cell and tissue protocols, primarily involving a patient's own (autologous) adult stem cells, allowing patients to undergo cellular-based treatments. As more and more cellular-based therapies become standard of care, we intend to focus on the unity of medical and scientific explanations for future clinical procedures and outcomes and the provision of adult stem cells for future personal medical and aesthetic applications. Among the initiatives that we are currently pursuing is our ThermoStem™ Program that would involve the use of brown fat in connection with the cell-based treatment of obesity, weight loss, diabetes, hypertension, other metabolic disorders and cardiac deficiencies. We have also obtained a license which permits us to use technology for adult stem cell treatment of disc and spine conditions, including bulging and herniated discs. The technology is an advanced stem cell injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the legs and feet. See "Brown Adipose (Fat) Program" and "Disc/Spine Program" below.



We also operate a wholly-owned subsidiary, Stem Pearls, LLC, which offers facial creams and other skin care products with certain ingredients that may include plant stem cells and/or other plant derived stem cell optimization or regenerative compounds. See “Stem Pearls®” below.

We currently are seeking to develop an infrastructure to establish a laboratory for the possible development of cellular-based treatment protocols, stem cell-related intellectual property (“IP”) and research applications. See “Laboratory” below.

We are a development stage enterprise. Our primary activities in the stem cell area have been the development of our business plan, negotiating strategic alliances and other agreements, and raising capital. We have not generated any revenues from our operations. The implementation of our business plan, as discussed below, will require the receipt of sufficient equity and/or debt financing to purchase necessary equipment, technology and materials, retire our outstanding debt (see Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources – Availability of Additional Funds”), establish our laboratory, and otherwise fund our research and development and other operations. We intend to seek such financing from current shareholders and debtholders as well as from other accredited investors. We anticipate that we will require an aggregate of between approximately \$20,000,000 and \$40,000,000 in funding to repay our outstanding debt (\$3,190,000 as of December 31, 2011, excluding debt discount) (assuming that no debt is converted into equity) and implement our business plan as further discussed in this Item 1 (assuming the receipt of no revenues from operations). In the event we do not obtain the required aggregate amount of financing or revenues, we intend to use funds received in the following order of priority:

Program	Anticipated Amount of Required Funding	Purpose	Anticipated Timeframe
ThermoStem™ (see “Brown Adipose (Fat) Program” below)	\$1,000,000	Development of data and know-how with regard to the extraction of brown fat cells, the modification of cellular culturing protocols and the undertaking of preclinical studies.	Second quarter of 2012 through fourth quarter of 2012
Laboratory (see “Laboratory” below)	\$500,000	Commencement of laboratory operations, including purchase of necessary equipment	Third quarter of 2012
Stem Pearls® (see “Stem Pearls®” below)	\$100,000	Marketing efforts	Third quarter of 2012
Stem Cell Treatments (see “Disc/Spine Program” below)	\$100,000	Development of reproducible cell-based culture system	Third quarter of 2012
Stem Cell Treatments (see “Disc/Spine Program” below)	\$1,000,000	Pre-IND/IDE (investigational new drug/investigational device exemption) study with respect to development of treatment protocol	Third quarter of 2012 through first quarter of 2013
Stem Cell Treatments (see “Disc/Spine Program” below)	\$5,000,000 - \$20,000,000	Pre-IND/IDE meeting with FDA, filing of IND/IDE and commencement of Phase I clinical trials	First quarter of 2013 through third quarter of 2013
ThermoStem (see “Brown Adipose (Fat) Program” below)	\$5,000,000 - \$10,000,000	Pre-IND/IDE meeting with FDA, filing of IND/IDE and commencement of Phase I clinical trials	Second quarter of 2013 through first quarter of 2015

No assurance can be given that the anticipated amounts of required funding are correct or that we will be able to accomplish the above goals within the timeframes set forth in the above table. We will also require a substantial amount of additional funding to further implement our business plan beyond the Phase I clinical trials and other efforts discussed above. No assurance can be given that we will be able to obtain any required financing on commercially reasonable terms or otherwise. We may also seek to have our debtholders convert all or a portion of their debt into equity. No assurance can be given that we will be able to convert such debt into equity on commercially reasonable terms or otherwise. If we are unable to obtain adequate funding, we may be required to significantly curtail or discontinue our proposed operations. See Item 7 (“Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results and Financial Condition - We will need to obtain additional financing to satisfy debt obligations and continue our operations.”) on page 33.



## **Strategy**

We are concentrating our initial efforts with respect to an initiative related to the use of brown adipose (fat) for therapeutic and aesthetic purposes. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of metabolism, thus potentially being involved in caloric regulation. We intend to initiate research activities in this area in connection with the treatment of obesity, weight loss, diabetes, hypertension, other metabolic disorders and cardiac deficiencies. We have labeled this initiative our ThermoStem™ Program. See “Brown Adipose (Fat) Program” below.

We will also be concentrating on an initiative for the development of a stem cell delivery system designed to deliver cells and other potential therapeutic material to the spine and discs, as well as the development of appropriate stem cells to be used for transplantation into a disc. We intend to advance the design of the stem cell delivery device and enhance the therapeutic protocols in preparation for clinical trials related to the treatment of bugling and herniated discs and degenerative disc disease. See “Disc/Spine Program” below.

In connection with the technology license discussed in “Disc/Spine Program” below, we intend to establish stem cell therapy facilities, or sublicense the technology to third parties who would establish stem cell therapy facilities, that would offer cellular-based treatment programs with regard to disc and spine conditions. As our operations grow, we plan to extend our services to include cellular therapy for the treatment of other diseases, injuries and disorders. We expect that any such adult stem cell therapy facilities will be established initially outside the United States. Subject to our compliance with all domestic regulatory restrictions, as discussed in “Government Regulation – U.S. Government Regulation” below, and in the event that demand for stem cell therapies increases, we intend to establish additional stem cell therapy facilities within the United States as well.

We also offer facial creams and other skin care products with certain ingredients that may include plant stem cells and/or other plant derived stem cell optimization or regenerative compounds. See “Stem Pearl®” below.

We intend to develop a laboratory capable of performing cellular characterization and culturing and therapeutic outcomes analysis with the goal of producing a clinically-approved adult stem cell product and stem cell-related IP.

## **Treatment**

Regenerative cell therapy relies on replacing diseased, damaged or dysfunctional cells with healthy, functioning ones or repairing damaged or diseased tissue. A great range of cells can serve in cell therapy, including cells found in

peripheral and umbilical cord blood, bone marrow and adipose (fat) tissue. Physicians have been using adult stem cells from bone marrow to treat various blood cancers for over 40 years. Recently, the use of stem cells has begun to be used to treat various other diseases. We intend to use and develop cell and tissue regenerative therapy protocols, primarily involving a patient's own (autologous) adult stem cells (non-embryonic) to allow patients to undergo cellular-based treatments.

We intend to concentrate initially on therapeutic areas where risk to the patient is low, recovery is relatively easy, and where (i) results can be demonstrated through sufficient clinical data; (ii) patients and referring doctors will be comfortable with the procedure; and (iii) recovery, monitoring, patient follow-up and data collection/analysis is far less complicated than more invasive protocols. We believe that there will be readily identifiable groups of patients who will benefit from these procedures.

Accordingly, we plan to focus our initial therapy efforts in offering cellular-based treatment programs in selective areas of medicine where the treatment protocol is minimally invasive. Such areas may include the treatment of the disc and spine and metabolic-related disorders, as well as for aesthetic purposes. We anticipate that substantially all of our procedures will be private pay (meaning that they will not be subject to reimbursement by governmental and other third party payers).

Due to current domestic regulatory limitations, in all likelihood, any treatment centers that we establish will initially need to be established outside the United States. We are investigating the Caribbean region for such purposes; however, we have no definitive plans or arrangements to open a treatment facility in the Caribbean region or elsewhere. Alternatively, we may seek to license our technology to third parties for use at their treatment facilities. In the event we determine to establish such a center, we anticipate that it would require between \$1,000,000 and \$2,000,000 in funding for such purposes and that it would take approximately six to twelve months to become operational. As indicated above, we have no definitive plans or arrangements in this regard and it is unlikely that we will establish a treatment facility within the next twelve months. Subject to our compliance with all domestic regulatory restrictions, as discussed in “Government Regulation – U.S. Government Regulation” below, and in the event that demand for stem cell therapies increases, we intend to establish treatment facilities in the United States.

Following our initial efforts in this regard, we intend to extend our services to cellular therapy for the treatment of diseases and other injuries, that may include heart disease, diabetes, wounds, burns and autoimmune diseases (including rheumatoid arthritis, Type 1 diabetes, Crohn’s Disease and multiple sclerosis). The costs of entry into these market places will be higher, in that most procedures would need to be performed in a hospital or hospital-like setting to better assure the well-being of the patient and success of the outcome.

We intend that the majority of our procedures will involve adult stem cells harvested from a patient’s own (autologous) cells so that there is no chance of rejection or disease being spread from donor to patient. We intend to focus on developing personalized, patient-specific treatment programs that provide for additional or follow-on therapies, patient outcome monitoring, and the accumulation/analysis of critical medical data. We also intend to carefully monitor patient response and satisfaction.

### **Brown Adipose (Fat) Program**

Brown fat is one of two types of known adipose (fat) tissue found in the human body and is involved in homeostasis by creating a metabolic tissue capable of producing heat. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of metabolism, thus potentially being involved in caloric regulation.

In June 2011, we launched the initial research phase of what we believe will develop into a technology that involves the use of brown fat in a cell-based therapeutic/aesthetic program referred to as the ThermoStem™ Program. The ThermoStem™ Program will focus on treatments for obesity, weight loss, diabetes, hypertension, other metabolic disorders and cardiac deficiencies and will involve the study of stem cells, several genes, proteins and/or mechanisms that are related to these diseases and disorders.

We intend to use autologous cells (i.e., stem cells isolated from individual patients) that may be differentiated into progenitor or fully differentiated brown adipocytes, or a related cell type, that can be used therapeutically or aesthetically in patients. In addition to the brown fat stem cell platform, as the cellular program advances, we will seek to determine whether data from the program can lead to the use of allogeneic cells (i.e., stem cells from a genetically similar but not identical donor) or can be used in the development of a small molecule drug.

Our ThermoStem™ Program is in the initial research stage and, to date, we have not developed a clinical application or product. In August 2011, we entered into a Tangible Property License Agreement with the University of Utah Research Foundation and the University of Utah. Pursuant to the agreement, which has a two year term, we have been granted a non-exclusive license to use discarded adipose (fat) tissue samples for internal research purposes. Our initial research efforts in this regard will relate to the identification of tissue as brown fat. We anticipate that such initial efforts will be completed by the second quarter of 2012. Following such initial efforts, we intend to develop a brown fat cell line that can be used in preclinical studies. We expect that such development effort will be completed by the fourth quarter of 2012. We then intend to undertake preclinical studies in order to determine whether our proposed treatment protocol is safe. Such studies are expected to begin by the fourth quarter of 2012. Following the completion of such studies, if required, we intend to file an investigational new drug (“IND”) application with the U.S. Food and Drug Administration (the “FDA”) and initiate Phase I clinical trials. See “Government Regulation” below and Item 7 (“Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results and Financial Condition – We operate in a highly regulated environment and may be unable to comply with applicable federal, state, local, and international requirements. Failure to comply with applicable government regulation may result in a loss of licensure, registration, and approval or other government enforcement actions.”) on page 37. The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance. We expect that clinical trials will commence by the first quarter of 2014.

We anticipate that much of our development work in this area will take place at the University of Utah research laboratory; alternatively, we may seek to either use other outside contractors or develop our laboratory for such purposes. See “Laboratory” below.

We anticipate that we will require approximately \$1,000,000 in funding in order to develop data and know-how with regard to the extraction of brown fat stem cells, the modification of cellular culturing protocols and to undertake preclinical studies. We expect that we will require between \$5,000,000 and \$20,000,000 in funding in connection with our intended Phase I clinical studies.





## **Disc/Spine Program**

On April 6, 2012, a license agreement between Regenerative Sciences, LLC (“Regenerative”) and us became effective. Pursuant to the license agreement, we have obtained, among other things, a worldwide, exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain medical device for the administration of specific cells and/or cell products to the disc and/or spine (and other parts of the body) and a worldwide (excluding Asia and Argentina), exclusive, royalty-bearing license to utilize or sublicense a certain method for culturing cells for use in treating, among other things, disc and spine conditions, including bulging and herniated discs. The technology being licensed is an advanced stem cell injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the legs and feet.

The license agreement provides for the requirement that we achieve certain milestones or pay certain minimum royalty amounts in order to maintain the exclusive nature of the licenses. The license agreement also provides for a royalty-bearing sublicense of the technology to Regenerative for use for certain purposes. Further, the license agreement provides that Regenerative will furnish certain training, assistance and consultation services with regard to the licensed technology. Pursuant to the license agreement, on the effective date, we paid to Regenerative a net license fee of \$990,000 and issued to Regenerative a five year warrant for the purchase of 50,000,000 shares of our common stock.

We intend to develop a reproducible cell-based culture system in either a laboratory that we develop or an outside laboratory. We expect that we will require approximately \$100,000 in funding for such purpose and that such development efforts will be completed by the third quarter of 2012. We then intend to initiate a pre-IND study with respect to the development of a treatment protocol. We expect that such study will be completed by the first quarter of 2013 at an anticipated cost of approximately \$1,000,000. Following such study, we intend to file an IND with the FDA with respect to our proposed treatment protocol and initiate Phase 1 clinical trials. We expect that our IND will be filed with the FDA by the first quarter of 2013, our clinical trials will begin by the third quarter of 2013 and we will require between \$5,000,000 and \$20,000,000 in funding for such purposes. See “Government Regulation” below and Item 7 (“Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results and Financial Condition – We operate in a highly regulated environment and may be unable to comply with applicable federal, state, local, and international requirements. Failure to comply with applicable government regulation may result in a loss of licensure, registration, and approval or other government enforcement actions.”) on page 37. The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance.

In 2010, the FDA brought an action to permanently enjoin Regenerative from using its Regenexx™ procedure to process mesenchymal stem cells (“MSCs”) for the treatment of various orthopedic conditions. The lawsuit relates to a procedure utilized by Regenerative whereby a patient’s own MSC cells are extracted and isolated from the patient’s bone marrow, processed at a laboratory on site for two to three weeks to undergo expansion, and then returned to the same patient to treat a medical condition. The FDA has asserted that Regenerative’s stem cell procedure is subject to FDA jurisdiction and regulation as an unapproved drug and/or biologic. Regenerative takes the position that the Regenexx™ procedure is the practice of medicine and thereby is outside of the FDA’s jurisdiction. It also contends that the manipulation of the stem cells occurs in the normal course of medical practice which is regulated by Colorado, the state in which Regenerative is located. The FDA contends that it is not impinging on Regenerative’s ability to practice medicine; instead, it considers the product being reinjected into the patient to be a cultured cell product subject to the FDA’s regulations governing the use of human cells, tissues, and cellular and tissue-based products (“HCT/Ps”). According to the FDA’s position, the Regenexx™ procedure involves growth factors, reagents and drug products that cross state lines thereby placing the product in interstate commerce. Moreover, the FDA contends that the product is more than “minimally manipulated” and, consequently, does not meet the conditions listed in 21 C.F.R. Part 1271 that exempt HCT/Ps from being regulated as drugs, devices, and/or biological products. Regenerative has agreed to cease production of the cultured cell product while the case is pending. The outcome of this action could have a material effect on our business. In the event that the FDA prevails, in all likelihood, we will need to proceed with the FDA approval process for our initiatives as discussed above. If Regenerative succeeds in the action, depending upon the breadth of the decision or the settlement of the lawsuit, the extent of FDA oversight may be limited or the scope of the clinical trials needed to be performed in connection with our FDA approval process may be reduced. We can give no assurances in this regard. See “Government Regulation” below.

### **Stem Pearls®**

In February 2010, we established Stem Cellutrition, LLC, a stem cell-based cosmetic skincare company, to offer plant derived stem cell cosmetic products. In July 2011, Stem Cellutrition, LLC changed its name to Stem Pearls, LLC. We anticipate that Stem Pearls® cosmetic products will be sold and used as an adjunct to the therapy programs developed by us. We also intend to offer Stem Pearls® products directly to stores, through web-related sales or through cosmetic distributor companies to retail, spa, or other medical locations.

Stem Pearls, LLC has developed an initial product formulation derived from the stem cells of a rare-variety 18<sup>th</sup> century Swiss apple and has prepared and selectively distributed product samples. Stem Pearls, LLC has also developed a new logo and website design and has rebranded its product line. Stem Pearls, LLC has not yet marketed its products or generated any revenue. We anticipate that such marketing efforts will commence by the third quarter of 2012 at a cost of approximately \$100,000.

### **Laboratory**

We intend to develop a state-of-the-art facility to be used as a laboratory for the possible development of cellular-based treatment protocols and research applications. We anticipate that our laboratory will commence operations by the third quarter of 2012 and that we will require approximately \$500,000 in funding for such purposes. Pending the establishment of our laboratory operations, we intend to seek to utilize existing laboratories at medical centers and elsewhere.

As operations grow, our plans include the expansion of our laboratory to perform cellular characterization and culturing, stem cell-related IP development and therapeutic outcome analysis. As we develop our business and additional stem cell treatments are approved, we intend to establish ourselves as the provider of adult stem cells for therapies and expand to provide cells in other market areas for stem cell therapy, including with regard to the treatment of diabetes and other metabolic disorders, heart disease and autoimmune disease.

We plan to eventually open additional laboratories that are capable of supplying stem cells to physicians who use those cells to treat disease. We intend to position ourselves as a source and leader in providing those cells for treatments.

## **Technology**

We intend to utilize our laboratory or a third party laboratory in connection with cellular research activities. We also intend to seek to obtain cellular-based therapeutic technology licenses. We intend to seek to develop potential stem cell delivery systems or devices. The goal of these specialized devices is to deliver cells into specific areas of the body, control the rate, amount and types of cells used in a treatment, and populate these areas of the body with sufficient stem cells so that engraftment occurs.

We also intend to perform research to develop certain stem cell optimization compounds or “recipes” to enhance cellular growth and regeneration for the purpose of improving pre-treatment and post-treatment outcomes.

As laboratory and treatment procedures evolve, we may also seek to develop proprietary diagnostic methods using cellular biomarkers as a source for determining the potential development of disease and to evaluate the efficacy of anti-aging therapeutics and other pharmaceuticals.

We do not currently have any proprietary technology; however, we have filed for certain provisional patents and Regenerative (see “Disc/Spine Program”) has filed certain patent applications with regard to the technology that is the subject of the license agreement between us. We have trademark rights with respect to the names BioRestorative Therapies™, Stem The Tides of Time™, Stem Pearls™, ThermoStem™ and Stem Cellutrition™. Our success will depend in large part on our ability to develop and protect our proprietary technology. We intend to rely on a combination of patent, trade secret and know-how, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success will also depend upon our ability to avoid infringing upon the proprietary rights of others, for if we are judicially determined to have infringed such rights, we may be required to pay damages, alter our services, products or processes, obtain licenses or cease certain activities.

During the years ended December 31, 2011 and 2010, we incurred \$12,000 and \$11,620, respectively, in research and development expenses.

## **Scientific Advisors; Consultants**

We have established a Scientific Advisory Board whose purpose is to provide advice and guidance in connection with scientific matters relating to our business. Our initial two Scientific Advisory Board members are Dr. Naiyer Imam and Dr. Amit Patel. See Item 10 (“Directors, Executive Officers and Corporate Governance – Scientific Advisory Board”) for a listing of the principal positions for Drs. Imam and Patel.

We have engaged two consultants, TDA Consulting Services, Inc. (“TDA”) and Vintage Holidays L.L.C. (“Vintage”), to assist us with the implementation of our business plan. Pursuant to a February 17, 2011 consulting agreement with TDA, TDA is to provide consultation and assistance with regard to our efforts to establish an offshore stem cell treatment facility, develop business, including with regard to acquisition and joint venture opportunities, develop a physician distribution network for the sale of our stem cell skin care products, comply with regulatory requirements and have our securities listed on a securities exchange. Pursuant to the agreement with TDA, we paid TDA \$35,000 in consideration of services rendered to date and a \$25,000 retainer for services to be rendered during the term. We also agreed to pay TDA an aggregate of an additional \$130,000 and issue to TDA an aggregate of 10,500,100 shares of common stock. The agreement with TDA expired on March 31, 2012; however, we are continuing to utilize TDA’s services and are negotiating the terms of an extension to the agreement.

Pursuant to a February 17, 2011 consulting agreement with Vintage, as amended, which has a term that expires on December 31, 2012, Vintage is to provide consultation and assistance with regard to our efforts to market ourselves with respect to medical tourism, establish business relationships with governmental officials, and establish an offshore stem cell treatment facility. Pursuant to the agreement with Vintage, we paid Vintage \$20,000 in consideration of services rendered to date and a \$10,000 retainer for services to be rendered during the term. We also agreed to pay Vintage an aggregate of an additional \$170,000, issue to Vintage an aggregate of 5,000,000 shares of common stock and grant to Vintage options for the purchase of 2,000,000 shares of common stock.

## **Competition**

We will compete with many pharmaceutical, biotechnology, and medical device companies, as well as other private and public stem cell companies involved in the development and commercialization of cell-based medical technologies and therapies.

Regenerative medicine is rapidly progressing, in large part through the development of cell-based therapies or devices designed to isolate cells from human tissues. Most efforts involve cell sources, such as bone marrow, embryonic and fetal tissue, umbilical cord and peripheral blood and skeletal muscle.

Companies working in the area of regenerative medicine include, among others, Cytori Therapeutics, Osiris, Aastrom Biosciences, Aldagen, BioTime, Baxter International, Celgene, Geron, Harvest Technologies, Mesoblast, NeoStem, Stem Cells, Athersys, and Tissue Genesis. Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. We cannot with any accuracy forecast when or if these companies are likely to bring cell therapies to market for procedures that we are also pursuing.

Our skincare company will compete with other companies that offer a plant derived stem cell skin care line, such as EmergeLabs, Amatokin, Andalou Naturals, Xtemcell, Jeunesse Luminesce, Lifeline Skin Care, Reprint, Dermelect, G.M. Collin and Goldfaden, as well as generally with cosmetic companies, many of whom have substantially greater financial, technological, research and development, marketing and personnel resources than we do.



## **Customers**

Our treatment services are intended to be marketed to the general public via the Internet, and at trade shows to physicians and other health care professionals, skin care professionals and beauty product distributors. We intend to market our product portfolio for clinical applications and to research institutions and large pharmaceutical companies. Our Stem Pearls<sup>®</sup> product line is intended to be sold via the Internet ([www.stempearls.com](http://www.stempearls.com), which became operational during the first quarter of 2012, and [www.biorestorative.com](http://www.biorestorative.com)) and to stores either directly or by way of distributors.

## **Governmental Regulation**

### ***U.S. Government Regulation***

The health care industry is highly regulated in the United States. The federal government, through various departments and agencies, state and local governments, and private third-party accreditation organizations regulate and monitor the health care industry, associated products, and operations. The following is a general overview of the laws and regulations pertaining to our business.

### ***FDA Regulation of Stem Cell Treatment and Products***

The FDA regulates the manufacture of human stem cell treatments and associated products under the authority of the Public Health Safety Act (“PHSA”) and the Federal Food, Drug, and Cosmetic Act (“FDCA”). Stem cells can be regulated under FDA’s Human Cells, Tissues, and Cellular and Tissue-Based Products Regulations (“HCT/Ps”), or may also be subject to FDA’s drug, biological product, or medical device regulations.

### ***Human Cells, Tissues, and Cellular and Tissue-Based Products (“HCT/Ps”) Regulation***

Under Section 361 of the PHSA, the FDA issued specific regulations governing the use of HCT/Ps in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations (“CFR”), the FDA established a unified registration and listing system for establishments that manufacture and process HCT/Ps. The regulations also include provisions pertaining to donor eligibility determinations; current good tissue practices covering all stages of production, including harvesting, processing, manufacture, storage, labeling, packaging, and distribution; and other procedures to prevent the introduction, transmission, and spread of communicable diseases.

The HCT/P regulations strictly constrain the types of products that may be regulated solely under these regulations. Factors considered include the degree of manipulation, whether the product is intended for a homologous function, whether the product has been combined with noncellular or non-tissue components, and the product's effect or dependence on the body's metabolic function. In those instances where cells, tissues, and cellular and tissue-based products have been only minimally manipulated, are intended strictly for homologous use, have not been combined with noncellular or nontissue substances, and do not depend on or have any effect on the body's metabolism, the manufacturer is only required to register with the FDA, submit a list of manufactured products, and adopt and implement procedures for the control of communicable diseases. If one or more of the above factors has been exceeded, the product would be regulated as a drug, biological product, or medical device rather than an HCT/P.

Because we are a development stage enterprise and have not generated any revenues from operations, it is difficult to anticipate the likely regulatory status of the array of products and services that we may offer. We believe that some of the adult autologous (self-derived) stem cells that will be used in our cellular therapy and biobanking products and services, including the brown adipose (fat) tissue that we intend to use in our ThermoStem Program, may be regulated by the FDA as HCT/Ps under 21 C.F.R. Part 1271. This regulation defines HCT/Ps as articles “containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient.” However, the FDA may disagree with this position or conclude that some or all of our stem cell therapy products or services do not meet the applicable definitions and exemptions to the regulation. If we are not regulated solely under the HCT/P provisions, we would need to expend significant resources to comply with the FDA’s broad regulatory authority under the FDCA. There is also third party litigation pending that may result in the FDA further restricting or expanding the application of the regulation. In such litigation, the FDA has asserted that the defendants’ use of cultured stem cells to treat musculoskeletal and spinal injuries without FDA approval is in violation of the FDCA, claiming that the defendants’ product is a drug. The defendants have asserted that their procedure is part of the practice of medicine and therefore beyond the FDA’s regulatory authority. The uncertainty as to the outcome of the litigation makes the assessment of the regulatory status of our products and services even more unsettled.

If regulated solely under the FDA’s HCT/P statutory and regulatory provisions, once our laboratory in the United States becomes operational, it will need to satisfy the following requirements, among others, to process and store stem cells:

- registration and listing of HCT/Ps with the FDA;

- donor eligibility determinations, including donor screening and donor testing requirements;

- current good tissue practices, specifically including requirements for the facilities, environmental controls, equipment, supplies and reagents, recovery of HCT/Ps from the patient, processing, storage, labeling and document controls, and distribution and shipment of the HCT/Ps to the laboratory, storage, or other facility;

- tracking and traceability of HCT/Ps and equipment, supplies, and reagents used in the manufacture of HCT/Ps;

- adverse event reporting;

- FDA inspection;

importation of HCT/Ps; and

abiding by any FDA order of retention, recall, destruction, and cessation of manufacturing of HCT/Ps.

Non-reproductive HCT/Ps and non-peripheral blood stem/progenitor cells that are offered for import into the United States and regulated solely under Section 361 of the PHSA must also satisfy the requirements under 21 C.F.R. § 1271.420. Section 1271.420 requires that the importer of record of HCT/Ps offered for import must notify the appropriate FDA official prior to, or at the time of, importation and provide sufficient information for the FDA to make an admissibility decision. In addition, the importer must hold the HCT/P intact and under conditions necessary to prevent transmission of communicable disease until an admissibility decision is made by the FDA.

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions including public warning letters, fines, consent decrees, orders of retention, recall or destruction of product, orders to cease manufacturing, and criminal prosecution. If any of these events were to occur, it could materially adversely affect us.

To the extent that our cellular therapy activities are limited to developing products and services outside the United States, as described in detail below, the products and services would not be subject to FDA regulation, but will be subject to the applicable requirements of the foreign jurisdiction. We intend to comply with all applicable foreign governmental requirements.

### ***Drug and Biological Product Regulation***

An HCT/P product that does not meet the criteria for being solely regulated under Section 361 of the PHSA will be regulated as a drug, device or biological product under the FDCA and/or Section 351 of the PHSA, and applicable FDA regulations. The FDA has broad regulatory authority over drugs and biologics marketed for sale in the United States. The FDA regulates the research, clinical testing, manufacturing, safety, effectiveness, labeling, storage, recordkeeping, promotion, distribution, and production of drugs and biological products. The FDA also regulates the export of drugs and biological products manufactured in the United States to international markets.

For products that are regulated as drugs, an investigational new drug application (“IND”) and an approved new drug application (“NDA”) are required before marketing and sale in the United States pursuant to the requirements of 21 C.F.R. Parts 312 and 314, respectively. An IND application notifies the FDA of prospective clinical testing and allows the test product to be shipped in interstate commerce. Approval of a NDA requires a showing that the drug is safe and effective for its intended use and that the methods, facilities, and controls used for the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity. If regulated as a biologic, the

product must be subject to an IND to conduct clinical trials and a manufacturer must obtain an approved Biologics License Application (“BLA”) before introducing a product into interstate commerce. To obtain a BLA, a manufacturer must show that the proposed product is safe, pure, and potent and that the facility in which the product is manufactured, processed, packed, or held meets established quality control standards.

Drug and biological products must also comply with applicable registration, product listing, and adverse event reporting requirements as well as FDA's general prohibition against misbranding and adulteration. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of drugs and biologics for indications or uses that have not been approved by the FDA (i.e., "off label" promotion).

We are a development stage enterprise and have not generated any revenues from operations. In the event that the FDA does not regulate our services in the United States solely under the HCT/P regulation, our products and activities could be regulated as drug or biological products under the FDCA. If regulated as drug or biological products, we will need to expend significant resources to ensure regulatory compliance. If an IND and NDA or BLA are required for any of our products, there is no assurance as to whether or when we will receive FDA approval of the product. The process of designing, conducting, compiling and submitting the non-clinical and clinical studies required for NDA or BLA approval is time-consuming, expensive and unpredictable. The process can take many years, depending on the product and the FDA's requirements.

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

### ***Medical Device Regulation***

The FDA also has broad authority over the regulation of medical devices marketed for sale in the United States. The FDA regulates the research, clinical testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, promotion, distribution, and production of medical devices. The FDA also regulates the export of medical devices manufactured in the United States to international markets.

Under the FDCA, medical devices are classified into one of three classes- Class I, Class II, or Class III, depending upon the degree of risk associated with the medical device and the extent of control needed to ensure safety and effectiveness. Class I devices are subject to the lowest degree of regulatory scrutiny because they are considered low risk devices and need only comply with the FDA's General Controls. The General Controls include compliance with the registration, listing, adverse event reporting requirements, and applicable portions of the Quality System Regulation as well as the general misbranding and adulteration prohibitions.

Class II devices are subject to the General Controls as well as certain Special Controls such as 510(k) premarket notification. Class III devices are subject to the highest degree of regulatory scrutiny and typically include life supporting and life sustaining devices and implants. They are subject to the General Controls and Special Controls that include a premarket approval application (“PMA”). “New” devices are automatically regulated as Class III devices unless they are shown to be low risk, in which case they may be subject to de novo review to be moved to Class I or Class II. Clinical research of an investigational device is regulated under the IDE regulations of 21 C.F.R. Part 812. Nonsignificant risk devices are subject to abbreviated requirements that do not require a submission to FDA but must have Institutional Review Board (IRB) approval and comply with other requirements pertaining to informed consent, labeling, recordkeeping, reporting, and monitoring. Significant risk devices require the submission of an IDE application to FDA and FDA’s approval of the IDE application.

The FDA premarket clearance and approval process can be lengthy, expensive and uncertain. It generally takes three to twelve months from submission to obtain 510(k) premarket clearance, although it may take longer. Approval of a PMA could take one to four years, or more, from the time the application is submitted and there is no guarantee of ultimate clearance or approval. Securing FDA clearances and approvals may require the submission of extensive clinical data and supporting information to the FDA. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of devices for indications or uses that have not been cleared or approved by the FDA. In addition, modifications or enhancements of products that could affect the safety or effectiveness or effect a major change in the intended use of a device that was either cleared through the 510(k) process or approved through the PMA process may require further FDA review through new 510(k) or PMA submissions.

In the event we develop processes, products or services which qualify as medical devices subject to FDA regulation, we intend to comply with such regulations. If the FDA determines that our products are regulated as medical devices and we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, application integrity proceedings, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

### ***Current Good Manufacturing Practices and other FDA Regulations of Cellular Therapy Products***

Products that fall outside of the HCT/P regulations and are regulated as drugs, biological products, or devices must comply with applicable good manufacturing practice regulations. The current Good Manufacturing Practices (“cGMPs”) regulations for drug products are found in 21 C.F.R. Parts 210 and 211; the General Biological Product Standards for biological products are found in 21 C.F.R. Part 610; and the Quality System Regulation for medical devices are found in 21 C.F.R. Part 820. These cGMPs and quality standards are designed to ensure the products that are processed at a facility meet the FDA’s applicable requirements for identity, strength, quality, sterility, purity, and safety. In the event that our domestic U.S. operations are subject to the FDA’s drug, biological product, or device regulations, we intend to comply with the applicable cGMPs and quality regulations.

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.



### ***Good Laboratory Practices***

The FDA prescribes good laboratory practices (“GLPs”) for conducting nonclinical laboratory studies that support applications for research or marketing permits for products regulated by the FDA. These regulations are published in Part 58 of Title 21 of the Code of Federal Regulations. GLPs are intended to assure the quality and integrity of the safety data filed in research and marketing permits. GLPs provide requirements for organization, personnel, facilities, equipment, testing facilities operation, test and control articles, protocol for nonclinical laboratory study, records, reports, and disqualification by the FDA. To the extent that we are required to, or the above regulation applies, we intend that our domestic laboratory activities will comply with GLPs.

### ***Promotion of Foreign-Based Cellular Therapy Treatment—“Medical Tourism”***

We intend to establish, or license technology to third parties in connection with their establishment of, adult stem cell therapy facilities outside the United States. We also intend to work with hospitals and physicians to make the stem cell-based therapies available for patients who travel outside the United States for treatment. “Medical tourism” is defined as the practice of traveling across international borders to obtain health care. We intend to market our treatment services on the Internet and at trade shows to physicians and other health care professionals, skin care professionals, and beauty product distributors.

The Federal Trade Commission (“FTC”) has the authority to regulate and police advertising of medical treatments, procedures, and regimens in the United States under the Federal Trade Commission Act (“FTCA”). Under Sections 5(a) and 12 of the FTCA (15 U.S.C. §§45(a) and 52), the FTC has regulatory authority to prevent unfair and deceptive practices and false advertising. Specifically, the FTC requires advertisers and promoters to have a reasonable basis to substantiate and support claims. The FTC has many enforcement powers, one of which is the power to order disgorgement by promoters deemed in violation of the FTCA of any profits made from the promoted business and can order injunctions from further violative promotion. Advertising that we may utilize in connection with our medical tourism operations will be subject to FTC regulatory authority, and we intend to comply with such regulatory régime.

### ***Cosmetic and Skin Care Regulation***

We intend to develop skin care products derived from plant stem cells and have established Stem Pearls, LLC to develop and market plant-derived stem cell cosmetic products in the United States and abroad.

Depending upon product claims and formulation, skin care products may be regulated as cosmetics, drugs, devices, or combination cosmetics and drugs. We intend to only market cosmetic skin care products. The FDA has authority to regulate cosmetics marketed in the United States under the FDCA and the Fair Packaging and Labeling Act (“FPLA”) and its implementing regulations. The FTC regulates the advertising of cosmetics under the FTCA.

The FDCA prohibits the marketing of adulterated and misbranded cosmetics. Cosmetic ingredients must also comply with the FDA's ingredient, quality and labeling requirements and the FTC's requirements pertaining to truthful and non-misleading advertising. Cosmetic products and ingredients, with the exception of color additives, are not required to have FDA premarket approval. Manufacturers of cosmetics are also not required to register their establishments, file data on ingredients, or report cosmetic-related injuries to the FDA.

Stem Pearls, LLC, our cosmetics subsidiary, will be responsible for substantiating the safety and product claims of the cosmetic products and ingredients before marketing. The FDA or FTC may disagree with our characterization of one or more of the skin care products as a cosmetic or the product claims. This could result in a variety of enforcement actions which could require the reformulation or relabeling of our products, the submission of information in support of the product claims or the safety and effectiveness of our products, or more punitive action, all of which could have a material adverse effect on our business. If the FDA determines we have failed to comply with applicable requirements under the FDCA or FPLA, it can impose a variety of enforcement actions from public warning letters, injunctions, consent decrees and civil penalties to seizure of our products, total or partial shutdown of our production, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us. If the FTC determines we have failed to substantiate our claims, it can pursue a variety of actions including disgorgement of profits, injunction from further violative conduct, and consent decrees.

Some types of skin-care products are regulated as both cosmetics and drugs under the FDCA. Examples of drug-cosmetic combination products are facial moisturizers that contain sunscreen and skin protectant hand lotions. Products that are both cosmetics and drugs because of ingredients or intended use must satisfy the regulatory requirements for both cosmetics and drugs. The drug requirements include either FDA premarket approval under an NDA or an abbreviated new drug application ("ANDA"), or, more typically, implicit approval through conformance with the applicable FDA final regulation (also known as an over-the-counter drug monograph) that specifies the conditions that must be met for the drug to be generally recognized as safe and effective.

At present, we do not anticipate any of the products marketed as Stem Pearls® will be regulated as a combination cosmetic and drug or solely as a drug or device. However, the FDA may disagree with such a determination which could result in a variety of enforcement actions and significant additional expenditure to comply with all FDA regulations applicable to such products.

### ***Domestic State and Local Government Regulation***

Some states and local governments in the United States regulate stem cell collection, processing, and administration facilities and require these facilities to obtain specific licenses. Our Florida laboratory will be required to comply with Florida law, including becoming licensed as a clinical laboratory and being subject to inspection. Some states, such as New York and Maryland, require licensure of out-of-state facilities that process cell, tissue and/or blood samples of residents of those states. To the extent we are required to seek other state licensure, we will obtain the applicable state

licenses for our laboratory and treatment centers and comply with the current and any new licensing laws that become applicable in the future. There may also be applicable state and local requirements that apply to the labeling, operation, sale, and distribution of our skin care products, our stem cell therapy products, or any related services we may provide. To the extent additional state or local laws apply, we intend to comply with them.

### ***Federal Regulation of Clinical Laboratories***

Congress passed the Clinical Laboratory Improvement Amendments (“CLIA”) in 1988, which provided the Centers for Medicare and Medicaid Services (“CMS”) authority over all laboratory testing, except research, that are performed on humans in the United States. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations (“CMSO”) has the responsibility for implementing the CLIA program.

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability, and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. Laboratories that handle stem cells and other biologic matter are, therefore, included under the CLIA program. Under the CLIA program, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections, and pay fees. The failure to comply with CLIA standards could result in suspension, revocation, or limitation of a laboratory’s CLIA certificate. In addition, fines or criminal penalties could also be levied. To the extent that our business activities require CLIA certification, we intend to obtain and maintain such certification.

### ***Health Insurance Portability and Accountability Act—Protection of Patient Health Information***

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) included the *Administrative Simplification* provisions that required the Secretary of the Department of Health and Human Services (“HHS”) to adopt regulations for the electronic exchange, privacy, and security of individually identifiable health information that HIPAA protects (called "protected health information"). HHS published the *Standards for Privacy of Individually Identifiable Health Information* (“Privacy Rule”) and the *Security Standards for the Protection of Electronic Protected Health Information* (“Security Rule”) to protect the privacy and security of protected health information. The Privacy Rule specifies the required, permitted and prohibited uses and disclosures of an individual’s protected health information by health plans, health care clearinghouses, and any health care provider that transmits health information in electronic format (collectively called "covered entities"). The Security Rule establishes a national security standard for safeguarding protected health information that is held or transferred in electronic form (called "electronic protected health information"). The Security Rule addresses the technical and non-technical safeguards that covered entities must implement to secure individuals’ electronic protected health information.

In addition to covered entities, the Health Information Technology and Clinical Health Act (the "HITECH Act") made certain provisions of the Security Rule, as well as the additional requirements HITECH imposed that relate to security and that are imposed on covered entities, directly applicable as a matter of law to individuals and entities that perform permitted functions on behalf of covered entities when those function involve the use or disclosure of protected health information. These individuals and entities are called "business associates." Covered entities are required to enter into a contract with business associates, called a "business associate agreement," that also imposes many of the Privacy Rule requirements on business associates as a matter of contract.

Companies failing to comply with HIPAA and the implementing regulations may be subject to civil money penalties or in the case of knowing violations, potential criminal penalties, including monetary fines, imprisonment, or both.

To the extent that we are a covered entity or a business associate of a covered entity, we must comply with HIPAA and the implementing regulations. We must also comply with other additional federal or state privacy laws and regulations that may apply to certain diagnoses, such as HIV/AIDS, to the extent that they apply to us.

#### *Other Applicable U.S. Laws*

In addition to the above-described regulation by United States federal and state government, the following are other federal and state laws and regulations that could directly or indirectly affect our ability to operate the business:

- state and local licensure, registration, and regulation of the development of pharmaceuticals and biologics;

- state and local licensure of medical professionals;

- state statutes and regulations related to the corporate practice of medicine;

laws and regulations administered by U.S. Customs and Border Protection ("CBP") related to the importation of biological material into the United States;

- other laws and regulations administered by the U.S. Food and Drug Administration;

- other laws and regulations administered by the U. S. Department of Health and Human Services;

- state and local laws and regulations governing human subject research and clinical trials;
  
- the federal physician self-referral prohibition, also known as Stark Law, and any state equivalents to Stark Law;
  
- the federal Anti-Kickback Law and any state equivalent statutes and regulations;
  
- Federal and state coverage and reimbursement laws and regulations;

- state and local laws and regulations for the disposal and handling of medical waste and biohazardous material;

- Occupational Safety and Health (“OSHA”) regulations and requirements; and

the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to “Excess Benefit Transactions” with HUMC or other tax-exempt organizations.

### ***Foreign Government Regulation***

In general, we will need to comply with the government regulations of each individual country in which our therapy centers are located and products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. Due to the fact that there are new and emerging cell therapy and cell banking regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not always precisely understood today for each country, creating greater uncertainty for the international regulatory process. Furthermore, government regulations can change with little to no notice and may result in up-regulation of our product(s), thereby creating a greater regulatory burden for our cell processing and cell banking technology products. We have not yet thoroughly explored the applicable laws and regulations that we will need to comply with in foreign jurisdictions. It is possible that we may not be permitted to expand our business into one or more foreign jurisdictions.

We do not have any definitive plans or arrangements with respect to the establishment by us of stem cell therapy clinics in any country. We intend to explore any such opportunities as they arise.

### **Offices**

Our principal executive offices are located at 555 Heritage Drive, Jupiter, Florida, and our telephone number is (561) 904-6070. Our website is [www.biorestorative.com](http://www.biorestorative.com). Our internet website and the information contained therein or connected thereto are not intended to be incorporated by reference into this Annual Report.

### **Employees**

We currently have four employees all of whom are full-time employees. We believe that our employee relations are good.



**ITEM 1A. RISK FACTORS.**

Not applicable. See, however, Item 7 (“Management’s Discussion and Analysis of Financial Condition and Results of Operations - Factors That May Affect Future Results and Financial Condition”).

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

Not applicable.

**ITEM 2. PROPERTIES.**

Our principal executive offices and laboratory are located at 555 Heritage Drive, Jupiter, Florida. We occupy the premises pursuant to a three year lease that expires on January 31, 2014 and provides that no base rent is payable during the initial year and that a base monthly rent of \$6,234 and \$6,422 is payable during the second and third years, respectively.

Pursuant to the lease, we are responsible for our share of operating expenses (as defined in the lease), and we have the right to extend the term of the lease for a period of three years at a rent equal to the market rate (as defined in the lease).

Our Jupiter, Florida premises are suitable and adequate for our intended near-term domestic operations.

**ITEM 3. LEGAL PROCEEDINGS.**

None.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

**PART II****ITEM MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS**  
**5. AND ISSUER PURCHASES OF EQUITY SECURITIES.****Market Information**

Transactions in our common stock are reported under the symbol "BRTX" on the OTCQB tier of the OTC Markets. The following table sets forth the range of high and low bids reported in the over-the-counter market for our common stock. The prices shown below represent prices in the market between dealers in securities; they do not include retail markup, markdown or commissions, and do not necessarily represent actual transactions.

	High	Low
2010 Calendar Year		
First Quarter	\$0.025	\$0.007
Second Quarter	\$0.029	\$0.016
Third Quarter	\$0.019	\$0.015
Fourth Quarter	\$0.018	\$0.010
	High	Low
2011 Calendar Year		
First Quarter	\$0.015	\$0.010
Second Quarter	\$0.026	\$0.018
Third Quarter	\$0.025	\$0.010
Fourth Quarter	\$0.020	\$0.010

 **Holders**

As of March 26, 2012, there were 202 record holders of our shares of common stock.

**Dividends**

Holders of our shares of common stock are entitled to dividends when, as and if declared by our Board of Directors out of funds legally available.

We have not declared or paid any dividends in the past to the holders of our common stock and do not currently anticipate declaring or paying any dividends in the foreseeable future. We intend to retain earnings, if any, to finance the development and expansion of our business. Future dividend policy will be subject to the discretion of our Board of Directors and will be contingent upon future earnings, if any, our financial condition, capital requirements, general business conditions, and other factors. Therefore, we can give no assurance that any dividends of any kind will ever be paid to holders of our common shares.

**Recent Sales of Unregistered Securities**

During the three months ended December 31, 2011, we sold the following securities in transactions not involving any public offering. For each of the following transactions, we relied upon Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving any public offering. For each such transaction, we did not use general solicitation or advertising to market the securities, the securities were offered to a limited number of persons, the investors had access to information regarding us (including information contained in our Registration Statement on Form 10, as amended, our quarterly reports and current reports filed with the Securities and Exchange Commission and press releases made by us), and we were available to answer questions by prospective investors. We reasonably believe that each of the investors is an accredited investor.

Date Issued	Number of Shares	Purchaser(s)	Consideration(1)
October 1, 2011	807,700	TDA Consulting Services LLC (“TDA”)	\$ 6,672 (2)
October 13, 2011	4,000,000 (3)	(4)	\$ 100,000
November 1, 2011	807,700	TDA	\$ 6,672 (2)
November 4, 2011	20,000,000	(4)	\$ 141,780 (5)
November 7, 2011	250,000	(4)	\$ 1,983 (6)
November 10, 2011	1,500,000	(4)	\$ 10,633 (5)
November 28, 2011	250,000	(4)	\$ 1,983 (6)
December 1, 2011	807,700	TDA	\$ 6,672 (2)
December 20, 2011	4,000,000 (3)	(4)	\$ 100,000

(1) The value of the non-cash consideration was estimated to be the fair value (relative fair value in the case of shares issued in connection with debt issuance) of our restricted common stock. Since our shares are not currently publicly traded, the fair value of our equity instruments was estimated using a share price derived from the quarterly rolling weighted average cash price paid to us for the purchase of shares of common stock.

(2) Issued in consideration of business advisory services.

(3) Also received warrants for the purchase of 1,000,000 shares of common stock.

(4) Accredited investor.

(5) Issued as debt discount in connection with loans.

(6) Issued in consideration of debt extension.

**Issuer Purchases of Equity Securities**

The following table set forth certain information with respect to purchases of common stock made by us or any “affiliated purchaser” during the quarter ended December 31, 2011:

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Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Be Purchased Under the Plans or Programs
10/1/11 – 10/31/11 -		-	-	-
11/1/11 – 11/30/11 -		-	-	-
12/1/11 – 12/31/11	50,000,000	\$ 0.001	-	-
Total	50,000,000	\$ 0.001	-	-

(1) Purchases made by “affiliated purchasers”.

#### **ITEM 6. SELECTED FINANCIAL DATA.**

Not applicable.

#### **ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

The following discussion of results of operations and financial condition is based upon, and should be read in conjunction with, our consolidated financial statements and accompanying notes thereto, included elsewhere in this Annual Report following Item 15. This discussion contains forward-looking statements. Actual results could differ materially from the results discussed in the forward-looking statements. Reference is made to “Forward-Looking Statements” and Item 7 (“Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results and Financial Condition”) on page 33 for a discussion of some of the uncertainties, risks and assumptions associated with these statements.

#### **Overview**

Our goal is to become a medical center of excellence using cell and tissue regenerative therapy protocols, primarily involving a patient’s own (autologous) adult stem cells allowing patients to undergo cellular-based treatments. As more and more cellular therapies become standard of care, we intend to focus on the unity of medical and scientific explanations for future clinical procedures and outcomes and the provision of adult stem cells for future personal medical applications. Among the initiatives that we are currently pursuing is one that would involve the use of brown fat in connection with the cell-based treatment of obesity, weight loss, diabetes, hypertension, other metabolic

disorders and cardiac deficiencies. We have also entered into a license agreement which permits us to use technology for adult stem cell treatment of disc and spine conditions, including bulging and herniated discs. The technology is an advanced stem cell injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the legs and feet.



We also operate a wholly-owned subsidiary, Stem Pearls, LLC, which offers facial creams and other skin care products with certain ingredients that may include stem cells and/or other stem cell optimization or regenerative compounds.

We currently are developing an infrastructure to establish a laboratory for the possible development of cellular-based treatment protocols, stem cell-related intellectual property, and research applications.

We are a development stage enterprise. Our primary activities in the stem cell area have been the development of our business plan, negotiating strategic alliances and other agreements and raising capital. We have not generated any revenues. Our web site address is [www.biorestorative.com](http://www.biorestorative.com).

Since inception on December 30, 2008, we have incurred substantial losses. As of December 31, 2011 and December 31, 2010, our accumulated deficit was \$7,524,498 and \$3,450,561, respectively, our stockholders' deficiency was \$3,686,397 and \$744,222, respectively, and our working capital deficiency was \$3,788,947 and \$997,778, respectively. We have not yet generated revenues and our losses have principally been operating expenses incurred in development, marketing and promotional activities in order to commercialize our products and services. We expect to continue to incur substantial costs for development, marketing and promotional activities over at least the next year.

Based upon our working capital deficiency as of December 31, 2011 and the lack of any revenues, we require equity and/or debt financing to continue our operations. Between June 2009 and December 31, 2011, we raised an aggregate of \$3,573,639 in debt financing. As of December 31, 2011, our outstanding debt of \$3,190,000, together with interest at rates ranging between 10% and 15% per annum, was due between November 2011 and November 2012. Subsequent to December 31, 2011 and through April 10, 2012, we have received aggregate debt financing of \$1,600,500 and equity financing of \$650,000, the due date for repayment of \$1,610,000 of debt has been extended, \$175,000 of debt has been converted to equity and we have repaid \$50,000 of debt. As a result, we expect that the cash we have available will fund our operations only until May 2012. We are currently considering several different financing alternatives to support our operations thereafter. If we are unable to obtain such additional financing on a timely basis and, notwithstanding any request we may make, our debt holders do not agree to convert their notes into equity or extend the maturity dates of their notes, we may have to curtail our development, marketing and promotions activities, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately we could be forced to discontinue our operations and liquidate. See "Liquidity and Capital Resources" below.

## **Consolidated Results of Operations**

### **Year Ended December 31, 2011 compared with Year Ended December 31, 2010**

The following table presents selected items in our consolidated statements of operations for the years ended December 31, 2011 and 2010, respectively.

	Year Ended December 31,	
	2011	2010
Operating Expenses:		
Marketing and promotion	\$ 103,696	\$ 124,850
Payroll and benefits	1,380,867	760,171
Consulting expense	682,171	682,152
General and administrative	1,373,271	490,544
Research and development	12,000	11,620
Loss From Operations	(3,552,005)	(2,069,337)
Other income	-	11,432
Interest expense	(260,011 )	(24,155 )
Amortization of debt discount	(345,369 )	(181,739 )
Gain on settlement of note and payables, net	83,448	-
Net loss	\$(4,073,937)	\$(2,263,799)

### ***Marketing and promotion expenses***

Marketing and promotion expenses include advertising and promotion, marketing and seminars, meals, and entertainment and travel expenses. For the year ended December 31, 2011, marketing and promotion expenses decreased by \$21,154, or 17%, as compared to the year ended December 31, 2010. The decrease was primarily due to the fact that we spent much of 2011 reassessing and developing our business initiatives, rather than marketing products or services.

We expect that marketing and promotion expenses will increase in the future as we increase our marketing activities following full commercialization of our products and services.

### ***Payroll and benefits***

Payroll and benefits consist primarily of salaries, bonuses, payroll taxes, severance costs and stock-based compensation to employees. For the year ended December 31, 2011, payroll and benefits increased by \$620,696, or 82%, as compared to the year ended December 31, 2010. The increase resulted primarily due to an increase in salary and bonus payroll, plus severance payments, partially offset by reduced employee stock-based compensation expense.



***Consulting expenses***

Consulting expenses consist of consulting fees and stock-based compensation to consultants. For the year ended December 31, 2011, consulting expenses were consistent with those for the year ended December 31, 2010. Consulting expenses remained consistent primarily due to an increase in business development consulting services, offset by a decrease in marketing and medical advisory consulting services and a decrease in consultant stock-based compensation expense.

***General and administrative expenses***

General and administrative expenses consist primarily of corporate support expenses such as legal and professional fees, investor relations and telecommunications expenses. For the year ended December 31, 2011, general and administrative expenses increased \$882,727, or 180%, as compared to the year ended December 31, 2010. The increase resulted primarily from an increase in professional fees as a result of fees incurred in connection with our filings with the Securities and Exchange Commission.

We expect that our general and administrative expenses will continue to increase as we expand our staff, develop our infrastructure and incur additional costs to support the growth in our business.

***Research and development expenses***

Research and development expenses are expensed as they are incurred. For the year ended December 31, 2011, research and development increased by \$380, or 3%, as compared to the year ended December 31, 2010.

We believe that a substantial investment in research and development is essential in the long term to remain competitive. Accordingly, we expect that, subject to the receipt of necessary additional financing, our research and development expenses will increase as we grow.

***Other income***

Other income for the year ended December 31, 2010 represents income from the sale of sample products. No such samples were sold in 2011.

***Interest expense***

For the year ended December 31, 2011, interest expense increased \$235,856, or 976%, as compared to the year ended December 31, 2010. The increase was due to an increase in short-term borrowings.

***Amortization of debt discount***

For the year ended December 31, 2011, amortization of debt discount increased \$163,630, or 90%, as compared to the year ended December 31, 2010. The increase was due to the additional common stock issued in connection with the increase in, and negotiated extensions of short-term borrowings.

***Gain on settlement of note and payables, net***

Gain on settlement of note and payables for the year ended December 31, 2011 represented the difference between our recorded payment obligations and the agreed amount that was ultimately paid pursuant to various settlement agreements.

**Liquidity and Capital Resources****Liquidity**

We measure our liquidity in a number of ways, including the following:

	December 31,	
	2011	2010
Cash	\$71,508	\$18,074
Working Capital Deficiency	\$(3,788,947)	\$(997,778)
Notes Payable, current (excluding debt discount)	\$3,190,000	\$533,523

From inception on December 30, 2008 through December 31, 2011, we raised a total of \$3,573,639 from debt financing and \$891,300 from equity financing. As of December 31, 2011, we had \$71,508 in unrestricted cash and a working capital deficiency of \$3,788,947. Subsequent to December 31, 2011 and through April 10, 2012, we have received aggregate debt financing of \$1,600,500, we have received aggregate equity financing of \$650,000, the due date for repayment of \$1,610,000 of debt has been extended, \$175,000 of debt has been converted to equity, and we have repaid \$50,000 of debt. The Company currently has notes payable aggregating \$250,000 which are past their maturity dates. The Company is currently in the process of negotiating extensions or discussing conversions to equity with respect to these notes.

**Availability of Additional Funds**

Based upon our working capital deficiency of \$3,788,947 as of December 31, 2011 and the lack of any revenues, we require equity and/or debt financing to continue our operations. Between June 2009 and December 31, 2011, we raised \$3,573,639 in debt financing. As of December 31, 2011, our outstanding debt of \$3,190,000, together with interest at rates ranging between 10% and 15% per annum, was due between November 2011 and November 2012. Subsequent to December 31, 2011 and through April 10, 2012, we have received aggregate debt financing of \$1,600,500, we have received aggregate equity financing of \$650,000, the due date for repayment of \$1,610,000 of debt has been extended, \$175,000 of debt has been converted to equity, and we have repaid \$50,000 of debt. The Company currently has notes payable aggregating \$250,000 which are past their maturity dates. The Company is currently in the process of negotiating extensions or discussing conversions to equity with respect to these notes.



As a result, we believe that the cash we have available will fund our operations only until May 2012. Thereafter, we will need to raise further capital, through the sale of additional equity securities or otherwise, to support our future operations and to repay our debt (unless, if requested, the debt holders agree to convert their notes into equity or extend the maturity dates of their notes). Our operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products and services, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings.

We may be unable to raise sufficient additional capital when we need it or to raise capital on favorable terms. Debt financing may require us to pledge certain assets and enter into covenants that could restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to significantly curtail or discontinue operations or to obtain funds by entering into financing agreements on unattractive terms.

These conditions raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements included elsewhere in this Annual Report following Item 15 have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate our continuation as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The financial statements do not include any adjustment that might result from the outcome of this uncertainty.

During the year ended December 31, 2011, our sources and uses of cash were as follows:

### **Net Cash Used in Operating Activities**

We experienced negative cash flow from operating activities for the years ended December 31, 2011 and 2010 in the amounts of \$2,810,867 and \$729,218, respectively. The cash used in operating activities for the year ended December 31, 2011 was due to cash used to fund a net loss of \$4,073,937, reduced by net non-cash items related to depreciation and amortization, amortization of debt discount, a loss on the sale of property and equipment, a gain on the restructuring of a note and payables, and stock-based compensation in the aggregate amount of \$830,773, partially offset by \$432,297 of cash provided by changes in the levels of operating assets and liabilities primarily as a result of conserving cash by extending the payment of payables. The cash used in operating activities for the year ended December 31, 2010 was due to cash used to fund a net loss of \$2,263,799, adjusted for non-cash expenses related to depreciation, amortization of debt discount, and stock-based compensation in the aggregate amount of \$1,125,705, as well as a change in accounts payable and accrued expenses and other current liabilities of \$402,926.

**Net Cash Provided by (Used in) Investing Activities**

Investing activities provided cash of \$14,228 during the year ended December 31, 2011. During such year, we received proceeds from the sale of property and equipment of \$32,000 and used \$17,772 to purchase property and equipment. We used \$48,784 of cash during the year ended December 31, 2010 to acquire property and equipment and intangibles. The cash used in the year ended December 31, 2010 includes the cost to acquire medical equipment (\$23,060) and furniture and fixtures (\$22,323).

### **Net Cash Provided by Financing Activities**

Cash provided by financing activities during the years ended December 31, 2011 and 2010 was \$2,850,073 and \$796,034, respectively. During the year ended December 31, 2011, the net proceeds were from debt financing activities (\$2,962,500) and equity financing activities (\$200,000), offset by repayments of debt financing (\$308,427). During the year ended December 31, 2010, the net proceeds were from debt financing activities (\$332,654) and equity financing activities (\$668,175), offset by repayments of debt financing (\$176,795) and repurchases of common stock (\$28,000).

### **Critical Accounting Policies and Estimates**

#### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at dates of the financial statements and the reported amounts of revenue and expenses during the periods. Actual results could differ from these estimates. Our significant estimates and assumptions include the recoverability and useful lives of long-lived assets, the fair value of our stock, stock-based compensation, debt discount and a valuation allowance relating to our deferred tax assets.

#### **Deferred Tax Valuation Allowance**

We believe significant uncertainties exist regarding the future realization of deferred tax assets, and, accordingly, a full valuation allowance has been established. In subsequent periods, if and when we generate pre-tax income, a tax expense will not be recorded to the extent that the remaining valuation allowance can be used to offset that expense. Once a consistent pattern of pre-tax income is established or other events occur that indicate that the deferred tax assets will be realized, some or all of the existing valuation allowance will be reversed back to income. Should we generate pre-tax losses in subsequent periods, a tax benefit will not be recorded and the valuation allowance will be increased.

#### **Stock-Based Compensation**

We account for equity instruments issued to non-employees in accordance with accounting guidance which requires that such equity instruments are recorded at their fair value on the measurement date, which is typically the date the services are performed.

We account for equity instruments issued to employees in accordance with accounting guidance that requires awards are recorded at their fair value on the date of grant and are amortized over the vesting period of the award. We recognize compensation costs over the requisite service period of the award, which is generally the vesting term of the options associated with the underlying employment agreement, if applicable.

Since the shares underlying our 2010 Equity Participation Plan are not currently registered, the fair value of our restricted equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares.

The fair value of options is estimated using the Black-Scholes valuation model. These fair values were estimated using the following additional assumptions:

	Year Ended December 31, 2011	
Risk free interest rate	1.54	%
Expected term (years)	4.51	
Expected volatility	205	%
Expected dividends	0	%

*Risk-Free Interest Rate.* This is the United States Treasury rate for the day of the grant having a term equal to the expected term of the option. An increase in the risk-free interest rate will increase the fair value and the related compensation expense.

*Stock Price.* Since our shares are not currently publicly traded, the fair value of our equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares.

*Expected Term.* This is the period of time over which the award is expected to remain outstanding. The expected term of options granted during the periods was calculated using the simplified method set out in SEC Staff Accounting Bulletin, No. 107, as amended by No. 110, using the vesting period set forth in the option agreements and the expected contractual term of 10 years. The simplified method defines the expected term as the average of the contractual term and vesting period. An increase in the expected term will increase the fair value and the related compensation expense.

*Expected Volatility.* This is a measure of the amount by which our share price has fluctuated or is expected to fluctuate. Since the Company's stock has not been publicly traded for a long period of time, we use the average of the historic volatility of comparative companies. An increase in the expected volatility will increase the fair value and the related compensation expense.

*Dividend Yield.* We have not made any dividend payment nor do we have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease the fair value and the related compensation expense.



## Recently Issued Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-04, "Fair Value Measurement (Topic 820) - Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs." This ASU addresses fair value measurement and disclosure requirements within Accounting Standards Codification ("ASC") Topic 820 for the purpose of providing consistency and common meaning between U.S. GAAP and IFRSs. Generally, this ASU is not intended to change the application of the requirements in Topic 820. Rather, this ASU primarily changes the wording to describe many of the requirements in U.S. GAAP for measuring fair value or for disclosing information about fair value measurements. This ASU is effective for periods beginning after December 15, 2011. It is not expected to have any impact on our consolidated financial statements or disclosures.

## Off-Balance Sheet Arrangements

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

## Factors That May Affect Future Results and Financial Condition

The risk factors listed in this section provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Readers should be aware that the occurrence of any of the events described in these risk factors could have a material adverse effect on our business, results of operations and financial condition. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events, or otherwise.

*We have a very limited operating history; we have incurred substantial losses since inception; we expect to continue to incur losses for the near term; we have a substantial working capital deficiency and a stockholders' deficiency; the report of our independent registered public accounting firm contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.*

We have a very limited operating history. Since our inception, we have incurred net losses. As of December 31, 2011, we had a working capital deficiency of \$3,788,947 and stockholders' deficiency of \$3,686,397. The report of our independent registered public accounting firm with respect to our financial statements as of December 31, 2011 and

2010 and for the years then ended indicates that our financial statements have been prepared assuming that we will continue as a going concern. The report states that, since we are in the development stage, we have incurred net losses since inception and we need to raise additional funds to meet our obligations, there is substantial doubt about our ability to continue as a going concern. Our plans in regard to these matters are described in footnote 2 to our audited financial statements as of December 31, 2011 and 2010 and for the years then ended, and for the period from December 30, 2008 (inception) to December 31, 2011, which are included following Item 15 (“Exhibits and Financial Statement Schedules”). Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.



***We will need to obtain additional financing to satisfy debt obligations and continue our operations.***

As described in Item 7 (“Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Availability of Additional Funds”), between June 2009 and December 31, 2011, we raised an aggregate of \$3,573,629 in debt financing. Subsequent to December 31, 2011 and through April 10, 2012, we have received aggregate debt and equity financing of \$1,600,500 and \$650,000, respectively, \$175,000 of debt has been converted to equity and we have repaid \$50,000 of debt. As of April 10, 2012, the outstanding balance of our debt of \$4,565,500, together with accrued interest, was due and payable between February 2012 and March 2013. Unless we obtain additional financing or, upon our request, the debtholders agree to convert their debt into equity or extend the maturity dates of the debt, we will not be able to repay such debt. Even if we are able to satisfy our debt obligations, our cash balance and the revenues for the foreseeable future from our anticipated operations will not be sufficient to fund the development of our business plan, including in connection with the license obtained from Regenerative. Accordingly, we will be required to raise capital from one or more sources. There is no guarantee that adequate funds will be available when needed from additional debt or equity financing, or from other sources, or on terms attractive to us. Our inability to obtain sufficient funds in the future would, at a minimum, require us to delay, scale back, or eliminate some or all of our contemplated activities, which could have a substantial negative effect on our results of operations and financial condition. See Item I (“Business-Overview”) for a discussion of our financing requirements.

***Our business strategy is high-risk.***

We are focusing our resources and efforts primarily on the development of cellular-based services and products which will require extensive cash for research, development and commercialization activities. This is a high-risk strategy because there is no assurance that our services and products, including our recently launched brown fat research initiative, will ever become commercially viable (commercial risk), that we will prevent other companies from depriving us of market share and profit margins by offering services and products based on our inventions and developments (legal risk), that we will successfully manage a company in a new area of business, regenerative medicine, and on a different scale than we have operated in the past (operational risk), that we will be able to achieve the desired therapeutic results using stem and regenerative cells (scientific risk), or that our cash resources will be adequate to develop our services and products until we become profitable, if ever (financial risk). We are using our cash in one of the riskiest industries in the economy (strategic risk). This may make our stock an unsuitable investment for many investors.

***Except for the Regenerative license agreement, we do not have any agreements or understandings in place with respect to the implementation of our business strategy.***

Except for the Regenerative license agreement, we do not have any material agreements or understandings in place with respect to the implementation of our business strategy. No assurances can be given that we will be able to enter

into any necessary agreements with respect to the development of our business. Our inability to enter into any such agreements would have a material adverse effect on our results of operations and financial condition.

***We do not have any agreements, understandings or governmental approvals in place with respect to the establishment of treatment facilities.***

Due to current stringent regulatory restrictions in the United States, we anticipate that any stem cell therapy facilities that we establish would be outside the United States. We do not have any agreements, understandings or governmental approvals in place with respect to the establishment of any such facilities in any country. No assurances can be given that we will be able to obtain any required approvals, or enter into necessary agreements, for the establishment and operation of therapy centers.

***We depend on our executive officers and on our ability to attract and retain additional qualified personnel. A pending action against our Research Scientist may limit our ability to utilize fully his capabilities. We do not currently have a Chief Financial Officer.***

Our performance is substantially dependent on the performance of Mark Weinreb, our Chief Executive Officer. We rely upon him for strategic business decisions and guidance. Mr. Weinreb is subject to an employment agreement with us that is scheduled to expire in October 2015. We are also dependent on the performance of Francisco Silva, our Research Scientist, in establishing and developing our laboratory business. Mr. Silva is also subject to an employment agreement with us. In May 2011, Mr. Silva's former employer, DaVinci BioSciences, LLC (of which Mr. Silva is a member), obtained a preliminary injunction against Mr. Silva. Such injunction restrains and enjoins Mr. Silva from using or disseminating information he obtained from his former employer, including using such information to solicit his former employer's customers. A ruling on a permanent injunction motion is pending. Such motion also seeks to restrain and enjoin Mr. Silva from violating certain provisions of the operating agreement of his former employer that provide, among other things, that Mr. Silva shall not, while he is a member of his former employer and for a period of two years thereafter, engage in, or have any interest in, any entity that engages in the business of stem cell research tools and therapeutic applications or otherwise in a business that competes with his former employer's business in the geographic area in which his former employer conducts business. We are not a party to the action. We have been advised by Mr. Silva and his counsel that the enforceability of the noncompetition provision has been and will be challenged. The court has not yet further ruled on the permanent injunctive relief sought by the former employer and, pending resolution of this matter, Mr. Silva's ability to provide services to us that relate to the business of stem cell research tools and/or therapeutic applications, or otherwise in a business that competes with his former employer's business in the geographic area in which his former employer conducts business, may be limited. In the event we determine that any such limitation on the scope of Mr. Silva's responsibilities has a material adverse effect upon our business, we may find it necessary to seek to employ a new Research Scientist who has similar skills in the area of cellular biology. In addition, we do not currently have a Chief Financial Officer. Pending the hiring of a Chief Financial Officer, we are utilizing financial consultants with regard to the preparation of our financial statements. We believe that our future success in developing marketable services and products and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel, including a Chief Financial Officer. Competition for such personnel is intense, and there can be no assurance that we will be able to attract and retain such personnel. The loss of the services of Mr. Weinreb and/or Mr. Silva (or, in the case of Mr. Silva, any significant limitation on his ability to provide services to us) or the inability to attract and retain additional personnel, including a Chief Financial Officer and possibly a new Research Scientist, and develop expertise as needed would have a substantial negative effect on our results of operations and financial

condition. In addition, if we are named as a defendant in the action against Mr. Silva, we may incur substantial costs and our efforts and attention to the development of our business could be diverted.

*We may not be able to protect our proprietary rights.*

Our commercial success will depend in large part upon our ability to protect our proprietary rights. There is no assurance, for example, that any patents issued to us will not become the subject of a re-examination, will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of services and products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar services and products, duplicate any of our services and products, or design around our patents.

Our commercial success will also depend upon our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our services, products or processes, obtain licenses, or cease certain activities. If we are required in the future to obtain any licenses from third parties for some of our services and/or products, there can be no guarantee that we would be able to do so on commercially favorable terms, if at all. U.S. patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using.

Litigation, which would result in substantial costs to us and the diversion of effort on our part, may be necessary to enforce or confirm the ownership of any patents issued or licensed to us, or to determine the scope and validity of third-party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or a foreign patent office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us. Any such litigation or interference proceeding, regardless of outcome, could be expensive and time-consuming.

Successful challenges to our patents through oppositions, re-examination proceedings or interference proceedings could result in a loss of patent rights in the relevant jurisdiction. If we are unsuccessful in actions we bring against the patents of other parties, and it is determined that we infringe upon the patents of third-parties, we may be subject to litigation, or otherwise prevented from commercializing potential services and/or products in the relevant jurisdiction, or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations or from commercializing certain services and/or products, which could adversely affect our business and results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.



In addition to patents, we intend to also rely on unpatented trade secrets and proprietary technological expertise. Some of our intended future cell-related therapeutic services and/or products may fit into this category. We intend to rely, in part, on confidentiality agreements with our partners, employees, advisors, vendors, and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or that we will have adequate remedies for any breach, or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Failure to obtain or maintain patent protection, failure to protect trade secrets, third-party claims against our patents, trade secrets, or proprietary rights or our involvement in disputes over our patents, trade secrets, or proprietary rights, including involvement in litigation, could divert our efforts and attention from other aspects of our business and have a substantial negative effect on our results of operations and financial condition.

***We may not be able to protect our intellectual property in countries outside of the United States.***

Intellectual property law outside the United States is uncertain and, in many countries, is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the U.S. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

***We operate in a highly-regulated environment and may be unable to comply with applicable federal, state, local, and international requirements. Failure to comply with applicable government regulation may result in a loss of licensure, registration, and approval or other government enforcement actions.***

We intend to develop stem cell based therapeutic and aesthetic products. These products and operations are subject to regulation in the United States by the FDA, FTC, CMS, state authorities and comparable authorities in foreign jurisdictions. Government regulation is a significant factor affecting the research, development, formulation, manufacture, and marketing of our products. If we fail to comply with applicable regulations, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, operating restrictions and criminal prosecution.

The FDA requires facilities that are engaged in the recovery, processing, storage, labeling, packaging, or distribution of human cells, tissues, cellular and tissue-based products (“HCT/Ps”) or in the screening or testing of donors of HCT/Ps to register and list the HCT/Ps that it manufactures, comply with current Good Tissue Practices (“cGTPs”), and other procedures to prevent the introduction, transmission, and spread of communicable diseases. Our Florida-based laboratory, biobanking facility, and any treatment centers we open in the United States may be required to comply with the HCT/P regulations. In addition, any third party retained by us that engages in the manufacture of an HCT/P on our behalf must also comply with the HCT/P regulations. If we or our third-party contractors fail to register, update registration information, or comply with any HCT/P regulation, we will be out of compliance with FDA regulations, which could adversely affect our business. Furthermore, adverse events in the field of stem cell therapy may result in greater governmental regulation, which could create increased expenses, potential delays, or otherwise affect our business.

Because we are a development stage enterprise and have not generated any revenues from operations, it is difficult to anticipate the likely regulatory status of the array of products and services we may offer. We believe that some of our products and services may be regulated solely as HCT/Ps; however, it is possible that some or all of our products may be regulated as drugs, medical devices, and/or biological products and therefore will likely require FDA regulatory approval or clearance prior to being marketed in the United States. The FDA approval process can be lengthy, expensive, and uncertain and there is no guarantee of ultimate approval or clearance. FDA decisions regarding labeling and other matters could adversely affect the availability or commercial potential of our products. There are also many factors that can affect our ability to market a drug, biologic or medical device, including regulatory delays, the inability to successfully complete clinical studies, concerns about safety or efficacy and claims about adverse side effects. These products must also comply with the applicable current Good Manufacturing Practices (for drug products), Quality System Regulations (for medical devices), or General Biological Product Standards (for biological products) as set forth in Title 21 of the Code of Federal Regulations. These regulations govern the manufacture, processing, packaging, and holding of the products and include quality control, quality assurance, and maintenance of records and documentation. The FDA conducts inspections to enforce compliance with these regulations. We and any third-party contractor that manufactures these products on our behalf must comply with the applicable regulations. If we or any third party retained by us that engages in the manufacture of a drug, medical device, or biological product on our behalf fails to comply with the applicable regulations, we will be out of compliance with FDA regulations, which could adversely affect our business.

In addition, the FDA regulates and prescribes good laboratory practices (“GLPs”) for conducting nonclinical laboratory studies that support applications for research or marketing permits for products regulated by the FDA. GLPs provide requirements for organization, personnel, facilities, equipment, testing, facilities operation, test and control articles, protocol for nonclinical laboratory study, records, reports, and disqualification by the FDA to ensure the quality and integrity of the safety data filed in research and marketing permits. Failure to comply with the GLPs could adversely affect our business.

Although cosmetic products are subject to fewer regulatory requirements than drugs or medical devices, in the United States cosmetic products are subject to FDA and FTC requirements as well as applicable state and local requirements. It is also possible that some of the skin care products developed and marketed by our Stem Pearls® cosmetic skincare company may be regulated as both cosmetics and drugs under the FDCA. These products must satisfy the regulatory



requirements of both drugs and cosmetics. Failure to comply with the appropriate regulations could result in a restraining order, seizure, or criminal action, which could have an adverse effect on our business.

The Federal Trade Commission (“FTC”) regulates and polices advertising in the United States of medical treatments, procedures, and regimens that take place inside and outside of the United States. FTC regulations are designed to prevent unfair and deceptive practices and false advertising. The FTC requires advertisers and promoters to have a reasonable basis to substantiate and support claims. Failure to sufficiently substantiate and support claims can lead to enforcement action by the FTC, such as a disgorgement order of any profits made from the promoted business or an injunction from further violative promotion. Such enforcement actions could have an adverse effect on our business.

State and local governments impose additional licensing and other requirements for clinical laboratories and facilities that collect, process, and administer stem cells. Our laboratory and any future treatment facilities that we operate in the United States must comply with these additional licensing and other requirements. The licensing regulations require personnel with specific education, experience, training, and other credentials. There can be no assurance that these individuals can be retained or will remain retained or that the cost of retaining such individuals will not materially and adversely affect our ability to operate our business profitably. There can be no assurance that we can obtain the necessary licensure required to conduct business in any state or that the cost of compliance will not adversely affect our ability to operate our business profitably.

The Centers for Medicare and Medicaid Services (“CMS”) have authority to implement the Clinical Laboratories Improvement Amendments (“CLIA”) program. When we begin operations in the United States, we will need to comply with the CLIA program standards. CLIA is designed to establish quality laboratory testing by ensuring the accuracy, reliability, and timeliness of patient test results. Laboratories that handle stem cells and other biologic matter are included under the CLIA program. Under the CLIA program, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections, and pay fees. The failure to comply with CLIA standards could result in suspension, revocation, or limitation of a laboratory’s CLIA certificate. In addition, fines or criminal penalties could also be levied. To the extent that our business activities require CLIA certification, we intend to obtain and maintain such certification. There is no guarantee that we will be able to gain CLIA certification. Failure to gain CLIA certification or comply with the CLIA requirements will adversely affect our business.

HHS published the *Standards for Privacy of Individually Identifiable Health Information* (“Privacy Rule”) and the *Security Standards for the Protection of Electronic Protected Health Information* (“Security Rule”) pursuant to the Health Insurance Portability and Accountability Act (“HIPAA”). The Privacy Rule specifies the required, permitted and prohibited uses and disclosures of an individual’s protected health information by health plans, health care clearinghouses, and any health care provider that transmits health information in electronic format (collectively called “covered entities”). The Security Rule establishes a national security standard for safeguarding protected health information that is held or transferred in electronic form (called “electronic protected health information”). The Security Rule addresses the technical and non-technical safeguards that covered entities must implement to secure individuals’ electronic protected health information.

In addition to covered entities, the Health Information Technology and Clinical Health Act (the "HITECH Act") made certain provisions of the Security Rule, as well as the additional requirements HITECH imposed that relate to security and that are imposed on covered entities, directly applicable as a matter of law to individuals and entities that perform permitted functions on behalf of covered entities when those function involve the use or disclosure of protected health information. These individuals and entities are called "business associates." Covered entities are required to enter into a contract with business associates, called a "business associate agreement," that also imposes many of the Privacy Rule requirements on business associates as a matter of contract.

Companies failing to comply with HIPAA and the implementing regulations may be subject to civil money penalties or in the case of knowing violations, potential criminal penalties, including monetary fines, imprisonment, or both.

To the extent that our business requires compliance with HIPAA, we intend to fully comply with all requirements as well as to other additional federal or state privacy laws and regulations that may apply to us. As HIPAA is amended and changed, we will incur additional compliance burdens. We may be required to spend substantial time and money to ensure compliance with ever-changing federal and state standards as electronic and other means of transmitting protected health information evolve

In addition to the above-described regulation by United States federal and state government, the following are other federal and state laws and regulations that could directly or indirectly affect our ability to operate the business:

- state and local licensure, registration, and regulation of the development of pharmaceuticals and biologics;
- state and local licensure of medical professionals;
- state statutes and regulations related to the corporate practice of medicine;
- laws and regulations administered by U.S. Customs and Border Protection ("CBP") related to the importation of biological material into the United States;
- other laws and regulations administered by the U.S. Food and Drug Administration;
- other laws and regulations administered by the U. S. Department of Health and Human Services;
- state and local laws and regulations governing human subject research and clinical trials;

- the federal physician self-referral prohibition, also known as Stark Law, and any state equivalents to Stark Law;

- the federal Anti-Kickback Law and any state equivalent statutes and regulations;

- Federal and state coverage and reimbursement laws and regulations;

- state and local laws and regulations for the disposal and handling of medical waste and biohazardous material;

- Occupational Safety and Health (“OSHA”) regulations and requirements; and

the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to “Excess Benefit Transactions” with HUMC or other tax-exempt organizations.

Any violation of these laws could result in a material adverse effect on our business.

Since our stem cell therapy operations will in all likelihood initially commence in foreign jurisdictions, we will need to comply with the government regulations of each individual country in which our therapy centers are located and products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. Due to the fact that there are new and emerging cell therapy and cell banking regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not always precisely understood today for each country, creating greater uncertainty for the international regulatory process. Furthermore, government regulations can change with little to no notice and may result in up-regulation of our product(s), thereby creating a greater regulatory burden for our cell processing and cell banking technology products. We have not yet thoroughly explored the applicable laws and regulations that we will need to comply with in foreign jurisdictions. It is possible that we may not be permitted to expand our business into one or more foreign jurisdictions.

We intend to conduct our business in full compliance with all applicable federal, state and local, and foreign laws and regulations. However, the laws and regulations affecting our business are complex and often are not contemplated by existing legal régimes. As a result, the laws and regulations affecting our business are uncertain and have not been the subject of judicial or regulatory interpretation. Furthermore, stem cells and cell therapy are topics of interest in the government and public arenas. There can be no guarantee that laws and regulations will not be implemented, amended and/or reinterpreted in a way that will negatively affect our business.

***To operate and sell in international markets carries great risk.***

We intend to market our services and products both domestically and in foreign markets. A number of risks are inherent in international transactions. In order for us to service and market our products in non-U.S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances in these countries and must comply with the country specific regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International operations and sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our services and products by increasing the price of our services and products in the currency of the countries in which the services and products are offered.

There can be no assurance that we will obtain regulatory approvals or clearances in all of the countries where we intend to market our services and products, or that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances, or that we will be able to successfully commercialize our services and products in various foreign markets. Delays in receipt of approvals or clearances to market our services and products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

***Changing, new and/or emerging government regulations may adversely affect our business.***

Government regulations can change without notice. Due to the fact that there are new and emerging cell therapy and cell banking regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not known and may vary from country to country, creating greater uncertainty for the international regulatory process.

Anticipated or unanticipated changes in the way or manner in which the FDA and other similarly situated government authorities regulate services and products or classes/groups of services and products can delay, further burden, or alleviate regulatory pathways that were once available to other services and products. There are no guarantees that such changes to the regulatory process will not deleteriously affect our contemplated operations.

***There is uncertainty with regard to the extent of the FDA's regulatory authority.***

As discussed in Item 1 (“Business – Disc/Spine Program”), the FDA has brought an action to permanently enjoin Regenerative from using its Regenexx™ procedure to process mesenchymal stem cells (“MSCs”) for the treatment of various orthopedic conditions. The lawsuit relates to a procedure utilized by Regenerative whereby a patient’s own MSC cells are extracted and isolated from the patient’s bone marrow, processed at a laboratory on site for two to three weeks to undergo expansion, and then returned to the same patient to treat a medical condition. The FDA has asserted that Regenerative’s stem cell procedure is subject to FDA jurisdiction and regulation as an unapproved drug and/or biologic. Regenerative takes the position that the Regenexx™ procedure is the practice of medicine and thereby is outside of the FDA’s jurisdiction. It also contends that the manipulation of the stem cells occurs in the normal course of medical practice which is regulated by Colorado, the state in which Regenerative is located. The FDA contends that it is not impinging on Regenerative’s ability to practice medicine; instead, it considers the product being reinjected into the patient to be a cultured cell product subject to the FDA’s regulations governing the use of human cells, tissues, and cellular and tissue-based products (“HCT/Ps”). According to the FDA’s position, the Regenexx™ procedure involves growth factors, reagents and drug products that cross state lines thereby placing the product in interstate commerce. Moreover, the FDA contends that the product is more than “minimally manipulated” and, consequently, does not meet the conditions listed in 21 C.F.R. Part 1271 that exempt HCT/Ps from being regulated as drugs, devices, and/or biological products. Regenerative has agreed to cease production of the cultured cell product while the case is

pending. The outcome of this action could have a material effect on our business. In the event that the FDA prevails, in all likelihood, we will need to proceed with the FDA approval process for our initiatives as discussed above. If Regenerative succeeds in the action, depending upon the breadth of the decision or the settlement of the lawsuit, the extent of FDA oversight may be limited or the scope of the clinical trials needed to be performed in connection with our FDA approval process may be reduced. We can give no assurances in this regard. Pending a final determination of this action, there is great uncertainty with regard to the FDA's regulatory authority of the business in which we plan to operate. See Item 1 ("Business – Government Regulation").



***Despite our anticipation that the majority of our cellular-based procedures will be private-pay, our inability to obtain reimbursement for our therapies from private and governmental insurers could negatively impact demand for our services.***

Successful sales of health care services and products generally depends, in part, upon the availability and amounts of reimbursement from third party healthcare payor organizations, including government agencies, private healthcare insurers and other healthcare payors, such as health maintenance organizations and self-insured employee plans. Uncertainty exists as to the availability of reimbursement for such new therapies as stem cell-based therapies. There can be no assurance that such reimbursement will be available in the future at all or without substantial delay or, if such reimbursement is provided, that the approved reimbursement amounts will be sufficient to support demand for our services and products at a level that will be profitable.

***If safety problems are encountered by us or others developing new stem cell-based therapies, our stem cell initiatives could be materially and adversely affected.***

The use of stem cells for therapeutic indications is still in the very early stages of development. If an adverse event occurs during clinical trials related to one of our proposed services and/or products or those of others, the FDA and other regulatory authorities may halt clinical trials or require additional studies. The occurrence of any of these events would delay, and increase the cost of, our development efforts and may render the commercialization of our proposed services and/or products impractical or impossible.

***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 contemplated 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 vulnerable to competition and technological change, and also to physicians' inertia.***

We will compete with many domestic and foreign companies in developing our technology and products, including biotechnology, medical device and pharmaceutical companies. Many current and potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources. There is no assurance that our competitors will not succeed in developing alternative services and/or products that are more effective, easier to use, or more economical than those which we may develop, or that would render our services and/or products obsolete and non-competitive. In general, we may not be able to prevent others from developing and marketing competitive services and/or products similar to ours or which perform similar functions or which are marketed before ours.

Competitors may have greater experience in developing therapies or devices, conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercialization. It is possible that competitors may obtain patent protection, approval, or clearance from the FDA or achieve commercialization earlier than we can, any of which could have a substantial negative effect on our business.

We will compete against cell-based therapies derived from alternate sources, such as bone marrow, umbilical cord blood and potentially embryos. Doctors historically are slow to adopt new technologies like ours, whatever the merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires very significant marketing expenditures or definitive product performance and/or pricing superiority.

We expect that physicians' inertia and skepticism will also be a significant barrier as we attempt to gain market penetration with our future services and products. We may need to finance lengthy time-consuming clinical studies (so as to provide convincing evidence of the medical benefit) in order to overcome this inertia and skepticism particularly in reconstructive surgery, cell preservation, the cardiovascular area and many other indications.

***Most potential applications of our technology are pre-commercialization, which subjects us to development and marketing risks.***

We are in an early stage on the path to commercialization with many of our services and products, including with regard to our recently launched brown fat initiative. We believe that our long-term viability and growth will depend in large part on our ability to develop commercial quality cell processing devices and useful procedure-specific consumables, and to establish the safety and efficacy of our therapies through clinical trials and studies. There is no assurance that our development programs will be successfully completed or that required regulatory clearances or approvals will be obtained on a timely basis, if at all.



Successful development and market acceptance of our services and products will be subject to developmental risks, including failure of inventive imagination, ineffectiveness, lack of safety, unreliability, failure to receive necessary regulatory clearances or approvals, high commercial cost, preclusion or obsolescence resulting from third parties' proprietary rights or superior or equivalent services and products, competition from copycat services and products, and general economic conditions affecting purchasing patterns. There is no assurance that we will successfully develop and commercialize our services and products, or that our competitors will not develop competing technologies that are less expensive or superior. Failure to successfully develop and market our services and products would have a substantial negative effect on our results of operations and financial condition.

***Future clinical trial results may differ significantly from our expectations.***

In the event that we undertake clinical trials, we cannot guarantee that we will not experience negative results. Poor results in our clinical trials could result in substantial delays in commercialization, substantial negative effects on the perception of our services and products, and substantial additional costs. These risks may be increased by our reliance on third parties in the performance of many of the clinical trial functions, including clinical investigators, hospitals, and other third party service providers.

***Continued turmoil in the economy could harm our business.***

Negative trends in the general economy, including, but not limited to, trends resulting from an actual or perceived recession, tightening credit markets, increased cost of commodities, actual or threatened military action by the United States and threats of terrorist attacks in the United States and abroad, could cause a reduction of investment in and available funding for companies in certain industries, including ours. Our ability to raise capital has been and may in the future be adversely affected by downturns in current credit conditions, financial markets and the global economy.

***We may not have enough product liability insurance.***

The testing, manufacturing, marketing, and sale of our regenerative cell services and products will involve an inherent risk that product liability claims will be asserted against us, our distribution partners, or licensees. There can be no guarantee that our clinical trial and commercial product liability insurance will be adequate or will continue to be available in sufficient amounts or at an acceptable cost, if at all. A product liability claim, product recall, or other claim, as well as any claims for uninsured liabilities or in excess of insured liabilities, could have a substantial negative effect on our results of operations and financial condition. Also, well-publicized claims could cause our stock to fall sharply, even before the merits of the claims are decided by a court.



***In the past, we identified certain material weaknesses in the design or operation of internal control over financial reporting which could have adversely affected our ability to record, process, summarize and report financial data.***

We identified certain material weaknesses in the design or operation of internal control over financial reporting which could have adversely affected our ability to record, process, summarize, and report financial data. The material weaknesses related to our failure to maintain a fully integrated financial consolidation and reporting system throughout the three months ended March 31, 2011 and the years ended December 31, 2010 and 2009, our inability to properly apply highly specialized accounting principles to, and adequately disclose, complex transactions and our limited segregation of duties. We did not maintain a fully integrated financial consolidation and reporting system throughout the three months ended March 31, 2011 or the years ended December 31, 2010 and 2009 and, as a result, extensive manual analysis, reconciliation and adjustments were required in order to produce financial statements for external reporting purposes. Specifically, we did not effectively segregate certain accounting duties due to the small size of our accounting staff or maintain a sufficient number of adequately trained personnel necessary to anticipate and identify risks critical to financial reporting and the closing process. In addition, there were inadequate reviews and approvals by our personnel of certain reconciliations and other processes in day-to-day operations due to the lack of a full complement of accounting staff. We do not currently have a Chief Financial Officer and lack adequately trained in-house accounting personnel with appropriate United States generally accepted accounting principles (US GAAP) expertise for complex transactions. We do not currently have a sufficient complement of in-house technical accounting and external reporting personnel commensurate to support standalone external financial reporting requirements. In May 2011, we engaged outside consultants to assist in the financial function. Such engagements have increased the resources and technical expertise devoted to performing certain procedures and have remediated the material weaknesses described above. Notwithstanding the foregoing weaknesses, we believe that our audited financial statements as of December 31, 2011 and 2010 and for the years then ended fairly present, in all material respects, our financial condition as of such dates and our results of operations for such years and periods.

***We pay no dividends.***

We have never paid cash dividends in the past, and currently do not intend to pay any cash dividends in the foreseeable future.

***There is, at present, only a limited market for our common stock and there is no assurance that an active trading market for our common stock will develop.***

Although our common stock is quoted on the OTCQB market from time to time, the market for our common stock is extremely limited. In addition, although there have been market makers in our securities, we cannot assure that these market makers will continue to make a market in our securities or that other factors outside of our control will not cause them to stop market making in our securities. Making a market in securities involves maintaining bid and ask quotations and being able to effect transactions in reasonable quantities at those quoted prices, subject to various

securities laws and other regulatory requirements. Furthermore, the development and maintenance of a public trading market depends upon the existence of willing buyers and sellers, the presence of which is not within our control or that of any market maker. Market makers are not required to maintain a continuous two-sided market, are required to honor firm quotations for only a limited number of shares, and are free to withdraw firm quotations at any time. Even with a market maker, factors such as our past losses from operations and the small size of our company mean that there can be no assurance of an active and liquid market for our securities developing in the foreseeable future. Even if a market develops, we cannot assure that a market will continue, or that shareholders will be able to resell their securities at any price.

***Since our common stock is classified as “penny stock,” the restrictions of the SEC’s penny stock regulations may result in less liquidity for our common stock.***

The SEC has adopted regulations which define a “penny stock” to be any equity security that has a market price (as therein defined) of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transactions involving a penny stock, unless exempt, the rules require the delivery, prior to any transaction involving a penny stock by a retail customer, of a disclosure schedule prepared by the SEC relating to the penny stock market. Disclosure is also required to be made about commissions payable to both the broker/dealer and the registered representative and current quotations for the securities. Finally, monthly statements are required to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Because the market price for shares of our common stock is less than \$5.00, and we do not satisfy any of the exceptions to the SEC’s definition of penny stock, our common stock is classified as a penny stock. As a result of the penny stock restrictions, brokers or potential investors may be reluctant to trade in our securities, which may result in less liquidity for our common stock.

***Shareholders who hold unregistered shares of our common stock are subject to resale restrictions pursuant to Rule 144 due to our former status as a “shell company”; when such restrictions end, there will be a large number of shares of common stock eligible for resale - this may have a depressive effect upon the market value of our stock.***

Pursuant to Rule 144 promulgated under the Securities Act of 1933, as amended (“Rule 144”), a “shell company” is defined as a company that has no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents or assets consisting of any amount of cash and cash equivalents and nominal other assets. We previously were a “shell company” pursuant to Rule 144, and, as such, sales of our securities pursuant to Rule 144 cannot be made until we are subject to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, we have filed all of our required periodic reports with the Securities and Exchange Commission (the “SEC”) and a period of at least 12 months has elapsed from the date “Form 10 information” has been filed with the SEC reflecting our status as a non-“shell company.” We filed our Form 10 with the SEC on May 12, 2011 reflecting such non-“shell company” status. Because our unregistered securities cannot be sold pursuant to Rule 144 until at least May 12, 2012, any unregistered securities we sell in the future or issue to consultants or employees, in consideration for services rendered or for any other purpose, will have no liquidity until and unless such securities are registered with the SEC or until May 12, 2012, and we have complied with the other requirements of Rule 144. As a result, it may be more difficult for us to fund our operations and pay our consultants and employees with our securities instead of cash. In addition, it will be more difficult for us to raise funding through the sale of debt or equity securities unless we agree to register such securities with the SEC, which could cause us to expend additional resources in the future. Furthermore, effective as of May 12, 2012, a large number of our unregistered shares will become eligible for resale under Rule 144. Such eligibility may have a depressive effect upon the market value of our stock.



*In the event that a significant amount of our outstanding debt is converted into equity, the percentage ownership of existing stockholders will be substantially diluted.*

As of April 10, 2012, we had outstanding indebtedness in the amount of \$4,565,500. We intend to seek to have the debtholders convert all or a significant amount of such debt into equity. In the event of any such conversion, the percentage ownership of existing stockholders will be substantially diluted. In February 2012, our stockholders approved an amendment to our Articles of Incorporation pursuant to which the number of shares of common stock that we may issue was increased from 800,000,000 to 1,500,000,000.

*Our Board of Directors has the authority to effect a reverse split of our common stock. In the event that our Board implements such reverse split, it could have a material adverse effect upon the price of our shares*

In February 2012, our stockholders approved a proposal to grant to our Board the authority to effect a reverse split of our common stock at a ratio of not less than 1-for-10 and not more than 1-for-150, with our Board having the discretion as to whether or not the reverse split is to be effected, and with the exact ratio of any reverse split to be set at a whole number within the above range as determined by our Board in its discretion. If the reverse stock split is implemented, the principal effect will be to proportionately decrease the number of outstanding shares of our common stock based on the reverse stock split ratio selected by our Board. Proportionate voting rights and other rights and preferences of the holders of our common stock will not be affected by the proposed reverse stock split (other than as a result of the payment of cash in lieu of fractional shares). In such event, the reduction in the number of outstanding shares should be accompanied by a proportional increase in the price of our common stock; however, no assurance can be given that such price increase will occur or that any such price increase will be maintained.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Not applicable.

#### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The financial statements required by this Item 8 are included in this Annual Report following Item 15 hereof. As a smaller reporting company, we are not required to provide supplementary financial information.

#### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

In February 2011, we engaged Marcum LLP as our independent registered public accountants; prior to that date, we did not have independent auditors.

**ITEM 9A. CONTROLS AND PROCEDURES.**

**Disclosure Controls and Procedures**

Disclosure controls are procedures that are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), such as this Annual Report, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls are also designed with the objective of ensuring that such information is accumulated and communicated to our management, including the Principal Executive and Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Internal controls are procedures which are designed with the objective of providing reasonable assurance that (1) our transactions are properly authorized, recorded and reported; and (2) our assets are safeguarded against unauthorized or improper use, to permit the preparation of our condensed consolidated financial statements in conformity with United States generally accepted accounting principles.

In connection with the preparation of this Annual Report, management, with the participation of our Principal Executive and Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)). Based upon that evaluation, our Principal Executive and Financial Officer concluded that, as of December 31, 2011, our disclosure controls and procedures were effective.

**Changes in Internal Controls**

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Limitations of the Effectiveness of Control**

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations of any control system, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

**No Management Assessment Report Regarding Internal Control Over Financial Reporting or Attestation Report of Registered Public Accounting Firm**

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. This Annual Report also does not contain an attestation report of our registered public accounting firm regarding internal control over financial reporting since the rules for smaller reporting companies provide for this exemption.

**ITEM 9B. OTHER INFORMATION.**

None.

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**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

**Directors and Executive Officers**

Information regarding our directors and executive officers is set forth below. Each of our officers devotes his or her full business time in providing services on our behalf.

Name	Age	Positions Held
Mark Weinreb	59	Chief Executive Officer, President and Chairman of the Board
Mandy D. Clark	30	Vice President of Operations and Secretary
A. Jeffrey Radov	60	Director
Joel San Antonio	59	Director

**Mark Weinreb**

Mark Weinreb has served as our Chief Executive Officer since October 2010, as our President since February 2012 and as our Chairman of the Board since April 2011. From February 2003 to October 2009, Mr. Weinreb served as President of NeoStem, Inc., a public international biopharmaceutical company engaged in, among other things, adult stem cell-related operations. From October 2009 to October 2010, he was subject to a non-competition agreement with NeoStem and was not engaged in business. Mr. Weinreb also served as Chief Executive Officer and Chairman of the Board of Directors of NeoStem from February 2003 to June 2006. In 1976, Mr. Weinreb joined Bio Health Laboratories, Inc., a state-of-the-art medical diagnostic laboratory providing clinical testing services for physicians, hospitals, and other medical laboratories. He became the laboratory administrator in 1978 and then an owner and the laboratory's Chief Operating Officer in 1982. In such capacity, he oversaw all technical and business facets, including finance and laboratory science technology. Mr. Weinreb left Bio Health Labs in 1989 when the business was sold. In 1992, Mr. Weinreb founded Big City Bagels, Inc., a national chain of franchised upscale bagel bakeries and became Chairman and Chief Executive Officer of such entity. Big City Bagels went public in 1995, and in 1999 Mr. Weinreb redirected the company and completed a merger with an Internet service provider. From 2000 to 2002, Mr. Weinreb served as Chief Executive Officer of Jestertek, Inc., a software development company pioneering gesture recognition and control using advanced interactive proprietary video technology. Mr. Weinreb received a Bachelor of Arts degree in 1975 from Northwestern University and a Master of Science degree in 1982 in Medical Biology from C.W. Post, Long Island University. We believe that Mr. Weinreb's executive-level management experience, his extensive experience in the adult stem cell sector and his service on our Board since October 2010 give him the qualifications and skills to serve as one of our directors.



**Mandy D. Clark**

Mandy D. Clark has been our Vice President of Operations since August 2009. She has served as our Secretary since December 2010 and served on our Board from September 2010 to April 2011. From 2006 to 2009, Ms. Clark served as Educational Envoy and then CME/CE Coordinator for Professional Resources in Management Education, an accredited provider of continuing medical education. She conducted needs assessments nationally to determine in which areas clinicians most needed current education. She also oversaw onsite educational meetings and analyzed data for outcomes reporting. From 2005 to 2006, Ms. Clark served as surgical coordinator for Eye Surgery Associates and the Rand Eye Institute, two prominent physician practices in Florida. Ms. Clark has experience in medical editing for educational programs and is a published author of advanced scientific and clinical content on topics including Alzheimer's disease, breast cancer, sleep apnea and adult learning. She received a degree in Biology from Mercyhurst College.

**A. Jeffrey Radov**

A. Jeffrey Radov became a member of our Board in April 2011. Mr. Radov is an entrepreneur and businessman with 35 years of experience in media, communications and financial endeavors. Since 2002, he has served as the Managing Partner of Walworth Group, which provides consulting and advisory services to a variety of businesses, including hedge funds, media, entertainment and Internet companies, financial services firms and early stage ventures. Mr. Radov is also an advisor to GeekVentures, LLC, an incubator for technology startups in Israel. From 2008 to 2010, Mr. Radov was a Principal and Chief Operating Officer at Aldebaran Investments, LLC, a registered investment advisor. From 2005 to 2008, Mr. Radov was Chief Operating Officer at EagleRock Capital Management, a group of hedge funds. Prior to joining EagleRock, Mr. Radov was a founding investor in and Board member of Edusoft, Inc., an educational software company. From 2001 to 2002, Mr. Radov was a Founder-in-Residence at SAS Investors, an early-stage venture fund. From 1999 to 2001, Mr. Radov was CEO and Co-Founder of VocaLoca, Inc., an innovator in consumer-generated audio content on the Internet. Mr. Radov was a founding executive of About.Com, Inc., an online information source, and was its EVP of Business Development and Chief Financial Officer from its inception. In 1996, prior to founding About.Com, Mr. Radov was a Director at Prodigy Systems Company, a joint venture of IBM and Sears. Mr. Radov was also a principal in the management of a series of public limited partnerships that invested in the production and distribution of more than 130 major motion pictures. From 1982 to 1984, Mr. Radov was the Director of Finance at Rainbow Programming Enterprises, a joint venture among Cablevision Systems Corporation, Cox Broadcasting and Daniels & Associates. From 1977 to 1981, Mr. Radov was Director of Marketing at Winklevoss & Associates. Mr. Radov earned a Masters of Business Administration from The Wharton School of the University of Pennsylvania and holds a Bachelor of Arts degree from Cornell University. We believe that Mr. Radov's executive-level management experience and his extensive experience in the finance industry give him the qualifications and skills to serve as one of our directors.

**Joel San Antonio**



Joel San Antonio became a member of our Board in April 2011. Since August 2010, Mr. San Antonio has served as Chairman of Warrantech/AMT Warranty, an operating subsidiary of Amtrust Financial Services Inc. From February 1988 through August 2010, he was Chairman and Chief Executive Officer of Warrantech Corporation, a leading provider of third party administration for insurance products. Warrantech was acquired by Amtrust Financial Services in 2010. Prior to founding Warrantech, Mr. San Antonio founded Little Lorraine Ltd., a company engaged in the manufacture of various brands of women's apparel. Mr. San Antonio has served as Chairman of the Board of American Doctors Network, a technology company engaged in the development of electronic medical records. He is a former board member of SearchHelp Inc., a company committed to online child protection and family safety, MedStrong International Corporation, a company engaged in the storage of emergency medical information, and Marc Pharmaceuticals, Inc., a company that, in conjunction with the Weil Medical Center at Cornell University, was engaged in the development and commercialization of cancer treatment products. Mr. San Antonio is engaged in a variety of philanthropic and charitable activities. Mr. San Antonio graduated from Ithaca College with a Bachelor of Science in Business Administration. We believe that Mr. Antonio's executive-level management experience gives him the qualifications and skills to serve as one of our directors.

## **Scientific Advisory Board**

The following persons are the initial members of our Scientific Advisory Board:

Name	Principal Position
Naiyer Imam, M.D.	Chairman and Chief Executive Officer, Advanced Medical Imaging and Teleradiology, LLC
Amit Patel, M.D.	Associate Professor, Division of Cardiothoracic Surgery, University of Utah School of Medicine; Director of Clinical Regenerative Medicine and Tissue Engineering, University of Utah

## ***Family Relationships***

There are no family relationships among any of our executive officers and directors.

## ***Term of Office***

Each director will hold office until the next annual meeting of stockholders and until his successor is elected and qualified or until his earlier resignation or removal. Each executive officer will hold office until the initial meeting of the Board of Directors following the next annual meeting of stockholders and until his successor is elected and qualified or until his earlier resignation or removal.

## ***Audit Committee***

The Audit Committee of the Board of Directors is responsible for overseeing our accounting and financial reporting processes and the audits of our financial statements. The members of the Audit Committee are Messrs. Radov and San Antonio.

***Audit Committee Financial Expert***

Our Board of Directors has determined that Mr. Radov is an “audit committee financial expert,” as that is defined in Item 407(d)(5) of Regulation S-K. Mr. Radov is an “independent director” based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

***Section 16(a) Beneficial Ownership Reporting Compliance***

Section 16 of the Exchange Act requires that reports of beneficial ownership of common stock and changes in such ownership be filed with the Securities and Exchange Commission by Section 16 “reporting persons,” including directors, certain officers, holders of more than 10% of the outstanding common stock and certain trusts of which reporting persons are trustees. We are required to disclose in this Annual Report each reporting person whom we know to have failed to file any required reports under Section 16 on a timely basis during the fiscal year ended December 31, 2011. To our knowledge, based solely on a review of copies of Forms 3, 4 and 5 filed with the Securities and Exchange Commission and written representations that no other reports were required, during the fiscal year ended December 31, 2011, our officers, directors and 10% stockholders complied with all Section 16(a) filing requirements applicable to them, except that each of Messrs. Weinreb, Silva, Radov and San Antonio and Ms. Clark filed his or her respective Form 3 late, Gloria McConnell and Stem Cell Research Company, LLC, each a 10% stockholder during the year ended December 31, 2011, failed to file a Form 3 and Ms. McConnell failed to file a Form 4 with respect to one transaction.

***Code of Ethics for Senior Financial Officers***

Our Board of Directors has adopted a Code of Ethics for our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the Code of Ethics is posted on our website, [www.biorestorative.com](http://www.biorestorative.com). We intend to satisfy the disclosure requirement under Item 5.05(c) of Form 8-K regarding an amendment to, or a waiver from, our Code of Ethics by posting such information on our website, [www.biorestorative.com](http://www.biorestorative.com).

**ITEM 11. EXECUTIVE COMPENSATION.**

**Summary Compensation Table**

The following Summary Compensation Table sets forth all compensation earned in all capacities during the fiscal years ended December 31, 2011 and 2010 by our (i) principal executive officer, and (ii) all other executive officers, other than our principal executive officer, whose salaries for the 2011 fiscal year, as determined by Regulation S-K, Item 402, exceeded \$100,000 (the individuals falling within categories (i) and (ii) are collectively referred to as the “Named Executive Officers”):

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Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards	None or Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Mark Weinreb, Chief Executive Officer <sup>(1)</sup>	2011	\$390,000	\$195,000 <sup>(2)</sup>	\$123,900 <sup>(3)(4)</sup>	-	-	-	\$87,975 <sup>(5)</sup>	\$796,875
	2010	\$90,000	\$45,000 <sup>(2)</sup>	-	\$437,234 <sup>(3)(4)</sup>	-	-	-	\$572,234
Francisco Silva, Vice President of Research and Development <sup>(6)</sup>	2011	\$110,795	\$30,000	-	\$41,600 <sup>(3)</sup>	-	-	-	\$182,395
	2010	-	-	-	-	-	-	-	-

(1) Mr. Weinreb became our Chief Executive Officer in October 2010.

(2) Pursuant to Mr. Weinreb's employment agreement with us, he is entitled to receive a bonus equal to 50% of his annual salary. See "Employment Agreement" below.

(3) The amounts reported in these columns represent the grant date fair value of the option and stock awards granted during the years ended December 31, 2011 and 2010, calculated in accordance with FASB ASC Topic 718. For a detailed discussion of the assumptions used in estimating fair values, see Item 7 ("Management's Discussion and Analysis of Financial Condition and Results of Operations - Stock-Based Compensation").

(4) Includes \$404,751 related to a purported grant to Mr. Weinreb of an option for the purchase of 50,000,000 shares of common stock. Such grant was determined to be null and void. As discussed under "Employment Agreement" below, in May 2011, we granted to Mr. Weinreb 35,000,000 shares of common stock. No additional compensation is reflected in 2011 in connection with the 35,000,000 share grant since the grant date fair value of the 50,000,000 share option grant (which was subsequently determined to be null and void) is fully reflected for 2010 and the fair value of the 35,000,000 share grant is less than the amount so reflected for the option grant.

(5) Includes automobile and vacation allowances plus taxes paid by us on Mr. Weinreb's behalf.

(6) Mr. Silva became our Vice President of Research and Development in April 2011. In March 2012, he transitioned from such position to Research Scientist.

**Outstanding Equity Awards at Fiscal Year-End**

The following table provides information on outstanding equity awards as of December 31, 2011 to the Named Executive Officers:

Name	Option Awards		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options		Option Exercise Price	Option Expiration Date	Stock Awards		Market Value of Shares or Units of Stock That Have Not Vested	Equity Incentive Plan Awards: Number of Shares, or Other Rights That Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested
	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options	Number of Securities Underlying Unexercised Options	Number of Securities Underlying Unexercised Options			Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested			
Mark Weinreb	4,000,000	-	-	-	\$ 0.01	12/14/20	35,000,000	\$289,100	-	-	
Francisco Silva	2,000,000	2,000,000	-	-	\$ 0.01	04/15/21	-	-	-	-	
Francisco Silva	150,000	-	-	-	\$ 0.025	06/24/21	-	-	-	-	
Francisco Silva	1,000,000	-	-	-	\$ 0.02	11/16/21	-	-	-	-	

### Employment Agreement

On October 4, 2010, we entered into a three-year employment agreement with Mark Weinreb, our Chief Executive Officer. In February 2012, we and Mr. Weinreb agreed to extend the expiration date of the employment agreement to October 4, 2015. Pursuant to the employment agreement, Mr. Weinreb is entitled to receive a salary of \$360,000 per annum during the initial year, \$480,000 per annum during the second year and \$600,000 per annum during each of the final three years of the term and an annual bonus equal to 50% of his annual salary. In addition, pursuant to the employment agreement, in the event that Mr. Weinreb's employment is terminated by us without cause, or Mr. Weinreb terminates his employment for "good reason" or following a change in control, Mr. Weinreb would be entitled to receive a lump sum payment equal to the greater of (a) his base annual salary and bonus for the remainder of the term or (b) two times his then annual base salary and bonus. In addition, pursuant to the employment agreement, as amended, in January 2011 and May 2011, we granted to Mr. Weinreb 15,000,000 and 35,000,000 shares of common

stock, respectively. In connection with the stock grants, we agreed to pay all taxes payable by Mr. Weinreb as a result of the grants as well as all taxes incurred as a result of the tax payments made on his behalf. We and Mr. Weinreb initially agreed that the 35,000,000 share grant would not vest until we received equity and/or debt financing in an aggregate amount equal to three times the tax payable in connection with the grant. On November 4, 2011, we and Mr. Weinreb agreed that the 35,000,000 share grant will not vest until we receive equity and/or debt financing after such date of at least \$2,000,000. In April 2012, the vesting requirement was satisfied.



**Director Compensation**

The following table sets forth certain information concerning the compensation of our non-employee directors for the fiscal year ended December 31, 2011:

## Director Compensation

Name	Fees Earned or Paid in Cash	Stock Awards <sup>(1)</sup>	Option Awards <sup>(1)</sup>	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
A. Jeffrey Radov <sup>(2)</sup>	\$ 15,000	\$ 41,300	-	-	-	-	\$ 56,300
Joel San Antonio <sup>(2)</sup>	\$ 15,000	\$ 41,300	-	-	-	-	\$ 56,300
Dr. Kurt J. Wagner <sup>(3)</sup>	-	-	-	-	-	-	-
Dr. Joseph J. Ross <sup>(3)</sup>	-	-	-	-	-	-	-

(1) The amounts reported in this column represent the grant date fair value of the stock and option awards granted during the year ended December 31, 2011, calculated in accordance with FASB ASC Topic 718. For a detailed discussion of the assumptions used in estimating fair values, see Item 7 (“Management’s Discussion and Analysis of Financial Condition and Results of Operations - Stock-Based Compensation”).

(2) Appointed as a director in April 2011.

(3) Resigned as a director in April 2011.

Each of Messrs. Radov and San Antonio, our non-employee directors, is entitled to receive, as compensation for his services as a director, \$20,000 per annum, payable quarterly (subject to our cash needs). In February 2012, each of Messrs. Radov and San Antonio was granted a ten year option to purchase up to 30,000,000 shares of common stock at an exercise price of \$.021 per share. Such options vest to the extent of one-half thereof on the date of grant and one-half thereof on the one year anniversary of the date of grant.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The following table sets forth certain information regarding the beneficial ownership of our common stock, as of April 10, 2012, known by us, through transfer agent records, to be held by: (i) each person who beneficially owns 5% or more of the shares of common stock then outstanding; (ii) each of our directors; (iii) each of our Named Executive Officers (as defined above); and (iv) all of our directors and executive officers as a group.

The information in this table reflects “beneficial ownership” as defined in Rule 13d-3 of the Exchange Act. To our knowledge, and unless otherwise indicated, each shareholder has sole voting power and investment power over the shares listed as beneficially owned by such shareholder, subject to community property laws where applicable. Percentage ownership is based on 647,991,911 shares of common stock outstanding as of April 10, 2012.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned		Approximate Percent of Class	
Mark Weinreb 555 Heritage Drive Jupiter, Florida	182,309,991	(1)	27.3	%
Westbury (Bermuda) Ltd. Victoria Hall 11 Victoria Street Hamilton, Bermuda	55,750,000	(2)	8.3	%
Gloria McConnell  1260 NW 16 <sup>th</sup> Street  Boca Raton, Florida	46,120,382	(3)	7.1	%
A. Jeffrey Radov 8 Walworth Avenue Scarsdale, New York	27,500,000	(4)	4.1	%
Joel San Antonio 2200 Highway 121 Bedford, Texas	27,500,000	(4)	4.1	%
Francisco Silva 555 Heritage Drive Jupiter, Florida	6,150,000	(5)	*	
All directors and executive officers as a group (4 persons)	243,509,991	(1)(4)(6)	34.6	%

\*

Less than 1%.

(1) Includes (a) 20,667,000 shares of common stock issuable upon the exercise of currently exercisable options, (b) 41,034,483 shares of common stock held of record by Gloria McConnell over which Mr. Weinreb has voting power pursuant to a Shareholder Agreement and Irrevocable Proxy, dated January 20, 2011 (the “McConnell Shareholder Agreement”), as described in footnote (2) below, (c) 5,085,899 shares of common stock held of record by Stem Cell Research Company, LLC (“Stem Cell Research”) over which Mr. Weinreb has voting power pursuant to a Shareholder Agreement and Irrevocable Proxy, dated January 21, 2011 (the “Research Shareholder Agreement”), as described in footnote (2) below, (d) 21,522,609 shares of common stock held of record by Richard Proodian over which Mr. Weinreb has voting power pursuant to a Shareholder Agreement and Irrevocable Proxy, dated June 15, 2011, (e) 9,000,000 shares of common stock held of record by John Krowiak over which Mr. Weinreb has voting power pursuant to two Shareholder Agreement and Irrevocable Proxy documents, dated June 6, 2011 and June 13, 2011 and (f) 35,000,000 shares of common stock which are pledged as security for the payment of a promissory note.



- (2) Includes 20,000,000 shares issuable upon the exercise of a currently exercisable warrant.
- (3) Includes 5,085,899 shares of common stock held of record by Stem Cell Research of which, we have been advised, Ms. McConnell is the President and sole member. Pursuant to the McConnell Shareholder Agreement, for a period of three years ending January 20, 2014, Ms. McConnell has agreed to vote her shares of common stock as directed by Mr. Weinreb and has granted to Mr. Weinreb an irrevocable proxy in connection therewith. Pursuant to the Research Shareholder Agreement, for a period of three years ending January 21, 2014, Stem Cell Research has agreed to vote its shares as directed by Mr. Weinreb and has granted to Mr. Weinreb an irrevocable proxy in connection therewith.
- (4) Includes (a) 2,500,000 shares of common stock issued subject to continued service as a director until April 21, 2012 and (b) 15,000,000 shares of common stock issuable upon the exercise of currently exercisable options.
- (5) Represents shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.
- (6) Includes 4,950,000 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

*Securities Authorized for Issuance Under Equity Compensation Plans*

The following table sets forth information as of December 31, 2011 with respect to compensation plans (including individual compensation arrangements) under which our common stock are authorized for issuance, aggregated as follows:

- All compensation plans previously approved by security holders; and
- All compensation plans not previously approved by security holders.

**EQUITY COMPENSATION PLAN INFORMATION**

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	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	26,150,000	\$ 0.012	128,850,000
Equity compensation plans not approved by security holders	2,000,000	\$ 0.01	-
Total	28,150,000		128,850,000

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.**

In October 2010, certain of our then executive officers, directors, 5% or greater shareholders and consultants contributed to our capital 60,332,799 shares. Such capital contribution was made in order to enable us to have sufficient authorized and unissued shares of common stock in connection with our capital-raising efforts and for other corporate purposes and without additional consideration to the executive officers, directors, shareholders or consultants. The number of additional shares contributed is as follows:

Name	Total Number of Shares Contributed
Gloria J. McConnell	12,576,811
Richard M. Proodian	9,511,874
Stem Cell Research Company, LLC	32,082,535
Todd Adler	6,161,579

On December 15, 2010, we entered into a termination agreement with Gloria McConnell, our former President (the “McConnell Termination Agreement”), pursuant to which Ms. McConnell was entitled to receive \$120,000, as severance, payable over a two year period. In addition, pursuant to the McConnell Termination Agreement, we agreed to reissue to Ms. McConnell 12,576,811 shares of our common stock. These shares had previously been contributed to capital by Ms. McConnell in October 2010 in order to enable us to fulfill our obligation to issue shares to third parties. Further, pursuant to the McConnell Termination Agreement, Ms. McConnell has agreed to certain restrictive covenants, including non-competition and non-solicitation restrictions, and limitations on the number of shares that she can sell to 250,000 shares on any particular day and 5,000,000 shares during any three calendar month period. In November 2011, we entered into an agreement with Ms. McConnell pursuant to which we paid her \$22,500 in full settlement of our outstanding \$87,500 obligation to her.

On January 20, 2011, Ms. McConnell and Mr. Weinreb entered into a Shareholder Agreement and Irrevocable Proxy, pursuant to which Ms. McConnell has agreed that, for a period of three years, she would vote her shares of common stock as determined by Mr. Weinreb.

Effective January 29, 2011, we terminated our relationship with Tommy Berger, one of our founders. Pursuant and subject to the terms and conditions of a termination agreement between the parties (the “Berger Termination Agreement”), Mr. Berger waived any rights he may have had pursuant to a certain employment agreement entered into with us in August 2010 (to which Stem Cell Research Company, LLC (“Stem Cell Research”) was also a party) (the “Berger Employment Agreement”) and we agreed to pay to Stem Cell Research \$180,000 over a 12 month period. In addition, pursuant to the Berger Termination Agreement, each of Mr. Berger and Stem Cell Research has agreed to certain restrictive covenants, including non-competition and non-solicitation restrictions, restrictions on actions that would cause a change of control and limitations on the number of shares that they can sell to 250,000 shares on any particular day and 5,000,000 shares during any three calendar month period. Further, concurrently with the execution

of the Berger Termination Agreement, in connection with our agreement to pay to Stem Cell Research the \$180,000 payment discussed above, Stem Cell Research executed a shareholder agreement and irrevocable proxy pursuant to which it has agreed that, for a three year period, it would vote its shares of common stock as directed by Mr. Weinreb. We are aware that, in the Berger Employment Agreement, Stem Cell Research was referred to as Mr. Berger's "company"; however, we have no knowledge as to any control that Mr. Berger may currently exercise with respect to Stem Cell Research and, as previously indicated, we have been advised that Ms. McConnell is the President and sole member of Stem Cell Research. In November 2011, we entered into an agreement with Stem Cell Research and Mr. Berger pursuant to which we paid Stem Cell Research \$50,000 in full settlement of our outstanding \$100,000 obligation to it.



On June 17, 2011, Richard Proodian, our former Chief Financial Officer, executed a termination agreement with us (the “Proodian Termination Agreement”) pursuant to which Mr. Proodian was entitled to receive, as severance, \$50,000 (less amounts paid as salary for the period after June 15, 2011), payable over the balance of 2011. In addition, pursuant to the Proodian Termination Agreement, Mr. Proodian has agreed to certain restrictive covenants, including non-competition and non-solicitation restrictions, and limitations on the number of shares that he can sell to 250,000 shares on any particular day and 5,000,000 shares during any three calendar month period. Further, in connection with the execution of the Proodian Termination Agreement, Messrs. Proodian and Weinreb entered into a Shareholder Agreement and Irrevocable Proxy pursuant to which Mr. Proodian has agreed that, for a period of three years, he would vote his shares of common stock as determined by Mr. Weinreb. In January 2012, we entered into an agreement with Mr. Proodian pursuant to which we paid him and his designee an aggregate of approximately \$23,000 in full settlement of our approximately \$46,000 outstanding obligation to him.

On April 2, 2012, Stem Cell Cayman, Ltd., one of our wholly-owned subsidiaries, borrowed \$1,500,000 from Westbury (Bermuda) Ltd. (“Westbury”), one of our principal shareholders. The promissory note evidencing the loan provides for interest at the rate of 15% per annum, payable monthly, and the payment of the principal amount one year from the date of issuance (subject to acceleration under certain circumstances). In consideration of the loan, we issued to Westbury a five year warrant for the purchase of 20,000,000 shares of our common stock at an exercise price of \$.03 per share.

### ***Director Independence***

#### *Board of Directors*

Our Board of Directors is currently comprised of Mark Weinreb, A. Jeffrey Radov and Joel San Antonio. Each of Messrs. Radov and San Antonio is currently an “independent director” based on the definition of independence in Listing Rule 5605(a)(2) of the listing standards at The Nasdaq Stock Market.

#### *Audit Committee*

The members of our Board’s Audit Committee currently are Messrs. Radov and San Antonio, each of whom is an “independent director” based on the definition of independence in Listing Rule 5605(a)(2) of the listing standards of The Nasdaq Stock Market and Rule 10A-3(b)(1) under the Securities Exchange Act of 1934.

*Nominating Committee*

The members of our Board’s Nominating Committee currently are Messrs. Radov and San Antonio, each of whom is an “independent director” based on the definition of independence in Listing Rule 5605(a)(2) of the listing standards of The Nasdaq Stock Market.

*Compensation Committee*

The members of our Board’s Compensation Committee currently are Messrs. Radov and San Antonio, each of whom is an “independent director” based on the definition of independence in Listing Rule 5605(a)(2) of the listing standards of The Nasdaq Stock Market.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.**

In February 2011, we engaged Marcum LLP as our independent registered public accountants to audit our financial statements as of December 31, 2010 and 2009, for the years then ended and for the period from December 30, 2008 (inception) to December 31, 2010; prior to that date, we did not have independent auditors. Marcum LLP has also served as our independent registered public accountants for the year ended December 31, 2011.

The following is a summary of the fees billed or expected to be billed to us by Marcum LLP, our independent registered public accountants, for professional services rendered with respect to the fiscal years ended December 31, 2011 and 2010:

Fee Category	Fiscal 2011 Fees	Fiscal 2010 Fees
Audit Fees(1)	\$ 90,000	\$ 100,845
Audit-Related Fees(2)	\$ -	\$ -
Tax Fees(3)	\$ 8,500	\$ 8,595
All Other Fees(4)	\$ -	\$ -

(1)

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Audit Fees consist of fees billed for services rendered for the audit of our consolidated financial statements for the fiscal years ended December 31, 2011 and 2010.

- (2) Audit-Related Fees consist of fees billed for assurance and related services that are reasonably related to the performance of the audit of our financial statements and are not reported under "Audit Fees."
- (3) Tax Fees consist of fees billed for professional services related to preparation of our U.S. federal and state income tax returns and tax advice.
- (4) All Other Fees consist of fees billed for products and services provided by our independent registered public accountants, other than those disclosed above.

The Audit Committee is responsible for the appointment, compensation and oversight of the work of the independent registered public accountants, and approves in advance any services to be performed by the independent registered public accountants, whether audit-related or not. The Audit Committee reviews each proposed engagement to determine whether the provision of services is compatible with maintaining the independence of the independent registered public accountants. Substantially all of the fees shown above were pre-approved by our Board as the Audit Committee was not established until April 2011.

**PART IV**

ITEM 15. **EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.**

- 2.1 Acquisition and Reorganization Agreement, dated as of April 17, 2009, by and between Traxxec Inc. and Stem Cell Assurance LLC<sup>1</sup>
- 3.1 Certificate of Amendment to Articles of Incorporation filed on February 13, 2012
- 3.2 Articles of Incorporation, as amended
- 3.3 Articles of Merger with respect to merger of Stem Cell Assurance, Inc. and BioRestorative Therapies, Inc.<sup>2</sup>
- 3.4 Amended and Restated Corporate By-Laws, effective as of August 15, 2011<sup>2</sup>
- 10.1 2010 Equity Participation Plan, as amended<sup>1</sup>
- 10.2 Employment Agreement, dated October 4, 2010, between Stem Cell Assurance, Inc. and Mark Weinreb (“Weinreb Employment Agreement”<sup>1</sup>)
- 10.3 Amendment to Weinreb Employment Agreement, dated May 31, 2011<sup>1</sup>
- 10.4 Amendment to Weinreb Employment Agreement, dated February 10, 2012
- 10.5 Termination Agreement, dated as of December 15, 2010, between Stem Cell Assurance, Inc. and Gloria McConnell<sup>1</sup>
- 10.6 Shareholder Agreement and Irrevocable Proxy, dated as of January 20, 2011, between Gloria McConnell and Mark Weinreb<sup>1</sup>
- 10.7 Termination Agreement, dated as of January 21, 2011, by and among Stem Cell Assurance, Inc., Stem Cell Research Company, LLC and Tommy Berger<sup>1</sup>
- 10.8 Shareholder Agreement and Irrevocable Proxy, dated as of January 21, 2011, between Stem Cell Research Company, LLC and Mark Weinreb<sup>1</sup>
- 10.9 Lease Agreement, effective as of February 1, 2011, between Orange Coast, LLC and Stem Cell Assurance, Inc.<sup>1</sup>
- 10.10 First Amendment to Lease, dated March 11, 2011, between Orange Coast, LLC and Stem Cell Assurance, Inc.<sup>1</sup>
- 10.11 Consulting Agreement, dated as of February 17, 2011, between Stem Cell Assurance, Inc. and TDA Consulting Services, Inc. <sup>1</sup>
- 10.12 Consulting Agreement, dated as of February 17, 2011, between the Company and Vintage Holidays L.L.C. <sup>1</sup>
- 10.13 Letter agreement, dated January 1, 2012, between the Company and Vintage Holidays, L.L.C.
- 10.14 Credit Support, Security and Registration Rights Agreement, dated as of August 17, 2010, between Stem Cell Assurance, Inc. and Quick Capital of L.I. Corp. <sup>1</sup>
- 10.15 Settlement Agreement, dated as of February 23, 2011, by and among Stem Cell Assurance, Inc., Quick Capital of L.I. Corp. and Olde Estate, LLC<sup>1</sup>
- 10.16 Employment Agreement, dated as of December 1, 2010, between Stem Cell Assurance, Inc. and Mandy Clark (“Clark Employment Agreement”)
- 10.17 Amendment to Clark Employment Agreement, dated February 10, 2012
- 10.18 Form of Promissory Note issued by Stem Cell Assurance, Inc./BioRestorative Therapies, Inc. between November 2010 and December 2011<sup>1</sup>
- 10.19 Promissory Note, dated February 1, 2011, issued by Stem Cell Assurance, Inc. in the principal amount of \$266,055.31<sup>1</sup>
- 10.20 Promissory Note, dated February 9, 2011, issued by Stem Cell Cayman Ltd. in the principal amount of \$1,050,000<sup>1</sup>



- 10.21 Form of Stock Option Agreement, dated December 15, 2010, between Stem Cell Assurance, Inc. and each of Mark Weinreb and Mandy Clark<sup>1</sup>
- 10.22 Form of Stock Option Agreement, dated December 15, 2010, between Stem Cell Assurance, Inc. and each of Kurt Wagner, M.D. and Joseph Ross, M.D. <sup>1</sup>
- 10.23 Consulting Agreement, dated as of April 7, 2011, between Stem Cell Assurance, Inc. and Joseph Ross, M.D. <sup>1</sup>
- 10.24 Letter agreement, dated April 2, 2011, between Stem Cell Assurance, Inc. and Kurt Wagner, M.D. <sup>1</sup>
- 10.25 Letter agreement, dated April 7, 2011, between Stem Cell Assurance, Inc. and Joseph Ross, M.D. <sup>1</sup>
- 10.26 Amended and Restated Executive Employment Agreement, dated May 10, 2011, between Stem Cell Assurance, Inc. and Francisco Silva (“Silva Employment Agreement”)
- 10.27 Amendment to Silva Employment Agreement, dated November 4, 2011
- 10.28 Stock Option Agreement, dated April 5, 2011, between Stem Cell Assurance, Inc. and Francisco Silva<sup>1</sup>
- 10.29 Stock Option Agreement, dated April 21, 2011, between Stem Cell Assurance, Inc. and Mandy Clark<sup>1</sup>
- 10.30 Stock Grant Agreement, dated April 21, 2011, between Stem Cell Assurance, Inc. and Joel San Antonio<sup>1</sup>
- 10.31 Stock Grant Agreement, dated April 21, 2011, between Stem Cell Assurance, Inc. and A. Jeffrey Radov<sup>1</sup>
- 10.32 Stock Grant Agreement, dated May 31, 2011, between Stem Cell Assurance, Inc. and Mark Weinreb<sup>1</sup>
- 10.33 Letter agreement, dated as of November 4, 2011, between BioRestorative Therapies, Inc. and Mark Weinreb<sup>1</sup>
- 10.34 Scientific Advisory Board Agreement, dated as of June 10, 2011, between Stem Cell Assurance, Inc. and Naiyer Imam, M. D. <sup>1</sup>
- 10.35 Stock Option Agreement, dated as of June 10, 2011, between Stem Cell Assurance, Inc. and Naiyer Imam, M. D. <sup>1</sup>
- 10.36 Termination Agreement, dated as of June 15, 2011, between Stem Cell Assurance, Inc. and Richard Proodian<sup>1</sup>
- 10.37 Shareholder Agreement and Irrevocable Proxy, dated June 15, 2011, between Richard Proodian and Mark Weinreb<sup>1</sup>
- 10.38 Scientific Advisory Board Agreement, dated as of June 24, 2011, between Stem Cell Assurance, Inc. and Amit Patel, M. D. <sup>1</sup>
- 10.39 Stock Option Agreement, dated as of June 24, 2011, between Stem Cell Assurance, Inc. and Amit Patel, M. D. <sup>1</sup>
- 10.40 Tangible Property License Agreement, entered into as of August 22, 2011, by and between the University of Utah Research Foundation, the University of Utah and Stem Cell Assurance, Inc.<sup>3</sup>
- 10.41 Promissory Note, dated November 4, 2011, issued by Stem Cell Cayman Ltd. in the principal amount of \$1,000,000<sup>1</sup>
- 10.42 Settlement Agreement, dated as of November 8, 2011, between BioRestorative Therapies, Inc. and Gloria McConnell<sup>1</sup>
- 10.43 Settlement Agreement, dated as of November 8, 2011, among BioRestorative Therapies, Inc., Stem Cell Research Company, LLC and Tommy Berger<sup>1</sup>
- 10.44 License Agreement, dated as of January 27, 2012, between Regenerative Sciences, LLC and BioRestorative Therapies, Inc. (“License Agreement”)

- 10.45 Amendment to License Agreement, dated March 21, 2012
- 10.46 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Mark Weinreb
- 10.47 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and A. Jeffrey Radov
- 10.48 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Joel San Antonio
- 10.49 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Francisco Silva
- 10.50 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Mandy Clark
- 10.51 Promissory Note, dated March 30, 2012, issued by Stem Cell Cayman Ltd. in the principal amount of \$1,500,000
- 10.52 Form of Exchange Agreement between BioRestorative Therapies, Inc. and debtholders
- 14 Code of Ethics
- 21 Subsidiaries<sup>1</sup>
- 31.1 Principal Executive Officer Certification
- 31.2 Principal Financial Officer Certification
- 32 Section 1350 Certification
- 101.INS XBRL Instance Document
- 101.SCH XBRL Schema Document
- 101.CAL XBRL Calculation Linkbase Document
- 101.DEF XBRL Definition Linkbase Document
- 101.LAB XBRL Label Linkbase Document
- 101.PRE XBRL Presentation Linkbase Document

<sup>1</sup>Incorporated by reference to the exhibits included with our Registration Statement on Form 10, as amended, filed with the Securities and Exchange Commission.

<sup>2</sup> Incorporated by reference to the exhibits included with our Current Report on Form 8-K for an event dated August 15, 2011 filed with the Securities and Exchange Commission.

<sup>3</sup> Incorporated by reference to the exhibit included with our Current Report on Form 8-K for an event dated August 22, 2011 filed with the Securities and Exchange Commission.



**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIORESTORATIVE  
THERAPIES, INC.

Dated: April 16, 2012 By: */s/ Mark Weinreb*  
Mark Weinreb  
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Capacity	Date
<i>/s/ Mark Weinreb</i> Mark Weinreb	Chief Executive Officer, President, Chairman of the Board and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	April 16, 2012
<i>/s/ A. Jeffrey Radov</i> A. Jeffrey Radov	Director	April 16, 2012
<i>/s/ Joel San Antonio</i> Joel San Antonio	Director	April 16, 2012

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**CONSOLIDATED FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Audit Committee of the Board of Directors  
and Stockholders of BioRestorative Therapies, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of BioRestorative Therapies, Inc. and Subsidiaries (the "Company") (a company in the development stage) (formerly known as Stem Cell Assurance, Inc.) as of December 31, 2011 and 2010, and the related consolidated statements of operations, changes in stockholders' deficiency and cash flows for the years then ended and for the period from December 30, 2008 (inception) to December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioRestorative Therapies, Inc. and Subsidiaries as of December 31, 2011 and 2010, and the results of their operations and their cash flows for the years then ended and for the period from December 30, 2008 (inception) to December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully discussed in Note 2 to the consolidated financial statements, the Company is in the development stage, has incurred net losses since inception and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Marcum LLP

Marcum LLP

New York, NY

April 16, 2012

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Consolidated Balance Sheets**

	December 31,	
	2011	2010
Assets		
Current Assets:		
Cash	\$71,508	\$18,074
Prepaid expenses and other current assets	46,915	-
Total Current Assets	118,423	18,074
Property and equipment, net	94,827	446,756
Intangible assets, net	3,308	3,676
Security deposit	4,415	-
Total Assets	\$220,973	\$468,506
Liabilities and Stockholders' Deficiency		
Current Liabilities:		
Accounts payable	\$426,184	\$160,187
Accrued expenses and other current liabilities	440,229	341,618
Notes payable, net of debt discount of \$149,043 and \$19,476 at December 31, 2011 and December 31, 2010, respectively	3,040,957	514,047
Total Current Liabilities	3,907,370	1,015,852
Notes payable - less current maturities	-	196,876
Total Liabilities	3,907,370	1,212,728
Commitments and contingencies		
Stockholders' Deficiency:		
Preferred stock, \$0.01 par value; Authorized, 1,000,000 shares; none issued and outstanding at December 31, 2011 and December 31, 2010	-	-
Common stock, \$0.001 par value; Authorized, 1,500,000,000 shares; Issued 635,614,845 and 461,148,534 shares at December 31, 2011 and December 31, 2010, respectively;	635,615	461,149

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Outstanding 607,683,811 and 433,217,500 shares at December 31, 2011 and December 31, 2010, respectively

Additional paid-in capital	3,234,486	2,270,219
Shares issuable	-	6,971
Deficit accumulated during development stage	(7,524,498)	(3,450,561)
Treasury stock, at cost, 27,931,034 shares at December 31, 2011 and December 31, 2010	(32,000 )	(32,000 )
Total Stockholders' Deficiency	(3,686,397)	(744,222 )
Total Liabilities and Stockholders' Deficiency	\$220,973	\$468,506

See Notes to these Consolidated Financial Statements

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Consolidated Statements of Operations**

	For The Years Ended		Period from
	December 31,	December 31,	December 30,
	2011	2010	2008 (Inception)
			to
			December 31,
			2011
Revenues	\$-	\$-	\$ -
Operating Expenses			
Marketing and promotion	103,696	124,850	307,818
Payroll and benefits	1,380,867	760,171	2,141,038
Consulting expense	682,171	682,152	2,220,608
General and administrative	1,373,271	490,544	2,092,089
Research and development	12,000	11,620	23,620
Total Operating Expenses	3,552,005	2,069,337	6,785,173
Loss From Operations	(3,552,005 )	(2,069,337 )	(6,785,173 )
Other Income (Expense)			
Other income	-	11,432	11,457
Interest expense	(260,011 )	(24,155 )	(288,498 )
Amortization of debt discount	(345,369 )	(181,739 )	(556,096 )
Gain on settlement of note and payables, net	83,448	-	83,448
Total Other Expense	(521,932 )	(194,462 )	(749,689 )
Net Loss	\$(4,073,937 )	\$(2,263,799 )	\$ (7,534,862 )
Net Loss Per Share - Basic and Diluted	\$(0.01 )	\$(0.00 )	
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	561,287,751	470,404,418	

See Notes to these Consolidated Financial Statements

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Consolidated Statements of Changes in Stockholders' Deficiency****For the period December 30, 2008 (Inception) to December 31, 2011**

	Common Stock		Additional	Due	Deficit	Accumulated	Treasury	Total	
	Shares	Amount	Paid-In	Shares From	During	Development	Stock	Shares	Amount
			Capital	Issuance	Development	Stage	Shares	Amount	Amount
Balance - December 30, 2008 (Inception)	301,999,999	\$ 302,000	\$(302,000)	\$ -	\$ -	\$ -	-	\$ -	\$ -
Net loss for the period ended December 31, 2008	-	-	-	-	-	-	-	-	-
Balance - December 31, 2008 (Inception)	301,999,999	\$ 302,000	\$(302,000)	\$ -	\$ -	\$ -	-	\$ -	\$ -
Recapitalization of accumulated deficit of Stem Cell Assurance, LLC at time of formation	-	-	(10,364 )	-	-	10,364	-	-	-
Shares issued pursuant to reverse recapitalization (at \$0.001)	100,403,621	100,404	(100,404)	-	-	-	-	-	-
Shares issued pursuant to reverse recapitalization and subsequently cancelled - (at \$0.001)	(85,862,068 )	(85,862 )	85,862	-	-	-	-	-	-
Shares issued for cash - May 1, 2009 (at \$0.035)	360,000	360	12,140	-	-	-	-	-	12,500
Shares issued for cash - May 26, 2009 (at \$0.10)	10,000	10	990	-	-	-	-	-	1,000
Shares issued for cash - June 19, 2009 (at \$0.033)	200,000	200	6,300	-	-	-	-	-	6,500

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Shares issued for consulting services - (at \$0.035)	4,108,000	4,108	140,083	-	-	-	-	-	144,191
Shares issued as debt discount in connection with notes payable - August 5, 2009 (at \$0.007)	5,000,000	5,000	31,301	-	-	-	-	-	36,301
Shares issued for cash - September 10, 2009 (at \$0.013)	375,000	375	4,625	-	-	-	-	-	5,000
Shares issued as debt discount in connection with notes payable - October 5, 2009 (at \$0.004)	5,000,000	5,000	16,032						21,032
Shares issued as debt discount in connection with notes payable - November 5, 2009 (at \$0.027)	5,000,000	5,000	-	-	-	-	-	-	5,000
Subtotal	336,594,552	\$336,595	\$(115,435)	\$ -	\$ -	\$ 10,364	-	\$ -	\$231,524

See Notes to these Consolidated Financial Statements.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Consolidated Statements of Changes in Stockholders' Deficiency****For the period December 30, 2008 (Inception) to December 31, 2011****(continued)**

	Common Stock		Additional Paid-In Capital	Due Shares From Issuer		Deficit Accumulated During Development Stage	Treasury Stock Shares	Amount	Total
	Shares	Amount							
Carried Forward	336,594,552	\$336,595	\$(115,435)	\$ -	\$-	\$10,364	-	\$ -	\$231,524
Shares issued as debt discount with connection with notes payable - (at \$0.003)	15,500,000	15,500	36,851	-	-	-	-	-	52,351
Shares issued in connection with debt financings and credit facilitations - December 14, 2009 (at \$0.003)	2,500,000	2,500	6,189	-	-	-	-	-	8,689
Shares issued as debt discount in connection with notes payable - December 15, 2009 (at \$0.003)	8,000,000	8,000	59,949	-	-	-	-	-	67,949
Shares held as collateral in connection with note payable -	20,000,000	20,000	510,000	-	(530,000)	-	-	-	-

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December 15,  
2009 (at \$0.027)

Shares issued for  
consulting  
services - (at  
\$0.027)

27,665,948	27,666	705,482	-	-	-	-	-	733,148
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Warrants  
granted in  
connection with  
consulting  
services -  
August 6, 2009  
(at \$0.01)

-	-	52,379	-	-	-	-	-	52,379
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Net loss

-	-	-	-	-	(1,197,126)	-	-	(1,197,126)
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Balance as of  
December 31,  
2009

410,260,500	\$410,261	\$1,255,414	\$ -	\$(530,000)	\$(1,186,762)	-	\$ -	\$(51,087 )
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Shares issued for  
cash - February  
16, 2010 (at  
\$0.004)

26,000,000	26,000	89,700	-	-	-	-	-	115,700
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Shares issued for  
cash - February  
16, 2010 (at  
\$0.003)

12,000,000	12,000	23,600	-	-	-	-	-	35,600
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Shares held as  
collateral  
returned -  
February 16,  
2010 (at \$0.027)

(20,000,000 )	(20,000 )	(510,000 )	-	530,000	-	-	-	-
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Subtotal

428,260,500	\$428,261	\$858,714	\$ -	\$-	\$(1,186,762)	-	\$ -	\$100,213
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See Notes to these Consolidated Financial Statements.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Consolidated Statements of Changes in Stockholders' Deficiency****For the period December 30, 2008 (Inception) to December 31, 2011****(continued)**

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Shares Issuable	Due From Development Stage	Deficit Accumulated During Development Stage	Treasury Stock Shares	Treasury Stock Amount	Total
Carried Forward	428,260,500	\$428,261	\$858,714	\$-	\$-	\$(1,186,762)	-	\$-	\$100,213
Shares issued for cash - June 1, 2010 (at \$0.025)	500,000	500	12,000	-	-	-	-	-	12,500
Shares issued for cash - (at \$0.01)	37,750,000	37,750	339,750	-	-	-	-	-	377,500
Shares issued for consulting services - (at \$0.007)	42,937,500	42,938	261,156	-	-	-	-	-	304,094
Purchase of treasury shares - August 25, 2010 (at \$0.002)	-	-	-	-	-	-	(12,413,793)	(22,000)	(22,000)
Purchase of treasury shares - October 11, 2010 (at \$0.001)	-	-	-	-	-	-	(15,517,241)	(10,000)	(10,000)

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Shares issued for cash - October 12, 2010 (at \$0.02)	6,250,000	6,250	118,750	-	-	-	-	-	125,000
Shares issued pursuant to reverse recapitalization and retired - October 13, 2010 (at \$0.001)	(60,332,799 )	(60,333 )	60,333	-	-	-	-	-	-
Shares issued for consulting services - November 3, 2010 (at \$0.008)	958,333	958	6,871	-	-	-	-	-	7,829
Shares issued in connection with the exercise of warrants - December 3, 2010 (at \$0.015)	125,000	125	1,750	-	-	-	-	-	1,875
Shares issued/issuable as debt discount in connection with notes payable - (at \$0.007)	4,700,000	4,700	27,210	6,971	-	-	-	-	38,881
Subtotal	461,148,534	\$461,149	\$1,686,534	\$6,971	\$-	\$(1,186,762)	(27,931,034)	\$(32,000)	\$935,892

See Notes to these Consolidated Financial Statements.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Consolidated Statements of Changes in Stockholders' Deficiency****For the period December 30, 2008 (Inception) to December 31, 2011****(continued)**

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Shares Issuable	Due From Lenders	Deficit Accumulated During Development Stage	Treasury Stock Shares	Treasury Stock Amount	Total
Carried Forward	461,148,534	\$461,149	\$1,686,534	\$6,971	\$-	\$(1,186,762)	(27,931,034)	\$(32,000)	\$935,892
Stock-based compensation expense	-	-	583,685	-	-	-	-	-	583,685
Net loss	-	-	-	-	-	(2,263,799)	-	-	(2,263,799)
Balance - December 31, 2010	461,148,534	\$461,149	\$2,270,219	\$6,971	\$-	\$(3,450,561)	(27,931,034)	\$(32,000)	\$(744,222 )
Shares issued for consulting services - (at \$0.008)	17,077,000	17,077	123,980	-	-	-	-	-	141,057
Shares issued to board of directors - April 21, 2011 (at \$0.008)	10,000,000	10,000	62,275	-	-	-	-	-	72,275
Shares reissued to former President - January 12,	12,576,811	12,577	(12,577 )	-	-	-	-	-	-

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2011 (at par value)

Shares issued pursuant to settlement agreement - February 23, 2011 (at \$0.008)	8,312,500	8,312	60,350	-	-	-	-	-	68,662
Shares issued as debt discount in connection with notes payable - (at \$0.007)	68,500,000	68,500	413,407	(6,971)	-	-	-	-	474,936
Shares issued to CEO pursuant to employment agreement - (at \$0.008)	50,000,000	50,000	73,900	-	-	-	-	-	123,900
Shares and warrants issued for cash - (at \$0.025)	8,000,000	8,000	192,000	-	-	-	-	-	200,000
Stock-based compensation - options			50,932	-	-	-	-	-	50,932
Net loss	-	-	-	-	-	(4,073,937)	-	-	(4,073,937)
Balance - December 31, 2011	635,614,845	\$635,615	\$3,234,486	\$-	\$-	\$(7,524,498)	(27,931,034)	\$(32,000)	\$(3,686,397)

See Notes to these Consolidated Financial Statements.



**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Consolidated Statements of Cash Flows**

	For The Years Ended		Period from
	December 31,	December 31,	December 30,
	2011	2010	2008 (Inception)
			to
			December 31,
			2011
Cash Flows From Operating Activities			
Net loss	\$(4,073,937)	\$(2,263,799)	\$ (7,534,862 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt discount	345,369	181,739	556,096
Depreciation and amortization	90,412	48,358	145,182
Loss on sale of property and equipment	21,614	-	21,614
Stock-based compensation	456,826	895,608	2,282,151
Gain on settlement of note and payables, net	(83,448 )	-	(83,448 )
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(46,915 )	5,950	(46,915 )
Security deposit	(4,415 )	-	(4,415 )
Accounts payable	268,516	81,918	368,703
Accrued expenses and other current liabilities	215,111	321,008	552,729
Total Adjustments	1,263,070	1,534,581	3,791,697
Net Cash Used in Operating Activities	(2,810,867)	(729,218 )	(3,743,165 )
Cash Flows From Investing Activities			
Purchases of property and equipment	(17,772 )	(45,383 )	(163,243 )
Proceeds from sale of property and equipment	32,000	-	32,000
Acquisition of intangible assets	-	(3,401 )	(3,676 )
Net Cash Provided by (Used in) Investing Activities	14,228	(48,784 )	(134,919 )
Cash Flows From Financing Activities			
Proceeds from notes payable	2,962,500	332,654	3,573,639
Repayment of notes payable	(308,427 )	(176,795 )	(485,222 )
Advances from officer	26,000	-	26,000
Repayment of advances from officer	(26,000 )	-	(26,000 )
Proceeds from exercise of warrants	-	1,875	1,875

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Repurchase of common stock	(4,000 )	(28,000 )	(32,000 )
Sale of common stock and warrants for cash	200,000	666,300	891,300
Net Cash Provided by Financing Activities	2,850,073	796,034	3,949,592
Net Increase In Cash	53,434	18,032	71,508
Cash - Beginning	18,074	42	-
Cash - Ending	\$71,508	\$18,074	\$ 71,508

See Notes to these Consolidated Financial Statements

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Consolidated Statements of Cash Flows—Continued**

	For The Years Ended		Period from
	December 31,	December 31,	December 30,
	2011	2010	2008 (Inception)
			to
			December 31,
			2011
Supplemental Disclosures of Cash Flow Information:			
Cash paid during the period for:			
Interest	\$ 186,150	\$ 16,847	\$ 202,997
Non-cash investing and financing activities:			
Shares issued as debt discount in connection with notes payable	\$474,936	\$31,910	\$ 698,168
Shares returned as collateral in connection with note payable	\$-	\$(530,000)	\$ -
Shares issued in connection with reverse recapitalization	\$-	\$-	\$ 362,000
Shares issued pursuant to reverse recapitalization and subsequently cancelled	\$-	\$60,333	\$ 146,195
Shares issued (issuable) as debt discount in connection with note payable	\$6,971	\$(6,971)	) \$ -
Purchase of property and equipment for note payable	\$-	\$291,055	\$ 291,055
Purchase of property and equipment for accounts payable	\$-	\$60,000	\$ 60,000
Accrued payable for treasury shares repurchased	\$-	\$7,000	\$ 7,000
Shares reissued to former President	\$12,577	\$-	\$ 12,577
Property and equipment returned in connection with settlement of note payable, net	\$226,043	\$-	\$ 226,043

See Notes to these Consolidated Financial Statements

## **BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

### **(A COMPANY IN THE DEVELOPMENT STAGE)**

#### **Notes to Consolidated Financial Statements**

##### **Note 1 - Business Organization and Nature of Operations**

On April 17, 2009, Stem Cell Assurance, LLC (“SCA, LLC”) completed a transaction with Traxxec, Inc. (“Traxxec”), a company incorporated on June 13, 1997 under the laws of the state of Nevada under the name “Columbia River Resources Inc.” Pursuant to the agreement, SCA, LLC was converted into Traxxec, Inc. and the former members of SCA, LLC were issued approximately 302,000,000 shares, or approximately 75% of the outstanding shares of common stock of Traxxec, Inc. In addition, on April 17, 2009, pursuant to the agreement, an additional 60,000,000 shares were issued to a shareholder of Traxxec. Traxxec was a non-operating shell company and was authorized to issue 1,000,000 shares of preferred stock and 500,000,000 shares of common stock. On the date of the transaction, Traxxec had 0 shares of preferred stock and 40,403,621 shares of common stock issued and outstanding. The transaction was accounted for as a reverse recapitalization, whereby SCA, LLC is deemed to be the acquirer for accounting purposes. The net assets received in the transaction were recorded at historical costs. On August 17, 2009, Traxxec, Inc. changed its name to Stem Cell Assurance, Inc. (“SCA, Inc.”). On July 20, 2011, SCA, Inc. entered into an agreement and plan of merger (the “Merger Agreement”) with BioRestorative Therapies, Inc., a Nevada corporation that was formed concurrently as a wholly-owned subsidiary of SCA, Inc. Pursuant to the Merger Agreement, effective August 15, 2011, BioRestorative Therapies, Inc. merged with and into SCA, Inc. (the surviving corporation) solely to effect a name change to BioRestorative Therapies, Inc.. BioRestorative Therapies, Inc. has wholly-owned subsidiaries including Stem Pearls, LLC, formerly Stem Cellutrition, LLC, which plans to offer and sell facial creams and products, Lipo Rejuvenation Centers, Inc., which is inactive, and Stem Cell Cayman Ltd. (“Cayman”), which the Company formed as a wholly-owned subsidiary in the Cayman Islands (collectively, the “Company”).

The consolidated financial statements set forth in this report for all periods prior to the reverse recapitalization are the historical financial statements of SCA, LLC and have been retroactively restated to give effect to the transaction. The operations of SCA, LLC from December 30, 2008 (inception) to the date of the transaction have been included in operations.

The Company has been presented as a "development stage enterprise". The Company's primary activities since inception have been the research and development of its business plan, negotiating strategic alliances and other agreements, and raising capital. To date, the Company has not generated any revenues from its operations.

The Company's goal is to become a medical center of excellence, using cell and tissue regenerative therapy protocols, primarily involving a patient's own (autologous) adult stem cells (non-embryonic), for personal, medical and aesthetic applications.

## **Note 2 - Going Concern and Management Plans**

As of December 31, 2011, the Company had a working capital deficiency and a stockholders' deficiency of \$3,788,947 and \$3,686,397, respectively. The Company has not generated any revenues and has incurred net losses of \$7,534,862 during the period from December 30, 2008 (inception) through December 31, 2011. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company's primary source of operating funds since inception has been its stockholders and note financings. The Company intends to raise additional capital through private debt and equity investors. The Company is currently a development stage company and there is no assurance that these funds will be sufficient to enable the Company to fully complete its development activities or attain profitable operations.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate the continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

Subsequent to December 31, 2011, the Company raised \$1,600,500 and \$650,000 through debt and equity financing, respectively, exchanged \$175,000 of debt into equity, and extended the maturities of \$1,610,000 of notes. The Company currently has notes payable aggregating \$250,000 which are past their maturity dates. The Company is currently in the process of negotiating extensions or discussing conversions to equity with respect to these notes. See Note 10 – Subsequent Events for additional details.

## **BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

### **(A COMPANY IN THE DEVELOPMENT STAGE)**

#### **Notes to Consolidated Financial Statements**

#### **Note 3 - Summary of Significant Accounting Policies**

##### Principles of Consolidation

The consolidated financial statements of the Company include the accounts of Cayman, Stem Pearls, LLC, formerly Stem Cellutrition, LLC, and Lipo Rejuvenation Centers, Inc. (an inactive entity). All significant intercompany transactions have been eliminated in the consolidation.

##### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at dates of the financial statements and the reported amounts of revenue and expenses during the periods. Actual results could differ from these estimates. The Company's significant estimates and assumptions include the recoverability and useful lives of long-lived assets, the fair value of the Company's stock, stock-based compensation, debt discount and the valuation allowance relating to the Company's deferred tax assets.

##### Concentrations of Credit Risk

The Company maintains deposits in a financial institution which is insured by the Federal Deposit Insurance Corporation ("FDIC"). At various times, the Company has deposits in this financial institution in excess of the amount insured by the FDIC. As of December 31, 2011 and 2010, the Company had \$29,097 and \$0, respectively, deposited with an offshore financial institution which is not insured by the FDIC.

### Cash

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of December 31, 2011 and 2010, the Company does not have any cash equivalents.

### Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation which is recorded using the straight line method at rates sufficient to charge the cost of depreciable assets to operations over their estimated useful lives, which range from 3 to 5 years. Maintenance and repairs are charged to operations as incurred.

### Intangible Assets

Intangible assets are comprised of trademarks. Once placed into service, the Company amortizes the cost of the intangible assets over their useful lives, which is estimated to be 10 years, on a straight line basis.

### Advertising

Advertising costs are charged to operations as incurred. For the years ended December 31, 2011 and December 31, 2010, the Company incurred advertising costs of \$101,982 and \$124,850, respectively. For the period from December 30, 2008 (Inception) to December 31, 2011, the Company's total advertising expense amounted to \$307,818.

### Research and Development

Research and development expenses are charged to operations as incurred. For the years ended December 31, 2011 and December 31, 2010, the Company incurred research and development expenses of \$12,000 and \$11,620, respectively. For the period from December 30, 2008 (inception) to December 31, 2011, the Company's total research and development expenses amounted to \$23,620.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 3 - Summary of Significant Accounting Policies - Continued**

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in the financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts (“temporary differences”) at enacted tax rates in effect for the years in which the temporary differences are expected to reverse.

The Company adopted the provisions of Accounting Standards Codification (“ASC”) Topic 740-10, which prescribes a recognition threshold and measurement process for financial statements recognition and measurement of a tax position taken or expected to be taken in a tax return.

The Company classifies interest expense and any related penalties related to income tax uncertainties as a component of income tax expense. No interest or penalties have been recognized as of December 31, 2011 and 2010.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company’s consolidated financial statements as of December 31, 2011 and 2010. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

Net Loss Per Common Share



Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding, plus the issuance of common shares, if dilutive, resulting from the exercise of outstanding stock options and warrants.

The Company's weighted average number of common shares as of December 31, 2011 includes issued and outstanding common shares and the underlying shares issuable upon the exercise of the 20,000,000 and 2,000,000 exercisable options and warrants, respectively, with an exercise price of \$0.01 or less. The Company's weighted average number of common shares as of December 31, 2010 includes issued and outstanding common shares and the underlying shares issuable upon the exercise of the 72,000,000 and 2,000,000 exercisable options and warrants, respectively, with an exercise price of \$0.01 or less. See Note 9 – Stockholders' Deficiency. In accordance with ASC 260 – Earnings Per Share ("ASC 260"), the Company has given effect to the issuance of these options and warrants in computing basic and diluted net loss per share.

The Company's issued and outstanding common shares as of December 31, 2011 include 40,000,000 shares of stock awards that are non-vested. In accordance with ASC 260, the Company has not given effect to the issuance of these shares in computing basic net loss per share.

Potentially dilutive securities realizable from the vesting of 40,000,000 shares of restricted stock and the exercise of options and warrants for the purchase of 6,150,000 and 2,000,000 shares, respectively, as of December 31, 2011 are excluded from the computation of diluted net loss per share because the effect of their inclusion would have been anti-dilutive. There were no potentially dilutive securities as of December 31, 2010.

### Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. Since the shares underlying the Company's 2010 Equity Participation Plan (the "Plan") are not currently registered, the fair value of the Company's restricted equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares.

Stock-based compensation for non-employees and directors is reflected in consulting expenses in the consolidated statements of operations. Stock-based compensation for employees is reflected in payroll and benefits in the consolidated statements of operations.



## **BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

### **(A COMPANY IN THE DEVELOPMENT STAGE)**

#### **Notes to Consolidated Financial Statements**

#### **Note 3 - Summary of Significant Accounting Policies – Continued**

##### Reclassifications

Certain prior period amounts have been reclassified for comparative purposes to conform to the fiscal 2011 presentation. These reclassifications have no impact on previously reported net loss.

##### Impairment of Long-lived Assets

The Company reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The Company has not identified any such impairment losses.

##### Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of ASC 820 “Fair Value Measurements and Disclosures” which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 — quoted prices in active markets for identical assets or liabilities

Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 — inputs that are unobservable (for example, cash flow modeling inputs based on assumptions)

The carrying amounts of cash, accounts payable, and accrued liabilities approximate fair value due to the short-term nature of these instruments. The carrying amounts of our short term credit obligations approximate fair value because the effective yields on these obligations, which include contractual interest rates taken together with other features such as concurrent issuance of warrants and/or embedded conversion options, are comparable to rates of returns for instruments of similar credit risk.

#### Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2011-04, “Fair Value Measurement (Topic 820) - Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs.” This ASU addresses fair value measurement and disclosure requirements within ASC Topic 820 for the purpose of providing consistency and common meaning between U.S. GAAP and IFRSs. Generally, this ASU is not intended to change the application of the requirements in Topic 820. Rather, this ASU primarily changes the wording to describe many of the requirements in U.S. GAAP for measuring fair value or for disclosing information about fair value measurements. This ASU is effective for periods beginning after December 15, 2011. It is not expected to have any impact on the Company’s consolidated financial statements or disclosures.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company’s financial statements upon adoption.

#### Subsequent Events

The Company evaluates events that have occurred after the balance sheet date but before the financial statements are issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the consolidated financial statements, except as disclosed in Note 11.

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Notes to Consolidated Financial Statements****Note 4 - Property and Equipment**

Property and equipment include the following:

	December 31,	
	2011	2010
Office equipment	\$7,670	\$7,487
Medical equipment	118,301	474,356
Furniture and fixtures	19,322	7,142
Computer software and equipment	17,636	12,541
	162,929	501,526
Less: accumulated depreciation	(68,102 )	(54,770 )
Property and equipment, net	\$94,827	\$446,756

Depreciation expense amounted to \$90,044 and \$48,358 for the years ended December 31, 2011 and 2010, respectively. Depreciation expense for the period from December 30, 2008 (inception) to December 31, 2011 was \$144,814. See Note 6, Notes Payable, for details regarding the redelivery of medical equipment.

**Note 5 - Accrued Expenses and Other Liabilities**

Accrued expenses and other current liabilities are comprised of the following:

	December 31,	
	2011	2010
Accrued loan interest	\$39,283	\$11,116

Credit card payable	17,026	20,132
Accrued payroll and severance	250,571	230,370
Other accrued expenses	89,200	80,000
Deferred rent	44,149	-
Total	\$440,229	\$341,618

**Note 6 - Notes Payable**

During 2010, the Company purchased certain property and equipment with a value of \$304,055. In February 2011, the Company renegotiated the terms of the then \$291,055 payable with the vendor and entered into a promissory note. In accordance with ASC 470, the Company reclassified a portion of this payable to long-term on the balance sheet as of December 31, 2010, since the event occurred after the balance sheet date, but before the financial statements were issued. The agreement provided for an immediate principal payment of \$25,000, plus monthly installments of \$8,094, including an effective interest rate of 6%. The Company made \$48,019 of principal payments during the year ended December 31, 2011. The scheduled maturity of the note was February 1, 2014 and was collateralized by the equipment purchased. On August 23, 2011, the Company received a notice from the vendor stating that it is in default under the terms of the equipment purchase agreement, for non-payment of certain installment payment obligations. On November 10, 2011, the Company and the equipment vendor agreed to settle the remaining \$243,036 due pursuant to the note for \$48,564 and the redelivery to the vendor of the equipment that had been purchased, which resulted in a \$31,571 loss on the restructuring of the note. The outstanding balance of this note as of December 31, 2011 and 2010 was \$0 and \$291,055, respectively.

As of December 31, 2010, the Company included \$6,971 of the debt discount as shares issuable as the note payable agreement was made but the 1,000,000 shares were not issued until subsequent to year end. In January 2011, the Company issued 1,000,000 shares of common stock with a relative fair value of \$6,971 to a private debt investor.

## **BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

### **(A COMPANY IN THE DEVELOPMENT STAGE)**

#### **Notes to Consolidated Financial Statements**

##### **Note 6 - Notes Payable - Continued**

During the years ended December 31, 2011 and 2010, the Company and its wholly-owned subsidiary, Cayman, obtained new debt financing in the aggregate amount of \$2,962,500 (\$2,050,000 obtained by Cayman) and \$332,654, respectively. \$1,962,500 of the debt issued in 2011 is repayable three months from the date of issuance of the respective notes; however, the Company and Cayman have the right to extend the maturity date for an additional three months. During the initial three month period of the notes, the rate of interest is 10% per annum; during any extension period, the interest rate is increased to 15% per annum. The Company is using the effective interest rate method of recording interest expense, which reflects the weighted average interest on a ratable basis over the expected term of the debt. \$1,000,000 of the debt issued in 2011 is repayable one year from the date of issuance of the respective note and the rate of interest is 15% per annum. In connection with the new debt financings, an aggregate of 59,250,000 and 4,700,000 shares of common stock of the Company were issued to the lenders during 2011 and 2010, respectively, with a relative fair value of \$417,875 and \$31,910, respectively. These shares were accounted for as a debt discount and amortized over the estimated life of the related debt.

During the year ended December 31, 2011, the Company exercised its option to extend the maturity date for an additional three month period for notes with an aggregate principal amount of \$2,110,000. During the year ended December 31, 2011, the maturity dates of twelve notes payable with an aggregate principal balance of \$1,650,000 were further extended to November 2011 through June 2012 and the investors received an aggregate of 8,250,000 shares of common stock with a relative fair value of \$57,061 as compensation for the additional extension. All of the further extended notes bear a 15% interest rate per annum payable monthly. The Company has certain notes payable aggregating \$160,000 which matured on November 10, 2011. In January 2012, these notes were extended to May 10, 2012. The notes bear a 15% interest rate per annum payable monthly. The Company repaid other notes payable with an aggregate principal balance of \$211,844 during the year ended December 31, 2011. All of the notes outstanding as of December 31, 2011 are scheduled to mature during 2012.

The Company recorded amortization of debt discount of \$345,369 and \$181,739 during the years ended December 31, 2011 and 2010, respectively. Aggregate amortization of debt discount from December 30, 2008 (inception) to December 31, 2011 was \$556,096.



**Note 7 - Income Taxes**

The tax effects of temporary differences that give rise to deferred tax assets are presented below:

	For The Years Ended December 31,	
	2011	2010
<b>Deferred Tax Assets:</b>		
Net operating loss carryforward	\$2,544,500	\$1,140,100
Stock-based compensation	234,900	221,800
Accrued compensation	61,500	62,700
Charitable contribution carryforward	100	100
Total deferred tax assets	2,841,000	1,424,700
<b>Deferred Tax Liabilities:</b>		
Fixed asset depreciation	(21,000 )	(148,100 )
Total deferred tax liabilities	(21,000 )	(148,100 )
Total deferred tax asset	2,820,000	1,276,600
Valuation allowance	(2,820,000)	(1,276,600)
Deferred tax asset, net of valuation allowance	\$-	\$-
Changes in valuation allowance	\$1,543,400	\$827,100

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Notes to Consolidated Financial Statements****Note 7 - Income Taxes – Continued**

The income tax provision (benefit) consists of the following:

	For The Years Ended December 31,	
	2011	2010
Federal:		
Current	\$-	\$-
Deferred	(1,380,937)	(740,037)
State and local:		
Current	-	-
Deferred	(162,463 )	(87,063 )
	(1,543,400)	(827,100)
Change in valuation allowance	1,543,400	827,100
Income tax provision (benefit)	\$-	\$-

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	For The Years Ended December 31,	
	2011	2010
Tax benefit at federal statutory rate	(34 )%	(34 )%
State income taxes, net of federal tax benefit	(4 )%	(4 )%
Change in valuation allowance	38 %	38 %
Effective income tax rate	- %	- %

The Company assesses the likelihood that deferred tax assets will be realized. To the extent that realization is not likely, a valuation allowance is established. Based upon the Company's history of losses since inception, management believes that it is more likely than not that future benefits of deferred tax assets will not be realized, and therefore, a full valuation allowance has been established as of December 31, 2011 and 2010.

At December 31, 2011 and 2010, the Company had approximately \$6,700,000 and \$3,000,000, respectively, of federal and state net operating losses that may be available to offset future taxable income. The net operating loss carry forwards, if not utilized, will expire from 2029 to 2031 for federal purposes. In accordance with Section 382 of the Internal Revenue Code, the usage of the Company's net operating loss carry forward as of April 2009 is deemed to be limited due to the change in ownership at that time.

The Company files income tax returns in the U.S. federal jurisdiction and the state of Florida, and is subject to examination by the various taxing authorities. The Company's federal and state income tax returns for the tax years after 2009 remain subject to examination.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 8 - Commitments and Contingencies**

Operating Lease

On January 20, 2011, the Company entered into a three year lease agreement with respect to premises located at the Alexandria Innovation Center in Jupiter, Florida. The lease, as amended on March 11, 2011, expires on January 31, 2014. No base rent is payable during the initial year and the lease provides for a base monthly rent of \$6,234 during the second year and \$6,422 during the third year. The Company has the right to lease the premises for an additional three years at the then fair market value rent. The aggregate base rent payable over the lease term is being recognized on a straight-line basis. See Note 5, Accrued Expenses and Other Liabilities, for the deferred rent balance.

The Company leased office space in Boca Raton, Florida under a month to month operating lease. Effective May 1, 2011, the Company terminated this lease.

Rent expense amounted to \$84,541 and \$29,000 for the years ended December 31, 2011, and 2010, respectively. Rent expense for the period from December 30, 2008 (inception) to December 31, 2011 was approximately \$131,541. Rent expense is reflected in general and administrative expenses in the consolidated statements of operations.

Letters of Credit

The Company has purchased certain equipment from suppliers by means of letters of credit. As of December 31, 2011 and 2010, there were no outstanding balances for these letters of credit.

Pursuant to a Credit Support, Security and Registration Rights Agreement, dated as of August 17, 2010, between the Company and Quick Capital of L.I. Corp. (“Quick Capital”), and in connection with issuances of certain letters of credit with regard to purchases of equipment by the Company, the Company issued to Quick Capital 24,937,500 shares of common stock valued at \$182,044 for their consulting services. See Note 8 - Commitments and Contingencies – Settlement Agreements.

#### Litigations, Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. Such matters are subject to many uncertainties, and outcomes are not predictable with assurance. In the opinion of management, the ultimate disposition of these matters will not have a material adverse effect on the Company’s consolidated financial position or results of operations.

#### Consulting Agreements

##### *Business Advisory Services*

Pursuant to a March 1, 2011 agreement for business advisory services, which has a term that expires on March 31, 2012, the retained firm is to provide consultation and assistance with regard to the Company’s efforts to have its securities listed on the OTC Bulletin Board or a securities exchange, establish an offshore stem cell treatment facility, develop business, including with regard to acquisition and joint venture opportunities, develop a physician distribution network for the sale of the Company’s stem cell skin care products, and comply with regulatory requirements. Pursuant to the agreement, the Company paid \$35,000 in consideration of services rendered to date and a \$25,000 retainer, included in prepaid expenses and other current assets, for services to be rendered during the term. The Company also agreed to pay an additional \$130,000 fee, and issue 10,500,100 shares of common stock, both of which are to be paid, expensed and issued in equal monthly installments during the term of the agreement. Through December 31, 2011, the Company issued 8,077,000 shares of common stock valued at \$66,716 which was expensed during the period. Subsequent to December 31, 2011 and through the filing date of this report, the Company issued 2,423,100 shares of common stock valued at \$20,015 in connection with this agreement. Though the business advisory agreement expired on March 31, 2012, we continue to utilize the firm’s services and are in the process of negotiating an extension to our agreement.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 8 - Commitments and Contingencies – Continued**

Consulting Agreements - Continued

*Marketing Consulting Services*

Pursuant to a March 1, 2011 agreement for marketing consulting services, which had an initial term that expired on June 30, 2011, the retained firm is to provide consultation and assistance with regard to the Company's efforts to market itself with respect to medical tourism, establish business relationships with governmental officials, and establish an offshore stem cell treatment facility. Pursuant to the agreement, the Company paid \$20,000 in consideration of services rendered to date and a \$10,000 retainer for services to be rendered during the term. The Company also agreed to pay an additional \$20,000 fee, and issue 5,000,000 shares of common stock, both of which are to be paid, expensed and issued in equal monthly installments during the term of the agreement. On July 1, 2011 and again on September 1, 2011, the agreement was extended for additional three month terms and the Company agreed to pay an additional \$5,000 fee monthly in advance on the first day of each month. Through December 31, 2011, the Company issued 5,000,000 shares of common stock valued at \$41,300 which was expensed during the period. On January 1, 2012, the agreement was extended for an additional twelve months. See Note 10, Subsequent Events – Extension of Marketing Consulting Services Agreement for additional details.

*Former Director*

Effective April 7, 2011, the Company entered into a consulting agreement with a former director in connection with the implementation of its business plan. Pursuant to the agreement, subject to the satisfaction of certain performance conditions, the former director is entitled to receive options for the purchase of up to 5,000,000 shares of common stock, pursuant to the Plan, at an exercise price equal to the fair market value on the date of grant. The Company will recognize expense associated with this award if and when it becomes probable that the consultant will satisfy the conditions. As of December 31, 2011, these options have not yet been granted.

Employment Agreements

*Chief Executive Officer*

Effective October 4, 2010, the Company entered into an employment agreement with its Chief Executive Officer (the "CEO"). The employment agreement provided for an initial term of three years. The employment agreement provides for a minimum salary of \$360,000 during the initial year, \$480,000 during the second year and \$600,000 during the third year. As of December 31, 2011, the accrued and unpaid salary and vacation pay was \$81,800. In the event the term of the employment agreement is extended beyond the initial term, the base salary payable shall be increased by 20% per annum. The agreement also includes certain severance provisions.

Pursuant to the employment agreement, the CEO is entitled to an annual bonus in an amount equal to 50% of his then current salary. The bonus shall be payable in quarterly installments, commencing on the three month anniversary of the commencement of the employment agreement and continuing on each three month anniversary and shall not be subject to any condition. As of December 31, 2011, the accrued and unpaid bonus was \$60,000.

On December 23, 2010, pursuant to the Plan and in connection with the employment agreement, the Company granted to its CEO an option for the purchase of 50,000,000 shares of its common stock at an exercise price of \$0.001 per share, valued at \$409,441. The options vested immediately, which resulted in the grant date value being expensed immediately, and were exercisable for a period of ten years from the date of grant.

In January 2011, pursuant to an amended employment agreement, the Company issued 15,000,000 shares of common stock to its CEO. In connection with this issuance, the Company immediately recorded the \$123,900 value of the common stock as stock-based compensation expense. The Company has agreed to be responsible for the payment of all taxes incurred by the CEO as a result of the grant, as well as all taxes incurred as a result of such tax payments on the CEO's behalf. As of December 31, 2011, the accrued and unpaid tax payment was \$20,000.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 8 - Commitments and Contingencies – Continued**

Employment Agreements – Continued

*Chief Executive Officer - Continued*

Effective May 31, 2011 (the “Modification Date”), the Company’s employment agreement with its CEO was amended to provide that the option granted to him on December 23, 2010 for the purchase of 50,000,000 shares of common stock (the “Original Grant”) was null and void. In addition, concurrently, the Company granted to the CEO 35,000,000 shares of common stock (the “Modified Grant”) pursuant to the Plan (as defined below). The shares were to vest at such time as the Company received equity and/or debt financing in an aggregate amount equal to three times the tax payable in connection with the grant. The Company has agreed to be responsible for the payment of all taxes incurred by the CEO as a result of the grant, as well as all taxes incurred as a result of such tax payments on the CEO’s behalf. The Company will not recognize any incremental compensation expense for the modification of the grant because (1) the grant date fair value of the immediately vested Original Grant was fully recognized on the grant date; and (2) the fair value of the Modified Grant was less than the fair value of the Original Grant, both as of the Modification Date. On November 4, 2011, the Company and the CEO further modified the CEO’s 35,000,000 share restricted stock grant such that vesting is now subject to the receipt of at least \$2,000,000 in additional equity and/or debt financing after such date.

See Note 10 – Subsequent Events – CEO Compensation for updates associated with the CEO’s compensation arrangement.

*Administrative and Compliance Support Services*



Effective April 15, 2011, the Company entered into an agreement for administrative and compliance support services with an entity, in exchange for \$4,000 per month. In addition, on April 27, 2011, the Company granted to the entity a ten-year option to purchase 200,000 shares of common stock at an exercise price of \$0.02 per share, pursuant to the Plan. Options for the purchase of 100,000 of such shares became exercisable immediately and options for the purchase of the remaining 100,000 shares became exercisable when the key employee of the consultant became a full-time employee of the Company on November 1, 2011. Aggregate stock-based compensation of \$1,620 was recognized during 2011, including the immediate recognition of the grant date value of the first tranche plus the November 1, 2011 value of the second tranche.

*Vice President of Operations*

Effective December 1, 2010, the Company entered into an employment agreement with its Vice President of Operations (“VP of Operations”). Pursuant to the employment agreement, the VP of Operations is entitled to receive \$75,000 per annum (subject to an increase to \$90,000 per annum effective upon her relocation to the Company’s Jupiter, Florida offices; such relocation occurred as of February 1, 2011). The agreement also provides for certain severance provisions. Effective January 1, 2012, the employment agreement was amended such that the VP of Operations is entitled to receive a salary of \$100,000 per annum.

On April 21, 2011, the Company granted to its Vice President of Operations a ten-year option to purchase 300,000 shares of common stock at an exercise price of \$0.02 per share, pursuant to the Plan, of which 100,000 shares are immediately exercisable, 100,000 are exercisable on the first anniversary of the grant and 100,000 are exercisable on the second anniversary of the grant. The \$2,430 grant date fair value will be recognized one-third immediately with the balance amortized ratably over the vesting period.

See Note 10 – Subsequent Events – Option Grants for additional awards granted to the Vice President of Operations.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 8 - Commitments and Contingencies – Continued**

Employment Agreements – Continued

*Vice President of Research and Development*

Effective April 5, 2011, the Company entered into an at will employment agreement, as amended on May 10, 2011, with its Vice President of Research and Development (“VP of R&D”). Pursuant to the employment agreement, the VP of R&D is entitled to receive \$150,000 per annum. In addition, subject to the satisfaction of certain performance conditions, he is entitled to a cash bonus of up to \$55,000 and option grants for the purchase of up to 3,150,000 shares of common stock at an exercise price equal to the fair market value on the date of grant. The agreement also provides for severance. Concurrently with the execution of the employment agreement, the Company granted a ten-year option to purchase 4,000,000 shares of common stock at an exercise price of \$0.01 per share, pursuant to the Plan. Options for the purchase of 2,000,000 of such shares became exercisable immediately and options for the purchase of the remaining 2,000,000 shares become exercisable on the first anniversary of the date of grant. The \$32,400 grant date fair value will be recognized one-half immediately with the balance amortized ratably over the vesting period. On June 24, 2011, the VP of R&D qualified to receive a cash bonus of \$10,000 and vested ten-year options for the purchase of 150,000 shares of common stock at an exercise price of \$0.025 per share, pursuant to his employment agreement. The \$1,200 grant date value of these options was recognized immediately. On November 4, 2011, the VP of R&D’s employment agreement was amended, including modification of some of the vesting performance criteria, which resulted in him immediately qualifying for a \$20,000 cash bonus and vested ten-year options for the purchase of 1,000,000 shares of common stock at an exercise price of \$0.02 per share. The \$8,000 grant date value of these options was recognized immediately. See Note 10 – Subsequent Events – Option Grants for additional awards granted to the VP of R&D and the transition of his position to Research Scientist.

Following the execution of the employment agreement, the VP of R&D was sued by his former employer with regard to certain confidentiality and non-competition restrictions in an agreement to which he was a party. The former employer obtained a preliminary injunction against the VP of R&D which enjoins him from using or disseminating information he obtained from his former employer, including using such information to solicit his former employer’s customers. Management has indicated that the Company has taken actions to limit the VP of R&D’s activities and it is

monitoring the court's determinations. The Company is not currently a party to the action.

#### Tangible Property License

On August 22, 2011, the Company entered into a Tangible Property License Agreement (the "Utah Agreement") with the University of Utah Research Foundation and the University of Utah (together "Utah"). Pursuant to the Utah Agreement, which has a term of two years, the Company has been granted a non-exclusive license to use discarded adipose (fat) tissue samples for internal research purposes. The Company agreed to pay between \$1,000 and \$1,500 per sample, depending on the quantity ordered. The Company has the right to terminate the Utah Agreement at any time with ninety days written notice and Utah may immediately terminate the Utah Agreement, if the Company ceases to carry on its business or upon material breach of the Utah Agreement by the Company.

#### Termination Agreements

##### *Former President*

In January 2011, pursuant to a Termination Agreement dated December 15, 2010, the Company reissued 12,576,811 shares of common stock to its former President. In addition, the Company agreed to pay \$120,000 of severance ratably over a 24 month period and took responsibility for approximately \$20,152 of business related credit card indebtedness. On November 8, 2011, the Company agreed to settle the remaining \$87,500 of severance due pursuant to the former President's termination agreement for \$22,500 and the Company recognized a \$65,000 gain on restructuring the payable balance. In addition, the Company agreed to pay-off the remaining business related credit card indebtedness by December 31, 2011.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 8 - Commitments and Contingencies – Continued**

Termination Agreements - Continued

*Founder/Stem Cell Research Company, LLC*

Effective January 29, 2011, the Company terminated its relationship with a founder of the Company. Pursuant and subject to the terms and conditions of the Termination Agreement between the parties, the founder waived any rights he may have had pursuant to a certain employment agreement entered into with the Company in August 2010 and the Company agreed to pay to Stem Cell Research Company, LLC (“Stem Cell Research”), a principal shareholder of the Company, \$180,000 over a 12 month period. In addition, pursuant to the Termination Agreement, the founder and Stem Cell Research have agreed to certain restrictive covenants, including with regard to the sale of shares of common stock of the Company. On November 8, 2011, the Company agreed to settle the remaining \$100,000 due pursuant to the founder’s termination agreement for \$50,000 and the Company recognized a \$50,000 gain on restructuring the payable balance.

*Other Employee*

On April 4, 2011, the Board was informed of an employee’s resignation and it authorized the payment of \$25,000 ratably over the eight months following the termination date, of which none was outstanding at December 31, 2011. Pursuant to the provisions of the Plan, the Board determined that the immediately vested options granted on December 15, 2010 to this employee for the purchase of 2,000,000 shares of common stock of the Company, for which the Company immediately recorded a charge equal to the \$15,840 grant date value, shall remain exercisable until, and shall thereupon terminate if not exercised, two years from the date of termination of employment.

*Former Chief Financial Officer*

In June 2011, the Company and its former Chief Financial Officer (the “Former CFO”) entered into an agreement whereby, effective June 25, 2011, the Former CFO (1) resigned his director and officer positions with the Company and its subsidiaries; (2) became subject to a two year non-compete and non-solicitation restriction; plus certain restrictions on the sale of the Company’s common stock; and (3) will receive an aggregate amount of \$50,000 of severance from the Company in full satisfaction of all obligations ratably over the remainder of the calendar year, of which \$46,154 was outstanding and included in accrued expenses and other current liabilities in the consolidated balance sheet at December 31, 2011. Pursuant to the Former CFO’s December 15, 2010 option grant (see Note 9 – Stockholder’s Deficiency – Stock Options), his options to purchase 4,000,000 shares of Company common stock were forfeited three months after his termination date, but no stock-based compensation expense was reversed because the options were fully vested. See Note 10 – Subsequent Events – Settlement Agreement for additional details.

#### New Director Compensation

On April 4, 2011, two non-employees were elected to serve as directors of the Company. On April 21, 2011, the two new non-employee directors were each granted 5,000,000 shares of common stock. One-half of the shares vested and were expensed upon grant and the other half vests on the first anniversary of the grant. The aggregate \$82,600 grant date fair value will be recognized one-half immediately with the balance amortized ratably over the vesting period. In addition, each of the new directors will receive \$20,000 in cash, payable in four quarterly installments of \$5,000 (subject to deferral if the remaining directors determine that the Company needs to conserve its cash), of which \$30,000 was outstanding and included in accrued expenses and other current liabilities in the consolidated balance sheet at December 31, 2011.

#### New Scientific Advisory Board Compensation

Effective June 10, 2011, the Company established a Scientific Advisory Board and reserved 5,000,000 shares of common stock to be issued to members (“Advisors”) pursuant to the Plan, as either options or restricted stock grants.

Pursuant to a June 10, 2011 agreement between the Company and its first appointed Advisor, the Advisor is entitled to: (1) an immediate grant of a vested five-year option to purchase 500,000 shares of common stock at an exercise price of \$0.024 per share; and (2) a grant on each successive anniversary date, on which he remains an Advisor, of a vested five-year option to purchase 250,000 shares of common stock at an exercise price per share equal to the fair market value of the common stock on the date of grant. The Company immediately recognized the \$3,450 grant date fair value of the initial award.

## **BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

### **(A COMPANY IN THE DEVELOPMENT STAGE)**

#### **Notes to Consolidated Financial Statements**

#### **Note 8 - Commitments and Contingencies – Continued**

##### New Scientific Advisory Board Compensation – Continued

Pursuant to a June 24, 2011 agreement between the Company and its second appointed Advisor, the Advisor is entitled to: (1) an immediate grant of a five-year option to purchase 2,000,000 shares of common stock at an exercise price of \$0.025 per share, of which 667,000 shares are immediately exercisable, 667,000 are exercisable on the first anniversary of the grant and 666,000 are exercisable on the second anniversary of the grant; and (2) a grant on the third anniversary of the award and each subsequent anniversary, on which he remains an Advisor, of a vested five-year option to purchase 250,000 shares of common stock at an exercise price per share equal to the fair market value of the common stock on the date of grant. The \$14,600 grant date fair value of the initial award will be recognized one-third immediately with the balance amortized ratably over the vesting period.

##### Settlement Agreements

Also see Note 6, Notes Payable for details related to the Company's equipment note settlement agreement.

##### *Quick Capital of L.I. Corp.*

Effective February 23, 2011, the Company entered into a Settlement Agreement with Quick Capital and Olde Estate, LLC ("Olde Estate"). Pursuant to the Settlement Agreement, the Company paid to Quick Capital approximately \$36,000 and issued to Olde Estate 8,312,500 shares of its common stock valued at \$68,662, which was immediately expensed, in satisfaction of the Company's monetary and stock issuance obligations to Quick Capital and Olde Estate under a Credit Support, Security and Registration Rights Agreement, dated as of August 17, 2010.

*Sound Surgical Technologies, LLC*

On March 8, 2011, the Company and Sound Surgical Technologies, LLC (“Sound Surgical”) entered into a Settlement Agreement and Release of Claim (the “Settlement Agreement”) pursuant to which the parties agreed that the Company’s purchase from Sound Surgical of one piece of equipment was cancelled, the Company’s obligations under a certain purchase agreement were terminated and the Company retained one piece of purchased equipment. On March 8, 2011, the Company paid to Sound Surgical \$65,000 in connection with the purchase of the retained equipment and to complete the Settlement Agreement.

Sale of Equipment

On August 22, 2011, the Company sold equipment for \$32,000 to a third party. The Company purchased the equipment in September 2010 for \$65,000 and recognized a loss on sale of equipment of \$21,614 which was recorded in general and administrative expenses in the consolidated statement of operations.

**Note 9 - Stockholders’ Deficiency**

Authorized Capital

The Company is authorized to issue 1,500,000,000 shares (increased from 800,000,000 shares on February 10, 2012 (see Note 10) and 500,000,000 shares on December 7, 2010) of common stock, \$0.001 par value, and 1,000,000 shares of preferred stock, \$0.01 par value. The holders of the Company’s common stock are entitled to one vote per share. Subject to the rights of holders of preferred stock, if any, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors out of legally available funds. Subject to the rights of holders of preferred stock, if any, upon liquidation, dissolution or winding up of the Company, holders of common stock are entitled to share ratably in all assets of the Company that are legally available for distribution.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 9 - Stockholders' Deficiency – Continued**

2010 Equity Participation Plan

On November 17, 2010, the Board of Directors of the Company adopted the 2010 Equity Participation Plan. Pursuant to the Plan, up to 100,000,000 shares of common stock were initially authorized to be issued to the Company's employees, non-employee directors, consultants and advisors. Stockholder approval of the Plan was obtained effective as of December 15, 2010.

On March 28, 2011, the Board of Directors of the Company increased the number of shares of common stock that may be issued pursuant to the Plan to 200,000,000. Stockholder approval of the increase was obtained effective as of April 4, 2011.

Common Stock Issuances

The Company issued for consulting services 43,895,833 shares of common stock valued at \$311,923 in 2010. The fair market value of such instruments was calculated on the date of issuance.

The Company sold 82,500,000 shares for aggregate cash proceeds of \$666,300 in 2010.

In 2010, warrants were exercised for the purchase of 125,000 shares at an aggregate exercise price of \$1,875.



Stockholders cancelled an aggregate of 60,332,799 shares in 2010.

The Company repurchased 15,517,241 shares from stockholders for an aggregate purchase price of \$10,000 in 2010.

On November 8, 2010, the Company entered into a Settlement Agreement with a shareholder. The Company had agreed to purchase from the shareholder 12,413,793 shares of Company stock for the total sum of \$22,000 for the purpose of retirement to treasury. Pursuant to the settlement agreement, the Company and the shareholder agreed to three installment payments of \$8,000, \$7,000 and \$7,000 payable in November and December 2010 and January 2011, respectively. Of this amount, \$7,000 was recorded as a current liability as of December 31, 2010 and was paid in 2011.

During the year ended December 31, 2009, the Company issued 20,000,000 shares of common stock to a lender valued at \$530,000 as collateral for certain loans. These shares were returned to the Company in February 2010.

In October and December 2011, the Company issued an aggregate of 8,000,000 shares of common stock at a price of \$0.025 per share to two investors for aggregate gross proceeds of \$200,000. In connection with the purchases, the Company issued aggregate warrants to the investors valued at \$31,233 for the purchase of an aggregate of 2,000,000 shares of common stock, which are exercisable over a period of five years at an exercise price of \$0.03 per share of common stock.

See Note 6, Notes Payable for details associated with common stock issued in conjunction with the issuances and extensions of notes payable.

See Note 8, Commitments and Contingencies - Termination Agreements for details associated with a common stock reissuance to the Company's Former President.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 9 - Stockholders' Deficiency – Continued**

Stock Warrants

On August 12, 2010, the Company issued warrants to a consultant for the purchase of 125,000 shares of the Company's common stock, valued at \$808. The warrants vested immediately, expire on August 12, 2013 and have an exercise price of \$0.015 per share. The warrants were exercised during the year ended December 31, 2010.

The Company recorded stock-based compensation expense of \$0 and \$808 during the years ended December 31, 2011 and 2010, respectively, and \$52,378 during the period from December 30, 2008 (inception) to December 31, 2011, related to consultant warrant grants, which is reflected as consulting expenses in the consolidated statements of operations. As of December 31, 2011, there was no unrecognized consultant stock-based compensation expense related to warrant grants.

In applying the Black-Scholes option pricing model, the Company used the following weighted average assumptions:

	<b>For The Years Ended</b>			
	<b>December 31,</b>			
	2011		2010	
Risk free interest rate	0.44	%	1.21	%
Expected term (years)	2.50		3.00	
Expected volatility	185	%	207	%
Expected dividends	0.00	%	0.00	%

The weighted average estimated fair value of the warrants granted during the year ended December 31, 2010 was approximately \$0.006 per share.

A summary of the warrant activity during the years ended December 31, 2011 and 2010 is presented below:

	<b>Number of Warrants</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Life In Years</b>	<b>Aggregate Intrinsic Value</b>
Outstanding, December 31, 2009	2,000,000	\$ 0.010		
Granted	125,000	0.015		
Exercised	(125,000 )	0.015		
Forfeited	-	-		
Outstanding, December 31, 2010	2,000,000	\$ 0.010		
Issued	2,000,000	0.030		
Exercised	-	-		
Forfeited	-	-		
Outstanding, December 31, 2011	4,000,000	\$ 0.020	3.7	\$ -
Exercisable, December 31, 2011	4,000,000	\$ 0.020	3.7	\$ -

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Notes to Consolidated Financial Statements****Note 9 - Stockholders' Deficiency – Continued**Stock Warrants - Continued

The following table presents information related to warrants at December 31, 2011:

Warrants Outstanding	Warrants Exercisable	Warrants Exercisable	Warrants Exercisable
Exercise Price	Number of Warrants	Weighted Average Remaining Life In Years	Number of Warrants
\$ 0.01	2,000,000	2.6	2,000,000
0.03	2,000,000	4.9	2,000,000
	4,000,000	3.7	4,000,000

Stock Options

The Company has computed the fair value of options granted using the Black-Scholes option pricing model. Forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate will be adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate, when it is material. The expected term of options granted represents the estimated period of time that options granted are expected to be outstanding. The Company utilizes the "simplified" method to develop an estimate of the expected term of "plain vanilla" option grants. Since the Company's stock has not been publicly traded for a long period of time, the Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of these options, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the options.

In applying the Black-Scholes option pricing model, the Company used the following weighted average assumptions:

	<b>For The Years Ended</b>			
	<b>December 31,</b>			
	2011		2010	
Risk free interest rate	1.54	%	1.93	%
Expected term (years)	4.51		5.00	
Expected volatility	205.00	%	207.00	%
Expected dividends	0.00	%	0.00	%

The weighted average estimated fair value of the stock options granted during the years ended December 31, 2011 and 2010 was approximately \$0.008 per share.

See Note 8, Commitments and Contingencies for details associated with certain grants of options as compensation to employees, directors and consultants.

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 9 - Stockholders' Deficiency – Continued**

Stock Options - Continued

*Employee Awards*

The Company recorded stock-based compensation expense of \$38,968 and \$424,474 during the years ended December 31, 2011 and 2010, respectively, and \$464,249 during the period from December 30, 2008 (inception) to December 31, 2011, related to employee stock option grants, which is reflected as payroll and benefits expense in the consolidated statements of operations. As of December 31, 2011, there was \$5,063 of unrecognized employee stock-based compensation expense related to stock option grants that will be amortized over a weighted average period of 0.5 years.

*Director Awards*

On December 15, 2010, five directors of the Company were granted ten-year, immediately vested options to purchase an aggregate of 20,000,000 shares of common stock at an exercise price of \$0.01 per share. The grant date value of \$158,403 was immediately recorded as consulting expense.

On April 2, 2011, a director of the Company resigned. Pursuant to the provisions of the Plan, the Board determined that the options granted on December 15, 2010 for the purchase of 4,000,000 shares of common stock of the Company shall remain exercisable until, and shall thereupon terminate if not exercised, two years from the date of resignation.

On April 7, 2011, a director of the Company resigned. Pursuant to the provisions of the Plan, the Board determined that the options granted on December 15, 2010 for the purchase of 4,000,000 shares of common stock of the Company shall remain exercisable until, and shall thereupon terminate if not exercised, five years from the date of resignation.

The Company recorded stock-based compensation expense of \$0 and \$158,403 during the years ended December 31, 2011 and 2010, respectively, and \$158,403 during the period from December 30, 2008 (inception) to December 31, 2011, related to director stock option grants. As of December 31, 2011, there was no unrecognized employee stock-based compensation expense related to stock option grants.

#### *Consultant Awards*

The Company recorded stock-based compensation expense of \$11,966 and \$0 during the years ended December 31, 2011 and 2010, respectively, and \$11,966 during the period from December 30, 2008 (inception) to December 31, 2011, related to consultant and advisory board stock option grants, which is reflected as consulting expenses in the consolidated statements of operations. As of December 31, 2011, there was \$6,894 of unrecognized consultant and advisory board stock-based compensation expense related to stock option grants that will be amortized over a weighted average period of 1.5 years.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****(A COMPANY IN THE DEVELOPMENT STAGE)****Notes to Consolidated Financial Statements****Note 9 - Stockholders' Deficiency – Continued**Stock Options - Continued*Option Award Summary*

A summary of the option activity during the years ended December 31, 2011 and 2010 is presented below:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Life In Years</b>	<b>Aggregate Intrinsic Value</b>
Outstanding, December 31, 2009	-	\$ -		
Granted	72,000,000	0.004		
Exercised	-	-		
Voided	-	-		
Forfeited	-	-		
Outstanding, December 31, 2010	72,000,000	\$ 0.004		
Granted	8,150,000	0.017		
Exercised	-	-		
Voided	(50,000,000)	0.001		
Forfeited	(4,000,000 )	0.010		
Outstanding, December 31, 2011	26,150,000	\$ 0.012	8.6	\$ -
Exercisable, December 31, 2011	22,617,000	\$ 0.011	8.8	\$ -

The following table presents information related to stock options at December 31, 2011:



Options Outstanding	Options Exercisable	Options Exercisable	Options Exercisable
Exercise Price	Number of Options	Weighted Average Remaining Life In Years	Number of Options
\$0.010	22,000,000	9.0	20,000,000
0.020	1,500,000	9.8	1,300,000
0.024	500,000	4.4	500,000
0.025	2,150,000	5.4	817,000
	26,150,000	8.8	22,617,000

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 9 - Stockholders' Deficiency – Continued**

Common Stock Awards

See Note 8, Commitments and Contingencies for details associated with certain grants of common stock as compensation to employees, directors and consultants.

*Employee Awards*

The Company recorded stock-based compensation expense of \$123,900 and \$0 during the years ended December 31, 2011, and 2010, respectively, and \$123,900 during the period from December 30, 2008 (inception) to December 31, 2011, related to employee stock grants, which is reflected as payroll and benefits expense in the consolidated statements of operations. As of December 31, 2011, there was no unrecognized employee stock-based compensation expense related to employee stock grants.

*Director Awards*

The Company recorded stock-based compensation expense of \$72,275 and \$14,600 during the years ended December 31, 2011 and 2010, respectively, and \$234,690 during the period from December 30, 2008 (inception) to December 31, 2011, related to director stock grants, which is reflected as consulting expenses in the consolidated statements of operations. As of December 31, 2011, there was \$10,325 of unrecognized director stock-based compensation expense related to stock grants that will be amortized over a weighted average period of 0.3 years.

*Consultant Awards*

On September 1, 2011, the Company granted 4,000,000 shares of common stock to its legal counsel. The \$33,040 grant date fair value was recognized immediately on the grant date.

The Company recorded stock-based compensation expense of \$209,717 and \$297,323 during the years ended December 31, 2011 and 2010, respectively, and \$1,398,980 during the period from December 30, 2008 (inception) to December 31, 2011, related to consultant stock grants, which is reflected as consulting expenses in the consolidated statements of operations. As of December 31, 2011, there was no unrecognized consultant stock-based compensation expense.

#### *Stock Award Summary*

A summary of common stock award activity for the years ended December 31, 2011 and 2010 is presented below:

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>	<b>Total Grant Date Fair Value</b>
Non-vested, December 31, 2009	-	\$ -	\$ -
Granted	43,895,833	0.00711	311,923
Vested	(43,895,833)	0.00711	(311,923 )
Forfeited	-	-	-
Non-vested, December 31, 2010	-	\$ -	\$ -
Granted	85,389,500	0.00826	705,317
Vested	(45,389,500)	0.00826	(374,917 )
Forfeited	-	-	-
Non-vested, December 31, 2011	40,000,000	\$ 0.00826	\$ 330,400

See Note 10 – Subsequent Events – CEO Compensation for details associated with the subsequent vesting of a 35,000,000 share stock award.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 10 – Subsequent Events**

Extension of Marketing Consulting Services Agreement

On January 1, 2012, the agreement for marketing consulting services was further extended to December 31, 2012, pursuant to which the Company will pay a cash fee of \$10,000 per month and the Company granted an immediately vested, five-year option to purchase 2,000,000 shares of common stock at an exercise price of \$0.02 per share. The grant date value of \$12,800 was recognized immediately.

Settlement Agreement

On January 4, 2012, the Company agreed to settle the remaining \$46,154 due pursuant to the Former CFO's termination agreement for \$23,077 and the Company recorded a \$23,077 gain on settlement of the payable.

License Agreement

On January 27, 2012, the Company entered into a license agreement with Regenerative Sciences, LLC ("RS") (as amended on March 21, 2012, the "RS Agreement. On April 6, 2012, the RS Agreement became effective. Pursuant to the RS Agreement, the Company obtained, among other things, a worldwide, exclusive, royalty-bearing license from RS to utilize or sublicense a certain medical device for the administration of specific cells and/or cell products to the disc and/or spine (and other parts of the body) and a worldwide (excluding Asia and Argentina), exclusive, royalty-bearing license to utilize or sublicense a certain method for culturing cells for use in repairing damaged areas. The RS Agreement provides for the requirement by the Company to achieve certain milestones or pay certain minimum royalty amounts in order to maintain the exclusive nature of the licenses. The RS Agreement also provides for a royalty-bearing sublicense of the technology to RS for use for certain purposes. Further, the RS Agreement provides that RS will furnish certain training, assistance and consultation services with regard to the licensed

technology. Pursuant to the RS Agreement, on the effective date, the Company paid to RS a net license fee of \$990,000 and issued to RS a warrant for the purchase of 50,000,000 shares of common stock of the Company. The warrant was divided into three tranches. The exercise of the second and third tranches is subject to specified performance criteria. The exercise price for the initial tranche is \$0.03 per share and the exercise price for the second and third tranches is the greater of \$0.03 per share or the then fair market value, as defined in the RS Agreement.

### Option Grants

On February 10, 2012, the Company granted ten-year options to employees and directors to purchase an aggregate of 114,000,000 shares of common stock at an exercise price of \$0.021 per share. The options vest as follows: (i) an option granted to the CEO to purchase 50,000,000 shares of common stock vests to the extent of one-third of the shares immediately, one-third on the first anniversary of the date of grant and one-third on the second anniversary of the date of grant; and (ii) options to purchase an aggregate of 64,000,000 shares of common stock vest to the extent of one-half of the shares immediately and one-half on the first anniversary of the date of grant. The aggregate grant date value of \$889,200 will be recognized proportionate to the vesting period.

### CEO Compensation

On February 10, 2012, the Board approved (1) the extension of the CEO's employment agreement for an additional two years (through October 2015) at the same compensation as the third year; and (2) the payment of a \$70,000 discretionary bonus to the CEO in connection with the signing of the RS Agreement. The employment agreement shall be extended for successive one year periods unless either party provides ninety days written notice to the other party. On April 4, 2012, the CEO's 35,000,000 share stock grant vested as a result of raising in excess of \$2,000,000 of financing since November 4, 2011. The Company had previously agreed to fund the CEO's tax liability (approximately \$115,000) in connection with such vesting. The discretionary bonus and tax liability are unpaid as of the date of this report. See Note 10 – Subsequent Events – Option Grants above for details associated with a 2012 CEO option grant.

### Shareholder Actions

On February 10, 2012, the shareholders of the Company approved (a) an increase in the authorized common stock to 1,500,000,000 shares from 800,000,000 shares; and (b) giving the Board the discretion to effect a reverse stock split of the Company's common stock by a ratio of not less than 1-for-10 and not more than 1-for-150. The Board has not yet approved a reverse stock split.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

**(A COMPANY IN THE DEVELOPMENT STAGE)**

**Notes to Consolidated Financial Statements**

**Note 10 – Subsequent Events - Continued**

Notes Payable

Subsequent to December 31, 2011, the Company issued an additional \$1,600,500 of notes payable. In connection with \$100,500 of the financing, 2,010,000 shares of common stock, with a relative fair value of \$14,247, were issued to the lenders and were recorded as a debt discount. These notes are payable 3-6 months from the date of issuance and have a rate of interest of 10-15% per annum. In connection with \$1,500,000 of the financing, a five-year warrant to purchase 20,000,000 shares of common stock at an exercise price of \$0.03 per share, with a relative fair value of \$112,824, was issued to a shareholder of the Company and was recorded as a debt discount. The note is payable one year from the date of issuance and has a rate of interest of 15% per annum.

Subsequent to December 31, 2011, the maturity dates of sixteen notes payable with an aggregate principal balance of \$1,610,000 were extended to May 2012 through November 2012 and the investors received an aggregate of 1,125,000 shares of common stock with a relative fair value of \$8,925. All of the extended notes bear a 15% interest rate per annum payable monthly.

Subsequent to December 31, 2011, the Company repaid a note payable with a principal amount of \$50,000.

Subsequent to December 31, 2011, the Company and five investors agreed to exchange five notes with an aggregate principal balance of \$175,000 for an aggregate of 6,750,000 shares of common stock and five-year warrants to purchase an aggregate of 3,500,000 shares of common stock at an exercise price of \$0.03 per share. The warrants had an aggregate grant date value of \$94,658. The investors received piggyback registration rights related to the stock and the stock issuable pursuant to the warrants.

Issuance of Common Stock

Subsequent to December 31, 2011, the Company issued an aggregate of 26,000,000 shares of common stock at a price of \$0.025 per share to investors for aggregate gross proceeds of \$650,000. In consideration of the purchase, the Company issued warrants for the purchase of an aggregate of 7,500,000 shares of common stock, which are exercisable over a period of five years at exercise prices ranging from \$0.030 to \$0.035 per share of common stock. The warrants had an aggregate grant date value of \$190,105.

#### Investor Relations Agreement

On April 3, 2012, the Company entered into a six-month agreement with a consultant to provide investor relations services whereby the consultant will be paid \$15,000 per month. Unless the agreement is terminated 30 days prior to the end of the six-month period, the agreement will continue with the consultant being paid \$10,000 per month, subject to a 60 day termination notice.

#### Additional Warrant

On April 9, 2012, the Company issued a warrant to a shareholder in lieu of reimbursing certain costs associated with a contemplated financing that did not occur. The immediately vested, five-year warrant entitles the shareholder to purchase 4,000,000 shares of common stock at an exercise price of \$0.03 per share. The warrant had a grant date value of \$102,849 which was recognized immediately.