

BioRestorative Therapies, Inc.  
Form 10-K  
March 31, 2015

**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, 2014**

**.. 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)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**91-1835664**

(I.R.S. Employer Identification No.)

**40 Marcus Drive, Melville, New York 11747**

(Address of principal executive offices) (Zip Code)

**(631) 760-8100**

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
None	Not applicable

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

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

(Title of Class)

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

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

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

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

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

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

Large accelerated filer

Accelerated filer

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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, 2014, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$5,692,745 based on the closing sale price as reported on the OTC Bulletin Board. As of March 30, 2015, there were 37,149,052 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None

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## **PART I**

### **Forward-Looking Statements**

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

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

**ITEM 1.**

**BUSINESS.**

**(a)**

**Business Development**

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 were incorporated in Nevada on June 13, 1997. On August 15, 2011, we changed our name from “Stem Cell Assurance, Inc.” to “BioRestorative Therapies, Inc.” Effective January 1, 2015, we reincorporated in Delaware.

During the year ended December 31, 2014, we raised an aggregate of \$2,718,000 in connection with sales of common stock and warrants and from the exercise of warrants, and an aggregate of \$795,000 in debt financing. As of December 31, 2014, our outstanding debt of \$5,851,496, together with interest at rates ranging between 8% and 15% per annum, was due through October 2015. Subsequent to December 31, 2014 and through March 31, 2015, we have received aggregate equity financing and debt financing of \$801,000 and \$30,000, respectively, we have received research and development fees of \$227,234, and \$50,000 and \$5,984 of debt and accrued interest, respectively, has been converted into common stock. Giving effect to the above actions, we currently have notes payable aggregating \$5,000 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 our outstanding indebtedness.

In March 2014, we entered into a Research and Development Agreement with Rohto Pharmaceutical Co., Ltd., a Japanese pharmaceutical company (the “Rohto Agreement”). Pursuant to the Rohto Agreement, we have been engaged to provide research and development services with regard to stem cells. The Rohto Agreement provided for an initial payment to us of \$150,000 (which we received in March 2014) and provides for the payment of up to an additional \$100,000 subject to the satisfaction of certain milestones, of which \$50,000 has been received through March 31, 2015. The term of the Rohto Agreement ends on June 19, 2015.

In March 2014, we entered into a Research Agreement with Pfizer, Inc. (the “Pfizer Agreement”). Pursuant to the Pfizer Agreement, we have been engaged to provide research and development services with regard to brown fat. The Pfizer Agreement provides for an initial payment to us of \$250,000 (which we received) and the payment of up to an additional \$525,000 during the two year term of the Pfizer Agreement, of which \$355,359 has been received.

In May 2014, Stem Cell Cayman Ltd, one of our wholly-owned subsidiaries, borrowed \$500,000 from Westbury (Bermuda) Ltd. (“Westbury”), one of our principal shareholders. The promissory note evidencing the loan (the “Note”) provides for the payment of the principal amount, together with interest at the rate of 15% per annum, on May 7, 2015. The Note also provides for the mandatory prepayment of the principal amount to the extent of any monies

received by us pursuant to the Rohto Agreement and/or the Pfizer Agreement. Pursuant to such provision, as of March 31, 2015, \$89,063 in principal has been prepaid and \$316,297 of mandatory prepayments were unpaid. Interest on the entire principal amount of the Note is payable until such time as the principal amount is paid in full.



In August 2014, we entered into a lease for 6,800 square feet of space located at 40 Marcus Drive, Melville, Long Island, New York. We have relocated our corporate and laboratory operations from Jupiter, Florida to such location. The lease provides for a five year, three month term from the commencement date (as defined in the lease) (subject to extension at our option for a period of five years) and an annual base rental during the initial term ranging between \$132,600 and \$149,260. Our Jupiter, Florida lease expired in December 2014.

In December 2014, we met with representatives of the Food and Drug Administration's Center for Biologics, Evaluation and Research's Office of Cellular, Tissue and Gene Therapies to discuss our plans for an Investigational New Drug submission and clinical trial with respect to our brtxDISC™ product. See "Business – General."

In February 2015, we hired Edward L. Field to serve as President of our Disc/Spine Division.

In March 2015, we and Mark Weinreb, our Chief Executive Officer, agreed to extend the term of his employment agreement to December 31, 2017. See Item 11 ("Executive Compensation – Employment Agreements").

(b)

Business

## General

We develop products and medical therapies using cell and tissue protocols, primarily involving adult (non-embryonic) stem cells, including pursuant to the following programs:

***Disc/Spine Program.*** Our lead cell therapy candidate, *brtxDISC*™ (Disc Implanted Stem Cells), is a product formulated from autologous (or person's own) cultured mesenchymal stem cells ("MSCs") collected from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of protruding and bulging lumbar discs in patients suffering from chronic lumbar disc disease. The treatment involves collecting a patient's own stem cells, culturing and cryopreserving the cells, and then having a physician inject *brtxDISC*™ into the patient's damaged disc in an outpatient procedure. The treatment is intended for patients whose pain has not been alleviated by non-invasive procedures and potentially face the prospect of surgery. We intend to commence clinical trials using *brtxDISC*™ and its related collection and delivery procedure by early 2016. See "Disc/Spine Program" below.

***ThermoStem*® Program** We are developing an allogeneic cell-based therapy to target obesity and metabolic disorders using brown adipose (fat) derived stem cells to generate brown adipose tissue ("BAT"). BAT is intended to mimic

naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. 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. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. See “Brown Adipose (Fat) Program” below.

We have also licensed and developed other products that are in various stages of research and commercialization, including a curved needle device designed to deliver cells and/or other therapeutic products or material to the spine and discs. See “Curved Needle Device” below.

In addition, we have developed 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. We also offer plant stem cell-based facial creams and beauty products under the Stem Pearls® brand. See “Cosmetic Products” below.

## 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 (non-embryonic) stem cells. These cells are important for the purpose of medical therapies aiming to replace lost or damaged cells or tissues or to otherwise treat disorders.

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 almost 60 years (the first successful bone marrow transplant was performed in 1956). Recently, physicians have begun to use stem cells to treat various other diseases. We intend to develop cell and tissue products and regenerative therapy protocols, primarily involving adult stem cells, to allow patients to undergo cellular-based treatments.

We intend to concentrate initially on therapeutic areas in which risk to the patient is low, recovery is relatively easy, results can be demonstrated through sufficient clinical data, and patients and physicians will be comfortable with the procedure. We believe that there will be readily identifiable groups of patients who will benefit from these procedures.

Accordingly, we plan to focus our initial efforts in offering cellular-based products and treatment programs in selective areas of medicine for which the treatment protocol is minimally invasive. Such areas include the treatment of the disc and spine and metabolic-related disorders. We will seek to obtain third party reimbursement for our products and procedures; however; patients may be required to pay for our products and procedures out of pocket in full and without the ability to be reimbursed by any governmental and other third party payers.

We have obtained patent pending licenses and have undertaken research and development efforts in connection with the development of products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. See “Disc/Spine Program”, “Brown Adipose (Fat) Program” and “Curved Needle Device” below.

We also offer human and plant stem cell derived cosmetic and skin care products. See “Cosmetic Products” below.

We have established a laboratory facility and will seek to further develop cellular-based treatments, products and protocols, stem cell-related intellectual property (“IP”) and translational research applications. See “Laboratory” below.

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”) and otherwise fund our operations. We intend to seek such financing from current shareholders and debtholders as well as from other accredited investors. We also intend to seek to raise capital through investment bankers and from biotech funds, strategic partners and other financial institutions. 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 Disc/Spine Program, as further discussed in this Item 1 (assuming the receipt of no revenues from operations) and repay our outstanding debt (\$5,851,496 as of December 31, 2014) (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.”).

## **Disc/Spine Program**

### *General*

Among the initiatives that we are currently pursuing is our Disc/Spine Program, with our initial product being called *brtxDISC*<sup>™</sup>. We have obtained a license (see “License” below) that permits us to use technology for adult stem cell treatment of disc and spine conditions, including protruding and bulging discs. The technology is an advanced stem cell culture and injection procedure into the intervertebral disc (“IVD”) that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the legs and feet.

Lower back pain is the most common, most disabling, and most costly musculoskeletal ailment faced worldwide. It is estimated that 84% of the global populace will have an occurrence of lower back pain during their lifetime and that 11% will have chronic lower back pain. Annual direct healthcare costs relating to lower back pain in the United States

are estimated to be in excess of \$90 billion. Clinical studies have documented that the source of the pain is most frequently damage to the IVD. This can occur when forces, whether a single load or repetitive microtrauma, exceed the IVD's inherent capacity to resist those loads. Aging, obesity, smoking, lifestyle, and certain genetic factors may predispose one to an IVD injury.

While once thought to be benign, the natural history of lower back pain is often one of chronic recurrent episodes of pain leading to progressive disability. This is believed to be a direct result of the IVD's poor healing capacity after injury. The IVD is the largest avascular (having few or no blood vessels) structure in the body and is relatively acellular (containing no cells). Therefore, its inherent capacity to heal after injury is poor. The clinical rationale of *brtxDISC*<sup>®</sup> is to deliver a high concentration of the patient's own MSCs into the site of pathology to promote healing and relieve pain.

We are concentrating on the development of a mesenchymal stem cell product derived from autologous (or a person's own) human bone marrow, cultured and formulated to be delivered into a protruding or bulging disc. We intend to commence clinical trials using *brtxDISC*<sup>™</sup> and its related collection and delivery procedure by early 2016.

In addition to developing *brtxDISC*<sup>™</sup>, we may also seek to sublicense the technology to third parties for use in connection with cellular-based treatment programs with regard to disc and spine related conditions.

We have established a laboratory to perform cellular characterization and culturing for the production of cell products for use in our clinical trials. This capability may also enable us to develop our pipeline of future products and expand our stem cell-related IP. See "Laboratory" and "Technology; Research and Development" below.

#### *brtxDISC*<sup>™</sup>

Our lead therapeutic product, *brtxDISC*<sup>™</sup>, is an autologous hypoxic (low oxygen) cultured mesenchymal stem cell product derived from an adult patient's bone marrow and formulated with a proprietary carrier. The cryopreserved sterile cellular product will be provided to the clinician in vials for injection into damaged lumbar discs. The therapeutic application of *brtxDISC*<sup>™</sup>, in treatment of chronic lumbar disc disease, is performed using a standard 20 gauge 3.5 inch introducer needle and a 25 gauge 6 inch needle that extends into the disc region where the product is delivered. Specific medical practitioners will be provided training using the product with regard to the injection procedure. It is anticipated that the treatment and delivery of the product will be a 30 minute outpatient procedure.

MSCs used in *brtxDISC*<sup>™</sup> are similar to other MSCs under development by others; however, in order to enhance the survivability of our bone marrow-derived MSCs in the avascular environment of the damaged disc, *brtxDISC*<sup>™</sup> is expanded under hypoxic conditions for a period of three weeks. This process results in a cell population with enhanced viability and therapeutic potential following injection locally into injured spinal discs. A study has demonstrated that MSCs preconditioned in hypoxic environment show enhanced skeletal muscle regeneration, improved blood flow and vascular formation compared to MSCs cultured under normoxic (normal oxygen) conditions.





*Production and Delivery*

The production of *brtxDISC*<sup>™</sup> begins with the physician collecting bone marrow from the patient under a local anesthesia. Peripheral blood is also collected from the patient. The physician will then send the patient's bone marrow and blood samples to our laboratory for culturing and proprietary carrier preparation. The hypoxic culturing process applied is intended to result in the selection of a cell population that is suitable for an improved possibility of survival in the internal disc environment. The cell culturing process and product formulation will take approximately three weeks. We will then send the therapeutic cryopreserved stem cells (*brtxDISC*<sup>™</sup>) in a sterile vial back to the physician's offices where it will be thawed prior to the procedure. The following chart illustrates the process.

### *License*

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 (excluding Asia and Argentina), exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain method for culturing cells for use in treating, among other things, disc and spine conditions, including protruding and bulging discs. The technology that has been licensed is an advanced stem cell culture and injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the legs and feet. Pursuant to the license agreement, we have also obtained 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). We intend to advance the design of this curved needle device to facilitate the delivery of substances, including living cells, to specific locations within the body and minimize the potential for damage to nearby structures.

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.

### *Clinical Trial*

In December 2014, we held a pre-investigational new drug (“IND”) meeting with the Food and Drug Administration’s (“FDA”) Office of Cellular Tissue and Gene Therapies within the FDA’s Center for Biologics, Evaluation and Research. At the meeting, representatives of the FDA commented on our plans for an IND submission and a clinical trial with regard to *brtxDISC*<sup>TM</sup>. No obstacles were identified at the meeting by the FDA representatives that we believe would materially impact the IND plans for a clinical trial with regard to *brtxDISC*<sup>TM</sup> in patients with chronic lumbar disc disease. We intend to file an IND application with the FDA with respect to our proposed treatment protocol and initiate a clinical trial. We anticipate that we will begin a Phase I clinical trial by early 2016. The principal investigator for our clinical trial is intended to be Dr. Gregory E. Lutz, our Chief Medical Advisor for Spine Medicine. See Item 10 (“Directors, Executive Officers and Corporate Governance-Scientific Advisors”).

The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee that the clinical trial(s) will be commenced or completed or that the product will ultimately receive 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 – Risks Related to Our Cell Therapy Product Development Efforts; and – Risks Related to Government Regulation”).



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

We are engaging in research efforts with respect to a platform technology utilizing brown adipose (fat) for therapeutic purposes. We have labeled this initiative our *ThermoStem*<sup>®</sup> Program. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of healthy metabolism, thus potentially being involved in caloric regulation. This pre-clinical program involves the use of a cell-based (brown adipose tissue) treatment for metabolic disease, such as type 2 diabetes, obesity, hypertension and other metabolic disorders and cardiac deficiencies. Although we have had initial success in transplanting the tissue in animals, we are currently exploring ways to deliver the brown fat tissue into humans. We may also identify other naturally occurring and chemically engineered molecules that may enhance brown adipose tissue performance.

Brown fat is a specialized adipose (fat) tissue found in the human body that plays a key role in the evolutionarily conserved mechanisms underlying thermogenesis (generation of non-shivering body heat) and energy homeostasis in mammals - long known to be present at high levels in hibernating mammals and human newborns. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of healthy metabolism, thus potentially being involved in caloric regulation.

Obesity, the abnormal accumulation of white fat tissue, leads to a number of metabolic disorders and is the driving force behind the rise of type 2 diabetes and cardiovascular diseases worldwide. Pharmacological efforts to alter metabolic homeostasis through modulating central control of appetite and satiety have had limited market penetration due to significant psychological and physiological safety concerns directly attributed to modulating these brain centers. Adipose tissue is one of the largest organs in the human body and plays a key role in central energy balance and lipid homeostasis. Two types of adipose tissues are found in mammals, white and brown adipose tissues. White adipose tissue function is to store energy, whereas brown adipose tissue (“BAT”) specializes in energy expenditure. Recent advancements in unraveling the mechanisms that control the induction, differentiation, proliferation, and thermogenic activity of BAT, along with the application of imaging technologies for human BAT visualization, have generated optimism that these advances may provide novel strategies for targeting BAT activation/thermogenesis, leading to efficacious and safe obesity targeted therapies. It is estimated that by 2030 one billion persons worldwide will suffer from obesity and twice that number will be overweight.

In June 2011, we launched the initial research phase of what we believe will develop into a platform technology that involves the use of brown fat in a cell-based therapeutic program referred to as the *ThermoStem*<sup>®</sup> Program. The *ThermoStem*<sup>®</sup> Program will focus on treatments for metabolic disorders such as type 2 diabetes, obesity, hypertension, and cardiac deficiencies, and will involve the study of brown adipose derived stem cells (“BADSC”), brown adipose tissue, a therapeutic delivery system, and potentially molecules that would regulate brown adipose tissue function.

We are developing an allogeneic cell-based therapy to target obesity and metabolic disorders using BADSC. Our goal is to develop implantable brown adipose tissue intended to mimic ones naturally occurring in the human body. We have isolated and characterized a human multipotent stem cell population that resides within BAT depots. We have expanded these stem cells to clinically relevant numbers and successfully differentiated them into functional brown adipocytes. 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).

In order to deliver these differentiated cells into target locations *in vivo*, we seeded BADSC onto 3-dimensional biological scaffolds. Pre-clinical animal models, with diet-induced obesity that were transplanted with differentiated BADSC, supported by a biological scaffold, presented significant reductions in weight and blood glucose levels compared to saline injected controls. Our allogeneic brown adipose derived stem cell platform potentially provides a therapeutic and commercial model for the cell-based treatment of obesity and related metabolic disorders.

Our *ThermoStem*<sup>®</sup> Program is in the pre-clinical research stage. We have developed our first generation of brown adipose tissue construct and we are currently in development of the next generation of BAT. We are exploring potential delivery systems for the therapy.

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”) (the “Utah Research Agreement”). 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 Utah 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 Utah 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 initially 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 Utah Research Agreement). In May 2014, we entered into an amendment to the Utah Research Agreement. Pursuant to the amendment, the parties agreed that (i) no fees were payable by us to the University for the five month period ending May 15, 2014, (ii) effective with the payment due on June 15, 2014, the monthly fee payable by us to the University was reduced from \$41,667 to \$20,000 and (iii) the scope of the work to be performed by the University was reduced. The Utah Research Agreement is scheduled to expire on June 14, 2015.

In March 2014, we entered into a Research Agreement with Pfizer Inc. (the “Pfizer Research Agreement”), a global pharmaceutical company. Pursuant to the Pfizer Research Agreement, we have been engaged to provide research and development services with regard to brown fat. The Pfizer Research 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.

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 third quarter of 2015. Following the completion of such studies, if required, we intend to file an IND application with the FDA and initiate Phase I clinical trials, expected to commence in 2017. 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 – Risks Related to Our Cell Therapy Product Development Efforts; and – Risks Related to Government Regulation”). The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance.



We anticipate that much of our development work in this area will take place at our new laboratory facility, the University's research laboratory (until the expiration date or any extension), other outside core facilities at academic, research or medical institutions, or other contractors. See "Laboratory" below.

### **Curved Needle Device**

Pursuant to the Regenerative license agreement discussed under "Disc/Spine Program License" above, we have licensed and further developed a curved needle device ("CND") that is a needle system with a curved inner cannula to allow access to difficult-to-locate regions for the delivery or removal of fluids and other substances. The CND is intended to deliver stem cells and/or other therapeutic products or material to the interior of a human intervertebral disc, the spine region, or potentially other areas of the body. The device relies on the use of pre-curved nested cannulae that allow the cells or material to be deposited in the posterior and lateral aspects of the disc to which direct access is not possible due to outlying structures such as vertebra, spinal cord and spinal nerves. We anticipate that the use of the CND will facilitate the delivery of substances, including living cells, to specific locations within the body and minimize the potential for damage to nearby structures. The device may also have more general use applications. We anticipate that FDA approval or clearance will be necessary for the CND prior to commercialization. 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 – Risks Related to Our Cell Therapy Product Development Efforts; and – Risks Related to Government Regulation"). The FDA review and approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance.

### **Laboratory**

We have established a new laboratory in Melville, New York to be used for research purposes and the possible development of cellular-based treatment protocols. We are also 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, product, protocol and stem cell-related IP development, translational research and therapeutic outcome analysis. In addition, we expect to expand our laboratory capabilities to include a cGMP (current good manufacturing practices) facility providing the regulatory standard to culture cells and prepare the formulation used in our *brtxDISC*<sup>TM</sup> product. As we develop our business and additional stem cell treatments are approved, we will seek to establish ourselves as a key provider of adult stem cells for therapies and expand to provide cells in other market areas for stem cell therapy. We may also use outside laboratories specializing in cell therapy services and manufacturing of cell products.





## 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” above), in connection with cellular research activities. We also intend to seek to obtain cellular-based therapeutic technology licenses and increase our IP portfolio. We intend to seek to develop potential stem cell delivery systems or devices. The goal of these specialized delivery systems or 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 there is a successful therapeutic result.

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.

We have filed six United States patent applications with regard to three patent families. Patent applications with regard to one such family have been filed in five foreign jurisdictions. In addition, a PCT application has been filed with regard to a second patent family. Regenerative has filed two patent applications with regard to the technology that is the subject of the license agreement between us (see “Disc/Spine Program” above). Our patent applications and those of Regenerative are currently in prosecution.

In March 2014, we entered into a Research and Development Agreement with Rohto Pharmaceutical Co., Ltd. (the “Rohto Research Agreement”), a Japanese pharmaceutical company. Pursuant to the Rohto Research Agreement, we have been engaged to provide research and development services with regard to stem cells. The Rohto Research 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 Rohto Research Agreement is scheduled to expire in June 2015.

In March 2014, we entered into the Pfizer Research Agreement, as discussed above under “Brown Adipose (Fat) Program”.

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.

During the years ended December 31, 2014 and 2013, we incurred \$1,430,614 and \$1,594,054, respectively, in research and development expenses.

## **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 may enter into arrangements with third party cosmetic companies or business partners with regard to the commercial distribution of anti-aging skin care products that utilize our extract as a potential principal cosmetic ingredient. No such arrangements are currently in place or under consideration.

### **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 18<sup>th</sup> century Swiss apple. Stem Pearls® currently offers its products via the Internet ([www.stempearls.com](http://www.stempearls.com) and [www.biorestorative.com](http://www.biorestorative.com)). Stem Pearls, LLC has not yet commenced widespread marketing efforts or generated any significant revenue.

## **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 five Scientific Advisory Board members are Dr. Wayne Marasco, Chairman, Dr. Amit Patel, Dr. Naiyer Imam, and Dr. Wayne Olan and Dr. Joy Cavagnaro. 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, Cavagnaro 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, adipose tissue, 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, Vericel Corporation, BioTime, Celgene, Harvest Technologies, Arteriocyte, Celling Biosciences, Mesoblast, NeoStem, Athersys, Tissue Genesis, Ember Therapeutics (recently merged with Mariel Therapeutics) and Discgenics. 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, 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 cell and tissue therapeutic products are intended to be marketed to physicians, other health care professionals, hospitals, research institutions, pharmaceutical companies and the military. It is anticipated that physicians who are trained and skilled in performing spinal injections will be the physicians most likely to treat discs with injections of *brtxDISC*<sup>™</sup>. These physicians would include interventional physiatrists (physical medicine physicians), pain management-anesthesiologists, interventional radiologists and neurosurgeons.

Our cosmetic ingredients are available to cosmetic manufacturers and distributors, and our Stem Pearls<sup>®</sup> cosmetic products are available via the Internet; however, we have not yet developed marketing plans for either product line.

## **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<sup>®</sup> 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.

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

- registration and listing of HCT/Ps with the FDA;
- donor eligibility determinations, including donor screening and donor testing requirements;



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

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

- adverse event reporting;

- FDA inspection;

- importation of HCT/Ps; and

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

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

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

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

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

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

For products that are regulated as drugs, an investigational new drug application (“IND”) and an approved new drug application (“NDA”) are required before marketing and sale in the United States pursuant to the requirements of 21 C.F.R. Parts 312 and 314, respectively. An IND application notifies the FDA of prospective clinical testing and allows the test product to be shipped in interstate commerce. Approval of a NDA requires a showing that the drug is safe and effective for its intended use and that the methods, facilities, and controls used for the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity. If regulated as a biologic, the product must be subject to an IND to conduct clinical trials and a manufacturer must obtain an approved Biologics License Application (“BLA”) before introducing a product into interstate commerce. To obtain a BLA, a manufacturer must show that the proposed product is safe, pure, and potent and that the facility in which the product is manufactured, processed, packed, or held meets established quality control standards.

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

We are a development stage enterprise and have not generated 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.

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 may 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. Similar laws and requirements are likely to exist in other countries and we intend to comply with such requirements.

### *Cosmetic and Skin Care Regulation*

We may seek to continue our development of a human adult stem cell-derived extract for use in anti-aging skin care products and offer skin care cosmetic products derived from plant stem cells. We have established Stem Pearls, LLC to develop and market plant-derived stem cell cosmetic products in the United States and abroad.

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

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

Stem Pearls, LLC, our cosmetics subsidiary, will be responsible for substantiating the safety and product claims of the cosmetic products and ingredients before marketing. Separately, we may enter into arrangements with third party cosmetic companies or business partners with regard to the commercial development and distribution of anti-aging skin care products that use our human adult stem cell-derived extract as a potential principal cosmetic ingredient.

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 typically include FDA premarket approval under an NDA or an abbreviated new drug application (“ANDA”), or, for over-the-counter products, 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. Over-the-counter drug products that do not meet the applicable FDA regulation require FDA approval under an NDA or ANDA prior to over-the-counter sale.

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.

With regard to the human adult stem cell-derived extract, 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.

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.



The HITECH Act also established notification requirements in the event that a breach of the protected health information occurs at a covered entity or business associate. These notification obligations mandate that each affected individual whose protected health information was impermissibly accessed receive written notification mailed to his residence of record and that the Secretary of HHS and potentially the media also be notified. HHS, through its Office for Civil Rights, investigates breach reports and determines whether administrative or technical modifications are required and whether civil or criminal sanctions should be imposed. Companies failing to comply with HIPAA and the implementing regulations may also be subject to civil money penalties or in the case of knowing violations, potential criminal penalties, including monetary fines, imprisonment, or both. In some cases, the State Attorneys General may seek enforcement and appropriate sanctions in federal court.

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

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

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

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

- state and local licensure of medical professionals;

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

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

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

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

- state and local laws and regulations governing human subject research and clinical trials;

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

- state and local laws and regulations for the disposal and handling of medical waste and biohazardous material;
- Occupational Safety and Health (“OSHA”) regulations and requirements;
- 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;
- 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); and
- state and other Federal laws addressing the privacy of health information.

### ***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 40 Marcus Drive, Melville, New York, and our telephone number is (631) 760-8100. Our website is [www.biorestorative.com](http://www.biorestorative.com). Our internet website and the information contained therein or connected thereto are not intended to be incorporated by reference into this Annual Report.

**Employees**

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



**ITEM 1A. RISK FACTORS.**

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

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

Not applicable.

**ITEM 2.**

**PROPERTIES.**

Our principal executive offices and laboratory are located at 40 Marcus Drive, Melville, New York. We occupy 6,800 square feet of space at the premises pursuant to a lease that was entered into in August 2014 and provides for a term of 63 months from the commencement date (as defined in the lease); we have an option to extend the term of the lease for five years. The lease provides for an annual base rental during the initial term ranging between \$132,600 and \$149,260.

Our premises are suitable and adequate for our current operations.

**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 \$5,000 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 (or alternatively \$52,000 per year from September 2009) as well as the repayment of the alleged loan with interest, reimbursement for certain out-of-pocket fees and expenses, two weeks vacation pay per year, and the issuance of 80,000 shares of our common stock or warrants for the purchase of 80,000 shares of our common stock (or alternatively the market value of such securities). A trial of the action is scheduled to commence in June 2015. On March 13, 2015, we filed with the court a settlement offer.

**ITEM 4.**

**MINE SAFETY DISCLOSURES.**

Not applicable.

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

Transactions in our common stock are 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
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

	High	Low
2014 Calendar Year		
First Quarter	\$0.90	\$0.28
Second Quarter	\$0.60	\$0.24
Third Quarter	\$0.40	\$0.25
Fourth Quarter	\$0.52	\$0.26

**Holder**

As of March 30, 2015, there were 258 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, 2014, we issued the following securities in transactions not involving any public offering. For each of the following transactions, we relied upon Section 4(a)(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, 2013, Quarterly Reports on Form 10-Q for the periods ended March 31, 2014, June 30, 2014 and September 30, 2014 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		Term (Years)	Purchaser(s)	Consideration (1)
		Shares	Exercise Price			
10/3/14	8,819	-	\$ -	-	(2 )	\$ 2,910 (3)
10/7/14	48,388	-	\$ -	-	(2 )	\$ 15,000 (3)
10/8/14-12/22/14	1,000,000	250,000	\$ 0.75	5	(4 )	\$ 300,000
10/23/14-12/31/14	290,000	-	\$ -	-	(2 )	\$ 63,800 (3)
10/28/14	170,782	-	\$ -	-	(4 )	\$ 31,765 (5)
10/31/14	14,286	-	\$ -	-	(2 )	\$ 5,000 (3)
11/20/14	110,000	110,000	\$ 0.75	2	(2 )	\$ 33,000 (6)
11/24/14-12/8/14	800,000	400,000	\$ 0.45	(7) 5	(4 )	\$ 200,000
11/30/14	12,500	-	\$ -	-	(2 )	\$ 5,000 (3)
12/31/14	450,000	-	\$ -	-	(4 )	\$ 99,000 (8)
12/31/14	29,476	-	\$ -	-	(2 )	\$ 14,738 (3)

The value of the non-cash consideration was estimated to be the fair value of our restricted common stock. Since (1) 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) Consultant.

(3) Issued in consideration of consulting services

(4) Accredited investor.



(5) Issued in connection with the conversion of convertible notes payable.

(6) Issued pursuant to the exercise of warrants.

(7) Warrants to purchase 200,000 and 200,000 shares of common stock have exercise prices per share of \$0.40 and \$0.50, respectively.

(8) Issued in connection with the extension of notes payable.

### **Issuer Purchases of Equity Securities**

During the quarter ended December 31, 2014, 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, 2014 and 2013 and for the years ended December 31, 2014 and 2013 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

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. Among the initiatives that we are currently pursuing is our Disc/Spine Program with our initial therapeutic product being called *brtxDISC*<sup>™</sup> (Disc Implanted Stem Cells). We have obtained a license that permits us to use technology for adult stem cell treatment of disc and spine conditions, including protruding and bulging lumbar 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*<sup>®</sup> 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.

We are also developing a curved needle device (“CND”) that is a needle system to allow access to difficult to locate regions for the delivery or removal of fluids and other substances. The CND is intended to deliver stem cells and/or other therapeutic products or material to the interior of a human intervertebral disc, the spine region, or potentially other areas of the body.

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 have relocated our offices to Melville, New York where we have established a new laboratory facility in order to increase our capabilities for the further development of possible cellular-based treatments, products and protocols, stem cell-related intellectual property and translational research applications.

As of December 31, 2014, the deficit accumulated was \$25,400,026, our stockholders’ deficiency was \$6,888,393 and our working capital deficiency was \$8,410,686. While we have recently begun to generate a modest amount of revenue, our losses have principally been operating expenses incurred in research and 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, 2014 and our forecast for continued operating losses, we require equity and/or debt financing to continue our operations. As of December 31, 2014, our outstanding debt of \$5,851,496, together with interest at rates ranging between 8% and 15% per annum, was due on various dates through October 2015. Subsequent to December 31, 2014 and through March 31, 2015, we have received aggregate equity financing and debt financing of \$801,000 and \$30,000, respectively, we have received research and development fees of \$227,234, and \$50,000 and \$5,984 of debt and accrued interest, respectively, has been converted into common stock. Giving effect to the above actions, we currently have notes payable aggregating \$5,000 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 April 2015. We are currently in the process of negotiating extensions or discussing conversions to equity with respect to our outstanding indebtedness. 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.

## Recent Developments

### Research and Development Agreements

On October 10, 2014, we entered into an agreement with a consultant for services regarding pre-investigational New Drug Application (“Pre-IND”) and investigational New Drug (“IND”) regulatory support regarding our *brtxDISC*<sup>TM</sup> product. The consultant is entitled to milestone based payments up to a total cost of \$225,000, payable upon the completion of certain tasks. The agreement will continue until May 2015, the estimated date of the final milestone, and will automatically renew for successive one-year periods. We can terminate the agreement at any time by providing thirty days prior written notice.

### Operating Lease

On August 25, 2014, we entered into a lease for 6,800 square feet of space located in Melville, New York. We have relocated our corporate and laboratory operations from Jupiter, Florida to such location. The lease provides for a five year, three month term from the commencement date (as defined in the lease) (subject to extension at our option for a period of five years) and an annual base rental during the initial term ranging between \$132,600 and \$149,260. In consideration of certain lease concessions made by the landlord valued at \$71,050, concurrently with the lease execution, we issued to the principals of the landlord an aggregate of 284,200 shares of our common stock and five year warrants to purchase an aggregate of 142,100 shares of our common stock at an exercise price of \$0.50 per share.

## Consolidated Results of Operations

### Year Ended December 31, 2014 Compared with Year Ended December 31, 2013

The following table presents selected items in our consolidated statements of operations for the years ended December 31, 2014 and 2013, respectively:

	For The Years Ended December 31,	
	2014	2013
Revenues	\$415,996	\$1,680
Cost of sales	213,834	208
Gross Profit	202,162	1,472
Operating Expenses		
Marketing and promotion	125,626	114,951
Consulting	1,310,121	779,462
Research and development	1,430,614	1,594,054
General and administrative	2,258,307	2,265,275
Total Operating Expenses	5,124,668	4,753,742
Loss From Operations	(4,922,506)	(4,752,270)
Other (Expense) Income		
Interest expense	(285,275 )	(371,281 )
Amortization of debt discount	(464,470 )	(405,531 )
Loss on extinguishment of note and payables, net	(49,094 )	(7,200 )
Warrant modification expense	(50,035 )	(214,912 )
Gain on settlement of notes and payables	183,768	-
Total Other Expense	(665,106 )	(998,924 )
Net Loss	\$(5,587,612)	\$(5,751,194)

### ***Revenues***

For the year ended December 31, 2014, we generated \$413,777 of revenues through the services provided pursuant to our research and development agreements and \$2,219 of sales of Stem Pearls<sup>®</sup> skincare products. For the year ended December 31, 2013, revenues consisted only of \$1,680 of sales of Stem Pearls<sup>®</sup> skincare products.

### ***Cost of sales***

For the year ended December 31, 2014, cost of sales was \$213,834 as compared to \$208 for 2013. For the year ended December 31, 2014, cost of sales consisted primarily of \$198,162 of costs related to our research and development

agreements. For the year ended December 31, 2013, cost of sales consisted of the costs of the underlying Stem Pearls® skincare products.

***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, 2014, marketing and promotion expenses increased by \$10,675, or 9%, from \$114,951 to \$125,626, as compared to the year ended December 31, 2013.

We expect that marketing and promotion expenses will continue to 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, 2014, consulting expenses increased \$530,659, or 68%, from \$779,462 to \$1,310,121, as compared to the year ended December 31, 2013. The increase is primarily due to an approximate \$525,000 increase in non-cash stock-based compensation to directors, consultants and advisors and an approximate \$40,000 increase in directors fees related to the resignation of one the members of our Board of Directors, whereby we agreed to pay the director for the remainder of his 2014 compensation, and the increase of our Board of Directors by one member, partially offset by an approximate \$34,000 reduction of cash consulting fees.

### ***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, 2014, research and development expenses decreased by \$163,440 from \$1,594,054 to \$1,430,614, or 10%, as compared to the year ended December 31, 2013. The decrease is primarily related to the amendment of our University of Utah Research Agreement resulting in a reduction of expense related to our brown fat and disc/spine initiatives as compared to the prior period of approximately \$135,000, the reclassification of a portion of our Vice President of Research and Development's salary of approximately \$128,000 to cost of sales for services related to our research and development agreements and a reduction of our Chief Executive Officer's salary during 2014 which resulted in approximately \$88,000 less expense in 2014 as compared to 2013, partially offset by an increase in non-cash stock-based compensation to our Vice President of Research and Development of approximately \$96,000, cash compensation to our Chief Medical Advisor for Spine Medicine of \$95,000 and a one-time bonus of \$25,000 earned by our Vice President of Research and Development.

We expect that our research and development expenses will 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, 2014, general and administrative expenses decreased by \$6,968, or less than 1%, from \$2,265,275 to \$2,258,307, as compared to the year ended December 31, 2013.

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, 2014, interest expense decreased \$86,006, or 23%, as compared to the year ended December 31, 2013. The decrease was due to a reduction in interest-bearing short-term borrowings as compared to the year ended December 31, 2013 including the restructuring of our largest note payable.

***Amortization of debt discount***

For the year ended December 31, 2014, amortization of debt discount increased \$58,939, or 15%, as compared to the year ended December 31, 2013. The increase was primarily due to the recognition of expense related to the beneficial conversion features of convertible notes and the timing of the recognition of the debt discount expense.

***Loss on extinguishment of notes payable***

For the year ended December 31, 2014, we recorded a loss on extinguishment of notes payable of \$49,094, which is associated with investors' conversion of debt into equity securities, as compared to a loss on extinguishment of notes payable of \$7,200 for the year ended December 31, 2013.

***Warrant modification expense***

During the year ended December 31, 2014, we recorded expense related to the modification of outstanding warrants of \$50,035, as compared to expense related to the modification of outstanding warrants of \$214,912 for the year ended December 31, 2013.

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



During the year ended December 31, 2014, we recorded a gain on settlement of note and payables, net, of \$183,768 related to a \$166,668 gain on the amendment of our University of Utah Research Agreement regarding our brown fat and disc/spine initiatives whereby a portion of the fees payable to the University of Utah were cancelled, a \$9,600 gain on the settlement of accrued expenses to consultants and a \$7,500 gain on the settlement of a convertible note. 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,	
	2014	2013
Cash	\$91,798	\$201,098
Working Capital Deficiency	\$(8,247,881)	\$(7,262,748)
Notes Payable (Gross - Current)	\$5,851,496	\$5,227,390

### Availability of Additional Funds

Based upon our working capital and stockholders' deficiency of \$8,410,686 and \$6,888,393, respectively, as of December 31, 2014, 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.

As of December 31, 2014, our outstanding debt of \$5,851,496, together with interest at rates ranging between 8% and 15% per annum, was due on various dates through October 2015. Subsequent to December 31, 2014 and through March 31, 2015, we have received aggregate equity and debt financing of \$801,000 and \$30,000, respectively, we have received research and development fees of \$227,234, plus \$50,000 and \$5,984 of debt and accrued interest, respectively, has been exchanged for common stock. Giving effect to the above actions, we currently have notes payable aggregating \$5,000 which are either past due or payable on demand. As of the date of filing, our outstanding debt was as follows:

Maturity Date	Principal Amount
Past Due/On Demand	\$5,000
QE 6/30/15	4,943,811
QE 9/30/15	290,000
QE 12/31/15	592,685
	\$5,831,496

Based upon our working capital deficiency, outstanding debt and forecast for continued operating losses we expect that the cash we currently have available will fund our operations through April 2015. 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, 2014, 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, 2014 and 2013 in the amounts of \$3,227,851 and \$2,672,404, respectively. The net cash used in operating activities for the year ended December 31, 2014 was primarily due to cash used to fund a net loss of \$5,587,612, adjusted for non-cash expenses in the aggregate amount of \$1,878,162, partially offset by \$481,599 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, 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 \$1,559,567, partially offset by \$1,519,223 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, 2014, net cash used in investing activities was \$167,396, primarily due to cash used for the purchase of furniture, computer equipment and medical equipment. 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.

**Net Cash Provided by Financing Activities**

Net cash provided by financing activities during the years ended December 31, 2014 and 2013 was \$3,285,947 and \$2,884,299, respectively. During the year ended December 31, 2014, \$567,947 of net proceeds were from debt financings and \$2,718,000 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, 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).

## **Critical Accounting Policies and Estimates**

### Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at dates of the financial statements and the reported amounts of revenue and expenses during the periods. The Company's significant estimates and assumptions include the recoverability and useful lives of long-lived assets, the fair value of the Company's equity securities and the valuation allowance related to the Company's deferred tax assets. Certain of the Company's estimates, including the carrying amount of the intangible assets, could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's 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 patents being licensed, less 2.3 years elapsed since the application date of the respective patents), 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

### *Research and Development Agreements*

Our policy is to recognize research and development revenues on a straight-line basis over the term of the agreement, regardless of the payment structure, subject to potential acceleration upon achievement of contractually specified deliverables.

On March 19, 2014, we entered into a one-year agreement with a Japanese pharmaceutical company to perform specified research and development activities related to stem cells. The agreement may be terminated earlier or extended, as provided for in the agreement. Payment terms are (1) \$150,000 at commencement; (2) \$50,000 upon achievement of a specified deliverable; and (3) \$50,000 upon achievement of the final specified deliverable. As of December 31, 2014, the initial \$150,000 payment had been received and \$34,281 was recorded as deferred revenues on the consolidated balance sheet.

On March 24, 2014, we entered into a two-year agreement with a U.S. pharmaceutical company to perform specified research and development activities related to brown fat. The agreement may be terminated earlier or extended, as provided for in the agreement. Payment terms are (1) \$250,000 at commencement; (2) \$356,250 payable in four equal quarterly installments, subject to acceleration upon achieving a specified deliverable; and (3) \$168,750 payable in two equal bi-annual installments, subject to acceleration upon achieving a specified deliverable. As of December 31, 2014, the initial \$250,000 payment and the first two quarterly payments of \$89,063 each related to (2) above had been received and \$130,068 was recorded as deferred revenues on the consolidated balance sheet.

During the year ended December 31, 2014, we recognized revenue related to research and development agreements of \$413,776. We did not recognize any revenue related to research and development agreements during the year ended December 31, 2013.

#### *Other*

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.

For the years ended December 31, 2014 and December 31, 2013, our recognized revenue related to sale of Stem Pearls® skincare products of \$2,220 and \$1,680, respectively.

#### 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.

## Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers,” (“ASU 2014-09”). ASU 2014-09 supersedes the revenue recognition requirements in Accounting Standards Codification (“ASC”) 605 - Revenue Recognition and most industry-specific guidance throughout the ASC. The standard requires that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective on January 1, 2017 and should be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application. We are currently evaluating the impact of the adoption of ASU 2014-09 on our consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-10, “Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation,” (“ASU 2014-10”). ASU 2014-10 removes the definition of a development stage entity from the ASC, thereby removing the financial reporting distinction between development stage entities and other reporting entities from GAAP. In addition, ASU 2014-10 eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of operations, cash flows, and stockholders’ equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early adoption is permitted. We elected to adopt ASU 2014-10 effective with the Quarterly Report on Form 10-Q for the period ended June 30, 2014 and its adoption resulted in the removal of previously required development stage disclosures.

In June 2014, the FASB issued ASU No. 2014-12, "Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period," ("ASU 2014-12"). The amendments in ASU 2014-12 require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in ASC Topic No. 718, "Compensation - Stock Compensation" as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. We do not anticipate that the adoption of ASU 2014-12 will have a material impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern” (“ASU 2014-15”). ASU 2014-15, which is effective for annual reporting periods ending after December 15, 2016, extends the responsibility for performing the going-concern assessment to management and contains guidance on how to perform a going-concern assessment and when going-concern disclosures would be required under U.S. GAAP. We elected to adopt ASU 2014-15 effective with the Quarterly Report on Form 10-Q for the period ended September 30, 2014. Management’s evaluations regarding the events and conditions that raise substantial doubt regarding our ability to continue as a going concern have been discussed above and also disclosed in the footnotes to the December 31, 2014 consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

### **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.

### **RISKS RELATED TO OUR BUSINESS GENERALLY**

*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, 2014, we had a working capital deficiency of \$8,410,686 and stockholders’ deficiency of \$6,888,393. The report of our

independent registered public accounting firm with respect to our financial statements as of December 31, 2014 and 2013 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 have incurred net losses since inception and we need to raise additional funds to meet our obligations and sustain our operations, 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, 2014 and 2013 and for the years then ended, 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”), as of December 31, 2014, our outstanding debt of \$5,851,496, together with interest at rates ranging between 8% and 15% per annum, are due on various dates through October 2015. Subsequent to December 31, 2014 and through March 31, 2015, we have received aggregate equity and debt financing of \$801,000 and \$30,000, respectively, we have received research and development fees of \$227,234, and \$50,000 and \$5,984 of debt and accrued interest, respectively, has been converted into common stock. Giving effect to the above actions, we currently have notes payable aggregating \$5,000 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 our outstanding indebtedness. As of March 31, 2015, the outstanding balance of our debt of \$5,831,496, together with accrued interest, was due and payable between on demand and October 2015. Unless we obtain additional financing or, upon our request, the debt holders 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 April 2015. 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 products and services which will require extensive cash for research, development and commercialization activities. This is a high-risk strategy because there is no assurance that our products and services, including our Disc/Spine Program and our ThermoStem<sup>®</sup> 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 products and services 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 license agreement, the research agreement with the University of Utah and the 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 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 December 2017. We are also dependent on the performance of Edward Field, President of our Disc/Spine Division, and Francisco Silva, our Vice President of Research and Development, in establishing and developing our products and operations. Mr. Field and Mr. Silva are also subject to employment agreements 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, Mr. Field 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.

***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.

## **RISKS RELATED TO OUR CELL THERAPY PRODUCT DEVELOPMENT EFFORTS**

*Our future success is significantly dependent on the timely and successful development and commercialization of brtxDISC™, our lead product candidate for the treatment of chronic lumbar disc disease; if we encounter delays or difficulties in the development of this product candidate, as well as any other product candidates, our business prospects would be significantly harmed.*

We are dependent upon the successful development, approval and commercialization of our product candidates. Before we are able to seek regulatory approval of our product candidates, we must conduct and complete extensive clinical trials to demonstrate their safety and efficacy in humans. Our lead product candidate, *brtxDISC*<sup>™</sup>, is in early stages of development and we must first complete pre-clinical work to submit an IND for FDA approval to commence clinical trials.

Clinical testing is expensive, difficult to design and implement, and can take many years to complete. Importantly, a failure of one or more of these or any other clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to complete our clinical studies, receive regulatory approval or commercialize our cell therapy product candidates, including the following:

- suspensions, delays or changes in the design, initiation, enrollment, implementation or completion of required clinical trials; adverse changes in our financial position or significant and unexpected increases in the cost of our clinical development program; changes or uncertainties in, or additions to, the regulatory approval process that require us to alter our current development strategy; clinical trial results that are negative, inconclusive or less than desired as to safety and/or efficacy, which could result in the need for additional clinical studies or the termination of the product's development; delays in our ability to manufacture the product in quantities or in a form that is suitable for any required clinical trials;
- intellectual property constraints that prevent us from making, using, or commercializing any of our cell therapy product candidates;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of these product candidates may be insufficient or inadequate: inability to generate sufficient pre-clinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;



· imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors or approved products post-market for related technology that raises FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

- difficulty collaborating with patient groups and investigators;
  
- failure by our CROs, other third parties, or us to adhere to clinical study requirements;
  
- failure to perform in accordance with the FDA's current good clinical practices, or cGCP requirements, or applicable regulatory guidelines in other countries;
  
- delays in having patients qualify for or complete participation in a study or return for post-treatment follow-up;
  
- patients dropping out of a study;
  
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
  
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
  
- transfer of manufacturing processes from our academic collaborators to larger-scale facilities operated by either a contract manufacturing organization, or CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
  
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing; and
  
- the FDA may not accept clinical data from trials that are conducted at clinical sites in countries where the standard of care is potentially different from the United States.

Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to, conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Even if we are able to successfully complete our clinical development program for our product candidates, and ultimately receive regulatory approval to market one or more of the products, we may, among other things:

- obtain approval for indications that are not as broad as the indications we sought;
- have the product removed from the market after obtaining marketing approval;
- encounter issues with respect to the manufacturing of commercial supplies;
- be subject to additional post-marketing testing requirements; and/or
- be subject to restrictions on how the product is distributed or used.

***We may experience delays in enrolling patients in our clinical trials which could delay or prevent the receipt of necessary regulatory approvals.***

We may not be able to initiate or complete as planned any clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other regulatory authorities. We also may be unable to engage a sufficient number of clinical trial sites to conduct our trials.

We may face challenges in enrolling patients to participate in our clinical trials due to the novelty of our cell-based therapies, the size of the patient populations and the eligibility criteria for enrollment in the trial. In addition, some patients may have concerns regarding cell therapy that may negatively affect their perception of therapies under development and their decision to enroll in the trials. Furthermore, patients suffering from diseases within target indications may enroll in competing clinical trials, which could negatively affect our ability to complete enrollment of our trials. Enrollment challenges in clinical trials often result in increased development costs for a product candidate, significant delays and potentially the abandonment of the clinical trial.

***We may have other delays in completing our clinical trials and we may not complete them at all.***

We have not commenced the clinical trials necessary to obtain FDA approval to market *brtxDISC*<sup>™</sup> or any of our other products in development. Our management lacks significant experience in completing clinical trials and bringing

a drug through commercialization. Clinical trials for *brtxDISC*<sup>™</sup> and other products in development may be delayed or terminated as a result of many factors, including the following:

- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons;

- failure by regulators to authorize us to commence a clinical trial;

- suspension or termination by regulators of clinical research for many reasons, including concerns about patient safety or our failure, or the failure of our contract manufacturers, to comply with cGMP requirements;

delays or failure to obtain clinical supply for our products necessary to conduct clinical trials from contract manufacturers;

- treatment candidates demonstrating a lack of efficacy during clinical trials;

- inability to continue to fund clinical trials or to find a partner to fund the clinical trials;

- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and

- delays in completing data collection and analysis for clinical trials.

Any delay or failure to complete clinical trials and obtain FDA approval for our product candidates could have a material adverse effect on our cost to develop and commercialize, and our ability to generate revenue from, a particular product candidate.

***The development of our cell therapy product candidates are subject to uncertainty because autologous cell therapy is inherently variable.***

When manufacturing an autologous cell therapy, the number and the composition of the cell population varies from patient to patient. Such variability in the number and composition of these cells could adversely affect our ability to manufacture autologous cell therapies in a cost-effective or profitable manner and meet acceptable product release specifications for use in a clinical trial or, if approved, for commercial sale. As a consequence, the development and regulatory approval process for autologous cell therapy products could be delayed or may never be completed.

***Any disruption to our access to the media (including cell culture media) and reagents we are using in the clinical development of our cell therapy product candidates could adversely affect our ability to perform clinical trials and seek future regulatory submissions.***

Certain media (including cell culture media) and reagents, as well as devices, materials and systems, that we intend to use in our planned clinical trials, and that we may need or use in commercial production, are provided by unaffiliated third parties. Any lack of continued availability of these media, reagents, devices, materials and systems for any reason would have a material adverse effect on our ability to complete these studies and could adversely impact our ability to achieve commercial manufacture of our planned therapeutic products. Although other available sources for these media, reagents, devices, materials and systems may exist in the marketplace, we have not evaluated their cost,

effectiveness, or intellectual property foundation and therefore cannot guarantee the suitability or availability of such other potential sources.

***Products that appear promising in research and development may be delayed or may fail to reach later stages of clinical development.***

The successful development of cellular based products is highly uncertain. Product candidates that appear promising in research and development may be delayed or fail to reach later stages of development. Decisions regarding the further development of product candidates must be made with limited and incomplete data, which makes it difficult to ensure or even accurately predict whether the allocation of limited resources and the expenditure of additional capital on specific product candidates will result in desired outcomes. Pre-clinical and clinical data can be interpreted in different ways, and negative or inconclusive results or adverse events during a clinical trial could delay, limit or prevent the development of a product candidate.

***Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.***

The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include decrease or elimination of pain, adequate duration of response, a delay in the progression of the disease, an improvement in function and/or decrease in disability.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

***We presently lack manufacturing capabilities to produce our product candidates at commercial scale quantities and do not have an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the products.***

Currently, we expect our laboratory to exclusively provide the cell processing services necessary for clinical production of *brtxDISC*<sup>™</sup> for our disc clinical trial. To date, we have not produced any products at our laboratory. We expect that we would need to significantly expand our manufacturing capabilities to meet potential commercial demand for *brtxDISC*<sup>™</sup> and any other of our product candidates, if approved, as well as any of our other product candidates that might attain regulatory approval. Such expansion would require additional regulatory approvals. Even if we increase our manufacturing capabilities, it is possible that we may still lack sufficient capacity to meet demand. Ultimately, if we are unable to supply our products to meet commercial demand, whether because of processing constraints or other disruptions, delays or difficulties that we experience, sales of the products and their long term commercial prospects could be significantly damaged.



We do not presently have a third-party manufacturer for *brtxDISC*<sup>TM</sup> or any of our other product candidates. If our facilities at which these product candidates would be manufactured or our equipment were significantly damaged or destroyed, or if there were other disruptions, delays or difficulties affecting manufacturing capacity, our planned and future clinical studies and commercial production for these product candidates would likely be significantly disrupted and delayed. It would be both time consuming and expensive to replace this capacity with third parties, particularly since any new facility would need to comply with the regulatory requirements.

Ultimately, if we are unable to supply our cell therapy product candidates to meet commercial demand (assuming commercial approval is obtained), whether because of processing constraints or other disruptions, delays or difficulties that we experience, our production costs could dramatically increase and sales of the product and its long-term commercial prospects could be significantly damaged.

***The commercial potential and profitability of our products are unknown and subject to significant risk and uncertainty.***

Even if we successfully develop and obtain regulatory approval for our cell therapy product candidates, the market may not understand or accept the products, which could adversely affect both the timing and level of future sales. Ultimately, the degree of market acceptance of our product candidates (or any of our future product candidates) will depend on a number of factors, including:

- the clinical effectiveness, safety and convenience of the product particularly in relation to alternative treatments;
- our ability to distinguish our products (which involve adult cells) from any ethical and political controversies associated with stem cell products derived from human embryonic or fetal tissue; and
- the cost of the product, the reimbursement policies of government and third-party payors and our ability to obtain sufficient third-party coverage or reimbursement.

Even if we are successful in achieving sales of our product candidates, it is not clear to what extent, if any, the products will be profitable. The costs of goods associated with production of cell therapy products are significant. In addition, some changes in manufacturing processes or procedures generally require FDA or foreign regulatory authority review and approval prior to implementation. We may need to conduct additional pre-clinical studies and clinical trials to support approval of any such changes. Furthermore, this review process could be costly and time-consuming and could delay or prevent the commercialization of product candidates.

***We may have difficulties in sourcing brown adipose (fat) tissue.***

Our research agreement with the University of Utah (due to terminate in June 2015) has provided an opportunity for us to obtain brown adipose (fat) tissue that we use to identify and characterize brown adipose derived stem cells for use in our pre-clinical ThermoStem<sup>®</sup> Program. There is no certainty that we will be able to continue to collect brown adipose samples through our University of Utah tissue procurement program or establish relationships with other potential sources of brown adipose tissue. The loss of brown tissue procurement would have a material adverse effect upon our ability to advance the ThermoStem<sup>®</sup> Program.

***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, unless certain milestones are satisfied, we will be required to pay to Regenerative minimum amounts of between \$225,000 and \$475,000 during the period from April 2017 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 (if the milestones are not satisfied). Any loss of such exclusive rights would have a material adverse effect upon our business, results of operations and financial condition.

***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 products and/or services 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 products and/or services impractical or impossible.

***Ethical and other concerns surrounding the use of stem cell therapy may negatively impact the public perception of our stem cell products and/or services, thereby suppressing demand for our products and/or 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 products and/or services that are more effective, easier to use, or more economical than those which we may develop, or that would render our products and/or services obsolete and non-competitive. In general, we may not be able to prevent others from developing and marketing competitive products and/or services 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, adipose tissue, 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 products and services. 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.

***We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.***

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute the shares of our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy.

Further, collaborations involving our product candidates, such as our collaborations with third-party research institutions, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;



- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
  
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
  
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
  
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
  
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
  
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
  
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
  
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our

existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.



***We have limited experience in the development and marketing of cell therapies and may be unsuccessful in our efforts to establish a profitable business.***

Over the past four years, our business plan has been focused on capturing a piece of the burgeoning field of cell therapy. We have limited experience in the areas of cell therapy product development and marketing, and in the related regulatory issues and processes. Although we have recruited a team that has experience with designing and conducting clinical trials, as a company, we have limited experience in conducting clinical trials and no experience in conducting clinical trials through to regulatory approval of any product candidate. In part because of this lack of experience, we cannot be certain that planned clinical trials will begin or be completed on time, if at all. We cannot assure that we will successfully achieve our clinical development goals or fulfill our plans to capture a piece of the cell therapy market.

***Our cell therapy business is based on novel technologies that are inherently expensive, risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.***

The clinical development, commercialization and marketing of cell and tissue-based therapies are at an early-stage, substantially research-oriented, and financially speculative. To date, very few companies have been successful in their efforts to develop and commercialize a cell therapy product. In general, cell-based or tissue-based products may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their approval or commercial use. In addition, *brtxDISC*<sup>™</sup> is a cell-based candidate that is produced by using a patient's own stem cells derived from bone marrow. Regulatory approval of novel product candidates such as *brtxDISC*<sup>™</sup>, which is manufactured using novel manufacturing processes, can be more complex and expensive and take longer than other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to the FDA's lack of experience with them. To our knowledge, the FDA has not yet approved a disc related stem cell therapy product. This lack of experience may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, which would increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. Furthermore, the number of people who may use cell or tissue-based therapies is difficult to forecast with accuracy. Our future success is dependent on the establishment of a large global market for cell- and tissue-based therapies and our ability to capture a share of this market with our product candidates.

***Our cell therapy product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated

regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a biologics license application, or BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a biologics license application, or BLA. The law is complex and is still being interpreted and implemented by the FDA, although the agency has approved one biosimilar product. As a result, its ultimate impact, implementation, and meaning are still subject to some uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products. Additionally, a U.S. Federal District Court recently interpreted the BPCIA patent resolution process in a manner very favorable to biosimilar applicants. *Amgen, Inc. v. Sandoz, Inc.*, Case No. 14-cv-04741-RS (N.D. Cal. March 19, 2015). If this decision is upheld on appeal, it will limit our ability to prevent the market entry of competing biosimilar products.

We believe that, if any of our product candidates are approved as a biological product under a BLA, it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA could permit biosimilar applicants to reference approved biologics other than our therapeutic candidates, thus circumventing our exclusivity and potentially creating the opportunity for competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

***We may be subject to significant product liability claims and litigation, including potential exposure from the use of our product candidates in human subjects, and our insurance may be inadequate to cover claims that may arise.***

Our business, once we commence human clinical trials, exposes us to potential product liability risks inherent in the testing, processing and marketing of cell therapy products. Such liability claims may be expensive to defend and result in large judgments against us. We face an inherent risk of product liability exposure related to the testing of our current and any future product candidates in human clinical trials and will face an even greater risk with respect to any commercial sales of our products should they be approved. No product candidate has been widely used over an extended period of time, and therefore safety data is limited. Cell therapy companies derive the raw materials for manufacturing of product candidates from human cell sources, and therefore the manufacturing process and handling requirements are extensive, which increases the risk of quality failures and subsequent product liability claims.

We will need to increase our insurance coverage when we begin clinical trials and commercializing product candidates, if ever. At that time, we may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all, or if claims against us substantially exceed our coverage, then our financial position could be significantly impaired.

Whether or not we are ultimately successful in any product liability litigation that may arise, such litigation could consume substantial amounts of our financial and managerial resources, decreased demand for our products and injure our reputation.

We seek to maintain errors and omissions, directors and officers, workers' compensation and other insurance at levels we believe to be appropriate to our business activities. If, however, we were subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our own limited resources, which could have a material adverse effect on our financial condition, results of operations and business. Additionally, liability or alleged liability could harm our business by diverting the attention and resources of our management and damaging our reputation.

***Our internal computer systems, or those that are expected to be used by our clinical investigators, clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates.***

We rely on information technology systems to keep financial records, maintain laboratory and corporate records, communicate with staff and external parties and operate other critical functions. Any significant degradation or failure of these computer systems could cause us to inaccurately calculate or lose data. Despite the implementation of security measures, these internal computer systems and those used by our clinical investigators, clinical research organizations, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. The techniques that could be used by criminal elements or foreign governments to attack these computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. While we have not experienced any such system failure, theft of information, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our clinical development activities. For example, the loss of clinical trial data from historical or future clinical trials could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption, theft of information, or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the clinical development and the future development of our product candidates could be delayed.

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

We intend to market our products and services both domestically and in foreign markets. A number of risks are inherent in international transactions. In order for us to market our products and services 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 products and services in the currency of the countries in which the products and services 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 products and services, 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 products and services in various foreign markets. Delays in receipt of approvals or clearances to market our products and services 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.

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

Successful sales of health care products and services 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 products and services at a level that will be profitable.

**RISKS RELATED TO OUR INTELLECTUAL PROPERTY**

***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 products and services incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products and services, duplicate any of our products and services, 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 products, services 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 products and/or services, 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. Although we conducted a freedom to operate (“FTO”) search on the licensed technology associated with our Disc/Spine Program, modifications made, and/or further developments that may be made, to that technology may not be covered by the initial FTO. No FTO has been undertaken with respect to our ThermoStem® brown fat initiative.

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 products and/or services 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 products and/or services, 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 products and/or services 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.

***Changes to United States patent law may have a material adverse effect on our intellectual property rights.***

The Leahy-Smith America Invents Act, or AIA, which was signed into law in 2011, significantly changes United States patent law. It may take some time to establish what the law means, since it is just being interpreted by the lower courts, and any lower court decisions have not been reviewed by either the Federal Circuit Court of Appeals or the Supreme Court, a process that will take years. The first major change is that AIA switches the U.S. patent system from a "first to invent" system to a "first to file" system. Now that the first to file system is in effect, there is a risk that another company may independently develop identical or similar patents at approximately the same time, and be awarded the patents instead of us. Further, for the second major change, AIA abolished interference proceedings, and establishes derivation proceedings to replace interference proceedings in all cases in which the time period for instituting an interference proceeding has not lapsed where an inventor named in an earlier application derived the claimed invention from a named inventor. Now that the derivation proceedings are in effect, there is a risk that the inventorship of any pending patent application can be challenged for reasons of derivation. The third major change is that AIA established post-grant opposition proceedings that will apply only to patent applications filed after "first to file" became effective. Post-grant opposition will enable a person who is not the patent owner to initiate proceedings in the Patent Office within nine months after the grant of a patent that can result in cancellation of a patent as invalid. In addition to AIA, recent court decisions have created uncertainty with regard to our ability to obtain and maintain patents. Therefore there is a risk that any of our patents once granted may be subject to post-grant opposition, which will increase uncertainty on the validity of any newly granted patent or may ultimately result in cancellation of the patent.



***In certain countries, patent holders may be required to grant compulsory licenses, which would likely have a significant and detrimental effect on any future revenues in such country.***

Many countries, including some countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly common in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to our product candidates, which may limit our potential revenue opportunities, including with respect to any future revenues that may result from our product candidates.

## **RISKS RELATED TO GOVERNMENT REGULATION**

***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 and related device accessories. 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, or 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, or 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.



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

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

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

HHS published the *Standards for Privacy of Individually Identifiable Health Information* (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.

The HITECH Act also established notification requirements in the event that a breach of the protected health information occurs at a covered entity or business associate. These notification obligations mandate that each affected individual whose protected health information was impermissibly accessed receive written notification mailed to his residence of record and that the Secretary of HHS and potentially the media also be notified. HHS, through its Office for Civil Rights, investigates breach reports and determines whether administrative or technical modifications are required and whether civil or criminal sanctions should be imposed. Companies failing to comply with HIPAA and the implementing regulations may also be subject to civil money penalties or in the case of knowing violations, potential criminal penalties, including monetary fines, imprisonment, or both. In some cases, the State Attorneys General may seek enforcement and appropriate sanctions in federal court.

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

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

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



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

- the federal Anti-Kickback Law and any state equivalent statutes and regulations;
- Federal and state coverage and reimbursement laws and regulations;
- state and local laws and regulations for the disposal and handling of medical waste and biohazardous material;
- Occupational Safety and Health (“OSHA”) regulations and requirements;
- 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;
- 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); and
- state and other Federal laws governing the privacy of health information.

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

In the event we determine to operate 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.

***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.

***The development and commercialization of our product candidates is subject to extensive regulation by the FDA and other regulatory agencies in the United States and abroad, and the failure to receive regulatory approvals for our cell therapy product candidates would likely have a material and adverse effect on our business and prospects.***

To date, we have not received regulatory approval to market any of our product candidates in any jurisdiction. If we seek approval of any of our cell therapy product candidates, we will be required to submit to the FDA and potentially other regulatory authorities extensive pre-clinical and clinical data supporting its safety and efficacy, as well as information about the manufacturing process and to undergo inspection of our manufacturing facility or other contract manufacturing facilities, among other things. The process of obtaining FDA and other regulatory approvals is expensive, generally takes many years and is subject to numerous risks and uncertainties, particularly with complex and/or novel product candidates such as our cell-based product candidates. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application or may make it easier for our competitors to gain regulatory approval to enter the marketplace. Ultimately, the FDA and other regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our product candidate data are insufficient for approval without the submission of additional preclinical, clinical or other studies. In addition, varying agency interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any of the following factors, among others, could cause regulatory approval for our product candidates to be delayed, limited or denied:

the product candidates require significant clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be submitted to the FDA and other regulatory authorities;

data obtained from pre-clinical and nonclinical animal testing and clinical trials can be interpreted in different ways, and regulatory authorities may not agree with our respective interpretations or may require us to conduct additional testing;

negative or inconclusive results or the occurrence of serious or unexpected adverse events during a clinical trial could cause us to delay or terminate development efforts for a product candidate; and/or

- FDA and other regulatory authorities may require expansion of the size and scope of the clinical trials.

Any difficulties or failures that we encounter in securing regulatory approval for our product candidates would likely have a substantial adverse impact on our ability to generate product sales, and could make any search for a collaborative partner more difficult.

***We may be unsuccessful in our efforts to comply with applicable federal, state and international laws and regulations, which could result in loss of licensure, certification or accreditation or other government enforcement actions or impact our ability to secure regulatory approval of our product candidates.***

Although we seek to conduct our business in compliance with applicable governmental healthcare laws and regulations, these laws and regulations are exceedingly complex and often subject to varying interpretations. The cell therapy industry is the topic of significant government interest, and thus the laws and regulations applicable to our business are subject to frequent change and/or reinterpretation. As such, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all such healthcare laws and regulations. Failure to comply with such healthcare laws and regulations, as well as the costs associated with such compliance or with enforcement of such healthcare laws and regulations, may have a material adverse effect on our operations or may require restructuring of our operations or impair our ability to operate profitably.

Facilities engaged in the recovery, processing, storage, labeling, packaging or distribution of any HCT/Ps, or the screening or testing of a donor, are required to register with the FDA. Any third party retained by us to process our samples must be similarly registered with the FDA and comply with HCT/P regulations. We also are required to comply with FDA's cGTP regulations. If we fail to register or update registration information in a timely way, or fail to comply with cGTP regulations, we will be out of compliance with FDA regulations which could adversely affect our business. FDA's Quality System Regulation, or QSR, similarly governs the manufacture, processing, packaging and holding of cell therapy products regulated as medical devices. We must comply with cGMP or QSR requirements including quality control, quality assurance and the maintenance of records and documentation for certain products. We may be unable to comply with these cGMP or QSR requirements and with other FDA, state and foreign regulatory requirements. These requirements may change over time and we or third-party manufacturers may be unable to comply with the revised requirements.



***If we are unable to conduct clinical studies in accordance with regulations and accepted standards, we may be delayed in receiving, or may never receive, regulatory approvals of our product candidates from the FDA and other regulatory authorities.***

To obtain marketing approvals for our product candidates in the United States and abroad, we must, among other requirements, complete adequate and well-controlled clinical trials sufficient to demonstrate to the FDA and other regulatory bodies that the product candidate is safe and effective for each indication for which approval is sought. If the FDA finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury, due to, among other things, occurrence of a serious adverse event in an ongoing clinical trial, the FDA can place one or more of our clinical trials on hold. If safety concerns develop, we may, or the FDA or an institutional review board may require us to, stop the affected trials before completion.

The completion of our clinical trials also may be delayed or terminated for a number of other reasons, including if:

third-party clinical investigators do not perform the clinical trials on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices required by the FDA and other regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;

inspections of clinical trial sites by the FDA or by institutional review boards of research institutions participating in the clinical trials, reveal regulatory violations that require the sponsor of the trial to undertake corrective action, suspend or terminate one or more sites, or prohibit use of some or all of the data in support of marketing applications; or

the FDA or one or more institutional review boards suspends or terminates the trial at an investigational site, or precludes enrollment of additional subjects.

Our development costs will increase if there are material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly, we may never receive regulatory approval to market our product candidates.

***We will continue to be subject to extensive FDA regulation following any product approvals, and if we fail to comply with these regulations, we may suffer a significant setback in our business.***



Even if we are successful in obtaining regulatory approval of our product candidates, we will continue to be subject to the requirements of and review by, the FDA and comparable regulatory authorities in the areas of manufacturing processes, post-approval clinical data, adverse event reporting, labeling, advertising and promotional activities, among other things. In addition, any marketing approval we receive may be limited in terms of the approved product indication or require costly post-marketing testing and surveillance. Discovery after approval of previously unknown problems with a product, manufacturer or manufacturing process, or a failure to comply with regulatory requirements, may result in actions such as:

warning letters or untitled letters or other actions requiring changes in product manufacturing processes or restrictions on product marketing or distribution;

- product recalls or seizures or the temporary or permanent withdrawal of a product from the market; and
- fines, restitution or disgorgement of profits or revenue, the imposition of civil penalties or criminal prosecution.

The occurrence of any of these actions would likely cause a material adverse effect on our business, financial condition and results of operations.

***Health care companies have been the subjects of federal and state investigations, and we could become subject to investigations in the future.***

Both federal and state government agencies have heightened civil and criminal enforcement efforts. There are numerous ongoing investigations of health care companies, as well as their executives and managers. In addition, amendments to the Federal False Claims Act, including under Healthcare Reform, have made it easier for private parties to bring “*qui tam*” (whistleblower) lawsuits against companies under which the whistleblower may be entitled to receive a percentage of any money paid to the government. The Federal False Claims Act provides, in part, that an action can be brought against any person or entity that has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. The government has taken the position that claims presented in violation of the federal anti-kickback law, Stark Law or other healthcare-related laws, including laws enforced by the FDA, may be considered a violation of the Federal False Claims Act. Penalties include substantial fines for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person or entity and/or exclusion from the Medicare program. In addition, a majority of states have adopted similar state whistleblower and false claims provisions.

We are not aware of any government investigations involving any of our facilities or management. While we believe that we are in material compliance with applicable governmental healthcare laws and regulations, any future investigations of our business or executives could cause us to incur substantial costs, and result in significant liabilities or penalties, as well as damage to our reputation.

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

To the extent that health care providers cannot obtain coverage or reimbursement for our therapies and products, they may elect not to provide such therapies and products to their patients and, thus, may not need our services. Further, as cost containment pressures are increasing in the health care industry, government and private payors may adopt strategies designed to limit the amount of reimbursement paid to health care providers.

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

We may receive a portion of our revenues from services rendered to patients enrolled in federal health care programs, such as Medicare, and we may also directly or indirectly receive revenues from federal health care programs. Federal health care programs are subject to changes in coverage and reimbursement rules and procedures, including retroactive rate adjustments. These contingencies could materially decrease the range of services covered by such programs or the reimbursement rates paid directly or indirectly for our products and services. To the extent that any health care reform favors the reimbursement of other therapies over our therapeutic products under development, such reform could affect our ability to sell our services, which may have a material adverse effect on our revenues.

The limitation on reimbursement available from private and government payors may reduce the demand for, or the price of, our services, which could have a material adverse effect on our revenues. Additional legislation or regulation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future which could adversely affect the revenues generated from the sale of our products and services.

Furthermore, there has been a trend in recent years towards reductions in overall funding for Medicare and Medicaid. There has also been an increase in the number of people who do not have any form of health care coverage in recent years and who are not eligible for or enrolled in Medicare, Medicaid or other governmental programs. The extent to which the reforms brought about under Healthcare Reform may be successful in reducing the number of such uninsured is unclear, and the reduced funding of governmental programs and increase in uninsured populations could have a negative impact on the demand for our services to the extent they relate to products and services which are reimbursed by government and private payors.

***Unintended consequences of healthcare reform legislation in the United States may adversely affect our business.***

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

legislation causes such unintended consequences or indirect impact, it could have a material adverse effect on our business, financial condition and results of operations.

***Competitor companies or hospitals may be able to take advantage of EU rules permitting sales of unlicensed medicines for individual patients to sell competing products without a marketing authorization.***

The EU medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the EU and imported to treat specific patients or small groups of patients. In addition, advanced therapy medicinal products do not need a marketing authorization if they are prepared on a non-routine basis and are used within the same EU member state in a hospital in accordance with a medical prescription for an individual patient.

These exemptions could allow our competitors to make sales in the EU without having obtained a marketing authorization and without undergoing the expense of clinical trials, especially if those competitors have cell processing facilities in the relevant EU member state. Similarly, certain hospitals may be able to compete with us on the basis of these rules. Because any such sales would be made without a marketing authorization, there would be no need for the competitor company or hospital to refer to the clinical data in our marketing authorization dossiers, and so any data exclusivity protection that we may obtain for our products would not prevent such competing sales.

## ***RISKS RELATED TO OUR COMMON STOCK***

***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 March 31, 2015, we had outstanding indebtedness in the amount of \$5,831,496. 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, 2014, 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, 2014.

### ***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, 2014 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.

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**PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.****Directors and Executive Officers**

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

<b>Name</b>	<b>Age</b>	<b>Positions Held</b>
Mark Weinreb	62	Chief Executive Officer, President and Chairman of the Board
Edward L. Field	50	President, Disc/Spine Division
Francisco Silva	40	Vice President of Research and Development
Mandy D. Clyde	33	Vice President of Operations and Secretary
A. Jeffrey Radov	63	Director
Joseph Swiader	55	Director
Paul Jude Tonna	56	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 Laboratories 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. (now known as Gesturetek, Inc.), a software development company pioneering gesture recognition and control using advanced interactive proprietary video technology. Mr. Weinreb received a Bachelor of Arts degree from Northwestern University and a Master of Science degree 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.

**Edward L. Field**

Edward L. Field has served as President of our Disc/Spine Division since February 2015. Mr. Field served as Chief Operating Officer of Cytomedix, Inc. (now known as Nuo Therapeutics, Inc.), a regenerative therapies marketing and development company, from February 2012 to June 2014. From November 2004 to March 2010, Mr. Field served as President and Chief Operating Officer of Aldagen, Inc., a biotechnology company acquired by Cytomedix. From March 2010 to November 2010, he served as Aldagen's Chief Business Officer. From November 2010 to February 2012, Mr. Field served as Aldagen's Chief Operating Officer. From 2002 to September 2004, Mr. Field was President and Chief Executive Officer of Inologic, Inc., a biopharmaceutical company. From 1999 to 2002, he was President of Molecumetics, Ltd., a drug discovery and development subsidiary of Tredegar Corporation, until its merger with Therics, LLC, a regenerative medicine company. Mr. Field received a Master of Business Administration degree from the University of Virginia's Darden School of Business Administration and a Bachelor of Arts degree in Economics from Duke University.

**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.

**Joseph B. Swiader**

Joseph B. Swiader became a member of our Board and Chair of our Nominating Committee in June 2014. Mr. Swiader has extensive experience in both the financial and biotechnology sectors. He is currently managing partner of Wet Earth Partners LLC ("Wet Earth Partners"), which he founded in 2002. Wet Earth Partners invests in a range of ventures that include biotechnology, medical technology and consumer products. Previously he was a partner at Feirstein Capital Management, where he oversaw investments in biotechnology, pharmaceutical, medical technology and healthcare services companies. Earlier, Mr. Swiader was the Senior Global Healthcare Analyst at Scudder, Stevens & Clark (now part of Deutsche Asset & Wealth Management). Mr. Swiader was also a biotechnology and pharmaceutical analyst for the Dreyfus group of funds. He began his investment career in 1992 as a biotechnology analyst at JP Morgan Securities. Mr. Swiader received a Bachelor of Science degree in finance from Babson College. We believe that Mr. Swiader'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.

**Paul Jude Tonna**

Paul Jude Tonna became a member of our Board and Chair of our Compensation Committee in June 2014. Mr. Tonna is a highly regarded community leader and an accomplished businessman with an extensive history of public service. From 1994 to 2005 he served as a Suffolk County, New York Legislator, and from 2000 through 2002 was its Presiding Officer. He currently serves as Executive Director and a member of the Board of Advisors for The Energeia Partnership at Molloy College, a leadership academy based in Rockville Centre, New York, dedicated to identifying and addressing the serious, complex and multi-dimensional issues challenging the Long Island region. Mr. Tonna is a former Adjunct Professor in Theology & Religious Studies at St. John’s University. He served as Chairman of the Suffolk County Industrial Development Agency, and currently serves as Trustee of the Long Island State Parks & Recreation Commission and as Public Trustee of the Stationary Engineers Industry Stabilization Fund. Mr. Tonna is a board member of The Advanced Energy Research & Technology Center at Stony Brook University, The Long Island Index Advisory Board and Erase Racism’s College of Advisors. He also serves as the Executive Director of the Suffolk County Village Officials Association and the United States Green Building Council-Long Island Chapter. Mr. Tonna is a founding director of Empire National Bank and Chairman and Commissioner of the South Huntington Water District. Mr. Tonna holds an undergraduate degree in philosophy from New York University and a Master’s degree in theology from Immaculate Conception Seminary, and he conducted doctoral studies in systemic theology at Fordham University. We believe that Mr. Tonna’s executive-level management experience and his extensive experience in the Long Island community give 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:

<b>Name</b>	<b>Principal Positions</b>
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

Director, Endovascular and Minimally Invasive Image Guided Neurosurgery;

Wayne J. Olan, M.D.

Associate Professor, Neurosurgery and Radiology, George Washington University Medical Center;

Consulting Physician, Department of Radiology, National Institutes of Health

Joy Cavagnaro, Ph.D.,  
DABT, RAC

President and Founder, Access BIO, L.C.; Fellow, Academy of Toxicological Sciences and the Regulatory Professional Society;

Formerly Senior Pharmacologist and Director of Quality Assurance, Food and Drug Administration's Center for Biologics Evaluation and Research

### **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 Psychiatrist-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 Psychiatry Department at HSS and became Psychiatrist-in-Chief.

### **Family Relationships**

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

### **Term of Office**

We have a classified Board of Directors. The directors will hold office until the respective annual meetings of stockholders indicated below and until their respective successors are elected and qualified or until their earlier resignation or removal.

Name	Class	Term Expires
Mark Weinreb	III	2017

A. Jeffrey Radov	III	2017
Joseph Swiader	I	2015
Paul Jude Tonna	II	2016

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 Tonna.

### **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, 2014. 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, 2014, our officers, directors and 10% stockholders complied with all Section 16(a) filing requirements applicable to them, except that Janet H. Montgomery and Stuart H. Montgomery, then a 10% stockholder, filed their Form 3 late and Mr. Tonna filed one Form 4 late in which he reported one transaction (the purchase of common stock and warrants from us).

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

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





**ITEM 11.****EXECUTIVE COMPENSATION.****Summary Compensation Table**

The following Summary Compensation Table sets forth all compensation earned in all capacities during the fiscal years ended December 31, 2014 and 2013 by our (i) principal executive officer, and (ii) all other executive officers, other than our principal executive officer, whose total compensation for the 2014 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		Bonus		Option	All Other Compensation		Total
		Earned	Waived	Earned	Waived	Awards Earned	Earned	Waived	Earned
Mark Weinreb, Chief Executive Officer	2014	\$450,000 <sup>(1)</sup>	\$-	\$225,000 <sup>(3)</sup>	\$-	\$1,097,000 <sup>(4)</sup>	\$34,400 <sup>(1)</sup>	\$-	\$1,806,400
	2013	\$360,000 <sup>(2)</sup>	\$240,000 <sup>(2)</sup>	\$-	\$300,000 <sup>(3)</sup>	\$50,550	\$14,400 <sup>(2)</sup>	\$25,000 <sup>(2)</sup>	\$424,950
Francisco Silva, VP of Research and Development	2014	\$230,000	\$-	\$25,000	\$-	\$283,558	\$-	\$-	\$538,558
	2013	\$230,000	\$-	\$-	\$-	\$20,220	\$-	\$-	\$250,220
Mandy Clyde, VP of Operations	2014	\$118,000	\$-	\$-	\$-	\$86,825	\$-	\$-	\$204,825
	2013	\$118,000	\$-	\$-	\$-	\$16,176	\$-	\$-	\$134,176

Of the aggregate \$1,806,400 earned during 2014, \$1,097,000 represents the grant date value of non-cash stock-based compensation awards, irrespective of the vesting period of those awards. Of the \$709,400 earned cash compensation, \$135,122 and \$78,921 were paid in cash during 2014 and 2015 (prior to this Annual Report being filed), respectively, and \$495,357 remains unpaid. All Other Compensation represents \$14,400 of automobile allowance paid to, and \$20,000 of unpaid vacation for, Mr. Weinreb in 2014.

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) \$50,550 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 \$360,000 were paid in cash during 2013 and 2014, respectively, and none remains unpaid. All Other Compensation-Earned represents the automobile allowance paid to Mr. Weinreb in 2013.

(3) Pursuant to Mr. Weinreb’s employment agreement with us, he earned a bonus for 2013 and 2014 equal to 50% of his annual salary. See “Employment Agreement” below. Mr. Weinreb waived his entitlement to receive a bonus for

2013.

(4) The amounts reported in these columns represent the grant date fair value of the option awards granted during the years ended December 31, 2014 and 2013, 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.

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

The following table provides information on outstanding equity awards as of December 31, 2014 to the Named Executive Officers:

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Name	Option Awards			Stock Awards			Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested
	Number of securities underlying unexercised options	Number of securities underlying unexercised options	Equity incentive plan awards: Number of securities underlying unexercised options	Option exercise price	Option expiration date	Number of shares or units that have not vested	
Mark Weinreb	80,000	-	-	\$ 0.50	12/14/2020	- \$ -	\$ -
Mark Weinreb	1,000,000	-	-	\$ 1.05	2/10/2022	- \$ -	\$ -
Mark Weinreb	400,000	-	-	\$ 1.50	12/7/2022	- \$ -	\$ -
Mark Weinreb	250,000	-	-	\$ 0.60	10/4/2023	- \$ -	\$ -
Mark Weinreb	333,334	666,666 (1)	-	\$ 0.65	2/18/2024	- \$ -	\$ -
Mark Weinreb	-	3,000,000 (2)	-	\$ 0.33	10/23/2024	- \$ -	\$ -
Francisco Silva	80,000	-	-	\$ 0.50	4/4/2021	- \$ -	\$ -
Francisco Silva	3,000	-	-	\$ 1.25	6/23/2021	- \$ -	\$ -
Francisco Silva	20,000	-	-	\$ 1.00	11/16/2021	- \$ -	\$ -
Francisco Silva	40,000	-	-	\$ 1.05	2/10/2022	- \$ -	\$ -
Francisco Silva	80,000	10,000 (3)	60,000 (4)	\$ 1.40	5/2/2022	- \$ -	\$ -
Francisco Silva	80,000	-	-	\$ 1.50	12/7/2022	- \$ -	\$ -

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Francisco Silva	100,000	-	-	\$ 0.60	10/4/2023	-	\$ -	-	\$ -
Francisco Silva	83,334	166,666	(5) -	\$ 0.65	2/18/2024	-	\$ -	-	\$ -
Francisco Silva	40,000	-	-	\$ 0.53	3/12/2024	-	\$ -	-	\$ -
Francisco Silva	-	750,000	(6) -	\$ 0.33	10/23/2024	-	\$ -	-	\$ -
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	80,000	-	-	\$ 0.60	10/4/2023	-	\$ -	-	\$ -
Mandy Clyde	41,667	83,333	(7) -	\$ 0.65	2/18/2024	-	\$ -	-	\$ -
Mandy Clyde	-	200,000	(8) -	\$ 0.33	10/23/2024	-	\$ -	-	\$ -

(1) Option is exercisable to the extent of 333,333 shares effective as of each of February 18, 2015 and February 18, 2016.

(2) Option is exercisable to the extent of 1,000,000 shares effective as of each of October 23, 2015, October 23, 2016 and October 23, 2017.

(3) Option is exercisable effective as of May 3, 2015.

- Options are exercisable commencing on the date (provided that such date is during Mr. Silva's employment with us), if any, on which either (i) the United States Food and Drug Administration (the "FDA") approves our Biologics License Application with respect to any biologic product or (ii) a 510(k) Premarket Notification submission is made by us to the FDA with respect to a certain device.
- (4)
- (5) Option is exercisable to the extent of 83,333 shares effective as of each of February 18, 2015 and February 18, 2016.
- (6) Option is exercisable to the extent of 250,000 shares effective as of each of October 23, 2015, October 23, 2016 and October 23, 2017.
- (7) Option is exercisable to the extent of 41,667 shares effective as of February 18, 2015 and 41,666 shares effective as of February 18, 2016.
- (8) Option is exercisable to the extent of 66,667 shares effective as of each of October 23, 2015 and October 23, 2016 and 66,666 shares effective as of October 23, 2017.

## Employment Agreements

In March 2015, we entered into an employment agreement with Mark Weinreb, our Chief Executive Officer. Pursuant to the employment agreement, which expires on December 31, 2017, Mr. Weinreb is entitled to receive a salary of \$400,000 per annum. Mr. Weinreb is entitled to receive an annual bonus for 2015 equal to 50% of his annual base salary and an annual bonus for the years 2016 and 2017 equal to 50% of his annual base salary in the event certain performance goals, as determined by our Compensation Committee, are satisfied. Pursuant to the employment agreement, in the event that Mr. Weinreb's employment is terminated by us without "cause", or Mr. Weinreb terminates his employment for "good reason" (each as defined in the employment agreement), Mr. Weinreb would be entitled to receive severance in an amount equal to one time his then annual base salary and certain benefits, plus \$100,000 (in lieu of bonus). In addition, pursuant to the employment agreement, Mr. Weinreb would be entitled to receive such severance in the event that the term of his employment agreement is not extended beyond December 31, 2017 and, within three months of such expiration date, his employment is terminated by us without "cause" or Mr. Weinreb terminates his employment for any reason. Further, in the event that Mr. Weinreb's employment is terminated by us without "cause", or Mr. Weinreb terminates his employment for "good reason", following a "change in control" (as defined in the employment agreement), Mr. Weinreb would be entitled to receive severance in an amount equal to one and one-half times his then annual base salary and certain benefits, plus \$300,000 (in lieu of bonus).

Effective April 5, 2011, we entered into an at will employment agreement with Francisco Silva, our Vice President of Research and Development. Pursuant to the employment agreement, as amended, Mr. Silva is currently entitled to receive a salary of \$250,000 per annum. In addition, pursuant to the employment agreement, as amended in March

2015, Mr. Silva is entitled to receive an annual bonus of up to 20% of his annual salary based on the satisfaction of certain performance goals. Further, pursuant to the employment agreement, as amended, in the event that Mr. Silva's employment with us is terminated without cause, Mr. Silva would be entitled to receive a cash severance amount in an amount equal to 50% of his then annual base salary.

Effective December 1, 2010, we entered into an at will employment agreement with Mandy Clyde, our Vice President of Operations. Pursuant to the employment agreement, as amended, Ms. Clyde is currently entitled to receive a salary of \$118,000 per annum. Further, pursuant to the employment agreement, in the event that Ms. Clyde's employment with us is terminated without cause, Ms. Clyde would be entitled to receive a cash severance amount of \$50,000.

## Director Compensation

The following table sets forth certain information concerning the compensation of our non-employee directors for the fiscal year ended December 31, 2014:

Name	Fees Earned		Option Awards <sup>(1)</sup>	Non-Equity Incentive Plan Compensation	Nonqualified	All Other Compensation	Total
	Cash	Stock Awards			Deferred Earnings		
A. Jeffrey Radov	\$ 40,000	\$ -	\$ 404,800 <sup>(2)</sup>	\$ -	\$ -	\$ -	\$ 444,800
Joel San Antonio <sup>(3)</sup>	\$ 20,000	\$ -	\$ 213,550 <sup>(4)</sup>	\$ -	\$ -	\$ 20,000 <sup>(5)</sup>	\$ 253,550
Joseph B. Swiader <sup>(6)</sup>	\$ 20,000	\$ -	\$ 215,700 <sup>(7)</sup>	\$ -	\$ -	\$ 45,000 <sup>(8)</sup>	\$ 280,700
Paul Jude Tonna <sup>(6)</sup>	\$ 20,000	\$ -	\$ 215,700 <sup>(7)</sup>	\$ -	\$ -	\$ -	\$ 235,700

The amounts reported in this column represent the grant date fair value of the option awards granted during the year ended December 31, 2014, calculated in accordance with FASB ASC Topic 718. For a detailed discussion of (1) the assumptions used in estimating fair values, see Note 10 – Stockholders' Deficiency in the notes that accompany our consolidated financial statements.

(2) As of December 31, 2014, Mr. Radov held options for the purchase of 2,450,000 shares of common stock.

(3) Mr. San Antonio resigned as a director in June 2014.

As of December 31, 2014, Mr. San Antonio held options for the purchase of 1,450,000 shares of common stock. (4) Includes \$96,250 incremental fair value of outstanding options held by Mr. San Antonio which were modified pursuant to his resignation agreement.

(5)

Pursuant to an agreement entered into with Mr. San Antonio in June 2014 in connection with his resignation, we agreed to pay Mr. San Antonio \$80,000 (including \$20,000 and \$40,000 for director services rendered during 2014 and 2013, respectively). We also agreed that all outstanding options held by Mr. San Antonio which were not then exercisable would vest and that all outstanding options would remain exercisable until their respective expiration dates notwithstanding his resignation.

(6) Messrs. Swiader and Tonna were elected directors in June 2014.

(7) As of December 31, 2014, each of Messrs. Swiader and Tonna held options for the purchase of 800,000 shares of common stock.



(8) Represents \$15,000 of earned consulting fees paid in stock to, and \$30,000 of unpaid cash consulting fees earned by, Wet Earth Partners LLC, an entity owned by Mr. Swiader.

Each of Messrs. Radov, Swiader and Tonna, our non-employee directors, is entitled to receive, as compensation for his services as a director, \$30,000 per annum plus \$10,000 per annum for all committee service, in each case payable quarterly (subject to our cash needs).

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

**Principal Stockholders**

The following table sets forth certain information regarding the beneficial ownership of our common stock, as of March 30, 2015, known by us, through transfer agent records, to be held by: (i) each person who beneficially owns 5% or more of the shares of common stock then outstanding; (ii) each of our directors; (iii) each of our Named Executive Officers (as defined above); and (iv) all of our directors and executive officers as a group.

The information in this table reflects “beneficial ownership” as defined in Rule 13d-3 of the Exchange Act. To our knowledge, and unless otherwise indicated, each shareholder has sole voting power and investment power over the shares listed as beneficially owned by such shareholder, subject to community property laws where applicable. Percentage ownership is based on 37,149,052 shares of common stock outstanding as of March 30, 2015.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned		Approximate Percent of Class	
Westbury (Bermuda) Ltd. Westbury Trust Victoria Hall 11 Victoria Street Hamilton, HMEX Bermuda	5,165,000	(1)	13.5	%
Mark Weinreb 40 Marcus Drive Melville, New York	4,096,667	(2)	10.4	%
Janet H. and Stuart H. Montgomery 2212 Paget Circle	2,754,428	(3)	7.2	%

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Naples, Florida

A. Jeffrey Radov 8 Walworth Avenue Scarsdale, New York	1,533,334	(4)	4.0	%
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Francisco Silva 40 Marcus Drive Melville, New York	619,667	(5)	1.6	%
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Mandy Clyde 40 Marcus Drive Melville, New York	329,334	(5)		*
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Joseph B. Swiader 6 Baldwin Road Middletown, Rhode Island	303,767	(6)		*
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Paul Jude Tonna 69 Chichester Road Huntington, New York	249,000	(7)		*
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All directors and executive officers as a group (7 persons)	7,131,769	(8)	17.0	%
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\* Less than 1%

- Based upon Schedule 13G filed with the Securities and Exchange Commission (the “SEC”) and other information known to us. Includes 1,050,000 shares of common stock issuable upon the exercise of currently exercisable warrants. The shares and warrants are owned directly by Westbury (Bermuda) Ltd. which is 100% owned by Westbury Trust.
- (1)
- (2) Includes 2,396,667 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

- Based upon Schedule 13G filed with the SEC and other information known to us. Includes for Janet H. Montgomery (i) 30,000 shares of common stock held in a retirement account for her benefit, (ii) 1,625,000 shares of common stock owned jointly with Stuart H. Montgomery, (iii) 250,000 shares of common stock subject to currently exercisable warrants held jointly with Stuart H. Montgomery, (iv) 162,857 shares of common stock owned by Vintage Holidays L.L.C. (“Vintage”), of which Janet H. Montgomery is the manager, and (v) 650,000 shares of common stock subject to currently exercisable warrants held by Vintage. Includes for Stuart H. Montgomery (i) 34,478 shares of common stock held in a retirement account for his benefit, (ii) 1,625,000 shares of common stock owned jointly with Janet H. Montgomery and (iii) 250,000 shares of common stock subject to currently exercisable warrants held jointly with Janet H. Montgomery. Janet H. Montgomery has sole voting and dispositive power over 842,857 shares of common stock and shared voting and dispositive power over 1,875,000 shares of common stock. Stuart H. Montgomery has sole voting and dispositive power over 36,571 shares of common stock and shared voting and dispositive power over 1,875,000 shares of common stock.
- (3)
- (4) Includes 1,283,334 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

- (5) Represents shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

Includes (i) 158,767 shares of common stock owned by Wet Earth Partners LLC (“Wet Earth”), an entity owned by Mr. Swiader, (ii) 100,000 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days and (iii) 25,000 shares of common stock issuable upon the exercise of warrants held by Wet Earth that are currently exercisable. Does not include shares of common stock to be issued to Wet Earth in connection with a Consulting Agreement entered into with us on October 14, 2014. Pursuant to the Consulting Agreement, Wet Earth is to be issued shares of common stock having an aggregate fair market value of \$5,000 on March 31, 2015. The exact number of shares to be issued cannot be determined until the date of issuance. For additional information regarding the Consulting Agreement, see “Certain Relationships and Related Transactions” below.

- (6) Represents (i) 112,000 shares of common stock held jointly with Mr. Tonna’s wife, (ii) 7,000 shares of common stock held by Mr. Tonna’s children and (iii) 130,000 shares of common stock issuable upon the exercise of options and warrants that are exercisable currently or within 60 days.

- (7) Includes 4,884,002 shares of common stock issuable upon the exercise of options and warrants that are exercisable currently or within 60 days.

### Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information as of December 31, 2014 with respect to compensation plans (including individual compensation arrangements) under which our common stock are authorized for issuance, aggregated as follows:

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

### EQUITY COMPENSATION PLAN INFORMATION

Number of securities to be issued upon exercise of	Weighted-average exercise price of	Number of securities remaining available for future issuance under
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	outstanding options (a)	outstanding options (b)	equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	15,584,000	\$ 0.61	3,516,000
Total	15,584,000	\$ 0.61	3,516,000

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

**Westbury**

In March 2013, Stem Cell Cayman, Ltd. (“Cayman”), one of our wholly-owned subsidiaries, borrowed \$450,000 from Westbury (Bermuda) Ltd. (“Westbury”), one of our principal stockholders which, as of March 30, 2015 beneficially owned 13.5% of our common stock. The loan amount was combined with the already outstanding \$3,550,000 of previous borrowings from Westbury into a new \$4,000,000 zero coupon note (the “\$4,000,000 Note”) which was scheduled to mature on July 31, 2014. In consideration of the \$450,000 loan, the settlement of accrued and unpaid interest of \$213,000, and for extending the maturity date of the note to July 31, 2014, we issued to Westbury 600,000 shares of common stock and a five year warrant to purchase 400,000 shares of common stock at an exercise price of \$2.50 per share. In August 2014, in consideration of an extension of the maturity date of the \$4,000,000 Note to December 31, 2014, we issued to Westbury 550,000 shares of common stock. In December 2014, in consideration of a further extension of the maturity date of the \$4,000,000 Note to June 30, 2015, we issued to Westbury 450,000 shares of common stock.

In May 2014, Cayman borrowed an additional \$500,000 from Westbury. The promissory note evidencing the loan (the “\$500,000 Note”) provides for the payment of the principal amount, together with interest at the rate of 15% per annum, on May 7, 2015. The \$500,000 Note also provides for the mandatory prepayment of the principal amount to the extent of any monies received by us pursuant to the Research and Development Agreement, dated as of March 19, 2014, between Rohto Pharmaceutical Co., Ltd. and us and/or the Research Agreement, dated as of March 24, 2014, between Pfizer Inc. and us. Pursuant to such provision, \$89,063 in principal has been prepaid. Interest on the entire principal amount of the \$500,000 Note is payable until such time as the principal amount is paid in full.

In December 2013, pursuant to a warrant repricing program implemented by us with respect to all outstanding and exercisable warrants, Westbury exercised warrants for the purchase of 800,000 shares of our common stock at an exercise price of \$0.30 per share. In connection with the warrant exercise, we granted to Westbury a new warrant for the purchase of 800,000 shares of our common stock at an exercise price of \$0.75 per share. The new warrant is exercisable until December 31, 2015 and can be redeemed by us under certain circumstances.

In February 2015, we sold 1,000,000 shares of common stock to Westbury at an aggregate purchase price of \$300,000. In consideration of the purchase, we issued to Westbury a five year warrant for the purchase of 250,000 shares of common stock at an exercise price of \$0.75 per share.

**Others**

In February 2011, we entered into a Consulting Agreement with Vintage Holidays L.L.C. (“Vintage”), a company owned by Janet H. Montgomery and Stuart H. Montgomery, two of our principal stockholders, and of which Janet H. Montgomery is the manager. On June 27, 2014, in consideration of services rendered by Vintage and the cancellation by Vintage of \$65,000 in accrued compensation, we issued to Janet H. Montgomery and Stuart H. Montgomery 500,000 shares of common stock and issued to Vintage a five year warrant for the purchase of 250,000 shares of common stock at an exercise price of \$1.00 per share.

In October 2014, we entered into a Consulting Agreement with Wet Earth Partners LLC (“Wet Earth”), an entity owned by Mr. Swiader, one of our non-employee directors. The Consulting Agreement expires on March 31, 2015. Pursuant to the terms of the Consulting Agreement, and in consideration of the services provided thereunder, Wet Earth is entitled to receive a monthly fee equal to (i) \$10,000 in cash and (ii) a number of shares of common stock having an aggregate fair market value of \$5,000.

## **Director Independence**

### **Board of Directors**

Our Board of Directors is currently comprised of Mark Weinreb (Chair), A. Jeffrey Radov, Joseph B. Swiader and Paul Jude Tonna. Each of Messrs. Radov, Swiader and Tonna is currently an “independent director” based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

### **Audit Committee**

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

### **Nominating Committee**

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

### **Compensation Committee**



The members of our Board's Compensation Committee currently are Messrs. Tonna (Chair) and Radov, each of whom is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

**ITEM 14.**

**PRINCIPAL ACCOUNTANT FEES AND SERVICES.**

Marcum LLP has served as our independent registered public accountants for the years ended December 31, 2014 and 2013.

The following is a summary of the fees billed or expected to be billed to us by Marcum LLP, our independent registered public accountants, for professional services rendered with respect to the fiscal years ended December 31, 2014 and 2013:

Fee Category	Fiscal	Fiscal
	2014	2013
	Fees	Fees
Audit Fees(1)	\$ 115,597	\$ 96,771
Audit-Related Fees(2)	-	-
Tax Fees(3)	9,000	7,500
All Other Fees(4)	-	-
	\$ 124,597	\$ 104,271

(1) Audit Fees consist of fees billed and expected to be billed for services rendered for the audit of our consolidated financial statements for the fiscal years ended December 31, 2014 and 2013.

(2) Audit-Related Fees consist of fees billed for assurance and related services that are reasonably related to the performance of the audit of our financial statements and are not reported under “Audit Fees.”

(3) Tax Fees consist of fees billed for professional services related to preparation of our U.S. federal and state income tax returns and tax advice.

(4) All Other Fees consist of fees billed for products and services provided by our independent registered public accountants, other than those disclosed above.

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

**PART IV**

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

- 3.1 Certificate of Incorporation<sup>1</sup>
- 3.2 Bylaws<sup>1</sup>
- 10.1 2010 Equity Participation Plan, as amended
- 10.2 Executive Employment Agreement, dated as of March 9, 2015, between BioRestorative Therapies, Inc. and Mark Weinreb
- 10.3 Consulting Agreement, dated as of February 17, 2011, between Stem Cell Assurance, Inc. and TDA Consulting Services, Inc.<sup>2</sup>
- 10.4 Letter agreement, dated April 18, 2012, between BioRestorative Therapies, Inc. and TDA Consulting Services, Inc.<sup>3</sup>
- 10.5 Letter agreement, dated December 7, 2012, between BioRestorative Therapies, Inc. and TDA Consulting Services, Inc.<sup>3</sup>
- 10.6 Letter agreement, dated March 12, 2014, between BioRestorative Therapies, Inc. and TDA Consulting Services, Inc.<sup>4</sup>
- 10.7 Consulting Agreement, dated as of February 17, 2011, between Stem Cell Assurance, Inc. and Vintage Holidays L.L.C.<sup>2</sup>
- 10.8 Letter agreement, dated January 1, 2012, between BioRestorative Therapies, Inc. and Vintage Holidays, L.L.C.<sup>3</sup>
- 10.9 Letter agreement, dated April 18, 2012, between BioRestorative Therapies, Inc. and Vintage Holidays, L.L.C.<sup>3</sup>
- 10.10 Letter agreement, dated December 7, 2012, between BioRestorative Therapies, Inc. and Vintage Holidays, L.L.C.<sup>3</sup>
- 10.11 Employment Agreement, dated as of December 1, 2010, between Stem Cell Assurance, Inc. and Mandy Clark (now known as Mandy Clyde) (“Clyde Employment Agreement<sup>2</sup>”)
- 10.12 Amendment to Clyde Employment Agreement, dated February 10, 2012<sup>5</sup>
- 10.13 Amendment to Clyde Employment Agreement, dated December 7, 2012<sup>3</sup>
- 10.14 Promissory Note, dated February 9, 2011, issued by Stem Cell Cayman Ltd. in the principal amount of \$1,050,000<sup>2</sup>
- 10.15 Form of Stock Option Agreement, dated December 15, 2010, between Stem Cell Assurance, Inc. and each of Mark Weinreb and Mandy Clyde<sup>2</sup>
- 10.16 Amended and Restated Executive Employment Agreement, dated May 10, 2011, between Stem Cell Assurance, Inc. and Francisco Silva (“Silva Employment Agreement<sup>2</sup>”)
- 10.17 Amendment to Silva Employment Agreement, dated November 4, 2011<sup>5</sup>
- 10.18 Amendment to Silva Employment Agreement, dated May 3, 2012<sup>3</sup>
- 10.19 Amendment to Silva Employment Agreement, dated December 7, 2012<sup>3</sup>
- 10.20 Amendment to Silva Employment Agreement, dated March 9, 2015
- 10.21 Stock Option Agreement, dated April 5, 2011, between Stem Cell Assurance, Inc. and Francisco Silva<sup>2</sup>
- 10.22 Stock Option Agreement, dated April 21, 2011, between Stem Cell Assurance, Inc. and Mandy Clyde<sup>2</sup>
- 10.23 Promissory Note, dated November 4, 2011, issued by Stem Cell Cayman Ltd. in the principal amount of \$1,000,000<sup>2</sup>
- 10.24 License Agreement, dated as of January 27, 2012, between Regenerative Sciences, LLC and BioRestorative Therapies, Inc. (“License Agreement<sup>3</sup>”)



- 10.25 Amendment to License Agreement, dated March 21, 2012<sup>5</sup>
- 10.26 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Mark Weinreb<sup>5</sup>
- 10.27 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and A. Jeffrey Radov<sup>5</sup>
- 10.28 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Joel San Antonio<sup>5</sup>
- 10.29 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Francisco Silva<sup>5</sup>
- 10.30 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Mandy Clyde<sup>5</sup>
- 10.31 Promissory Note, dated March 30, 2012, issued by Stem Cell Cayman Ltd. in the principal amount of \$1,500,000<sup>5</sup>
- 10.32 Form of Exchange Agreement between BioRestorative Therapies, Inc. and debtholders<sup>5</sup>
- 10.33 Assignment Agreement, dated as of June 15, 2012, between the University of Utah Research Foundation and BioRestorative Therapies, Inc.<sup>6</sup>
- 10.34 Research Agreement, dated as of June 15, 2012, between BioRestorative Therapies, Inc. and the University of Utah<sup>6</sup>
- 10.35 Amendment No. One, dated as of May 9, 2014, to Research Agreement, dated June 15, 2012, between BioRestorative Therapies, Inc. and the University of Utah<sup>4</sup>
- 10.36 Consulting Agreement, dated as of August 16, 2012, between Wayne A. Marasco, M.D., Ph.D. and BioRestorative Therapies, Inc.<sup>3</sup>
- 10.37 Letter agreement, dated December 5, 2012, between Stem Cell Cayman Ltd. and Westbury (Bermuda) Ltd.<sup>3</sup>
- 10.38 Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and Mark Weinreb<sup>3</sup>
- 10.39 Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and A. Jeffrey Radov<sup>3</sup>
- 10.40 Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and Joel San Antonio<sup>3</sup>
- 10.41 Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and Francisco Silva<sup>3</sup>
- 10.42 Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and Mandy Clyde<sup>3</sup>
- 10.43 Promissory Note, dated March 26, 2013, issued by Stem Cell Cayman Ltd. in the principal amount of \$450,000<sup>3</sup>
- 10.44 Letter agreement, dated March 26, 2013, among Stem Cell Cayman Ltd., BioRestorative Therapies, Inc. and Westbury (Bermuda) Ltd.<sup>3</sup>
- 10.45 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Mark Weinreb<sup>4</sup>
- 10.46 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and A. Jeffrey Radov<sup>4</sup>
- 10.47 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Joel San Antonio<sup>4</sup>

- 10.48 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Francisco Silva<sup>4</sup>
- 10.49 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Mandy Clyde<sup>4</sup>
- 10.50 Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and Mark Weinreb<sup>4</sup>
- 10.51 Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and A. Jeffrey Radov<sup>4</sup>
- 10.52 Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and Joel San Antonio<sup>4</sup>
- 10.53 Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and Francisco Silva<sup>4</sup>
- 10.54 Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and Mandy Clyde<sup>4</sup>
- 10.55 Consulting Agreement, dated as of February 20, 2014, between Gregory E. Lutz, M.D. and BioRestorative Therapies, Inc.<sup>4</sup>
- 10.56 Stock Option Agreement, dated as of March 12, 2014, between BioRestorative Therapies, Inc. and Francisco Silva<sup>4</sup>
- 10.57 Research and Development Agreement, dated as of March 19, 2014, between BioRestorative Therapies, Inc. and Rohto Pharmaceutical Co., Ltd<sup>7</sup>
- 10.58 Letter agreement, dated February 11, 2015, between BioRestorative Therapies, Inc. and Rohto Pharmaceutical Co., Ltd. with regard to Research and Development Agreement
- 10.59 Research Agreement, dated as of March 24, 2014 between Pfizer Inc. and BioRestorative Therapies, Inc.<sup>7</sup>
- 10.60 Promissory Note, dated May 7, 2014, issued by Stem Cell Cayman Ltd. in the principal amount of \$500,000<sup>8</sup>
- 10.61 Agreement, dated as of June 27, 2014, by and between BioRestorative Therapies, Inc. and Joel San Antonio<sup>9</sup>
- 10.62 Stock Option Agreement, dated as of June 27, 2014, between BioRestorative Therapies, Inc. and Paul Jude Tonna<sup>9</sup>
- 10.63 Stock Option Agreement, dated as of June 27, 2014, between BioRestorative Therapies, Inc. and Joseph B. Swiader<sup>9</sup>
- 10.64 Lease, dated as of August 25, 2014, between BioRestorative Therapies, Inc. and 50 Republic Road, LLC<sup>10</sup>
- 10.65 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and Mark Weinreb
- 10.66 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and A. Jeffrey Radov
- 10.67 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and Francisco Silva
- 10.68 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and Mandy Clyde
- 10.69 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and Joseph B. Swiader
- 10.70 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and Paul Jude Tonna

10.71	Letter agreement, dated December 31, 2014, between Stem Cell Cayman Ltd. and Westbury (Bermuda) Ltd.
10.72	Executive Employment Agreement, dated as of February 9, 2015, between BioRestorative Therapies, Inc. and Edward L. Field
10.73	Stock Option Agreement, dated as of February 9, 2015, between BioRestorative Therapies, Inc. and Edward L. Field
14	Code of Ethics <sup>5</sup>
21	Subsidiaries
23.1	Independent Registered Public Accounting Firm's Consent
31.1	Principal Executive Officer Certification
31.2	Principal Financial Officer Certification
32	Section 1350 Certification
101.INS	XBRL Instance Document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Label Linkbase Document
101.PRE	XBRL Presentation Linkbase Document

<sup>1</sup> Incorporated by reference to the exhibits included with our Current Report on Form 8-K for an event dated December 19, 2014 filed with the Securities and Exchange Commission.

<sup>2</sup> Incorporated by reference to the exhibits included with our Registration Statement on Form 10, as amended, filed with the Securities and Exchange Commission.

<sup>3</sup> Incorporated by reference to the exhibits included with our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the Securities and Exchange Commission.

<sup>4</sup> Incorporated by reference to the exhibits included with our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission.

<sup>5</sup> Incorporated by reference to the exhibits included with our Annual Report on Form 10-K for the year ended December 31, 2011 filed with the Securities and Exchange Commission.

<sup>6</sup> Incorporated by reference to the exhibits included with our Quarterly Report on Form 10-Q for the period ended June 30, 2012 filed with the Securities and Exchange Commission.

<sup>7</sup> Incorporated by reference to the exhibits included with our Amendment No. 1 to Quarterly Report on Form 10-Q/A for the period ended March 31, 2014. Certain portions of this exhibit have been omitted by redacting a portion of the text (indicated by asterisks in the text). This exhibit has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

<sup>8</sup> Incorporated by reference to the exhibits included with our Quarterly Report on Form 10-Q for the period ended March 31, 2014 filed with the Securities and Exchange Commission.

<sup>9</sup> Incorporated by reference to the exhibits included with our Quarterly Report on Form 10-Q for the period ended June 30, 2014 filed with the Securities and Exchange Commission.

<sup>10</sup> Incorporated by reference to the exhibit included with our Current Report on Form 8-K for an event dated August 25, 2014 filed with the Securities and Exchange Commission.



**SIGNATURES**

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

**BIORESTORATIVE  
THERAPIES, INC.**

Dated: March 31, 2015 By: /s/ Mark Weinreb  
Mark Weinreb  
Chief Executive Officer

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

<b>Signature</b>	<b>Capacity</b>	<b>Date</b>
/s/ Mark Weinreb Mark Weinreb	Chief Executive Officer, President, Chairman of the Board and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	March 31, 2015
/s/ A. Jeffrey Radov A. Jeffrey Radov	Director	March 31, 2015
/s/ Joseph B. Swiader Joseph B. Swiader	Director	March 31, 2015
/s/ Paul Jude Tonna Paul Jude Tonna	Director	March 31, 2015

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES**

CONSOLIDATED FINANCIAL STATEMENTS

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<u>Consolidated Statements of Operations for the Years Ended December 31, 2014 and 2013</u>	F-3
<u>Consolidated Statements of Changes in Stockholders' Deficiency for the Years Ended December 31, 2014 and 2013</u>	F-4
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2014 and 2013</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-7

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of BioRestorative Therapies, Inc. and Subsidiaries (the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of operations, changes in stockholders' deficiency, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioRestorative Therapies, Inc. and Subsidiaries as of December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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

/s/ Marcum LLP

Marcum LLP

New York, NY

March 31, 2015

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Consolidated Balance Sheets**

	December 31,	
	2014	2013
Assets		
Current Assets:		
Cash	\$91,798	\$201,098
Inventories	1,945	17,965
Prepaid expenses and other current assets	20,570	20,739
Total Current Assets	114,313	239,802
Property and equipment, net	493,856	35,568
Intangible assets, net	1,037,732	1,107,545
Security deposit	45,900	-
Total Assets	\$1,691,801	\$1,382,915
Liabilities and Stockholders' Deficiency		
Current Liabilities:		
Accounts payable	\$1,111,879	\$1,269,970
Accrued expenses and other current liabilities	1,466,506	1,176,662
Accrued interest	94,026	65,909
Current portion of notes payable, net of debt discount of \$113,257 and \$237,381 at December 31, 2014 and 2013, respectively	5,688,239	4,990,009
Deferred revenues	164,349	-
Total Current Liabilities	8,524,999	7,502,550
Accrued interest, non-current portion	5,195	41,434
Notes payable, non-current portion, net of debt discount of \$0 and \$3,110 at December 31, 2014 and 2013, respectively	50,000	524,000
Total Liabilities	8,580,194	8,067,984
Commitments and contingencies		
Stockholders' Deficiency:		
Preferred stock, \$0.01 par value;		
Authorized, 5,000,000 shares (see Note 10); none issued and outstanding at December 31, 2014 and 2013	-	-
Common stock, \$0.001 par value;		
Authorized, 200,000,000 shares (see Note 10); Issued 34,511,800 and 19,633,173 shares at December 31, 2014 and 2013, respectively;	34,512	19,633

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Outstanding 33,953,179 and 19,074,552 shares at December 31, 2014 and 2013,  
respectively

Additional paid-in capital	18,509,121	13,139,712
Accumulated deficit	(25,400,026)	(19,812,414)
Treasury stock, at cost, 558,621 shares at December 31, 2014 and 2013	(32,000 )	(32,000 )
Total Stockholders' Deficiency	(6,888,393 )	(6,685,069 )
Total Liabilities and Stockholders' Deficiency	\$1,691,801	\$1,382,915

See Notes to these Consolidated Financial Statements

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Consolidated Statements of Operations**

	For The Years Ended December 31,	
	2014	2013
Revenues	\$415,996	\$1,680
Cost of sales	213,834	208
Gross Profit	202,162	1,472
Operating Expenses		
Marketing and promotion	125,626	114,951
Consulting	1,310,121	779,462
Research and development	1,430,614	1,594,054
General and administrative	2,258,307	2,265,275
Total Operating Expenses	5,124,668	4,753,742
Loss From Operations	(4,922,506 )	(4,752,270 )
Other (Expense) Income		
Interest expense	(285,275 )	(371,281 )
Amortization of debt discount	(464,470 )	(405,531 )
Loss on extinguishment of note and payables, net	(49,094 )	(7,200 )
Warrant modification expense	(50,035 )	(214,912 )
Gain on settlement of notes and payables	183,768	-
Total Other Expense	(665,106 )	(998,924 )
Net Loss	\$(5,587,612 )	\$(5,751,194 )
Net Loss Per Share		
- Basic and Diluted	\$(0.22 )	\$(0.35 )
Weighted Average Number of Common Shares Outstanding		
- Basic and Diluted	25,538,075	16,526,793

See Notes to these Consolidated Financial Statements

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Consolidated Statements of Changes in Stockholders' Deficiency****For the Years Ended December 31, 2014 and 2013**

	Common Stock		Additional	Accumulated	Treasury Stock		Total
	Shares	Amount	Paid-In Capital	Deficit	Shares	Amount	
Balance - December 31, 2012	15,443,484	\$ 15,443	\$ 8,936,084	\$(14,061,220)	(558,621)	\$(32,000)	\$(5,141,693)
Shares and warrants issued for cash	840,589	841	904,159	-	-	-	905,000
Shares and warrants issued as debt discount in connection with notes payable	338,750	339	573,430	-	-	-	573,769
Shares issued in satisfaction of accrued interest	266,250	266	212,734	-	-	-	213,000
Shares and warrants issued in exchange of notes payable and accrued interest	818,495	819	416,862	-	-	-	417,681
Exercise of warrants for purchase of common stock	1,686,029	1,686	504,123	-	-	-	505,809
Warrant modification	-	-	214,912	-	-	-	214,912
Waiver of previously accrued executive salary and bonus	-	-	565,000	-	-	-	565,000
Stock-based compensation: shares of common stock options and warrants	239,537	239	137,816	-	-	-	138,055
	-	-	674,592	-	-	-	674,592

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Impact of share rounding as a result of reverse stock split	39	-	-	-	-	-	-
Net loss	-	-	-	(5,751,194 )	-	-	(5,751,194)
Balance - December 31, 2013	19,633,173	\$ 19,633	\$ 13,139,712	\$(19,812,414)	(558,621)	\$(32,000)	\$(6,685,069)
Shares and warrants issued for cash	8,671,983	8,672	2,596,328	-	-	-	2,605,000
Shares issued in satisfaction of accrued consulting services	595,455	595	139,405	-	-	-	140,000
Shares and warrant issued as payment for leasehold improvements	284,200	284	70,766	-	-	-	71,050
Exercise of warrants for purchase of common stock	376,667	377	112,623	-	-	-	113,000
Conversion of notes payable and accrued interest into common stock	1,784,777	1,785	357,926	-	-	-	359,711
Shares and warrants issued in exchange of note payable and accrued interest	1,101,453	1,101	341,925	-	-	-	343,026
Shares and warrants issued in connection with extension of notes payable	1,000,000	1,000	248,800	-	-	-	249,800
Warrant modification	-	-	50,035	-	-	-	50,035
Beneficial conversion features related to convertible notes payable	-	-	92,370	-	-	-	92,370
Stock-based compensation:							
shares of common stock	1,064,092	1,065	299,772	-	-	-	300,837
options and warrants	-	-	1,059,459	-	-	-	1,059,459

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Net loss	-	-	-	(5,587,612 )	-	-	(5,587,612)
Balance - December 31, 2014	34,511,800	\$34,512	\$18,509,121	\$(25,400,026)	(558,621)	\$(32,000)	\$(6,888,393)

See Notes to these Consolidated Financial Statements

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Consolidated Statements of Cash Flows**

	For The Years Ended	
	December 31,	
	2014	2013
Cash Flows From Operating Activities		
Net loss	\$(5,587,612)	\$(5,751,194)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount	464,470	405,531
Accretion of interest expense	24,934	5,066
Depreciation and amortization	96,685	104,811
Loss on sale of property and equipment	1,009	-
Stock-based compensation	1,360,296	812,647
Loss on extinguishment of note and payables, net	49,094	7,200
Gain on settlement of notes and payables	(183,768 )	-
Inventory write-down	15,407	-
Warrant modification expense	50,035	214,912
Warrant issued in connection with note payable	-	9,400
Changes in operating assets and liabilities:		
Inventories	613	(5,481 )
Prepaid expenses and other current assets	11,219	(2,306 )
Security deposit	(45,900 )	-
Accounts payable	(234,563 )	498,541
Accrued interest, expenses and other current liabilities	585,881	1,028,469
Deferred revenues	164,349	-
Total Adjustments	2,359,761	3,078,790
Net Cash Used in Operating Activities	(3,227,851)	(2,672,404)
Cash Flows From Investing Activities		
Purchases of property and equipment	(168,376 )	(11,160 )
Proceeds from sale of property and equipment	980	-
Net Cash Used In Investing Activities	(167,396 )	(11,160 )
Cash Flows From Financing Activities		
Proceeds from notes payable	795,000	1,454,000
Repayments of notes payable	(202,063 )	(5,500 )
Advances from director and officer	58,054	144,285
Repayment of advances from director and officer	(83,044 )	(119,295 )
Proceeds from exercise of warrants	113,000	505,809
Sales of common stock and warrants for cash	2,605,000	905,000
Net Cash Provided by Financing Activities	3,285,947	2,884,299
Net (Decrease) Increase In Cash	(109,300 )	200,735

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Cash - Beginning	201,098	363
Cash - Ending	\$91,798	\$201,098

See Notes to these Consolidated Financial Statements

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Consolidated Statements of Cash Flows — Continued**

	For The Years Ended December 31,	
	2014	2013
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	\$127,112	\$62,346
Non-cash investing and financing activities:		
Shares and warrants issued in connection with issuance or extension of notes payable	\$249,800	\$564,369
Shares issued in satisfaction of accrued interest	\$-	\$213,000
Shares and warrants issued in exchange for notes payable and accrued interest	\$343,026	\$417,681
Shares and warrant issued as payment for lease obligation and leasehold improvements	\$71,050	\$-
Conversion of notes payable and accrued interest into common stock	\$359,711	\$-
Shares issued in satisfaction of accrued consulting services	\$140,000	\$-
Recharacterization of accrued interest as principal with note payable reissuance	\$108,059	\$68,100
Beneficial conversion features set up as debt discount	\$92,370	\$-
Accrued purchases of property and equipment	\$258,774	\$-
Waiver of previously accrued executive salary and bonus	\$-	\$565,000

See Notes to these Consolidated Financial Statements

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

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

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

BioRestorative Therapies, Inc. has two wholly-owned subsidiaries, Stem Pearls, LLC (“Stem Pearls”) and Stem Cell Cayman Ltd. (“Cayman”), which the Company formed in the Cayman Islands (collectively, “BRT” or the “Company”). BRT develops products and medical therapies using cell and tissue protocols, primarily involving adult stem cells designed for personal medical applications. BRT’s website is at [www.biorestorative.com](http://www.biorestorative.com). BRT is currently pursuing a Disc/Spine Program. Its lead cell therapy candidate, btxDISC™ (Disc Implanted Stem Cells), is a product formulated from autologous (or a person’s own) cultured mesenchymal stem cells collected from the patient’s bone marrow. The product is intended to be used for the non-surgical treatment of protruding and bulging lumbar discs in patients suffering from chronic lumbar disc disease. BRT is also engaging in research efforts with respect to a platform technology utilizing brown adipose (fat) for therapeutic purposes and has labeled this initiative its ThermoStem® Program. It is a pre-clinical cell-based therapy to target obesity and metabolic disorders using brown adipose (fat) derived stem cells to generate brown adipose tissue and is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans." BRT has 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. The ingredient was developed pursuant to BRT’s “btx-C Cosmetic Program”. BRT’s Stem Pearls® brand offers plant stem cell-based cosmetic skincare products that are available for purchase online at [www.stempearls.com](http://www.stempearls.com).

Effective January 1, 2015, the Company changed its state of incorporation from the State of Nevada to the State of Delaware pursuant to a plan of conversion, dated December 22, 2014 (the “Plan of Conversion”). Pursuant to the Plan of Conversion, the Company also adopted new bylaws, which became effective on January 1, 2015.

Effective April 15, 2013, pursuant to authority granted by the stockholders to the Board of Directors of the Company, the Company implemented a 1-for-50 reverse split of the Company’s issued and outstanding common stock (the “Reverse Split”) and a reduction in the number of shares of common stock authorized to be issued by the Company from 1,500,000,000 to 100,000,000. All share and per share information in these consolidated financial statements has been retroactively adjusted to reflect the Reverse Split. See Note 10 – Stockholders’ Deficiency for additional details regarding the Company’s authorized capital.

#### **Note 2 – Going Concern and Management’s Plans**

As of December 31, 2014, the Company had a working capital deficiency and a stockholders' deficiency of \$8,410,686 and \$6,888,393, respectively. During the years ended December 31, 2014 and 2013, the Company incurred net losses of \$5,587,612 and \$5,751,194, respectively. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

Despite recent revenue generated from specific research and development contracts, the Company's primary source of operating funds since inception has been, and will continue to be for the foreseeable future, equity and debt financings. The Company intends to continue to raise additional capital through debt and equity financings. There is no assurance that these funds will be sufficient to enable the Company to fully complete its development activities or attain profitable operations. If the Company is unable to obtain such additional financing on a timely basis and, notwithstanding any request the Company may make, the Company's debt holders do not agree to convert their notes into equity or extend the maturity dates of their notes, the Company may have to curtail its development, marketing and promotional activities, which would have a material adverse effect on the Company's business, financial condition and results of operations, and ultimately the Company could be forced to discontinue its operations and liquidate.

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



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

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

#### **Note 2 – Going Concern and Management’s Plans – Continued**

Subsequent to December 31, 2014, (a) the Company has raised an aggregate of \$801,000 and \$30,000 through equity financing and debt financing, respectively, (b) the Company has received research and development payments of \$227,234 and (c) \$50,000 and \$5,984 of debt and accrued interest, respectively, has been converted into common stock. As a result, the Company expects to be able to fund its operations through April 2015. While there can be no assurance that it will be successful, the Company is in active negotiations to raise additional capital. As of the filing date of this report, the Company has notes payable with an aggregate principal balance of \$5,000 which are either past due or payable on demand. The Company is currently in the process of negotiating extensions or discussing conversions to equity with respect to these notes. However, there can be no assurance that the Company will be successful in extending or converting these notes. See Note 11– Subsequent Events for additional details.

#### Note 3 – Summary of Significant Accounting Policies

##### Principles of Consolidation

The consolidated financial statements of the Company include the accounts of Cayman and Stem Pearls. All significant intercompany transactions have been eliminated in the consolidation.

##### Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at dates of the financial statements and the reported amounts of revenue and expenses during the periods. The Company’s significant estimates and assumptions include the recoverability and useful lives of long-lived assets, the fair value of the Company’s equity securities and the valuation allowance related to the Company’s deferred tax assets. Certain of the Company’s estimates, including the carrying amount of the intangible assets, could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that

these external factors could have an effect on the Company's estimates and could cause actual results to differ from those estimates.

### Concentrations and Credit Risk

As of December 31, 2014, 75% of the face value of the Company's outstanding notes payable were sourced from a single entity (the "Bermuda Lender") and the maturity dates associated with these notes range from May 7, 2015 to June 30, 2015. See Note 7 – Notes Payable for additional discussion of the Bermuda Lender.

Two pharmaceutical clients comprised substantially all of the Company's revenue during the year ended December 31, 2014. See Revenue Recognition – Research and Development Agreements below.

### Cash

The Company maintains cash in bank accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts and periodically evaluates the creditworthiness of the financial institutions and has determined the credit exposure to be negligible.

### Inventories

The Company maintains finished goods inventories, consisting of Stem Pearls skincare products, which are available for sale. Inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method.

The Company periodically reviews for slow-moving, excess or obsolete inventories. Products that are determined to be obsolete, if any, are written down to net realizable value. During the year ended December 31, 2014, the Company recorded an inventory write-down of \$15,407.

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

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

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

##### Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation which is recorded commencing at the in-service date using the straight line method at rates sufficient to charge the cost of depreciable assets to operations over their estimated useful lives, which range from 3 to 5 years. Leasehold improvements are amortized over the lesser of (a) the useful life of the asset; or (b) the remaining lease term. Maintenance and repairs are charged to operations as incurred.

##### 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 patents which the Company is licensing, less 2.3 years elapsed since the application date of the respective patents), respectively. Once placed into service, the Company amortizes the cost of the intangible assets over their estimated useful lives on a straight line basis.

##### Impairment of Long-lived Assets

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

##### Revenue Recognition

*Research and Development Agreements*

The Company's policy relating to research and development agreements is to recognize research and development revenues associated with such agreements either (a) on a straight-line basis over the term of the agreement, or (b) in accordance with the milestone method of revenue recognition, depending on the nature of the contract terms, subject to potential acceleration upon achievement of contractually specified deliverables.

On March 19, 2014, the Company entered into a one-year agreement with a Japanese pharmaceutical company to perform specified research and development activities related to stem cells. The agreement may be terminated earlier or extended, as provided for in the agreement. Payment terms are (1) \$150,000 received at commencement (straight-line method); (2) \$50,000 upon achievement of a specified deliverable (milestone method); and (3) \$50,000 upon achievement of the final specified deliverable (milestone method). As of December 31, 2014, the initial \$150,000 payment had been received and \$34,281 remained in deferred revenues on the consolidated balance sheet. On February 11, 2015, the term of the agreement was extended by three months to June 19, 2015.

On March 24, 2014, the Company entered into a two-year agreement with a U.S. pharmaceutical company to perform specified research and development activities related to brown fat. The agreement may be terminated earlier or extended, as provided for in the agreement. Payment terms are (1) \$250,000 at commencement; (2) \$356,250 payable in four equal quarterly installments, subject to acceleration upon achieving a specified deliverable; and (3) \$168,750 payable in two equal bi-annual installments (all of which are being recognized pursuant to the straight-line method), subject to acceleration upon achieving a specified deliverable. As of December 31, 2014, the initial \$250,000 payment and the first two quarterly payments of \$89,063 related to (2) above had been received and \$130,068 was recorded as deferred revenues on the consolidated balance sheet.

During the year ended December 31, 2014, the Company recognized revenue related to research and development agreements of \$413,777. The Company did not recognize any revenue related to research and development agreements during the year ended December 31, 2013.

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

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

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

##### Revenue Recognition – Continued

###### *Other*

The Company's 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. The Company recognizes 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.

For the years ended December 31, 2014 and 2013, the Company recognized revenue related to sales of Stem Pearls® skincare products of \$2,219 and \$1,680, respectively.

##### Income Taxes

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

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

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's consolidated financial statements as of December 31, 2014 and 2013. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the consolidated statements of operations.

Net Loss Per Common Share

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

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	December 31,	
	2014	2013
Options	15,584,000	5,043,000
Warrants	8,248,683	4,795,890
Convertible notes	653,885	1,063,380
Total potentially dilutive shares	24,486,568	10,902,270

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

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

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

##### Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees, 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 the Company's 2010 Equity Participation Plan (the "Plan") were registered on May 27, 2014, the Company estimates the fair value of the awards granted under the Plan based on the market value of its freely tradable common stock as reported by the OTC Bulletin Board. The fair value of the Company's restricted equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares. Awards granted to directors are treated on the same basis as awards granted to employees.

##### Advertising

Advertising costs are charged to operations as incurred. For the years ended December 31, 2014 and December 31, 2013, the Company incurred advertising costs of \$15,280 and \$25,748, respectively. Advertising expense is reflected in marketing and promotion expenses in the consolidated statements of operations.

##### Research and Development

Research and development expenses are charged to operations as incurred. For the years ended December 31, 2014 and December 31, 2013, the Company incurred research and development expenses of \$1,430,614 and \$1,594,054, respectively.

## Reclassifications

Certain prior period amounts have been reclassified for comparative purposes to conform to the fiscal 2014 presentation. These reclassifications have no impact on the previously reported net loss.

## Fair Value of Financial Instruments

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

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

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

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

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

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



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

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

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

##### Convertible Instruments

GAAP requires companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. An exception to this rule is when the host instrument is deemed to be conventional, as that term is described under applicable GAAP.

When the Company has determined that the embedded conversion options should not be bifurcated from their host instruments, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments (the beneficial conversion feature) based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption.

##### Subsequent Events

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

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers,” (“ASU 2014-09”). ASU 2014-09 supersedes the revenue recognition requirements in ASC 605 - Revenue Recognition (“ASC 605”) and most industry-specific guidance throughout ASC 605. The standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective on January 1, 2017 and should be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application. The Company is currently evaluating the impact of the adoption of ASU 2014-09 on its consolidated financial position and results of operations.

In June 2014, the FASB issued ASU No. 2014-10, “Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation,” (“ASU 2014-10”). ASU 2014-10 removes the definition of a development stage entity from the Master Glossary of the ASC, thereby removing the financial reporting distinction between development stage entities and other reporting entities from GAAP. In addition, ASU 2014-10 eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of operations, cash flows, and stockholders’ equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early adoption is permitted. The Company adopted ASU 2014-10 during the year ended December 31, 2014 which resulted in the removal of previously required development stage disclosures. The Company’s planned principal operations are to develop technology using cell and tissue therapy protocols, primarily involving adult stem cells, allowing patients to undergo cellular-based treatments. The Company has established a new laboratory facility and is seeking to increase its capabilities for the further development of possible cellular-based treatment protocols, stem cell-related intellectual property and research applications. The Company’s activities are subject to significant risks and uncertainties, which are detailed in Note 2 – Going Concern and Management’s Plans.

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

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

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

##### Recently Issued Accounting Pronouncements – Continued

In June 2014, the FASB issued ASU No. 2014-12, "Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period," ("ASU 2014-12"). The amendments in ASU 2014-12 require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in ASC Topic No. 718, "Compensation - Stock Compensation" as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The Company does not anticipate that the adoption of ASU 2014-12 will have a material impact on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). ASU 2014-15, which is effective for annual reporting periods ending after December 15, 2016, extends the responsibility for performing the going-concern assessment to management and contains guidance on how to perform a going-concern assessment and when going-concern disclosures would be required under U.S. GAAP. The Company elected to adopt ASU 2014-15. Management's evaluations regarding the events and conditions that raise substantial doubt regarding the Company's ability to continue as a going concern have been disclosed in Note 2 – Going Concern and Management's Plans.

#### Note 4 – Property and Equipment

Property and equipment include the following:

	December 31,	
	2014	2013
Office equipment	\$8,466	\$7,670
Medical equipment	359,248	129,461
Furniture and fixtures	113,874	19,322
Computer software and equipment	66,458	20,169
Leasehold Improvements	103,582	-
	651,628	176,622
Less: accumulated depreciation	(157,772)	(141,054)
Property and equipment, net	\$493,856	\$35,568

Depreciation expense amounted to \$26,872 and \$34,999 for the years ended December 31, 2014 and 2013, respectively. Depreciation expense is reflected in general and administrative expenses in the consolidated statements of operations.

#### Note 5 – Intangible Assets

Intangible assets consist of the following:

	Patents and Trademarks	Licenses	Accumulated Amortization	Total
Balance as of January 1, 2013	\$ 3,676	\$1,226,500	\$ (52,819 )	\$1,177,357
Amortization expense	-	-	(69,812 )	(69,812 )
Balance as of December 31, 2013	\$ 3,676	\$1,226,500	\$ (122,631 )	\$1,107,545
Amortization expense	-	-	(69,813 )	(69,813 )
Balance as of December 31, 2014	\$ 3,676	\$1,226,500	\$ (192,444 )	\$1,037,732
Weighted average remaining amortization period at December 31, 2014 in years	6.0	14.9		

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements****Note 5 – Intangible Assets – Continued**

Amortization of intangible assets consists of the following:

	Patents and Trademarks	Licenses	Accumulated Amortization
Balance as of January 1, 2013	\$ 736	\$52,083	\$ 52,819
Amortization expense	368	69,444	69,812
Balance as of December 31, 2013	\$ 1,104	\$121,527	\$ 122,631
Amortization expense	368	69,445	69,813
Balance as of December 31, 2014	\$ 1,472	\$190,972	\$ 192,444

Amortization expense is reflected in general and administrative expenses in the consolidated statements of operations. Based upon the current intangible assets as of December 31, 2014, amortization expense is projected to be approximately \$70,000 per annum through 2029.

On January 27, 2012, the Company entered into a license agreement with a stem cell treatment company (“SCTC”) (as amended on March 21, 2012, the “SCTC Agreement”). On April 6, 2012 (the “Closing Date”), the Company and SCTC closed on the SCTC Agreement. Pursuant to the SCTC Agreement, the Company obtained, among other things, a worldwide, exclusive, royalty-bearing license from SCTC to utilize or sublicense a certain medical device patent (pending) 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. The SCTC Agreement provides that the Company must achieve certain milestones. As of December 31, 2014, the Company had not met any the milestones provided for in the SCTC Agreement to be fulfilled by April 6, 2014; however, it still had the ability to pay \$75,000 by April 6, 2015 in order to retain the exclusivity of the license. On March 5, 2015, the Company made the \$75,000 cash payment to retain the exclusivity of the license. Pursuant to the license agreement with SCTC, unless certain milestones are satisfied, the Company will be required to pay to SCTC minimum amounts of between \$225,000 and \$475,000 during the period from April 2017 to April 2019 in order to maintain its exclusive rights with regard to the disc/spine technology.

The SCTC Agreement also provides for an exclusive, royalty-bearing sublicense of certain of the licensed technology to SCTC for use for orthopedic purposes and a non-exclusive, royalty-bearing sublicense of certain of the licensed technology to SCTC for use (1) at a single facility in the Cayman Islands (or, under certain circumstances, at a different non-U.S. facility), and (2) at U.S. facilities (in accordance with protocols established by the Company), if and only if, upon resolution of a Food and Drug Administration (“FDA”) action, SCTC has the legal right to exploit the technology in the U.S. and the Company does not yet have such legal right. Further, the SCTC Agreement provides that SCTC will furnish certain training, assistance and consultation services with regard to the licensed technology. In addition, the Company had agreed to reimburse SCTC for 25% of its legal fees associated with what had been a pending court action with the FDA, subject to a maximum of \$4,500 per month and \$100,000 in the aggregate. In 2012, the District Court ruled in favor of the FDA, but SCTC 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 SCTC’s stem cell mixture meets the definition of drug and not HCT/P since it was more than minimally manipulated. SCTC has indicated that it does not intend to appeal the decision to the Supreme Court. While this decision is specific to SCTC’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. The Company is proceeding with the FDA approval process for its initiatives as discussed above.

Pursuant to the SCTC Agreement, on the Closing Date, the Company made a payment to SCTC consisting of a license fee of \$1,000,000, net of a sublicensing fee of \$10,000, which SCTC owed to the Company (which was recorded as revenue in the consolidated statements of operations), and issued to SCTC a warrant for the purchase of 1,000,000 shares of common stock of the Company (the “SCTC Warrant”). The vesting of the SCTC Warrant was divided into three tranches. The first tranche to purchase 300,000 shares of common stock was immediately exercisable. The exercise of the second and third tranches to purchase 350,000 shares of common stock each is subject to specified performance criteria. The exercise price for the initial tranche is \$1.50 per share and the exercise price for the second and third tranches is the greater of \$1.50 per share or the then fair market value of the common stock, as defined in the SCTC Agreement. The initial tranche had a grant date value of \$226,500 using the Black-Scholes model, which was recognized immediately. The Company recorded the \$1,000,000 cash payment and the \$226,500 value of the first tranche of the warrant as an intangible asset with an original estimated useful life of 17.7 years (20 year life of the underlying pending patent less 2.3 years since patent application).

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements****Note 5 – Intangible Assets – Continued**

The Company has not made an accounting entry related to the second and third tranches as it is not currently estimable when the specified performance criteria will be met. When, and if, the second and third tranches of the SCTC Warrant vest (or when the timing of vesting becomes estimable), the grant date value of these tranches will be added to the value of the intangible asset after calculating the grant date values using the Black-Scholes option pricing model using the final exercise prices as inputs to the model.

**Note 6 – Accrued Expenses and Other Current Liabilities**

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

	December 31,	
	2014	2013
Credit card payable	\$4,739	\$6,000
Accrued payroll and payroll taxes	679,277	672,535
Accrued purchases of property and equipment	174,801	-
Accrued research and development expenses	292,395	229,276
Accrued general and administrative expenses	315,294	266,541
Deferred rent	-	2,310
Total	\$1,466,506	\$1,176,662

During the year ended December 31, 2014, the Company received an aggregate of \$58,054 in non-interest bearing advances from a director, an officer and a family member of the same officer and made aggregate repayments of \$83,044 (inclusive of the \$24,990 outstanding balance as of December 31, 2013 discussed below), such that the Company had no remaining liability with regard to these advances as of December 31, 2014. During the year ended December 31, 2013, the Company received an aggregate of \$144,285 in advances from a director, an officer and a family member of the same officer and made aggregate repayments of \$119,295, such that the Company had a liability of \$24,990 with regard to these advances as of December 31, 2013.

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements**

## Note 7 – Notes Payable

A summary of the notes payable activity during the years ended December 31, 2014 and 2013 is presented below:

	Bermuda Lender	Convertible Notes	Other Notes	Debt Discount	Total
Outstanding, December 31, 2012	\$3,550,000	\$-	\$1,082,185	\$(76,719 )	\$4,555,466
Issuances	450,000	281,000 [1]	733,000	-	1,464,000
Conversion of accrued interest	-	-	68,100	-	68,100
Exchanges for equity	-	-	(404,285 )	-	(404,285 )
Repayments	-	-	(5,500 )	-	(5,500 )
Recognition of debt discount	-	-	-	(574,369)[1]	(574,369 )
Amortization of debt discount	-	-	-	405,531	405,531
Accretion of interest expense	-	-	-	5,066 [1]	5,066
Outstanding, December 31, 2013	\$4,000,000	\$281,000	\$1,473,500	\$(240,491)	\$5,514,009
Issuances	500,000	300,000 [1]	-	-	800,000
Exchanges for equity	-	(71,000 )	(203,000 )	-	(274,000 )
Conversions to equity	-	(342,500 )	-	-	(342,500 )
Repayments	(89,063 )	-	(113,000 )	-	(202,063 )
Recognition of debt discount	-	-	-	(347,170)[1]	(347,170 )
Amortization of debt discount	-	-	-	464,470	464,470
Recharacterization of accrued interest as principal	-	-	108,059 [3]	-	108,059
Accretion of interest expense	-	15,000 [2]	-	9,934 [1]	24,934
Settlement of accreted interest	-	(7,500 ) [2]	-	-	(7,500 )
Outstanding, December 31, 2014	\$4,410,937	\$175,000 [4]	\$1,265,559	\$(113,257)	\$5,738,239

During the years ended December 31, 2014 and 2013, notes with an aggregate principal amounts of \$30,000 and \$60,000, respectively, bear no interest and were issued for cash consideration of \$25,000 and \$50,000, respectively. The differences between the principal amounts of the notes and the cash received of \$5,000 and \$10,000, respectively, were recorded as debt discount and amortized to interest expense over the term of the notes.

[2]

During the year ended December 31, 2014, pursuant to the terms of certain notes payable with maturity dates ranging from January 8, 2014 to June 10, 2014, the aggregate principal balance of the notes was increased from \$90,000 to \$105,000. The aggregate \$15,000 of principal increases was accreted as interest expense. During the year ended December 31, 2014, \$7,500 of the principal increases was settled by the conversion of a convertible note with a maturity date of January 8, 2014 and original principal balance of \$30,000 into shares of the Company's common stock.

[3] During the year ended December 31, 2014, in connection with the extension of certain notes payable with maturity dates ranging from of August 8, 2013 to March 1, 2014, an aggregate \$108,059 of accrued interest was added to the aggregate principal balance of the notes, increasing the aggregate principal balance from \$752,500 to \$860,559.

[4] As of December 31, 2014, convertible notes with an aggregate principal balance of \$175,000 were convertible at the election of the Company. Of such convertible notes, notes with an aggregate principal balance of \$83,333 are also convertible, under certain circumstances, at the election of the holder pursuant to the terms of the notes.

## BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES

### Notes to Consolidated Financial Statements

#### Note 7 – Notes Payable – Continued

##### Bermuda Lender

On March 26, 2013, Cayman borrowed \$450,000 from the Bermuda Lender, which was combined with the already outstanding \$3,550,000 of previous borrowings from the Bermuda Lender into a new \$4,000,000 zero coupon note (the “\$4,000,000 Bermuda Lender Note”) which matured on July 31, 2014. In consideration of the additional \$450,000 loan, the waiver of accrued and unpaid interest of \$213,000, and an extension of the maturity date of the outstanding loan, the Company issued to the Bermuda Lender 600,000 shares of common stock (valued at \$480,000) and a five year warrant to purchase 400,000 shares of common stock at an exercise price of \$2.50 per share (valued at \$250,000). After determining that 266,250 shares of common stock (of the 600,000 shares issued) were, in effect, used to settle the aggregate \$213,000 accrued and unpaid interest, the Company determined that the relative fair value of the remaining equity securities issued was \$457,826, which amount was recorded as a debt discount and was amortized via the interest method over the sixteen month term of the \$4,000,000 Bermuda Lender Note in accordance with ASC 470-60. The effective annual interest rate of the \$4,000,000 Bermuda Lender Note is 11%.

On May 8, 2014, Cayman borrowed an additional \$500,000 from the Bermuda Lender and issued to the Bermuda Lender a one-year note payable in the principal amount of \$500,000 which bears interest at 15% per annum payable at maturity. The note also provides for the mandatory prepayment of the principal amount to the extent of any monies received by the Company pursuant to the research and development agreements discussed in Note 3 – Summary of Significant Accounting Policies – Revenue Recognition – Research and Development Agreements. Interest on the entire principal amount of the note is payable until such time as the principal amount is paid in full. On July 15, 2014, the Company received \$89,063 pursuant to the research and development agreements which triggered a mandatory principal prepayment of \$89,063. See Note 11 – Subsequent Events for details regarding monies received pursuant to the research and development agreements.

On August 13, 2014, Cayman and the Bermuda Lender agreed to extend the maturity date of the \$4,000,000 Bermuda Lender Note from July 31, 2014 to December 31, 2014. In consideration of the extension, the Company issued to the Bermuda Lender 550,000 shares of common stock. The \$121,000 fair value of the common stock was recorded as debt discount and was amortized over the remaining term of the \$4,000,000 Bermuda Lender Note.

On December 31, 2014, Cayman and the Bermuda Lender agreed to further extend the maturity date of the \$4,000,000 Bermuda Lender Note from December 31, 2014 to June 30, 2015. In consideration of the extension, the Company issued to the Bermuda Lender 450,000 shares of common stock. The \$99,000 fair value of the common stock was recorded as debt discount and will be amortized over the remaining term of the \$4,000,000 Bermuda Lender Note.

As of December 31, 2014, the Bermuda Lender is a related party as a result of the size of its ownership interest in the Company's common stock.

#### Convertible Notes

Between August 8, 2013 and December 18, 2013, the Company issued convertible notes with an aggregate principal amount of \$281,000, for cash consideration of \$271,000 (convertible notes with an aggregate principal amount of \$60,000 bear no interest and were issued for cash consideration of \$50,000 and the \$10,000 of interest, was recorded as debt discount and will be amortized over the term of the note, resulting in a weighted average effective interest rate of 100%). Convertible notes with an aggregate principal amount of \$221,000 bear interest at a rate of 12% per annum payable upon maturity. The convertible notes were initially payable 2-6 months from the date of issuance. Of the \$281,000 principal amount of convertible notes, \$171,000 are convertible into shares of the Company's common stock at the election of the Company while \$110,000 are convertible into shares of the Company's common stock at the election of the holder. The convertible notes are convertible during the period beginning five days prior to maturity and ending on the day immediately prior to maturity (the "Note Conversion Period"). The conversion price of the convertible notes is equal to the greater of (a) 55-65% (depending on the specific note) of the fair value of the Company's common stock or (b) \$0.05 per share. As of December 31, 2013, the convertible notes were not convertible. The Company evaluated the conversion options and determined that bifurcation was not necessary in accordance with ASC 815. The beneficial conversion features will be accounted for, if necessary, at the commitment date.

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

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

#### **Note 7 – Notes Payable – Continued**

##### Convertible Notes – Continued

Between January 17, 2014 and May 2, 2014, the Company issued convertible notes with an aggregate principal amount of \$175,000, for cash consideration of \$170,000 (a convertible note with a principal amount of \$30,000 bears no interest and was issued for cash consideration of \$25,000 and the \$5,000 difference was recorded as debt discount and was accreted as interest over the term of the note). Convertible notes with an aggregate principal amount of \$145,000 bear interest at a rate of 12% per annum payable upon maturity. The convertible notes were initially payable 3-12 months from the date of issuance. Of the \$175,000 principal amount of convertible notes, \$145,000 is convertible into shares of the Company's common stock at the election of the Company during the period beginning five days prior to maturity and ending on the day immediately prior to maturity at the greater of (a) 55%-60% (depending on the particular note) of the fair value of the Company's stock or (b) \$0.05 per share. The remaining \$30,000 is convertible into shares of the Company's common stock at the election of the holder any time after September 10, 2014 at the lesser of (a) \$0.50 per share or (b) 65% of the fair value of the Company's common stock, but with a floor of \$0.05 per share.

Between November 12, 2014 and December 2, 2014, the Company issued convertible notes in the aggregate principal amount of \$125,000 which bear interest at a rate of 10% per annum payable on maturity. The convertible notes are payable as follows: (i) \$41,667 of aggregate principal and the respective accrued interest on such principal is payable six months from the issuance date (the "First Maturity Date"), (ii) \$41,667 of principal and the respective accrued interest on such principal is payable two weeks following the First Maturity Date (the "Second Maturity Date"), and (iii) \$41,666 of principal and the respective accrued interest on such principal is payable one month following the First Maturity Date (the "Third Maturity Date"). Each \$41,667 and \$41,666 of aggregate principal and the respective accrued interest on such principal is convertible into shares of the Company's common stock at the election of the Company during the period beginning five days prior to each maturity date and ending on the day immediately prior to each maturity date at the greater of (a) 60% of the fair value of the Company's stock or (b) \$0.05 per share. In the event that the Company elects to effect a conversion, during the five day period following the conversion, the holders shall have the right to convert the then outstanding principal amount of the convertible notes, together with accrued and unpaid interest thereon, into shares of the Company's common stock at a conversion price equal to the conversion price in the Company-effected conversion.

During the year ended December 31, 2014, the Company elected to convert certain convertible notes with an aggregate principal balance of \$225,000 and aggregate accrued interest of \$13,565 into an aggregate of 1,202,744 shares of common stock at conversion prices ranging from \$0.14 to \$0.28 per share.

During the year ended December 31, 2014, the holders of certain convertible notes elected to convert such convertible notes with an aggregate principal balance of \$117,500 and aggregate accrued interest of \$3,646 into an aggregate of 582,033 shares of common stock at conversion prices ranging from \$0.19 to \$0.22 per share.

During the year ended December 31, 2014, the Company and certain lenders agreed to exchange certain convertible notes with an aggregate principal balance of \$71,000, along with accrued and unpaid interest of \$4,260, for an aggregate of 246,764 shares of common stock and an immediately vested, two-year warrant to purchase 100,000 shares of common stock at an exercise price of \$0.75 per share. The common stock and warrants had an aggregate grant date value of \$74,029 and, as a result, the Company recorded a gain on extinguishment of \$1,231. The lenders received piggyback registration rights related to the stock and the stock issuable pursuant to the warrants.

During the year ended December 31, 2014, the contingently adjustable conversion ratios associated with certain convertible notes were resolved. The Company estimated the intrinsic value of the embedded conversion options based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the convertible note. During the year ended December 31, 2014, the Company recognized \$92,370 of intrinsic value related to these beneficial conversion features as debt discount which was immediately amortized.

#### Other Notes

Other notes issued by the Company (“Other Notes”) predominantly bear interest at a rate of 15% per annum payable monthly. As of December 31, 2014, the Other Notes have maturity dates through October 2015.

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

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

#### **Note 7 – Notes Payable – Continued**

##### Other Notes – Continued

The holders of two Other Notes are entitled to five years of royalty payments associated with Cosmetic Revenues, as defined in the notes, ranging from 0.5% to 4.0% of Cosmetic Revenues, depending on the holder and the year the Cosmetic Revenues are earned. The final three years of royalty payments are subject to an annual dollar maximum of \$100,000 for one of the noteholders. Given that the Company has not yet generated any Cosmetic Revenues, no royalty payments have been earned.

In connection with the issuance and extension of Other Notes during the year ended December 31, 2013, the Company issued 5,000 shares of common stock, with a relative fair value of \$3,704. In connection with the issuances, five-year warrants to purchase an aggregate of 402,500 shares of common stock at exercise prices ranging from \$0.94 to \$2.50 per share, with a relative fair value of \$112,239, were issued as debt discount to the lenders and amortized over the term of the note.

In connection with the extension of Other Notes during the year ended December 31, 2014, the Company issued five-year warrants to purchase an aggregate of 190,000 shares of common stock at exercise prices ranging from \$0.50 to \$0.75 per share, with a grant date fair value of \$29,800, as debt discount to the lenders and amortized over the term of the note.

During the year ended December 31, 2013, the Company and certain lenders agreed to exchange certain Other Notes with an aggregate principal balance of \$404,285, along with accrued and unpaid interest of \$6,196, for an aggregate of 818,495 shares of common stock and five-year warrants to purchase an aggregate of 45,000 shares of common stock at an exercise price of \$1.50 per share. The stock and warrants had an aggregate issuance date value of \$417,681 and, as a result, the Company recorded a loss on extinguishment of \$7,200. The lenders received piggyback registration rights related to the stock and the stock issuable pursuant to the warrants.

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During the year ended December 31, 2014, the Company and certain lenders agreed to exchange certain Other Notes with an aggregate principal balance of \$203,000, along with accrued and unpaid interest of \$15,672, for an aggregate of 854,689 shares of common stock and an immediately vested, two-year warrant to purchase 100,000 shares of common stock at an exercise price of \$0.75 per share. The common stock and warrants had an aggregate grant date value of \$268,997 and, as a result, the Company recorded a loss on extinguishment of \$50,325. The lenders received piggyback registration rights related to the stock and the stock issuable pursuant to the warrants.

During the year ended December 31, 2014, the Company repaid certain Other Notes with an aggregate principal balance of \$113,000 and accrued interest of \$11,219.

See Note 11 – Subsequent Events for additional details regarding notes payable.



**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements**

## Note 8 – Income Taxes

United States and foreign components of loss before income taxes were as follows:

	For The Years Ended	
	December 31,	
	2014	2013
United States	\$(5,223,749)	\$(5,328,958)
Foreign	(363,863 )	(422,236 )
Loss before income taxes	\$(5,587,612)	\$(5,751,194)

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

	For The Years Ended	
	December 31,	
	2014	2013
Deferred Tax Assets:		
Net operating loss carryforward	\$4,820,500	\$5,327,000
Stock-based compensation	1,272,600	907,100
Accruals	240,700	139,800
Research & development tax credits	95,500	-
Other	2,100	2,700
Gross deferred tax assets	6,431,400	6,376,600
Deferred Tax Liabilities:		
Fixed assets	(93,200 )	-
Intangible assets	(8,100 )	(3,000 )
Gross deferred tax liabilities	(101,300 )	(3,000 )
Net deferred tax assets	6,330,100	6,373,600
Valuation allowance	(6,330,100)	(6,373,600)

Deferred tax asset, net of valuation allowance	\$-	\$-
Changes in valuation allowance	\$(43,500	) \$1,631,300

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

	For The Years Ended December 31,	
	2014	2013
Federal:		
Current	\$-	\$-
Deferred	38,921	(1,459,584)
State and local:		
Current	-	-
Deferred	4,579	(171,716 )
	43,500	(1,631,300)
Change in valuation allowance	(43,500)	1,631,300
Income tax provision (benefit)	\$-	\$-

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements****Note 8 – Income Taxes – Continued**

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

	For The Years Ended December 31,	
	2014	2013
Tax benefit at federal statutory rate	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(4.0 )%	(4.0 )%
Permanent differences	0.8 %	5.8 %
Research & development tax credits	(1.8 )%	0.0 %
Impact of Section 382 limit	41.2 %	0.0 %
True-ups and other	(1.4 )%	1.6 %
Change in valuation allowance	(0.8 )%	30.6 %
Effective income tax rate	0.0 %	0.0 %

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

At December 31, 2014 and 2013, the Company had approximately \$12,700,000 and \$14,000,000, respectively, of federal and state net operating losses that may be available to offset future taxable income. The net operating loss carry forwards, if not utilized, will expire from 2029 to 2034 for federal purposes. In accordance with Section 382 of the Internal Revenue Code, the usage of the Company's net operating loss carry forwards are subject to annual limitations due to greater than 50% ownership changes. The Section 382 limitation that became effective on or about July 2014 has resulted in (a) approximately \$5,700,000 of federal NOLs not being realizable; and (b) the reversal of approximately \$2,200,000 of net operating loss deferred tax assets.

The Company files income tax returns in the U.S. federal jurisdiction and the states of Florida and New York, and is subject to examination by the various taxing authorities beginning with the tax years ended December 31, 2011.

Note 9 – Commitments and Contingencies

Operating Lease

*Jupiter, Florida Lease*

The Company was a party to a three year lease agreement with respect to premises located at the Alexandria Innovation Center in Jupiter, Florida, which was scheduled to expire on January 31, 2014. No base rent was payable during the initial year and the lease provided for a base monthly rent of \$6,234 during the second year and \$6,422 during the third year. The Company had the right to lease the premises for an additional three years at the then fair market value rent. The aggregate base rent payable over the lease term was recognized on a straight-line basis.

On February 4, 2014, the Company and the landlord agreed to the surrender of a portion of the leased premises and also extended the term of the lease to July 31, 2014. The amended lease provided for a base rent of \$962 per month. The Company and the landlord subsequently agreed to a series of lease extensions, such that the lease ultimately terminated on December 31, 2014.

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

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

#### **Note 9 – Commitments and Contingencies – Continued**

##### Operating Lease – Continued

On February 11, 2014, the Company executed a Facility Use Agreement with the SCTC which permitted the Company to utilize the SCTC's laboratory facility and one office for research associated with its culturing and medical device license. Payment terms were \$3,750 per month through March 31, 2014 and \$100 per day for usage beyond that date. The Company ceased using the SCTC's laboratory facility on March 31, 2014.

On August 25, 2014, the Company entered into a lease for 6,800 square feet of space located in Melville, New York (the "Melville Lease"). Late in 2014, the Company relocated its corporate and laboratory operations from Jupiter, Florida to such location. The Melville Lease provides for a term of 63 months from the commencement date (as defined in the Melville Lease) (subject to extension at the option of the Company for a period of five years) and an annual base rental during the initial term ranging between \$132,600 and \$149,260. Pursuant to the Melville Lease, no rent was payable for the initial four months of the term.

In connection with the Melville Lease, the Company paid the landlord a cash security deposit of \$45,900, which is reflected on the consolidated balance sheet as of December 31, 2014. Additionally, in connection with the execution of the Melville Lease, the Company issued to the principals of the landlord an aggregate of 284,200 shares of its common stock and five-year warrants to purchase an aggregate of 142,100 shares of its common stock at an exercise price of \$0.50 per share as consideration for: (i) \$60,000 towards the leasehold improvements of the leased premises and (ii) \$11,050 of prepaid rent for the fifth month of the lease. During the year ended December 31, 2014, the Company has (i) recorded a credit to equity for the \$71,050 value of the common stock and warrants, (ii) capitalized \$60,000 of leasehold improvements which is included within property and equipment, net on the consolidated balance sheet as of December 31, 2014, and will be amortized over the term of the lease and (iii) recorded prepaid rent of \$11,050 within prepaid expenses and other current assets on the consolidated balance sheet as of December 31, 2014, which will be expensed following the fifth month of the lease.

Rent expense amounted to \$20,380 and \$99,175 for the years ended December 31, 2014 and 2013, respectively. Rent expense is reflected in general and administrative expenses in the consolidated statements of operations.

Litigations, Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business.

In November 2013, an action was commenced against the Company in the Circuit Court of Palm Beach County, Florida by an alleged former consultant. The action is associated with an alleged \$5,000 loan made in 2009 and an alleged consulting/employment agreement entered into with the Company 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 (or alternatively \$52,000 per year from September 2009) as well as the repayment of the alleged loan with interest, reimbursement for certain out-of-pocket fees and expenses, two weeks vacation pay per year, and the issuance of 80,000 shares of the Company's common stock or warrants for the purchase of 80,000 shares of the Company's common stock (or alternatively the market value of such securities). A trial of the action is scheduled to commence in June 2015. On March 13, 2015, the Company filed with the court a settlement offer in an amount which has been accrued.

The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

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

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

#### **Note 9 – Commitments and Contingencies – Continued**

##### Research Agreements

Effective June 15, 2012, the Company entered into an assignment agreement (the “Assignment Agreement”) with the research foundation of a state university (the “Foundation”), whereby the Foundation assigned all of its right, title and interest in specified patents to the Company in exchange for a cash payment of \$15,000. The Company also agreed to pay the Foundation a 5% royalty on Patent Revenue (as defined in the Assignment Agreement) over a 20 year period commencing on June 15, 2012. Through December 31, 2014, no royalties have been earned.

Effective June 15, 2012, the Company entered into a research agreement (the “Research Agreement”) with the same state university (the “University”). The Research Agreement has a term of three years. Pursuant to the Research Agreement, the University agreed to perform certain research services to be used by the Company. Pursuant to the Research Agreement, the Company agreed to pay the University a fee of \$500,000 for each twelve month period of the agreement, payable monthly. In addition, the Company agreed to pay to the University a 5% royalty, over a 20 year period commencing on June 15, 2012, on the net sales of all products and/or methods directly arising from inventions and improvements conceived or reduced to practice by the University in the course of performing research during the term of the Research Agreement. The Research Agreement can be cancelled without penalty upon (a) the second anniversary of the Research Agreement if eventual FDA approval does not appear likely or (b) other conditions specified in the Research Agreement. Through December 31, 2014, no royalties have been earned.

On May 9, 2014, the Company entered into an amendment to the Research Agreement. Pursuant to the amendment, the parties agreed that (i) no fees are payable by the Company to the University pursuant to the Research Agreement for the first five monthly payments in 2014 (\$208,335 of fees in total were cancelled, of which, \$104,168 was accrued for as of March 31, 2014), (ii) effective with the payment due on June 15, 2014, the monthly fee payable by the Company to the University pursuant to the Research Agreement will be reduced from \$41,667 to \$20,000 and (iii) the scope of the work to be performed by the University pursuant to the Research Agreement was reduced. The Research Agreement, as amended, is scheduled to expire on June 14, 2015. Concurrent with the execution of the amendment, the Company paid \$323,336 to the University, representing the balance due of all fees payable by the Company to date pursuant to the Research Agreement. As a result of the above, the Company recorded an immediate gain on settlement in the amount of \$166,668.

During the years ended December 31, 2014 and 2013, the Company recorded research and development expense of approximately \$264,000 and \$500,000, respectively in connection with the Research Agreement. As of December 31, 2014 and 2013, the Company had accrued approximately \$43,000 and \$353,000, respectively, in connection with the Research Agreement, which is included in accounts payable and accrued expenses and other current liabilities in the consolidated balance sheets.

### Consulting Agreements

#### *Marketing Consulting Services*

On June 27, 2014, a February 17, 2011 agreement for marketing consulting services that had expired on December 31, 2013 was further amended. Pursuant to the amendment, the agreement was reinstated effective as of April 1, 2014 and provided for an expiration date of December 31, 2014 (the “New Marketing Consulting Term”). In consideration of services rendered during the New Marketing Consulting Term and the settlement of the Company’s obligation to pay \$65,000 in cash to the consultant, the Company issued to a designee of the consultant 500,000 shares of common stock and issued to the consultant an immediately vested five-year warrant to purchase 250,000 shares of common stock at an exercise price of \$1.00 per share. The common stock and warrant had grant date values of \$110,000 and \$37,500, respectively, which were recognized immediately. During the years ended December 31, 2014 and 2013, the Company recorded consulting expense of \$82,500 and \$120,000, respectively, related to the marketing consulting agreement.



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

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

#### **Note 9 – Commitments and Contingencies – Continued**

##### Consulting Agreements – Continued

###### *Consulting Services*

On February 20, 2014, the Company executed a two-year consulting agreement with the Psychiatrist-In-Chief Emeritus for the Hospital for Special Surgery in New York City to become the Company's Chief Medical Advisor for Spine Medicine pursuant to which he oversees the clinical aspects of the brtxDISC™ Program. The agreement may be terminated earlier or extended, as provided for in the agreement. Pursuant to the agreement, the consultant is entitled to receive \$10,000 per month, escalating to \$20,000 per month upon the FDA approval of the Company's Investigational New Drug or Investigational Device Exemption application with respect to its brtxDISC™ Program. In addition, the Company granted the consultant a five-year option to purchase 300,000 shares of common stock at an exercise price of \$0.65 per share, pursuant to the Plan. The option vests ratably over three years on the grant date anniversaries and the grant date value of \$67,830 will be recognized proportionate to the vesting period. On October 8, 2014, the consulting agreement between the Company and its Chief Medical Advisor for Spine Medicine was amended such that the consultant will be entitled to receive \$15,000 per month (and eliminated the possible increase to \$20,000 per month). In connection with the amendment, the consultant was issued a five-year option to purchase 500,000 shares of the Company's common stock at an exercise price of \$0.32 per share. The option vests ratably over three years on the grant date anniversaries and the grant date value of \$124,200 will be recognized proportionate to the vesting period.

On March 12, 2014, as additional compensation for consulting services rendered, the Company granted to a consultant an immediately vested, five-year warrant to purchase 100,000 shares of common stock at an exercise price of \$0.53 per share. In addition, warrants to purchase an aggregate of 280,000 shares of common stock had their exercise prices reduced to \$0.53 per share from \$1.50 per share and such warrants, as well as a warrant to purchase 20,000 shares of common stock, had their term extended to March 12, 2019. The grant date value of the issued warrant of \$23,270 along with the incremental value related to the modification of the outstanding warrants of \$30,096 was recognized during the year ended December 31, 2014 as stock-based compensation expense, which is reflected as consulting expense in the consolidated statements of operations.

On July 23, 2014, the Company entered into a one-year agreement with a consultant to market research and development arrangements and other business transactions to potential strategic partners and other alliance candidates. In exchange for services provided by the consultant during the term, the Company agreed to issue 30,000 shares of common stock of the Company for each complete month during the term. During the year ended December 31, 2014, the Company issued to the consultant an aggregate 150,000 shares of common stock and the aggregate grant date value of \$33,000 was recognized immediately.

On October 7, 2014, the Company entered into an agreement with a consultant for services regarding the search for a President for the Company's Disc/Spine Division. The consultant was entitled to an initial retainer fee of \$15,000, payable in shares of the Company's common stock, and a second retainer fee of \$10,000 to be paid in cash. A final fee will be invoiced upon a selected candidate's acceptance of BRT's offer and commencement of employment equal to 28% of the candidate's first year base salary less the initial \$25,000 retainer fee. Pursuant to the agreement, the Company issued 48,388 shares of common stock related to the initial retainer to the consultant and the \$15,000 grant date value was reflected as consulting expense in the consolidated statements of operations. See Note 11 – Subsequent Events for additional details.

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

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

#### **Note 9 – Commitments and Contingencies – Continued**

##### Consulting Agreements – Continued

###### *Business Advisory Services*

On June 27, 2014, a February 17, 2011 agreement for business advisory services that had expired on December 31, 2013 was further amended. Pursuant to the amendment, the agreement was reinstated effective as of April 1, 2014 and provided for an expiration date of December 31, 2014 (the “New Business Advisory Term”). In consideration of services rendered during the New Business Advisory Term, the Company agreed to pay a cash fee of \$16,667 per month and the Company granted an immediately vested five-year warrant to purchase 250,000 shares of common stock at an exercise price of \$1.00 per share. The warrant had a grant date value of \$37,500 which was recognized immediately. On August 27, 2014, the Company and the consultant entered into an agreement pursuant to which the consultant waived the Company’s obligation to pay \$75,000 of accrued cash compensation to the consultant, in exchange for 300,000 shares of the Company’s common stock. On December 19, 2014, the agreement was further amended such that the term of the agreement was extended an additional six months until June 30, 2015. During the additional six-month period, the Company agreed to pay a cash fee of \$15,000 per month and the Company granted an immediately vested five-year warrant to purchase 100,000 shares of common stock at an exercise price of \$0.50 per share. The warrant had a grant date value of \$17,000 which was recognized immediately. During the years ended December 31, 2014 and 2013, the Company recorded cash consulting fee expense of \$150,000 and \$120,000, respectively, related to the business advisory agreement.

###### *Scientific Advisory Services*

On March 27, 2013, the Company granted a ten-year option to a member of its Scientific Advisory Board to purchase 60,000 shares of common stock at an exercise price of \$1.50 per share, pursuant to the Plan. The shares vest as follows: (i) 30,000 shares immediately and (ii) 30,000 shares on the first anniversary of the grant date. The grant date value of \$45,900 was recognized half immediately and half proportionate to the vesting period.

On June 10, 2013, the Company granted a five-year option to a member of its Scientific Advisory Board to purchase 5,000 shares of immediately-vested common stock at an exercise price of \$1.00 per share, pursuant to the Plan. The grant date value of \$2,056 was recognized immediately.

On July 2, 2013, the Company granted a ten-year option to a member of its Scientific Advisory Board to purchase 100,000 shares of common stock at an exercise price of \$1.00 per share, pursuant to the Plan. The shares vest as follows: (i) 50,000 shares immediately and (ii) 50,000 shares on the first anniversary of the grant date. The grant date value of \$47,960 was recognized half immediately and half proportionate to the vesting period.

On March 14, 2014, the Company executed an agreement, which will continue until terminated by either party, appointing a new Scientific Advisory Board member. Pursuant to the agreement, the Company immediately granted the new advisor a five-year option to purchase 25,000 shares of common stock at an exercise price of \$0.50 per share, pursuant to the Plan. The option vests as follows: (i) 12,500 shares immediately and (ii) 12,500 shares on the first anniversary of the grant date. In addition, on each annual anniversary date of the agreement, the advisor is entitled to a new five-year option to purchase 5,000 shares of the Company's common stock at an exercise price equal to the then fair market value of the common stock. The option grant date value of \$5,860 will be recognized proportionate to the vesting period.

On June 27, 2014, an August 16, 2012 agreement for scientific advisory services was further extended to August 16, 2016 such that the consultant will continue to serve as Chairman of the Company's Scientific Advisory Board, will earn \$10,000 per month and will be entitled to specified expense reimbursements. In addition, the Company granted a ten-year option to purchase 300,000 shares of common stock at an exercise price of \$0.285 per share, pursuant to the Plan. The option vests as follows: (i) 150,000 shares on August 16, 2015 and (ii) 150,000 shares on August 16, 2016. The option grant date value of \$81,000 will be recognized proportionate to the vesting period.

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

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

#### **Note 9 – Commitments and Contingencies – Continued**

##### Consulting Agreements – Continued

###### *Other*

On March 20, 2013, the Company granted an immediately vested, three-year warrant to purchase 10,000 shares of common stock at an exercise price of \$1.50 per share to a consultant. The grant date value of \$6,600 was recognized immediately.

On March 22, 2013, the Company granted an immediately vested, five-year warrant to purchase 100,000 shares of common stock at an exercise price of \$4.00 per share as consideration for legal services. The grant date value of \$59,000 was recognized immediately.

On December 23, 2013, the Company granted immediately vested, five-year warrants to purchase an aggregate of 100,000 shares of common stock at an exercise price of \$2.00 per share to consultants. The aggregate grant date value of \$16,770 was recognized immediately.

On July 22, 2014, the Company granted a consultant an immediately vested five-year warrant to purchase 10,000 shares of common stock at an exercise price of \$0.75 per share. The aggregate grant date value of \$1,500 was recognized immediately.

In addition to the issuances discussed elsewhere in this filing, during the years ended December 31, 2014 and 2013, an aggregate of 474,373 and 129,537 shares of immediately vested common stock valued at \$159,837 and \$77,555, respectively, were issued to consultants for various services rendered to the Company.

Employment Agreements

*Chief Executive Officer*

Effective December 2013, the Company and its Chief Executive Officer (“CEO”) agreed that the CEO’s 2013 salary would be reduced from \$600,000 to \$360,000 and that his 2013 bonus of \$300,000 and his 2013 vacation pay of \$25,000 would be waived. As a result, the Company imputed the value of the services contributed and recorded salary expense of \$565,000 for the year ended December 31, 2013 with a corresponding credit to stockholders’ deficiency.

During the year ended December 31, 2014, the Company and its CEO approved amendments to the employment agreement between the Company and the CEO, dated October 4, 2010, as amended, providing for (a) a reduction of the CEO’s annual salary from \$600,000 to \$450,000, effective October 1, 2014, and (b) a reduction of the CEO’s annual salary from \$450,000 to \$400,000, effective January 1, 2015. During the years ended December 31, 2014 and 2013, the Company recorded \$450,000 and \$600,000, respectively, in operating expenses with regard to the CEO’s base salary.

As of December 31, 2014 and 2013, the accrued and unpaid compensation (salary, bonus, tax liability, car allowance and vacation pay) for the CEO was \$574,278 and \$542,535, respectively, and was included in accrued expenses and other current liabilities in the consolidated balance sheets. See Note 11– Subsequent Events for additional details.

*Other*

In addition to the Company’s employment agreement with its CEO, as of December 31, 2014, two employees have “at-will” employment agreements with the Company that currently provide for aggregate cash severance payments of \$175,000, payable over twelve months, upon involuntary termination. See Note 11– Subsequent Events for additional details.

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

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

#### **Note 9 – Commitments and Contingencies – Continued**

##### Board of Directors

On June 27, 2014, a director of the Company resigned due to other business commitments. In consideration of director services performed to date, the Company agreed to pay an aggregate of \$80,000 (of which, \$50,000 was previously earned and accrued for), payable as follows: (i) \$30,000 immediately and (ii) the \$50,000 balance in six equal monthly installments commencing on July 31, 2014. In addition, all outstanding options held by the director which were not exercisable as of the date of resignation became exercisable on the earlier of (i) the date on which such options were scheduled to become exercisable or (ii) December 31, 2014, and all outstanding options shall remain exercisable until their respective expiration dates notwithstanding the director's resignation. As a result of the modification of the options, the Company recorded incremental stock-based compensation expense of \$96,250.

On June 27, 2014, the Company elected two new directors. Concurrent with the election, the Company granted the new directors ten-year options to purchase an aggregate of 600,000 shares of common stock at an exercise price of \$0.285 per share, pursuant to the Plan. The options vest as follows: (i) an aggregate of 200,000 shares on the date of grant; (ii) an aggregate of 200,000 shares on the first anniversary of the date of grant; and (iii) an aggregate of 200,000 shares on the second anniversary of the date of grant. The options have an aggregate grant date value of \$144,000 which will be recognized proportionate to the vesting period.

As of December 31, 2014 and 2013, \$105,000 and \$130,000 of director cash compensation, respectively, was outstanding and included in accrued expenses and other current liabilities in the consolidated balance sheets.

##### Related Party Agreement

Effective October 1, 2014, the Company entered into a three-month agreement with an affiliate of one of its directors for consulting services related to the Company's brtxDISC™ Program and ThermoStem® Program. Pursuant to the agreement, the affiliate of the director was entitled to a cash fee of \$10,000 per month and an amount of common

stock having a fair market value of \$5,000 as of the last day of each month during the term. On December 19, 2014, the agreement was amended such that the term of the agreement was extended until March 31, 2015. During the year ended December 31, 2014, the Company issued 36,786 shares of common stock pursuant to the agreement with a grant date fair value of \$15,000.

#### Note 10 – Stockholders’ Deficiency

##### Authorized Capital

As of December 31, 2014, the Company was authorized to issue 100,000,000 shares of common stock, \$0.001 par value, and 1,000,000 shares of preferred stock, \$0.01 par value. The holders of the Company’s common stock are entitled to one vote per share. Subject to the rights of holders of preferred stock, if any, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors out of legally available funds. Subject to the rights of holders of preferred stock, if any, upon liquidation, dissolution or winding up of the Company, holders of common stock are entitled to share ratably in all assets of the Company that are legally available for distribution.

On December 19, 2014, effective January 1, 2015, the Company’s shareholders approved the reincorporation of the Company from the State of Nevada to the State of Delaware and in connection therewith (i) approved an amendment to the Company’s Articles of Incorporation to increase the number of shares of common stock authorized to be issued by the Company from 100,000,000 to 200,000,000; and (ii) approved an amendment to the Company’s Articles of Incorporation to increase the number of shares of preferred stock authorized to be issued by the Company from 1,000,000 to 5,000,000.

##### 2010 Equity Participation Plan

On February 18, 2014 and October 23, 2014, the Board of Directors of the Company approved successive increases in the number of shares of common stock authorized to be issued pursuant to the Plan from 6,000,000 to 12,000,000 and then to 20,000,000. On December 19, 2014, the Company’s shareholders approved an increase in the number of shares of common stock authorized to be issued pursuant to the Plan to 20,000,000.



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

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

#### **Note 10 – Stockholders’ Deficiency – Continued**

##### Common Stock and Warrant Offerings

During the year ended December 31, 2013, the Company issued an aggregate of 840,589 shares of common stock at prices ranging from \$0.85 to \$1.50 per share to investors for aggregate gross proceeds of \$905,000. In connection with the purchases, the Company issued five-year warrants to purchase an aggregate of 403,590 shares of common stock at exercise prices ranging from \$1.50 to \$4.00 per share of common stock. The warrants had an aggregate grant date value of \$224,313.

During the year ended December 31, 2014, the Company issued an aggregate of 8,671,983 shares of common stock at prices ranging from \$0.25 to \$0.45 per share to investors for aggregate gross proceeds of \$2,605,000. In connection with the purchases, the Company issued warrants to purchase an aggregate of 2,330,693 shares of common stock at exercise prices ranging from \$0.30 to \$0.75 per share of common stock. The warrants have terms ranging from two to five years. The warrants had an aggregate grant date value of \$389,608.

See Note 7 – Notes Payable for details associated with common stock issued in conjunction with the extension and exchange of notes payable and related accrued interest.

See Note 9 – Commitments and Contingencies – Consulting Agreements for details associated with common stock issued in conjunction with consulting agreements.

##### Warrant and Option Valuation

The Company has computed the fair value of warrants and options granted using the Black-Scholes option pricing model. Option forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period.

This estimate will be adjusted periodically based on the extent to which actual option forfeitures differ, or are expected to differ, from the previous estimate, when it is material. The Company estimated forfeitures related to option grants at an annual rate ranging from 0% to 5% for options granted during the years ended December 31, 2014 and 2013. The expected term used for warrants and options issued to non-employees is the contractual life and the expected term used for options issued to employees and directors is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the “simplified” method to develop an estimate of the expected term of “plain vanilla” employee option grants. Since the Company’s stock has not been publicly traded for a sufficiently long period of time, the Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

#### Warrant Exercise and Reload Program

On November 27, 2013, the Company initiated a limited time program (the “Warrant Exercise and Reload Program”) which, at the election of any warrant holder, would permit them to immediately exercise their outstanding exercisable warrants at an exercise price of \$0.30 per share. In connection with the exercise of the warrant, in addition to having received the number of shares pursuant to such exercise, each holder received a new warrant for the same number of shares purchased with an exercise price of \$0.75 per share and an expiration date two years from the date of grant. The terms of the newly issued warrant permit the Company to redeem the new warrant for a total of \$1.00 if the common stock of the Company trades above \$1.25 for five consecutive trading days. Under the Warrant Exercise and Reload Program, warrants to purchase an aggregate of 376,667 and 1,686,029 shares of common stock were exercised during the years ended December 31, 2014 and 2013, respectively, for aggregate gross proceeds of \$113,000 and \$505,809, respectively. The Company recognized a warrant modification charge of \$50,035 and \$214,912 during the years ended December 31, 2014 and 2013, respectively, which represents the incremental value of the modified warrant and new warrant combined, as compared to the original warrant value, all valued as of the respective modification dates.

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements****Note 10 – Stockholders’ Deficiency – Continued**Stock Warrants

In applying the Black-Scholes option pricing model to warrants granted, the Company used the following assumptions:

	For The Year Ended	
	December 31,	
	2014	2013
Risk free interest rate	0.39% - 2.20 %	0.34% - 1.68 %
Expected term (years)	1.96 - 5.00	3.00 - 5.00
Expected volatility	116% - 122 %	132% - 135 %
Expected dividends	0.00 %	0.00 %

The weighted average estimated fair value of the warrants granted during the years ended December 31, 2014 and 2013 was approximately \$0.17 and \$0.36 per share, respectively.

See Note 7 – Notes Payable for details associated with the issuance of warrants in connection with note issuances and the exchange of notes payable. See Note 9 – Commitments and Contingencies – Consulting Agreements for details associated with the issuance of warrants as compensation. See Note 10 – Stockholders’ Deficiency – Common Stock and Warrant Offerings for details associated with the issuance of warrants in connection with common stock and warrant offerings.

The Company recorded stock-based compensation expense of \$185,266 and \$26,777 during the years ended December 31, 2014 and 2013, respectively, related to stock warrants issued as compensation, which is reflected as consulting expense in the consolidated statements of operations. As of December 31, 2014, there was no unrecognized stock-based compensation expense related to stock warrants.

A summary of the warrant activity during the years ended December 31, 2014 and 2013 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, December 31, 2012	3,334,800	\$ 1.69		
Granted	3,147,119	1.56		
Exercised	(1,686,029)	0.30	[1]	
Forfeited	-	-		
Outstanding, December 31, 2013	4,795,890	\$ 1.39		
Granted	3,849,460	0.70		
Exercised	(376,667 )	0.30	[1]	
Forfeited	(20,000 )	0.50		
Outstanding, December 31, 2014	8,248,683	\$ 0.90	3.2	\$ -
Exercisable, December 31, 2014	7,548,683	\$ 0.84	3.3	\$ -

During the year ended December 31, 2013, warrants to purchase an aggregate of 1,686,029 shares of common stock, with original exercise prices ranging from \$1.50 to \$4.00 per share, had their exercise prices reduced to \$0.30 per share pursuant to the Warrant Exercise and Reload Program. During the year ended December 31, 2014, [1] warrants to purchase an aggregate of 376,667 shares of common stock, with original exercise prices ranging from \$1.50 to \$4.00 per share, had their exercise prices reduced to \$0.30 per share pursuant to the Warrant Exercise and Reload Program.

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements****Note 10 – Stockholders’ Deficiency – Continued**Stock Warrants – Continued

The following table presents information related to stock warrants at December 31, 2014:

Exercise Price	Number of Warrants	Warrants Exercisable Weighted Average Remaining Life In Years	Number of Warrants
\$0.30	650,000	4.4	650,000
0.40	200,000	4.9	200,000
0.50	502,100	4.8	502,100
0.53	380,000	3.4	380,000
0.58	50,000	4.8	50,000
0.75	4,043,389	2.8	4,043,389
0.94	50,000	4.8	50,000
1.00	550,000	4.4	550,000
1.50	862,800	2.5	862,800
1.75	20,000	2.3	20,000
2.00	123,530	3.9	123,530
2.50	20,000	2.6	20,000
3.00	36,864	3.3	36,864
4.00	60,000	2.8	60,000
Variable[1]	700,000	-	-
	8,248,683	3.3	7,548,683

[1] Warrants to purchase 700,000 shares of common stock have an exercise price which is the greater of \$1.50 per share or the fair market value of the common stock on the date certain performance criteria are met. Exercisability

of warrants is subject to satisfaction of certain performance criteria which did not occur during the year ended December 31, 2014.

Stock Options

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following assumptions:

	For the Year Ended	
	December 31,	
	2014	2013
Risk free interest rate	1.50% - 2.54 %	1.13% - 2.66 %
Expected term (years)	5.00 - 10.00	5.00 - 10.00
Expected volatility	116% - 122 %	132% - 135 %
Expected dividends	0.00 %	0.00 %

The weighted average estimated fair value of the stock options granted during the years ended December 31, 2014 and 2013 was approximately \$0.27 and \$0.26 per share, respectively.

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

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

#### **Note 10 – Stockholders’ Deficiency – Continued**

##### Stock Options – Continued

See Note 9 – Commitments and Contingencies for details associated with certain grants of options as compensation to employees, directors and consultants.

On October 4, 2013, the Company granted ten-year options to employees, directors, and an advisor to purchase an aggregate of 980,000 shares of common stock at an exercise price of \$0.60 per share, pursuant to the Plan. The shares vest as follows: (i) 490,000 shares immediately and (ii) 490,000 shares on the first anniversary of the grant date. The grant date value of \$199,921 was recognized proportionate to the vesting period.

Between February 18, 2014 and March 12, 2014, the Company granted ten-year options to employees and directors to purchase an aggregate of 2,415,000 shares of common stock at exercise prices ranging from \$0.53 to \$0.65 per share, pursuant to the Plan. The shares vest as follows: (i) 831,669 shares immediately and (ii) 1,589,331 shares ratably over two years on the grant date anniversaries. The aggregate grant date value of \$566,483 will be recognized proportionate to the vesting period.

On June 16, 2014, the Company granted a five-year option to a consultant to purchase 60,000 shares of common stock at an exercise price of \$0.39 per share, pursuant to the Plan. The shares vest ratably over three months on the grant date anniversaries. The grant date value of \$18,600 was recognized proportionate to the vesting period.

On September 24, 2014, the Company granted a five-year option to a consultant to purchase 75,000 shares of common stock at an exercise price of \$0.33 per share, pursuant to the Plan. The shares vest ratably over three months on the grant date anniversaries. The grant date value of \$20,100 was recognized proportionate to the vesting period.

On October 23, 2014, the Company granted ten-year options to employees and directors to purchase an aggregate of 5,950,000 shares of common stock at an exercise price of \$0.33 per share, pursuant to the Plan. The shares vest ratably over three years on the grant date anniversaries. The grant date value of \$1,710,400 will be recognized proportionate to the vesting period.

On October 27, 2014, the Company granted a ten-year option to an advisor to purchase 250,000 shares of common stock at an exercise price of \$0.34 per share, pursuant to the Plan. The shares vest ratably over three years on the grant date anniversaries. The grant date value of \$78,500 will be recognized proportionate to the vesting period.

On November 17, 2014, the Company granted a ten-year option to an employee to purchase 100,000 shares of common stock at an exercise price of \$0.33 per share, pursuant to the Plan. The shares vest ratably over three years on the grant date anniversaries. The grant date value of \$31,600 will be recognized proportionate to the vesting period.



**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements****Note 10 – Stockholders’ Deficiency – Continued**Stock Options – Continued

The following table presents information related to stock option expense:

	For the Year Ended December 31,		Unrecognized at December 31,	Weighted Average Amortization Period (Years)
	2014	2013	2014	
Consulting	\$365,825	\$160,894	\$ 654,956	2.6
Research and development	328,740	251,758	712,551	[1] 2.5
General and administrative	179,628	235,163	961,378	2.6
	\$874,193	\$647,815	\$ 2,328,885	2.6

[1] Includes \$448,189 of expense that is subject to non-employee mark-to-market adjustments.

As of December 31, 2014, there was \$2,328,885 of unrecognized compensation expense which will be amortized over the weighted average remaining vesting period of 2.6 years.

A summary of the option activity during the years ended December 31, 2014 and 2013 is presented below:

	Weighted Average	Weighted Average Remaining	Aggregate
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	Number of Options	Exercise Price	Life In Years	Intrinsic Value
Outstanding, December 31, 2012	4,018,000	\$ 1.12		
Granted	1,145,000	0.68		
Exercised	-	-		
Forfeited	(120,000 )	0.50		
Outstanding, December 31, 2013	5,043,000	\$ 1.03		
Granted	10,575,000	0.41		
Exercised	-	-		
Forfeited	(34,000 )	1.31		
Outstanding, December 31, 2014	15,584,000	\$ 0.61	8.5	\$ 979,600
Exercisable, December 31, 2014	6,371,502	\$ 0.91	7.6	\$ 45,600

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**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements****Note 10 – Stockholders’ Deficiency – Continued**Stock Options – Continued

The following table presents information related to stock options at December 31, 2014:

Options Outstanding	Options Exercisable	Options Exercisable	Options Exercisable
	Outstanding	Average Remaining	Number of
Exercise Price	Number of	Life	Number of
	Options	In	Options
		Years	
\$0.285	900,000	9.5	200,000
0.320	500,000	-	-
0.330	6,125,000	4.7	75,000
0.340	250,000	-	-
0.390	60,000	4.5	60,000
0.500	345,000	4.9	332,500
0.530	40,000	9.2	40,000
0.600	980,000	8.8	980,000
0.650	2,675,000	9.1	1,125,002
1.000	131,000	8.0	131,000
1.050	2,270,000	7.1	2,270,000
1.100	5,000	2.4	5,000
1.200	10,000	1.4	10,000
1.250	43,000	1.9	43,000
1.400	350,000	4.5	200,000
1.500	900,000	7.9	900,000
	15,584,000	7.6	6,371,502

Compensatory Common Stock Issuances

See Note 9 – Commitments and Contingencies for details associated with certain issuances of common stock as compensation to employees, directors and consultants.

On October 4, 2013, the Company issued 50,000 shares of immediately vested common stock to its legal counsel. The \$12,500 grant date fair value was recognized immediately.

Between June 27, 2014 and December 31, 2014, the Company issued 150,000 shares of immediately vested common stock to its legal counsel. The \$33,000 grant date fair value was recognized immediately.

The following table presents information related to compensatory common stock issuances expense during the years ended December 31, 2014 and 2013:

	For the Year Ended		Unrecognized at
	December 31,	December 31,	December 31,
	2014	2013	2014
Consulting	\$276,500	\$111,351	\$ -
Research and development	24,337	26,704	-
	\$300,837	\$138,055	\$ -

**BIORESTORATIVE THERAPIES, INC. & SUBSIDIARIES****Notes to Consolidated Financial Statements****Note 10 – Stockholders’ Deficiency – Continued**Compensatory Common Stock Issuances – Continued

A summary of compensatory common stock issuances activity during the years ended December 31, 2014 and 2013 is presented below:

	Number of Shares	Weighted Average Issuance Date Fair Value	Total Issuance Date Fair Value
Non-vested, December 31, 2012	-	\$ -	\$ -
Granted	239,537	0.58	138,055
Vested	(239,537 )	0.58	(138,055 )
Forfeited	-	-	-
Non-vested, December 31, 2013	-	\$ -	\$ -
Granted	1,943,747	0.26	511,886
Vested	(1,943,747)	(0.26 )	(511,886 )
Forfeited	-	-	-
Non-vested, December 31, 2014	-	\$ -	\$ -

## Note 11 - Subsequent Events

Research and Development Agreements: Bermuda Lender

Subsequent to December 31, 2014, the Company received the third and fourth payments of four quarterly payments in the aggregate amount of \$177,234 pursuant to the research and development agreement with a U.S. pharmaceutical company discussed in Note 3 – Summary of Significant Accounting Policies – Revenue Recognition – Research and

Development Agreements. This payment triggered the mandatory principal prepayment of \$177,237 of the note payable that was issued to the Bermuda Lender on May 8, 2014. As of the filing date of this report, \$266,297 of mandatory prepayments to the Bermuda Lender related to the research agreement were unpaid.

Subsequent to December 31, 2014, the Company received payment in the amount of \$50,000 pursuant to the research and development agreement with a Japanese pharmaceutical company discussed in Note 3 – Summary of Significant Accounting Policies – Revenue Recognition – Research and Development Agreements. As of the filing date of this report, a \$50,000 mandatory prepayment to the Bermuda Lender related to the research and development agreement was unpaid.

#### Short Term Advances

Subsequent to December 31, 2014, the Company received an aggregate of \$60,055 in non-interest bearing advances from an officer and made aggregate repayments of \$60,055.

#### Notes Payable

Subsequent to December 31, 2014, the Company issued a convertible note with a principal amount of \$30,000 which bears interest at a rate of 12% annum payable upon maturity. The convertible note, is convertible into shares of the Company's common stock at the election of the Company during the period beginning five days prior to maturity and ending on the day immediately prior to maturity at the greater of (a) 55% of the fair value of the Company's stock or (b) \$0.10 per share.

Subsequent to December 31, 2014, the Company elected to convert a convertible note with a principal balance of \$50,000 and accrued interest of \$5,984 into 222,245 shares of common stock at a conversion price of \$0.25 per share.

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

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

#### **Note 11 - Subsequent Events – Continued**

##### Notes Payable - Continued

Notes payable, non-current portion represents notes payable that were either exchanged for equity or whose maturities were extended past December 31, 2015 after the balance sheet date but before the consolidated financial statements were issued. Accrued interest, non-current portion represents the accrued interest that, after the balance sheet date but before the consolidated financial statements were issued, was either exchanged for equity or converted into the principal amount of a note payable classified as non-current.

##### Employment Agreements

On February 9, 2015, the Company hired a President for its Disc/Spine Division. As compensation the Company granted to the President of its Disc/Spine Division a ten-year option to purchase 500,000 shares of common stock at an exercise price of \$0.46 per share, pursuant to the Plan. The shares vest annually over three years on the grant date anniversaries.

On March 9, 2015, the Company and the CEO agreed to extend the term of his employment agreement to December 31, 2017. Pursuant to the employment agreement, the CEO is entitled to receive a salary of \$400,000 per annum. The CEO is entitled to receive an annual bonus for 2015 equal to 50% of his annual base salary and an annual bonus for the years 2016 and 2017 equal to 50% of his annual base salary in the event certain performance goals, as determined by the Company's Compensation Committee, are satisfied. Pursuant to the employment agreement, in the event that the CEO's employment is terminated by the Company without "cause", or the CEO terminates his employment for "good reason" (each as defined in the employment agreement), the CEO would be entitled to receive severance in an amount equal to one time his then annual base salary and certain benefits, plus \$100,000 (in lieu of bonus). In addition, pursuant to the employment agreement, the CEO would be entitled to receive such severance in the event that the term of his employment agreement is not extended beyond December 31, 2017 and, within three months of such expiration date, his employment is terminated by the Company without "cause" or the CEO terminates his employment for any reason. Further, in the event that the CEO's employment is terminated by the Company without "cause", or the CEO terminates his employment for "good reason", following a "change in control" (as defined in the employment agreement),

the CEO would be entitled to receive severance in an amount equal to one and one-half times his then annual base salary and certain benefits, plus \$300,000 (in lieu of bonus).

On March 9, 2015, the Company agreed to amend the at will employment agreement with its Vice President of Research and Development (“VP of R&D”). Pursuant to the employment agreement, as amended, in the event that the VP of R&D’s employment with the Company is terminated without cause, the VP of R&D would currently be entitled to receive a cash severance payment of \$125,000.

#### Common Stock and Warrant Offerings

Subsequent to December 31, 2014, the Company issued an aggregate of 2,703,333 shares of common stock at prices ranging from \$0.25 to \$0.30 per share to investors for aggregate gross proceeds of \$801,000. In connection with the purchases, the Company issued warrants to purchase an aggregate of 850,833 shares of common stock at exercise prices ranging from \$0.40 to \$0.75 per share of common stock. The warrants have a term of five years. In connection with the common stock and warrant offerings, a previously outstanding warrant to purchase 80,000 shares of common stock at an exercise price of \$0.75 per share had its expiration date extended from December 31, 2015 to December 31, 2016.

#### Stock-Based Compensation

Subsequent to December 31, 2014, the Company issued an aggregate of 270,295 shares of common stock valued at \$73,528 to consultants pursuant to consulting agreements.

On January 23, 2015, the Company granted a five-year option to consultants to purchase an aggregate 100,000 shares of common stock at an exercise price of \$0.47 per share, pursuant to the Plan. The shares vest as follows: (i) 75,000 shares vest ratably over three months on the grant date anniversaries, (ii) 12,500 shares vest immediately and (iii) 12,500 shares vest on the grant date anniversary.