BioRestorative Therapies, Inc.
Form 10-K
April 11, 2014

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, 2013

.. **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 x

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 x

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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. x

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 x

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, 2013, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $8,451,297 based on the closing sale price as reported on the OTC Markets. As of April 9, 2014, there were 21,833,014 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,” “projec “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

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 significant 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, 2013, we raised an aggregate of $1,410,809 in connection with sales of common stock and warrants and from the exercise of warrants, and an aggregate of $1,454,000 in debt financing. As of December 31, 2013, our outstanding debt of $5,754,500, together with interest at rates ranging between 8% and 20% per annum, was due through October 2014. Subsequent to December 31, 2013 and through April 9, 2014, we have received aggregate equity financing, including proceeds received from the exercise of common stock purchase warrants, and debt financing of $625,000 and $140,000, respectively, we have received research and development fees of $150,000, the due date for the repayment of $752,500 of debt has been extended, $25,000 of debt has been repaid, and $274,000 and $19,932 of debt and accrued interest, respectively, has been exchanged for common stock. Giving effect to the above actions, we currently have notes payable aggregating $193,000 which are either past due or payable on demand. We are currently in the process of negotiating extensions or discussing conversions to equity with respect to these notes.

In March 2014, we entered into a Research and Development Agreement with Rohto Pharmaceutical Co., Ltd., a Japanese pharmaceutical company. Pursuant to the agreement, we have been engaged to provide research and development services with regard to stem cells. The agreement provides for an initial payment to us of $150,000 (which we received in March 2014) and the payment of up to an additional $100,000 subject to the satisfaction of certain milestones. The term of the agreement is one year.

In March 2014, we entered into a Research Agreement with Pfizer, Inc.. Pursuant to the agreement, we have been engaged to provide research and development services with regard to brown fat. The agreement provides for an initial payment to us of $250,000 and the payment of up to an additional $525,000 during the two year term of the

agreement.

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**

General

We develop products and medical procedures using cell and tissue protocols, primarily involving adult stem cells, including pursuant to the following programs:

- **brtxDISC™** (**D**isc **I**mplanted **S**tem **C**ells) is an investigational non-surgical treatment for protruding, bulging and herniated lumbar discs that is intended for patients who have failed non-invasive procedures and face the prospect of surgery. The treatment involves culturing a patient's own stem cells and then delivering them via a proprietary medical device to the damaged region of the disc in an outpatient procedure.

- **ThermoStem®** is a treatment using brown fat stem cells that is under development for metabolic disorders including diabetes and obesity. Initial preclinical research indicates that increased amounts of brown fat in the body may be responsible for additional caloric burning as well as reduced glucose and lipid levels.

- **brtx-C Cosmetic** is based on the development of a human cellular extract that has been demonstrated in *in vitro* skin studies to increase the production of collagen and fibronectin, which are proteins that are essential to combating the aging of skin. Potential cosmetic uses are being explored with third parties.

We also offer plant stem cell-based facial creams and beauty products under the **Stem Pearls®** brand.

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.

We are developing medical procedures using cell and tissue protocols, primarily involving adult stem cells (non-embryonic), designed for patients to undergo minimally invasive 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 applications. Among the initiatives that we are currently pursuing is our brtxDISC™ (**D**isc **I**mplanted **S**tem **C**ells) Program. We have obtained a license that permits us to use technology for adult stem cell treatment of disc and spine conditions, including protruding, 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. Another technology we are developing is our ThermoStem® Program. This pre-clinical program involves the use of brown fat in connection with the cell-based treatment of type 2 diabetes and obesity as well as hypertension, other metabolic disorders and cardiac deficiencies. See “Disc/Spine Program” and “Brown Adipose (Fat) Program” below.

We also offer stem cell derived cosmetic and skin care products. Pursuant to our brtx-C Cosmetic Program, we have developed an ingredient derived from human adult stem cells which can be used by third party companies in the development of their own skin care products. Separately, through our wholly-owned subsidiary, Stem Pearls, LLC, we 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 “Cosmetic Products” below.

We currently are seeking to establish a new laboratory facility and increase our capabilities for the further development of possible 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 significant 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, fund our research and development efforts, 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 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 $25,000,000 and $50,000,000 in funding to implement our business plan with regard to our brtxDISC™ Program, as further discussed in this Item 1 (assuming the receipt of no revenues from operations) and repay our outstanding debt ($5,754,500 as of December 31, 2013) (assuming that no debt is converted into equity). We will also require a substantial amount of additional funding to implement our other programs discussed in this Item 1. No assurance can be given that the anticipated amounts of required funding are correct or that we will be able to accomplish our goals within the timeframes projected. In addition, 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.”).

Strategy

We are 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 protruding, bulging and herniated discs and degenerative disc disease. We refer to this initiative as our brtxDISC™ (**D**isc **I**mplanted **S**tem **C**ells) Program. See “Disc/Spine Program” below.

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In connection with the technology license discussed in “Disc/Spine Program” below, we intend to market and/or sublicense the delivery device. We also intend to sublicense the technology to third parties for use at their stem cell therapy facilities in connection with cellular-based treatment programs with regard to disc and spine and other conditions.

We are also engaging in research efforts with respect to an initiative related to the use of brown adipose (fat) for therapeutic 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 continue our research activities in this area in connection with the treatment of type 2 diabetes and obesity as well as of hypertension, other metabolic disorders and cardiac deficiencies. We have labeled this initiative our ThermoStem® Program. See “Brown Adipose (Fat) Program” below.

Pursuant to our brtx-C Cosmetic Program, we have developed an ingredient derived from human adult stem cells which we are offering to third parties for use in their production of skin care products. 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 “Cosmetic Products” below.

We intend to establish 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. See “Laboratory” and “Technology” below.

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 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.

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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. We will seek to obtain third party reimbursement for our procedures and products; however; we anticipate that patients may be required to pay for our procedures and products out of pocket in full and without the ability to be reimbursed by any governmental and other third party payers (referred to as "private pay").

We intend that the majority of our disc/spine procedures will involve adult stem cells harvested from a patient's own (autologous) cells so that the chance of rejection or disease being spread from donor to patient is low. 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.

Disc/Spine Program

Pursuant to a license agreement between Regenerative Sciences, LLC ("Regenerative") and us that became effective in April 2012, 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 protruding, bulging and herniated discs. The technology that has been 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. 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 protruding, bulging and herniated discs and degenerative disc disease. We have labeled this initiative our brtxDISC™ (**D**isc **I**mplanted **S**tem **C**ells) Program.

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 certain of the technology to Regenerative for use for certain purposes, including in the Cayman Islands. Further, the license agreement requires that Regenerative furnish certain training, assistance and consultation services with regard to the licensed technology. Pursuant to the license agreement, we paid to Regenerative a net license fee of $990,000 and issued to Regenerative a five year warrant for the purchase of 1,000,000 shares of our common stock, of which the right to purchase 700,000 shares will vest only when specified performance criteria are met.

We intend to develop a reproducible cell-based culture system in either a laboratory that we develop or an outside laboratory. We then intend to initiate a pre-investigational new drug ("IND") study with respect to the development of a

treatment protocol. We expect that such study will be completed by the third quarter of 2014. Following such study, we intend to file an IND/investigational device exemption ("IDE") application with the FDA with respect to our proposed treatment protocol and initiate clinical trials. The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance. 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.").

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. In 2012, the District Court ruled in favor of the FDA, but Regenerative appealed the decision. In February 2014, the United States Court of Appeals for the D.C. Circuit affirmed the District Court's ruling, concluding that the FDA has the authority to regulate certain autologous stem cell procedures and that the Regenexx stem cell mixture meets the definition of drug and not HCT/P since it was more than minimally manipulated. Regenerative has indicated that it does not intend to appeal the decision to the Supreme Court. While this decision is specific to Regenerative's procedures and mixture, it indicates that stem cells, even when used in an autologous context, may be regulated as drugs, particularly when mixed with other substances or in other ways that may be considered to be more than minimally manipulated. Based on this outcome, it may be more likely that we will need to proceed with the FDA approval process for our initiatives as discussed above. See "Government Regulation" below.

Brown Adipose (Fat) Program

Brown fat is a population of adipose (fat) tissue found in the human body and it plays a key role in the evolutionarily conserved mechanisms underlying energy homeostasis in mammals. Human newborns and hibernating mammals have high levels of brown fat and its main function is to generate body heat and regulate metabolism. 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 program referred to as the ThermoStem® Program. The ThermoStem® Program will focus on treatments for type 2 diabetes and obesity, as well as for 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 adult stem cells that may be differentiated into progenitor or fully differentiated brown adipocytes, or a related cell type, which can be used therapeutically in patients. We are focusing on the development of treatment protocols that utilize allogeneic cells (i.e., stem cells from a genetically similar but not identical donor). As the cellular program advances, we will seek to use the data from the program 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 June 2012, we entered into an Assignment Agreement with the University of Utah Research Foundation (the "Foundation") and a Research Agreement with the University of Utah (the "University"). Pursuant to the Assignment Agreement, we acquired the rights to two patent applications that relate to human brown fat cell lines. In consideration for the assignment, we paid the Foundation $15,000 and agreed to pay a royalty on the Patent Revenue (as defined in the Assignment Agreement). Pursuant to the Research Agreement, the University has agreed to provide research services relating to the identification of brown fat tissue and the development and characterization of brown fat cell lines. Pursuant to the Research Agreement, all inventions, discoveries, patent rights, information, data, methods and techniques, including all cell lines, cell culture media and derivatives thereof, shall be owned by us and we have agreed to pay the University a fee at the rate of $500,000 per annum and a royalty on Net Sales (as defined in the Research Agreement). The Research Agreement has a three year term, except that it is terminable earlier under certain circumstances.

Following our research activities, we 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 2014. 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."). 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 third quarter of 2015.

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

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Cosmetic Products

brtx-C Cosmetic Program

Pursuant to our brtx-C Cosmetic Program, we have developed a human adult stem cell-derived extract that, when applied to human skin cells, significantly increases the production of collagen and fibronectin, which are proteins that are essential to combating the aging of skin.

We are seeking to enter into arrangements with third party cosmetic companies with regard to the commercial distribution of anti-aging skin care products that utilize our extract as a principal cosmetic ingredient.

Stem Pearls®

Our wholly-owned subsidiary, Stem Pearls, LLC, offers plant derived stem cell cosmetic products. Stem Pearls, LLC has developed an initial product formulation derived from the stem cells of a rare-variety 18th century Swiss apple. Stem Pearls® currently offers its products via the Internet (www.stempearls.com and www.biorestorative.com), and intends to offer its products to stores and through cosmetic distributors to retail, spa and medical locations. Stem Pearls, LLC has not yet commenced widespread marketing efforts or generated any significant revenue.

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 2014. We are currently utilizing existing laboratories at the University of Utah as discussed above under “Brown Adipose (Fat) Program.”

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 type 2 diabetes and obesity as well as other metabolic disorders, heart disease and autoimmune disease.

Technology; Research and Development

We intend to utilize our laboratory or a third party laboratory, such as the one we utilize at the University of Utah (see "Brown Adipose (Fat) Program") 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, media 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 have five non-provisional and two provisional patent applications pending in the United States and one application filed in five non-United States jurisdictions. In addition, 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 design mark BioRestorative Therapies® and the names BioRestorative Therapies™, brtxDISC™, ThermoStem®, Stem Pearls® and Stem The Tides of Time®. 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.

In March 2014, we entered into a Research and Development Agreement with Rohto Pharmaceutical Co., Ltd., a Japanese pharmaceutical company. Pursuant to the agreement, we have been engaged to provide research and development services with regard to stem cells. The agreement provides for an initial payment to us of $150,000 and the payment of up to an additional $100,000 subject to the satisfaction of certain milestones. The term of the agreement is one year.

In March 2014, we entered into a Research Agreement with Pfizer, Inc.. Pursuant to the agreement, we have been engaged to provide research and development services with regard to brown fat. The agreement provides for an initial payment to us of $250,000 and the payment of up to an additional $525,000 during the two year term of the agreement.

During the years ended December 31, 2013 and 2012, we incurred approximately $1,594,000 and $757,000, respectively, in research and development expenses. We have incurred approximately $2,564,000 in research and development expenses since inception.

Scientific Advisors

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 four Scientific Advisory Board members are Dr. Wayne Marasco, Chairman, Dr. Amit Patel, Dr. Naiyer Imam and Dr. Wayne Olan. In addition, Dr. Gregory Lutz has been retained as our Chief Medical Advisor for Spine Medicine. See Item 10 (“Directors, Executive Officers and Corporate Governance – Scientific Advisors”) for a listing of the principal positions for Drs. Marasco, Patel, Imam, Olan and Lutz.

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, Harvest Technologies, Mesoblast, NeoStem, Stem Cells, Athersys, Tissue Genesis and Ember Therapeutics. 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 cosmetic operations will compete with other companies that offer a plant derived stem cell skin care line or stem-cell derived extracts, such as EmergeLabs, Andalou Naturals, Jeunesse Luminesce, Lifeline Skin Care, Dermelect, G.M. Collin, Rahn and Tri-K, 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® product line is offered via the Internet (www.stempearls.com and www.biorestorative.com) and is intended to be sold to stores either directly or by way of distributors. Our cosmetic ingredients are being offered to cosmetic manufacturers and 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 significant 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. Recent third party litigation concerning the autologous use of a stem cell mixture to treat musculoskeletal and spinal injuries has increased the likelihood that some of our products and services are likely to be regulated as a drug or biological product and require FDA approval. In the litigation, the FDA

asserted that the defendants' use of cultured stem cells without FDA approval is in violation of the FDCA, claiming that the defendants' product is a drug. The defendants asserted that their procedure is part of the practice of medicine and therefore beyond the FDA's regulatory authority. The District Court ruled in favor of FDA, and in February 2014 the Circuit Court affirmed the District Court's holding.

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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.

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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 significant 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.

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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.

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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.

Separately, we have developed a human adult stem cell-derived extract that we intend to offer to third party companies for use in the development and production of anti-aging cosmetics and skin care products. At present we envision our role as being limited to that of an ingredient supplier and having no role in the development of the final consumer 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. Florida law requires that clinical laboratories obtain a license, and such laboratories are 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 licensures 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* (the “Privacy Rule”) and the *Security Standards for the Protection of Electronic Protected Health Information* (the “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 for Economic and Clinical Health Act (the "HITECH Act") made certain provisions of the Security Rule, as well as the additional requirements the HITECH Act imposed that relate to security or privacy 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 functions 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.

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Regulations implementing the majority of the requirements created by the HITECH Act were issued in January 2013 (the "Final Rule"). Among other things, the Final Rule broadened the definition of "business associate" to include subcontractors. As a result, a subcontractor who performs tasks involving the use or disclosure of protected health information on behalf of a business associate must likewise comply with the same obligations as the business associate.

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;

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- 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;
- 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; and
- the Physician Payments Sunshine Act (in the event that our products are classified as drugs, biologics, devices or medical supplies and are reimbursed by Medicare, Medicaid or the Children's Health Insurance Program).

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. 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 three 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 are located at 555 Heritage Drive, Jupiter, Florida. We occupy the premises pursuant to a lease that expires on July 31, 2014 and provides for a current base monthly rent of $962.

Our Jupiter, Florida premises are suitable and adequate for our current operations; however, we are seeking to relocate in order to be able to establish a laboratory.

ITEM 3. LEGAL PROCEEDINGS.

In November 2013, an action was commenced against us in the Circuit Court of Palm Beach County, Florida by an alleged former consultant. The action is associated with an alleged loan made in 2009 and an alleged consulting/employment agreement entered into with us effective in 2009. Pursuant to the action, the plaintiff is seeking to recover an unspecified amount of damages but at least approximately $193,000 of cash and warrants for the purchase of 80,000 shares of our common stock. We believe that the claims are without merit and we intend to vigorously defend the matter.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information

Transactions in our common stock are currently reported under the symbol "BRTX" on the OTC Bulletin Board. The following table sets forth the range of high and low bids reported in the over-the-counter market for our common stock. On April 15, 2013, we effected a 1 for 50 reverse split of our common stock. The prices shown below have been retroactively adjusted to give effect to the reverse split and 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
2012 Calendar Year		
First Quarter	$1.50	$0.50
Second Quarter	$1.75	$0.50
Third Quarter	$2.00	$0.85
Fourth Quarter[(1)]	$2.13	$0.80

	High	**Low**
2013 Calendar Year		
First Quarter	$1.95	$1.15
Second Quarter	$1.65	$0.70
Third Quarter	$0.99	$0.33
Fourth Quarter	$0.70	$0.40

(1) On November 5, 2012 our common stock began trading on the OTC Bulletin Board.

Holders

As of April 9, 2014, there were 227 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, 2013, we issued 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 Annual Report on Form 10-K for the year ended December 31, 2012, Quarterly Reports on Form 10-Q for the periods ended March 31, 2013, June 30, 2013 and September 30, 2013 and Current Reports on Form 8-K 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. The proceeds were used to reduce our working capital deficiency and for other corporate purposes.

Date Issued	Common Stock	Warrants Shares	Exercise Price	Term (Years)	Purchaser(s)	Consideration (1)	
10/4/13	50,000	-	$ -	-	(5)	$ 12,500	(2)
10/9/13	2,860	-	$ -	-	(5)	$ 1,659	(2)
10/31/13	3,750	-	$ -	-	(5)	$ 2,250	(2)
11/15/13	22,500	-	$ -	-	(5)	$ 13,050	(2)
11/15/13	22,500	-	$ -	-	(5)	$ 13,050	(2)
11/30/13	4,091	-	$ -	-	(5)	$ 2,250	(2)
12/3/13	110,230	-	$ -	-	(6)	$ 25,904	(4)
12/3/13	52,014	-	$ -	-	(6)	$ 12,223	(4)
12/18/13	6,300	-	$ -	-	(5)	$ 3,276	(2)
12/31/13	4,500	-	$ -	-	(5)	$ 2,250	(2)
11/30/13-12/31/13	1,686,029	1,686,029	$ 0.75	2	(6)	$ 505,809	(3)

(1) The value of the non-cash consideration was estimated to be the fair value of our restricted common stock. Since our shares are thinly traded in the open market, 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.

(2) Issued in consideration of consulting services.

(3) Issued pursuant to the exercise of warrants.

(4) Issued in connection with the exchange of notes payable.

(5) Consultant.

(6) Accredited investor.

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Issuer Purchases of Equity Securities

During the quarter ended December 31, 2013, there were no purchases of common stock made by us or any "affiliated purchaser".

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

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

The following discussion and analysis of the results of operations and financial condition of BioRestorative Therapies, Inc. (and including its subsidiaries, "BRT" or the "Company") as of December 31, 2013 and 2012 and for the years ended December 31, 2013 and 2012 should be read in conjunction with our financial statements and the notes to those financial statements that are included elsewhere in this Annual Report on Form 10-K following Item 15. References in this Management's Discussion and Analysis of Financial Condition and Results of Operations to "us," "we," "our," and similar terms refer to BRT. 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, which may influence the accuracy of the statements and the projections upon which the statements are based. Reference is made to "Factors That May Affect Future Results and Financial Condition" in this Item 7 for a discussion of some of the uncertainties, risks and assumptions associated with these statements.

Overview

We are a development stage enterprise whose primary activities since inception have been the development of our business plan, negotiating strategic alliances and other agreements, raising capital and the sponsorship of research and development activities.

Our goal is to develop technology using cell and tissue regenerative therapy protocols, primarily involving 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 our brtxDISC™ (**D**isc **I**mplanted **S**tem **C**ells) Program. We have obtained a license that permits us to use technology for adult stem cell treatment of disc and spine conditions, including protruding, 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. Another technology we are developing is our ThermoStem® Program. This pre-clinical program involves the use of brown fat in connection with the cell-based treatment of type 2 diabetes and obesity as well as hypertension, other metabolic disorders and cardiac

We also offer stem cell derived cosmetic and skin care products. Pursuant to our brtx-C Cosmetic Program, we have developed an ingredient derived from human adult stem cells which can be used by third party companies in the development of their own skin care products. Separately, through our wholly-owned subsidiary, Stem Pearls, LLC, we 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.

We currently are seeking to establish a new laboratory facility and increase our capabilities for the further development of possible cellular-based treatment protocols, stem cell-related intellectual property and research applications.

Since inception, we have incurred substantial losses. As of December 31, 2013, the deficit accumulated during the development stage was $19,812,414, our stockholders' deficiency was $6,685,069 and our working capital deficiency was $7,262,748. Through December 31, 2013, we have not yet generated significant revenues and our losses have principally been operating expenses incurred in development, marketing and promotional activities in order to commercialize our products and services, plus costs associated with meeting the requirements of being a public company. We expect to continue to incur substantial costs for these activities over at least the next year.

Based upon our working capital deficiency as of December 31, 2013 and the lack of substantial revenues from inception to December 31, 2013, we require equity and/or debt financing to continue our operations. Between December 2008 and December 31, 2013, we raised an aggregate of $7,293,139 in debt financing and $4,228,984 in equity financing, including proceeds received from the exercise of common stock purchase warrants. As of December 31, 2013, our outstanding debt of $5,754,500, together with interest at rates ranging between 8% and 20% per annum, was due on various dates through October 2014. Subsequent to December 31, 2013 and through April 9, 2014, we have received aggregate equity financing, including proceeds received from the exercise of common stock purchase warrants, and debt financing of $625,000 and $140,000, respectively, we have received research and development fees of $150,000, the due date for the repayment of $752,500 of debt has been extended, $25,000 of debt has been repaid and $274,000 and $19,932 of debt and accrued interest, respectively, has been exchanged for common stock. Giving effect to the above actions, we currently have notes payable aggregating $193,000 which are either past due or payable on demand. Based upon our working capital deficiency and outstanding debt, we expect to be able to fund our operations through May 2014. We are currently in the process of negotiating extensions or discussing conversions to equity with respect to these notes. 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 promotional 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, 2013 Compared with Year Ended December 31, 2012

The following table presents selected items in our consolidated statements of operations for the years ended December 31, 2013 and 2012, respectively:

	For The Years Ended December 31,	
	2013	2012
Revenues	$1,680	$15,589
Cost of goods sold	208	1,307
Gross Profit	1,472	14,282
Operating Expenses:		
Marketing and promotion	114,951	131,980
Consulting	779,462	1,744,024
Research and development	1,594,054	756,776
General and administrative	2,265,275	2,953,954
Total Operating Expenses	4,753,742	5,586,734
Loss From Operations	(4,752,270)	(5,572,452)
Other Income (Expense):		
Interest expense	(371,281)	(591,813)
Amortization of debt discount	(405,531)	(329,796)
Loss on extinguishment of notes payable	(7,200)	(69,708)
Warrant modification expense	(214,912)	-
Gain on settlement of note and payables, net	-	27,047
Total Other Expense	(998,924)	(964,270)
Net Loss	$(5,751,194)	$(6,536,722)

Gross profit

For the year ended December 31, 2013, revenues were $1,680 as compared to $15,589 for the year ended December 31, 2012. For the year ended December 31, 2013, our revenue was attributable to sales of Stem Pearls® skincare products. For the year ended December 31, 2012, our revenue consisted of $10,000 of sublicense fees and $5,589 attributable to sales of Stem Pearls® skincare products.

Cost of goods sold consisted of the costs of the underlying products. For the year ended December 31, 2013, cost of goods sold was $208 as compared to $1,307 for the year ended December 31, 2012.

Marketing and promotion

Marketing and promotion expenses include advertising and promotion, marketing and seminars, meals, entertainment and travel expenses. For the year ended December 31, 2013, marketing and promotion expenses decreased by $17,029, or 13%, due to cash constraints, from $131,980 to $114,951, as compared to the year ended December 31, 2012.

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.

Consulting

Consulting expenses consist of consulting fees and stock-based compensation to consultants. For the year ended December 31, 2013, consulting expenses decreased $964,562, or 55%, from $1,744,024 to $779,462, as compared to the year ended December 31, 2012. The decrease is primarily due to an approximate $928,000 decrease in non-cash stock-based compensation to directors, consultants and advisors.

Research and development

Research and development expenses include cash and non-cash compensation of (a) our Chief Executive Officer (in part); (b) our Vice President of Research and Development; and (c) our Scientific Advisory Board members, and costs related to our brown fat and disc/spine initiatives. Research and development expenses are expensed as they are incurred. For the year ended December 31, 2013, research and development expenses increased by $837,278 from $756,776 to $1,594,054, or 111%, as compared to the year ended December 31, 2012. The increase is related to the commencement of our brown fat and disc/spine initiatives at the end of the second quarter of 2012 (approximately $325,000 of the increase), plus cash ($202,000 of the increase) and non-cash ($310,000 of the increase) compensation of (a) our Chief Executive Officer (in part); (b) our Vice President of Research and Development; and (c) our Scientific Advisory Board members.

We expect that our research and development expenses will continue to increase with the continuation of the aforementioned initiatives.

General and administrative

General and administrative expenses consist primarily of salaries, bonuses, payroll taxes, severance costs and stock-based compensation to employees (excluding any cash or non-cash compensation of (a) our Chief Executive Officer attributable to research and development and (b) our Vice President of Research and Development) as well as corporate support expenses such as legal and professional fees, investor relations and occupancy related expenses. For the year ended December 31, 2013, general and administrative expenses decreased by $688,679, or 23%, from $2,953,954 to $2,265,275, as compared to the year ended December 31, 2012. The decrease is primarily due to a greater proportion of executive time devoted to research and development initiatives (approximately $260,000 of the decrease), a decrease in executive non-cash stock-based compensation (approximately $216,000 of the decrease) and the absence of 2013 tax liability reimbursements made by us associated with the vesting of executive restricted stock (approximately $193,000 in the year ended December 31, 2012).

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

Interest expense

For the year ended December 31, 2013, interest expense decreased $220,532, or 37%, as compared to the year ended December 31, 2012. The decrease was due to a reduction in interest-bearing short-term borrowings as compared to the year ended December 31, 2012 including the restructuring of our largest note payable.

Amortization of debt discount

For the year ended December 31, 2013, amortization of debt discount increased $75,735, or 23%, as compared to the year ended December 31, 2012, primarily due to an increase in the issuance of warrants in lieu of cash interest payments in conjunction with debt issuances, plus the timing of the recognition of the debt discount expense.

Loss on extinguishment of notes payable

For the year ended December 31, 2013, we recorded a loss on extinguishment of notes payable of $7,200, which is associated with investors' conversion of debt into equity securities, as compared to a loss on extinguishment of notes

payable of $69,708 for the year ended December 31, 2012.

Warrant modification expense

During the year ended December 31, 2013, we recorded expense of $214,912 related to the modification of outstanding warrants.

Gain on settlement of note and payables, net

During the year ended December 31, 2012, we recorded a gain on settlement of note and payables, net, of $27,407, which represented the difference between our recorded payment obligation and the agreed amount that was ultimately paid pursuant to various settlement agreements. There were no gains on settlement of notes or payables recorded during the year ended December 31, 2013.

Liquidity and Capital Resources

Liquidity

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

	December 31, 2013	2012
Cash	$201,098	$363
Working Capital Deficiency	$(7,262,748)	$(2,784,676)
Notes Payable (Gross - Current)	$5,227,390	$1,003,685

Availability of Additional Funds

Based upon our working capital and stockholders' deficiency of $7,262,748 and $6,685,069, respectively, as of December 31, 2013 and the lack of significant revenues from inception to December 31, 2013, we require additional equity and/or debt financing to continue our operations. These conditions raise substantial doubt about our ability to continue as a going concern.

Between December 2008 and December 31, 2013, we raised an aggregate of $7,293,139 in debt financing and $4,228,984 in equity financing, including proceeds received from the exercise of common stock purchase warrants. As of December 31, 2013, our outstanding debt of $5,754,500, together with interest at rates ranging between 8% and 20% per annum, was due on various dates through October 2014. Subsequent to December 31, 2013 and through April 9, 2014, we have received aggregate equity, including proceeds received from the exercise of common stock purchase warrants, and debt financing of $625,000 and $140,000, respectively, we have received research and development fees of $150,000, the due date for the repayment of $752,500 of debt has been extended, $25,000 of debt has been repaid and $274,000 and $19,932 of debt and accrued interest, respectively, has been exchanged for common stock. Giving effect to the above actions, we currently have notes payable aggregating $193,000 which are either past due or payable on demand. We are currently in the process of negotiating extensions or discussing conversions to equity with respect to these notes. As of the date of this filing, we have not received any notices of default with respect to these notes. As of the date that this Annual Report on Form 10-K was filed, our outstanding debt was as follows:

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Maturity Date	Principal Amount
Past Due/On Demand	$193,000
QE 6/30/14	180,000
QE 9/30/14	4,325,000
QE 12/31/14	642,685
QE 3/31/15	50,000
QE 6/30/15	283,873
	$5,674,558

Based upon our working capital deficiency and outstanding debt, we expect to be able to fund our operations through May 2014. Thereafter, we will need to raise further capital, through the sale of additional equity or debt securities, 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 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 obtain funds by entering into financing agreements on unattractive terms.

Our consolidated financial statements included elsewhere in this Annual Report on Form 10-K 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, 2013, 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, 2013 and 2012 in the amounts of $2,672,404 and $3,184,112, respectively. The net cash used in operating activities for the year ended December 31, 2013 was primarily due to cash used to fund a net loss of $5,751,194, adjusted for non-cash expenses in the aggregate amount of $2,119,501, partially offset by $959,289 of cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in accounts payable plus accrued expenses and other liabilities, due to cash constraints during the period.

The net cash used in operating activities for the year ended December 31, 2012 was primarily due to cash used to fund a net loss of $6,536,722, adjusted for non-cash expenses in the aggregate amount of $2,311,107, partially offset by $1,041,503 of cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in accounts payable plus accrued expenses and other liabilities, due to cash constraints during the period.

Net Cash Used in Investing Activities

During the year ended December 31, 2013, net cash used in investing activities was $11,160, primarily due to cash used for the purchase of medical equipment. During the year ended December 31, 2012, net cash used in investing activities was $1,002,533, primarily due to cash used to acquire an intangible asset (a license associated with our disc/spine initiative) in the amount of $1,000,000.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the years ended December 31, 2013 and 2012 was $2,884,299 and $4,115,500, respectively. During the year ended December 31, 2013, $1,473,490 of net proceeds were from debt financings and $1,410,809 of proceeds were from equity financings (including proceeds received in connection with the exercise of common stock purchase warrants). During the year ended December 31, 2012, $2,190,500 of net proceeds were from debt financings and $1,925,000 of proceeds were from equity financings.

Critical Accounting Policies and Estimates

Use of Estimates

The preparation of financial statements in conformity with GAAP requires us 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. Our significant estimates and assumptions include the recoverability and useful lives of long-lived assets, the fair value of our stock, stock-based compensation, warrants issued in connection with notes payable and the valuation allowance related to our deferred tax assets. Certain of our estimates, including the carrying amount of the intangible assets, could be affected by external conditions, including those unique to us and general economic conditions. It is reasonably possible that these external factors could have an effect on our estimates, and could cause actual results to differ from those estimates.

Intangible Assets

Intangible assets are comprised of trademarks and licenses with original estimated useful lives of 10 and 17.7 years (20 year life of underlying patent, less 2.3 years elapsed since patent application), respectively. Once placed into service, we amortize the cost of the intangible assets over their estimated useful lives on a straight line basis.

Impairment of Long-lived Assets

We review 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.

Revenue Recognition

For the year ended December 31, 2013, our $1,680 of revenue was attributable to sales of Stem Pearls® skincare products. For the year ended December 31, 2012, revenue consisted of $10,000 of sublicense fees and $5,589 was attributable to sales of Stem Pearls® skincare products. Our policy is to recognize product sales when the risk of loss and title to the product transfers to the customer, after taking into account potential returns. We recognize sublicensing and royalty revenue when all of the following have occurred: (i) persuasive evidence of an arrangement exists, (ii) the service is completed without further obligation, (iii) the sales price to the customer is fixed or determinable, and (iv) collectability is reasonably assured.

Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in our 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.

We 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.

Stock-Based Compensation

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

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, 2013, we had a working capital deficiency of $7,262,748 and stockholders' deficiency of $6,685,069. The report of our independent registered public accounting firm with respect to our financial statements as of December 31, 2013 and 2012 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 and sustain 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, 2013 and 2012 and for the years then ended, and for the period from December 30, 2008 (inception) to December 31, 2013, 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 December 2008 and December 31, 2013, we raised an aggregate of $7,293,139 in debt financing and $4,228,984 in equity financing, including proceeds received from the exercise of common stock purchase warrants. Subsequent to December 31, 2013 and through April 9, 2014, we have received aggregate equity, including proceeds received from the exercise of common stock purchase warrants, and debt financing of $625,000 and $140,000, respectively, we have received research and development fees of $150,000, the due date for the repayment of $752,500 of debt has been extended, $25,000 of debt has been repaid and $274,000 and $19,932 of debt and accrued interest, respectively, has been exchanged for common stock. Giving effect to the above actions, we currently have notes payable aggregating $193,000 which are either past due or payable on demand. We are currently in the process of negotiating extensions or discussing conversions to equity with respect to these notes. As of April 9, 2014, the outstanding balance of our debt of $5,674,558, together with accrued interest, was due and payable between on demand and April 2015. 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. Based upon our working capital deficiency and outstanding debt, we expect to be able to fund our operations through May 2014. 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 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.

We will need to enter into agreements in order to implement our business strategy.

Except for the Regenerative Sciences, LLC license agreement, the research agreement with the University of Utah and the recently executed research and development agreements with Rohto Pharmaceutical Co., Ltd. and Pfizer, Inc., 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 are required to pay certain minimum amounts to maintain our exclusive license rights with regard to the disc/spine technology. The loss of such exclusive rights would have a material adverse effect upon us.

Pursuant to the license agreement with Regenerative Sciences, LLC, unless certain milestones are satisfied, we will be required to pay to Regenerative minimum amounts of between $75,000 and $475,000 during the period from April 2015 to April 2019 in order to maintain our exclusive rights with regard to the disc/spine technology. No assurances can be given that we will have sufficient funds to pay such minimum amounts. Any loss of such exclusive rights would have a material adverse effect upon our business, results of operations and financial condition.

We depend on our executive officers and on our ability to attract and retain additional qualified personnel. 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 Vice President of Research and Development, in establishing and developing our laboratory business. Mr. Silva is also subject to an employment agreement with us. 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 the inability to attract and retain additional personnel, including a Chief Financial Officer, and develop expertise as needed would have a substantial negative effect on our results of operations and financial condition.

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 will be issued to us or, if issued, that such patent 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 any patents we obtain.

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. United States and foreign 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 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 United States. 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 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 and pursuant to our brtx-C Cosmetic Program may be regulated as both cosmetics and drugs under the FDCA. If they are, 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.

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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* (the “Privacy Rule”) and the *Security Standards for the Protection of Electronic Protected Health Information* (the “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 for Economic and Clinical Health Act (the "HITECH Act") made certain provisions of the Security Rule, as well as the additional requirements the HITECH Act imposed that relate to security and privacy 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 functions 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.

Regulations implementing the majority of the requirements created by the HITECH Act were issued in January 2013 (the “Final Rule”). Among other things, the Final Rule broadened the definition of “business associate” to include subcontractors. As a result, a subcontractor who performs tasks involving the use or disclosure of protected health information on behalf of a business associate must likewise comply with the same obligations as the business associate.

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;

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- 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;

- 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; and

- the Physician Payments Sunshine Act (in the event that our products are classified as drugs, biologics, devices or medical supplies and are reimbursed by Medicare, Medicaid or the Children's Health Insurance Program).

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. In 2012, the District Court ruled in favor of the FDA, but Regenerative appealed the decision. In February 2014, the United States Court of Appeals for the D.C. Circuit affirmed the District Court's ruling, concluding that the FDA has the authority to regulate certain autologous stem cell procedures and that the Regenexx stem cell mixture meets the definition of drug and not HCT/P since it was more than minimally manipulated. Regenerative has indicated that it does not intend to appeal the decision to the Supreme Court. While this decision is specific to Regenerative's procedures and mixture, it indicates that stem cells, even when used in an autologous context, may be regulated as drugs, particularly when mixed with other substances or in other ways that may be considered to be more than minimally manipulated. Based on this outcome, it may be more likely that we will need to proceed with the FDA approval process for our initiatives as discussed above. See Item 1 ("Business – Government Regulation").

Our inability to obtain reimbursement for our services and products from private and governmental insurers could negatively impact demand for our services and products.

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 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.

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 OTC Bulletin Board 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.

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 unless, among other things, we continue to remain subject to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and we file all of our required periodic reports with the Securities and Exchange Commission (the "SEC") under the Exchange Act. Because our unregistered securities cannot be sold pursuant to Rule 144 unless we continue to meet such requirements, 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 unless we continue to comply with such requirements. As a result, it may be more difficult for us to obtain financing to fund our operations and pay our consultants and employees with our securities instead of cash.

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 9, 2014, we had outstanding indebtedness in the amount of $5,674,558. 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.

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.

None.

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 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 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, 2013, our disclosure controls and procedures were effective.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Principal Executive and Financial Officer, and effected by the Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP including those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and the disposition of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP and that receipts and expenditures are being made only in accordance with authorizations of our management and Board of Directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 1992 framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2013.

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) under the Exchange Act) during the quarter ended December 31, 2013 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 Attestation Report of Registered Public Accounting Firm

This Annual Report does not contain an attestation report of our independent 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.

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	61	Chief Executive Officer, President and Chairman of the Board
Francisco Silva	39	Vice President of Research and Development
Mandy D. Clyde	32	Vice President of Operations and Secretary
A. Jeffrey Radov	62	Director
Joel San Antonio	61	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.

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Francisco Silva

Francisco Silva served as our Vice President of Research and Development from April 2011 until March 2012 and has served in such position since March 2013. He served as our Research Scientist from March 2012 to June 2012 and as our Chief Scientist from June 2012 to March 2013. From 2007 to 2011, Mr. Silva served as Chief Executive Officer of DV Biologics LLC, and as President of DaVinci Biosciences, LLC, companies engaged in the commercialization of human based biologics for both research and therapeutic applications. From 2003 to 2007, Mr. Silva served as Vice President of Research and Development for PrimeGen Biotech LLC, a company engaged in the development of cell based platforms. From 2002 to 2003, he was a Research Scientist with PrimeGen Biotech and was responsible for the development of experimental designs that focused on germ line reprogramming stem cell platforms. Mr. Silva has taught courses in biology, anatomy and advanced tissue culture at California State Polytechnic University. He has obtained a number of patents relating to stem cells and has had numerous articles published with regard to stem cell research. Mr. Silva graduated from California State Polytechnic University with a degree in Biology. He also obtained a Graduate Presidential Fellowship and MBRS Fellowship from California State Polytechnic University.

Mandy D. Clyde

Mandy D. Clyde 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. Clyde 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. Clyde served as surgical coordinator for Eye Surgery Associates and the Rand Eye Institute, two prominent physician practices in Florida. Ms. Clyde 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 and Chair of our Audit Committee 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 and Chair of our Compensation and Nominating Committees in April 2011. Mr. San Antonio is the Founder and Managing Partner of Stanwich Capital Advisors, LLC, a company that provides small to mid-size companies with alternative financing solutions. He is also the former CEO of Lochem Capital LLC, a nationwide factoring broker. Mr. San Antonio is co-founder and advisor to both the Greenwich Salad Company, a premier destination for individuals seeking healthy dining alternatives, and National Vehicle Services, a company engaged in providing roadside services for commercial vehicles. In 1984, Mr. San Antonio founded and took public Warrantech Corporation, a leading provider of third party administration for insurance companies. While serving as Warrantech's Chairman and Chief Executive Officer, he received Ernst and Young's "Entrepreneur of the Year" award for financial services and Warrantech earned the recognition of Fortune Magazine's "Top 100 Fastest Growing Companies." In 2007, Warrantech was acquired by a private equity firm and Mr. San Antonio remained as CEO. In 2010, Warrantech was acquired by AmTrust Financial Services, Inc. Mr. San Antonio continued as its Chairman until March 2012. Throughout his career, Mr. San Antonio has been involved in numerous business sectors ranging from insurance and financial services to travel and gaming. He sits on several boards, both public and private. Mr. San Antonio began his career in the apparel industry, founding Little Lorraine Ltd., a company engaged in the manufacture of various brands of women's apparel. He is a graduate of Ithaca College with a Bachelor of Science degree in Business Administration, and a graduate from Schiller College in Heidelberg, Germany with a degree in Cultural Arts. We believe that Mr. San Antonio's executive-level management experience gives him the qualifications and skills to serve as one of our directors.

Scientific Advisors

Scientific Advisory Board

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

Name	Principal Positions
Wayne Marasco, M.D., Ph.D. Chairman	Professor, Department of Cancer Immunology & AIDS, Dana-Farber Cancer Institute; Professor of Medicine, Harvard Medical School; Principal Faculty Member, Harvard Stem Cell Institute
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
Naiyer Imam, M.D.	Chairman and Chief Executive Officer, Advanced Medical Imaging and Teleradiology, LLC
Wayne J. Olan, M.D.	Director, Endovascular and Minimally Invasive Image Guided Neurosurgery; Associate Professor, Neurosurgery and Radiology, George Washington University Medical Center; Consulting Physician, Department of Radiology, National Institutes of Health

Chief Medical Advisor for Spine Medicine

Gregory E. Lutz, M.D. serves as our Chief Medical Advisor for Spine Medicine. Dr. Lutz is Associate Professor of Clinical Rehabilitation Medicine, Weill Medical College of Cornell. He is the Physiatrist-in-Chief Emeritus for Hospital for Special Surgery (“HSS”) and is a member of its board of trustees. Dr. Lutz is also consulting physician to the National Hockey League Players’ Association. He has been in practice at HSS since 1993. In 1997, Dr. Lutz established the Physiatry Department at HSS and became Physiatrist-in-Chief.

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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 (Chair) 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, 2013. 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, 2013, our officers, directors and 10% stockholders complied with all Section 16(a) filing requirements applicable to them.

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. 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.

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, 2013 and 2012 by our (i) principal executive officer, and (ii) all other executive officers, other than our principal executive officer, whose total compensation for the 2013 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"):

Name and Principal Position	Year	Salary Earned	Waived	Bonus Earned	Waived	Option Awards Earned	All Other Compensation Earned	Waived	Total Earned
Mark Weinreb, Chief Executive Officer	2013	$360,000 (1)	$240,000 (1)	$- (3)	$300,000 (3)	$50,550 (4)	$14,400 (1)	$25,000 (1)	$424,9
	2012	$509,000	$-	$324,500 (3)	$-	$696,000 (4)	$231,592	$-	$1,76
Francisco Silva, VP of Research and Development (5)	2013	$230,000	$-	$-	$-	$20,220 (4)	$-	$-	$250,2
	2012	$179,167	$-	$-	$-	$115,250 (4)(6)	$-	$-	$294,4
Mandy Clyde, VP of Operations	2013	$118,000	$-	$-	$-	$16,176 (4)	$-	$-	$134,1
	2012	$100,000	$-	$-	$-	$49,950 (4)	$-	$-	$149,9

(1) Of the aggregate $989,950 payable for services rendered during 2013, (a) $240,000, $300,000 and $25,000 in salary, bonus and unpaid vacation, respectively, were waived by Mr. Weinreb and (b) $50,500 represents the grant date value of non-cash stock-based compensation awards, irrespective of the vesting period of those awards. Of the $374,400 earned cash compensation, $14,400 and $20,000 were paid in cash during 2013 and 2014 (prior to this Annual Report being filed), respectively, while $340,000 remains unpaid. All Other Compensation-Earned represents the automobile allowance paid to Mr. Weinreb in 2013.

(2) Of the aggregate $1,761,092 earned during 2012, $696,000 represents the grant date value of non-cash stock-based compensation awards, irrespective of the vesting period of those awards. Of the earned remainder, $444,992, $437,619 and $182,535 were paid in cash during 2012, 2013 and 2014 (prior to this Annual Report being filed), respectively, and none remains unpaid. In addition to his contractual bonus, as discussed in footnote (3) below, a special bonus of $70,000 was awarded and paid to Mr. Weinreb in connection with our entering into the license agreement with Regenerative Sciences, LLC described in Item 1 of this Annual Report ("Business-Disc/Spine Program"). All Other Compensation includes $197,192 paid to reimburse Mr. Weinreb for tax payments due on his non-cash stock-based compensation, plus automobile and vacation allowances, of which none remains unpaid.

(3) Pursuant to Mr. Weinreb's employment agreement with us, he earns a bonus equal to 50% of his annual salary. See "Employment Agreement" below. Mr. Weinreb waived his entitlement to receive a bonus for 2013. Of the 2012 earned bonus amount, none remains unpaid.

(4) The amounts reported in these columns represent the grant date fair value of the option awards granted during the years ended December 31, 2013 and 2012, calculated in accordance with FASB ASC Topic 718. For a detailed discussion of the assumptions used in estimating fair values, see Note 10 – Stockholders' Deficiency in the notes that accompany our consolidated financial statements.

(5) Mr. Silva, our Vice President of Research and Development, served in such capacity from April 2011 to March 2012. In March 2012, he transitioned from such position to Research Scientist. In June 2012, Mr. Silva became our Chief Scientist. In March 2013, he reassumed the position of Vice President of Research and Development.

(6) Does not include $77,800 grant date value of performance based awards deemed not probable to vest through December 31, 2013. Subsequent to December 31, 2013, $31,000 grant date value of the performance based awards vested, despite previously being deemed not probable to vest. As of the filing date, the remaining $46,800 of performance based awards are deemed not probable to vest.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information on outstanding equity awards as of December 31, 2013 to the Named Executive Officers:

	Option Awards							Stock Awards			
Name	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable		Equity incentive plan awards: Number of securities underlying unexercised unearned options		Option exercise price	Option expiration date	Number of shares or units of stock that have not vested	Market value of shares or units that have not vested	Equity incentive plan awards: Number of unearned shares, units 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
Mark Weinreb	80,000	-		-		$ 0.50	12/14/2020	-	$ -	-	$ -
Mark Weinreb	666,667	333,333	(1)	-		$ 1.05	2/9/2022	-	$ -	-	$ -
Mark Weinreb	400,000	-		-		$ 1.50	12/7/2022	-	$ -	-	$ -
Mark Weinreb	125,000	125,000	(2)	-		$ 0.60	10/4/2023	-	$ -	-	$ -
Francisco Silva	80,000	-		-		$ 0.50	4/4/2021	-	$ -	-	$ -
Francisco Silva	3,000	-		-		$ 1.25	6/23/2021	-	$ -	-	$ -
Francisco Silva	20,000	-		-		$ 1.00	11/15/2021	-	$ -	-	$ -
Francisco Silva	40,000	-		-		$ 1.05	2/10/2022	-	$ -	-	$ -
Francisco Silva	30,000	20,000	(3)	100,000	(4)	$ 1.40	5/2/2022	-	$ -	-	$ -
Francisco Silva	80,000	-		-		$ 1.50	12/7/2022	-	$ -	-	$ -
Francisco Silva	50,000	50,000	(2)	-		$ 0.60	10/4/2023	-	$ -	-	$ -

Mandy Clyde	80,000	-		-	$ 0.50	12/14/2020	-	$ -	-	$ -
Mandy Clyde	6,000	-		-	$ 1.00	4/20/2021	-	$ -	-	$ -
Mandy Clyde	30,000	-		-	$ 1.05	2/9/2022	-	$ -	-	$ -
Mandy Clyde	50,000	-		-	$ 1.50	12/7/2022	-	$ -	-	$ -
Mandy Clyde	40,000	40,000	(2)	-	$ 0.60	10/4/2023	-	$ -	-	$ -

(1) Option is exercisable effective as of February 10, 2014.

(2) Option is exercisable effective as of October 4, 2014.

(3) Option is exercisable to the extent of 10,000 shares effective as of each of May 3, 2014 and May 3, 2015.

(4) Options for the purchase of 40,000 shares of common stock are exercisable commencing on the date, if any, on which we, as a direct result of Mr. Silva's efforts, receive a bona fide research grant of at least $250,000. Options for the purchase of 60,000 shares of common stock are exercisable commencing on the date (provided t