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

United States Securities and Exchange Commission

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

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

Commission File Number **0-54402**

BIORESTORATIVE THERAPIES, INC.

(Exact name of registrant as specified in its charter)

Nevada	**91-1835664**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
555 Heritage Drive, Jupiter, Florida	**33458**
(Address of principal executive offices)	(Zip Code)

(561) 904-6070

(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
None	**Not applicable**

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

Common Stock, par value $0.001 per share

(Title of Class)

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

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

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

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

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of June 30, 2013, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $8,451,297 based on the closing sale price as reported on the OTC Markets. As of April 9, 2014, there were 21,833,014 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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PART I

Forward-Looking Statements

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

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

ITEM 1. BUSINESS.

(a) Business Development

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

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

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

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

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

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

agreement.

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

(b) **Business**

General

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

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

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

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

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

Overview

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

We are developing medical procedures using cell and tissue protocols, primarily involving adult stem cells (non-embryonic), designed for patients to undergo minimally invasive cellular-based treatments. As more and more cellular-based therapies become standard of care, we intend to focus on the unity of medical and scientific explanations for future clinical procedures and outcomes and the provision of adult stem cells for future personal

medical applications. Among the initiatives that we are currently pursuing is our brtxDISC™ (**D**isc **I**mplanted **S**tem **C**ells) Program. We have obtained a license that permits us to use technology for adult stem cell treatment of disc and spine conditions, including protruding, bulging and herniated discs. The technology is an advanced stem cell injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the legs and feet. Another technology we are developing is our ThermoStem® Program. This pre-clinical program involves the use of brown fat in connection with the cell-based treatment of type 2 diabetes and obesity as well as hypertension, other metabolic disorders and cardiac deficiencies. See “Disc/Spine Program” and “Brown Adipose (Fat) Program” below.

We also offer stem cell derived cosmetic and skin care products. Pursuant to our brtx-C Cosmetic Program, we have developed an ingredient derived from human adult stem cells which can be used by third party companies in the development of their own skin care products. Separately, through our wholly-owned subsidiary, Stem Pearls, LLC, we offer facial creams and other skin care products with certain ingredients that may include plant stem cells and/or other plant derived stem cell optimization or regenerative compounds. See “Cosmetic Products” below.

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

We are a development stage enterprise. Our primary activities in the stem cell area have been the development of our business plan, negotiating strategic alliances and other agreements, and raising capital. We have not generated any significant revenues from our operations. The implementation of our business plan, as discussed below, will require the receipt of sufficient equity and/or debt financing to purchase necessary equipment, technology and materials, fund our research and development efforts, retire our outstanding debt (see Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources – Availability of Additional Funds”), establish our laboratory, and otherwise fund our operations. We intend to seek such financing from current shareholders and debtholders as well as from other accredited investors. We anticipate that we will require an aggregate of between approximately $25,000,000 and $50,000,000 in funding to implement our business plan with regard to our brtxDISC™ Program, as further discussed in this Item 1 (assuming the receipt of no revenues from operations) and repay our outstanding debt ($5,754,500 as of December 31, 2013) (assuming that no debt is converted into equity). We will also require a substantial amount of additional funding to implement our other programs discussed in this Item 1. No assurance can be given that the anticipated amounts of required funding are correct or that we will be able to accomplish our goals within the timeframes projected. In addition, no assurance can be given that we will be able to obtain any required financing on commercially reasonable terms or otherwise. We may also seek to have our debtholders convert all or a portion of their debt into equity. No assurance can be given that we will be able to convert such debt into equity on commercially reasonable terms or otherwise. If we are unable to obtain adequate funding, we may be required to significantly curtail or discontinue our proposed operations. See Item 7 (“Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results and Financial Condition - We will need to obtain additional financing to satisfy debt obligations and continue our operations.”).

Strategy

We are concentrating on an initiative for the development of a stem cell delivery system designed to deliver cells and other potential therapeutic material to the spine and discs, as well as the development of appropriate stem cells to be used for transplantation into a disc. We intend to advance the design of the stem cell delivery device and enhance the therapeutic protocols in preparation for clinical trials related to the treatment of protruding, bulging and herniated discs and degenerative disc disease. We refer to this initiative as our brtxDISC™ (**D**isc **I**mplanted **S**tem **C**ells) Program. See “Disc/Spine Program” below.

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

We are also engaging in research efforts with respect to an initiative related to the use of brown adipose (fat) for therapeutic purposes. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of metabolism, thus potentially being involved in caloric regulation. We intend to continue our research activities in this area in connection with the treatment of type 2 diabetes and obesity as well as of hypertension, other metabolic disorders and cardiac deficiencies. We have labeled this initiative our ThermoStem® Program. See “Brown Adipose (Fat) Program” below.

Pursuant to our brtx-C Cosmetic Program, we have developed an ingredient derived from human adult stem cells which we are offering to third parties for use in their production of skin care products. We also offer facial creams and other skin care products with certain ingredients that may include plant stem cells and/or other plant derived stem cell optimization or regenerative compounds. See “Cosmetic Products” below.

We intend to establish a laboratory capable of performing cellular characterization and culturing and therapeutic outcomes analysis with the goal of producing a clinically-approved adult stem cell product and stem cell-related IP. See “Laboratory” and “Technology” below.

Treatment

Regenerative cell therapy relies on replacing diseased, damaged or dysfunctional cells with healthy, functioning ones or repairing damaged or diseased tissue. A great range of cells can serve in cell therapy, including cells found in peripheral and umbilical cord blood, bone marrow and adipose (fat) tissue. Physicians have been using adult stem cells from bone marrow to treat various blood cancers for over 40 years. Recently, the use of stem cells has begun to be used to treat various other diseases. We intend to use and develop cell and tissue regenerative therapy protocols, primarily involving adult stem cells (non-embryonic) to allow patients to undergo cellular-based treatments.

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

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

We intend that the majority of our disc/spine procedures will involve adult stem cells harvested from a patient's own (autologous) cells so that the chance of rejection or disease being spread from donor to patient is low. We intend to focus on developing personalized, patient-specific treatment programs that provide for additional or follow-on therapies, patient outcome monitoring, and the accumulation/analysis of critical medical data. We also intend to carefully monitor patient response and satisfaction.

Disc/Spine Program

Pursuant to a license agreement between Regenerative Sciences, LLC ("Regenerative") and us that became effective in April 2012, we have obtained, among other things, a worldwide, exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain medical device for the administration of specific cells and/or cell products to the disc and/or spine (and other parts of the body) and a worldwide (excluding Asia and Argentina), exclusive, royalty-bearing license to utilize or sublicense a certain method for culturing cells for use in treating, among other things, disc and spine conditions, including protruding, bulging and herniated discs. The technology that has been licensed is an advanced stem cell injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the legs and feet. We intend to advance the design of the stem cell delivery device and enhance the therapeutic protocols in preparation for clinical trials related to the treatment of protruding, bulging and herniated discs and degenerative disc disease. We have labeled this initiative our brtxDISC™ (**D**isc **I**mplanted **S**tem **C**ells) Program.

The license agreement provides for the requirement that we achieve certain milestones or pay certain minimum royalty amounts in order to maintain the exclusive nature of the licenses. The license agreement also provides for a royalty-bearing sublicense of certain of the technology to Regenerative for use for certain purposes, including in the Cayman Islands. Further, the license agreement requires that Regenerative furnish certain training, assistance and consultation services with regard to the licensed technology. Pursuant to the license agreement, we paid to Regenerative a net license fee of $990,000 and issued to Regenerative a five year warrant for the purchase of 1,000,000 shares of our common stock, of which the right to purchase 700,000 shares will vest only when specified performance criteria are met.

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

treatment protocol. We expect that such study will be completed by the third quarter of 2014. Following such study, we intend to file an IND/investigational device exemption ("IDE") application with the FDA with respect to our proposed treatment protocol and initiate clinical trials. The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance. See "Government Regulation" below and Item 7 ("Management's Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results and Financial Condition – We operate in a highly regulated environment and may be unable to comply with applicable federal, state, local, and international requirements. Failure to comply with applicable government regulation may result in a loss of licensure, registration, and approval or other government enforcement actions.").

In 2010, the FDA brought an action to permanently enjoin Regenerative from using its Regenexx™ procedure to process mesenchymal stem cells ("MSCs") for the treatment of various orthopedic conditions. The lawsuit relates to a procedure utilized by Regenerative whereby a patient's own MSC cells are extracted and isolated from the patient's bone marrow, processed at a laboratory on site for two to three weeks to undergo expansion, and then returned to the same patient to treat a medical condition. The FDA has asserted that Regenerative's stem cell procedure is subject to FDA jurisdiction and regulation as an unapproved drug and/or biologic. Regenerative takes the position that the Regenexx™ procedure is the practice of medicine and thereby is outside of the FDA's jurisdiction. It also contends that the manipulation of the stem cells occurs in the normal course of medical practice which is regulated by Colorado, the state in which Regenerative is located. The FDA contends that it is not impinging on Regenerative's ability to practice medicine; instead, it considers the product being reinjected into the patient to be a cultured cell product subject to the FDA's regulations governing the use of human cells, tissues, and cellular and tissue-based products ("HCT/Ps"). According to the FDA's position, the Regenexx™ procedure involves growth factors, reagents and drug products that cross state lines thereby placing the product in interstate commerce. Moreover, the FDA contends that the product is more than "minimally manipulated" and, consequently, does not meet the conditions listed in 21 C.F.R. Part 1271 that exempt HCT/Ps from being regulated as drugs, devices, and/or biological products. Regenerative has agreed to cease production of the cultured cell product while the case is pending. In 2012, the District Court ruled in favor of the FDA, but Regenerative appealed the decision. In February 2014, the United States Court of Appeals for the D.C. Circuit affirmed the District Court's ruling, concluding that the FDA has the authority to regulate certain autologous stem cell procedures and that the Regenexx stem cell mixture meets the definition of drug and not HCT/P since it was more than minimally manipulated. Regenerative has indicated that it does not intend to appeal the decision to the Supreme Court. While this decision is specific to Regenerative's procedures and mixture, it indicates that stem cells, even when used in an autologous context, may be regulated as drugs, particularly when mixed with other substances or in other ways that may be considered to be more than minimally manipulated. Based on this outcome, it may be more likely that we will need to proceed with the FDA approval process for our initiatives as discussed above. See "Government Regulation" below.

Brown Adipose (Fat) Program

Brown fat is a population of adipose (fat) tissue found in the human body and it plays a key role in the evolutionarily conserved mechanisms underlying energy homeostasis in mammals. Human newborns and hibernating mammals have high levels of brown fat and its main function is to generate body heat and regulate metabolism. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of metabolism, thus potentially being involved in caloric regulation.

In June 2011, we launched the initial research phase of what we believe will develop into a technology that involves the use of brown fat in a cell-based therapeutic program referred to as the ThermoStem® Program. The ThermoStem® Program will focus on treatments for type 2 diabetes and obesity, as well as for hypertension, other metabolic disorders and cardiac deficiencies, and will involve the study of stem cells, several genes, proteins and/or mechanisms that are related to these diseases and disorders.

We intend to use adult stem cells that may be differentiated into progenitor or fully differentiated brown adipocytes, or a related cell type, which can be used therapeutically in patients. We are focusing on the development of treatment protocols that utilize allogeneic cells (i.e., stem cells from a genetically similar but not identical donor). As the cellular program advances, we will seek to use the data from the program in the development of a small molecule drug.

Our ThermoStem® Program is in the initial research stage and, to date, we have not developed a clinical application or product. In June 2012, we entered into an Assignment Agreement with the University of Utah Research Foundation (the "Foundation") and a Research Agreement with the University of Utah (the "University"). Pursuant to the Assignment Agreement, we acquired the rights to two patent applications that relate to human brown fat cell lines. In consideration for the assignment, we paid the Foundation $15,000 and agreed to pay a royalty on the Patent Revenue (as defined in the Assignment Agreement). Pursuant to the Research Agreement, the University has agreed to provide research services relating to the identification of brown fat tissue and the development and characterization of brown fat cell lines. Pursuant to the Research Agreement, all inventions, discoveries, patent rights, information, data, methods and techniques, including all cell lines, cell culture media and derivatives thereof, shall be owned by us and we have agreed to pay the University a fee at the rate of $500,000 per annum and a royalty on Net Sales (as defined in the Research Agreement). The Research Agreement has a three year term, except that it is terminable earlier under certain circumstances.

Following our research activities, we intend to undertake preclinical studies in order to determine whether our proposed treatment protocol is safe. Such studies are expected to begin by the fourth quarter of 2014. Following the completion of such studies, if required, we intend to file an investigational new drug ("IND") application with the U.S. Food and Drug Administration (the "FDA") and initiate Phase I clinical trials. See "Government Regulation" below and Item 7 ("Management's Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results and Financial Condition – We operate in a highly regulated environment and may be unable to comply with applicable federal, state, local, and international requirements. Failure to comply with applicable government regulation may result in a loss of licensure, registration, and approval or other government enforcement actions."). The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance. We expect that clinical trials will commence by the third quarter of 2015.

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

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Cosmetic Products

brtx-C Cosmetic Program

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

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

Stem Pearls®

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

Laboratory

We intend to develop a state-of-the-art facility to be used as a laboratory for the possible development of cellular-based treatment protocols and research applications. We anticipate that our laboratory will commence operations by the third quarter of 2014. We are currently utilizing existing laboratories at the University of Utah as discussed above under “Brown Adipose (Fat) Program.”

As operations grow, our plans include the expansion of our laboratory to perform cellular characterization and culturing, stem cell-related IP development and therapeutic outcome analysis. As we develop our business and additional stem cell treatments are approved, we intend to establish ourselves as the provider of adult stem cells for therapies and expand to provide cells in other market areas for stem cell therapy, including with regard to the treatment of type 2 diabetes and obesity as well as other metabolic disorders, heart disease and autoimmune disease.

Technology; Research and Development

We intend to utilize our laboratory or a third party laboratory, such as the one we utilize at the University of Utah (see "Brown Adipose (Fat) Program") in connection with cellular research activities. We also intend to seek to obtain cellular-based therapeutic technology licenses. We intend to seek to develop potential stem cell delivery systems or devices. The goal of these specialized devices is to deliver cells into specific areas of the body, control the rate, amount and types of cells used in a treatment, and populate these areas of the body with sufficient stem cells so that engraftment occurs.

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

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

We have five non-provisional and two provisional patent applications pending in the United States and one application filed in five non-United States jurisdictions. In addition, Regenerative (see “Disc/Spine Program”) has filed certain patent applications with regard to the technology that is the subject of the license agreement between us. We have trademark rights with respect to the design mark BioRestorative Therapies® and the names BioRestorative Therapies™, brtxDISC™, ThermoStem®, Stem Pearls® and Stem The Tides of Time®. Our success will depend in large part on our ability to develop and protect our proprietary technology. We intend to rely on a combination of patent, trade secret and know-how, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success will also depend upon our ability to avoid infringing upon the proprietary rights of others, for if we are judicially determined to have infringed such rights, we may be required to pay damages, alter our services, products or processes, obtain licenses or cease certain activities.

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

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

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

Scientific Advisors

We have established a Scientific Advisory Board whose purpose is to provide advice and guidance in connection with scientific matters relating to our business. Our four Scientific Advisory Board members are Dr. Wayne Marasco, Chairman, Dr. Amit Patel, Dr. Naiyer Imam and Dr. Wayne Olan. In addition, Dr. Gregory Lutz has been retained as our Chief Medical Advisor for Spine Medicine. See Item 10 (“Directors, Executive Officers and Corporate Governance – Scientific Advisors”) for a listing of the principal positions for Drs. Marasco, Patel, Imam, Olan and Lutz.

Competition

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

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

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

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

Customers

Our treatment services are intended to be marketed to the general public via the Internet, and at trade shows to physicians and other health care professionals, skin care professionals and beauty product distributors. We intend to market our product portfolio for clinical applications and to research institutions and large pharmaceutical companies. Our Stem Pearls® product line is offered via the Internet (www.stempearls.com and www.biorestorative.com) and is intended to be sold to stores either directly or by way of distributors. Our cosmetic ingredients are being offered to cosmetic manufacturers and distributors.

Governmental Regulation

U.S. Government Regulation

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

FDA Regulation of Stem Cell Treatment and Products

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

Human Cells, Tissues, and Cellular and Tissue-Based Products ("HCT/Ps") Regulation

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

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

Because we are a development stage enterprise and have not generated significant revenues from operations, it is difficult to anticipate the likely regulatory status of the array of products and services that we may offer. We believe that some of the adult autologous (self-derived) stem cells that will be used in our cellular therapy and biobanking products and services, including the brown adipose (fat) tissue that we intend to use in our ThermoStem Program, may be regulated by the FDA as HCT/Ps under 21 C.F.R. Part 1271. This regulation defines HCT/Ps as articles "containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient." However, the FDA may disagree with this position or conclude that some or all of our stem cell therapy products or services do not meet the applicable definitions and exemptions to the regulation. If we are not regulated solely under the HCT/P provisions, we would need to expend significant resources to comply with the FDA's broad regulatory authority under the FDCA. Recent third party litigation concerning the autologous use of a stem cell mixture to treat musculoskeletal and spinal injuries has increased the likelihood that some of our products and services are likely to be regulated as a drug or biological product and require FDA approval. In the litigation, the FDA

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

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

- registration and listing of HCT/Ps with the FDA;
- donor eligibility determinations, including donor screening and donor testing requirements;
- current good tissue practices, specifically including requirements for the facilities, environmental controls, equipment, supplies and reagents, recovery of HCT/Ps from the patient, processing, storage, labeling and document controls, and distribution and shipment of the HCT/Ps to the laboratory, storage, or other facility;
- tracking and traceability of HCT/Ps and equipment, supplies, and reagents used in the manufacture of HCT/Ps;
- adverse event reporting;
- FDA inspection;
- importation of HCT/Ps; and
- abiding by any FDA order of retention, recall, destruction, and cessation of manufacturing of HCT/Ps.

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

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

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

Drug and Biological Product Regulation

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

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

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

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

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

Medical Device Regulation

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

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

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

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

change in the intended use of a device that was either cleared through the 510(k) process or approved through the PMA process may require further FDA review through new 510(k) or PMA submissions.

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

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

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

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

Good Laboratory Practices

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

Promotion of Foreign-Based Cellular Therapy Treatment—"Medical Tourism"

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

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

Cosmetic and Skin Care Regulation

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

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

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

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