BioRestorative Therapies, Inc.
Form 10-K
March 22, 2017

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, 2016

[ ] **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	**91-1835664**
(State or other jurisdiction	

of incorporation or organization) (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)

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.

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, 2016, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $9,795,332 based on the closing sale price as reported on the OTCQB market. As of March 15, 2017, there were 5,276,027 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.

Intellectual Property

This Annual Report includes references to our federally registered trademarks, *BioRestorative Therapies,* the *Dragonfly Logo*, *brtxDISC, ThermoStem, Stem Cellutrition, Stem Pearls* and *Stem the Tides of Time.* The Dragonfly Logo is also registered with the U.S. Copyright Office. This Annual Report also includes references to trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this Annual Report appear without the ®, SM or ™ symbols, and copyrighted content appears without the use of the symbol ©, but the absence of use of these symbols does not reflect upon the validity or enforceability of the intellectual property owned by us or third parties.

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, 2016, we raised an aggregate of $3,711,236 in connection with sales of common stock and warrants and from the exercise of warrants, and an aggregate of $1,345,470 in net debt financing. As of December 31, 2016, our outstanding debt of $2,336,565, together with interest at rates ranging between 0% and 15% per annum, was due through October 2017. Subsequent to December 31, 2016 and through March 15, 2017, we have received aggregate equity proceeds (including proceeds received from the exercise of common stock purchase warrants) and debt proceeds of $945,000 and $200,000, respectively, debt and accrued interest of $325,000 and $9,679, respectively, has been converted into or exchanged for common stock, $89,000 of debt and net short-term advances have been repaid and the due date for the repayment of $322,000 of debt has been extended through April 2017. Giving effect to the above actions, we currently have notes payable aggregating $427,500 which are past due.

In February 2016, Robert B. Catell joined our Board of Directors. See Item 10 ("Directors, Executive Officers and Corporate Governance").

Between March 2016 and September 2016, we sold to John M. Desmarais, one of our directors and principal stockholders, an aggregate of 330,000 shares of our common stock at an aggregate purchase price of $1,240,000. In June 2016, we borrowed $500,000 from a trust for which Mr. Desmarais serves as a trustee and which was established for the benefit of his immediate family. See Item 10 ("Directors, Executive Officers and Corporate Governance") and Item 13 ("Certain Relationship and Related Transactions, and Director Independence").

In January 2017, we announced that we had submitted an investigational new drug, or an IND, application to the U.S. Food and Drug Administration, or the FDA, to obtain clearance to commence a Phase 2 clinical trial using our lead cell therapy candidate, *BRTX-100*, to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs. In February 2017, we received such clearance from the FDA.

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(b) Business

General

We develop therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult (non-embryonic) stem cells. Our two core programs, as described below, relate to the treatment of disc/spine disease and metabolic disorders:

Disc/Spine Program (brtxDisc). Our lead cell therapy candidate, BRTX-100, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells, or 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 BRTX-100 production process involves collecting bone marrow from a patient, isolating and culturing stem cells from the bone marrow and cryopreserving the cells. In an outpatient procedure, BRTX-100 is to be injected by a physician into the patient's damaged disc. The treatment is intended for patients whose pain has not been alleviated by non-surgical procedures or conservative therapies and who potentially face the prospect of surgery. In January 2017, we submitted an IND application to the FDA to obtain clearance to commence a Phase 2 clinical trial using our lead cell therapy candidate, BRTX-100, to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs. In February 2017, we received such clearance from the FDA. We intend to commence such clinical trial during the fourth quarter of 2017. See "Disc/Spine Program" below.

Metabolic Program (ThermoStem). We are developing a cell-based therapy to target obesity and metabolic disorders using brown adipose (fat) derived stem cells, or BADSC, to generate brown adipose tissue, or BAT. We refer to this as our *ThermoStem Program*. 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. In March 2014, we entered into a Research Agreement with Pfizer, Inc., a global pharmaceutical company, pursuant to which we were engaged to provide research and development services with regard to a joint study of the development and validation of a human brown adipose (fat) cell model. A United States patent related to the *ThermoStem Program* issued in September 2015. See "Metabolic Brown Adipose (Fat) Program" below.

We have also licensed a curved needle device designed to deliver cells and/or other therapeutic products or material to the spine and discs. In August 2015, a United States patent for this device was issued to the licensor, Regenerative Sciences, LLC. 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 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 have focused our initial efforts in offering cellular-based therapeutic 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 a patent, as well as licenses, for the exclusive use of a patent and a patent pending and have undertaken research and development efforts in connection with the development of therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. See “Disc/Spine Program”, “Metabolic Brown Adipose (Fat) Program” and “Curved Needle Device” below.

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 also offer plant stem cell derived facial creams and beauty products under the *Stem Pearls* brand. 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, or 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 between $8,000,000 and $10,000,000 in financing to commence and complete a Phase 2 clinical trial and we will require between $20,000,000 and $30,000,000 in further additional funding to complete our clinical trials using *BRTX-100*, as further discussed in this Item 1 (assuming the receipt of no revenues from operations), repay our outstanding debt ($2,336,565 as of December 31, 2016) (assuming that no debt is converted into equity) and fund general operations. 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 *BRTX-100*. 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, or 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. According to a recent market report, there are nearly 25 million people in the United States with chronic lower back pain of which approximately 5 million have pain caused by a protruding or bulging disc. We believe that between 500,000 and 1 million of these back pain sufferers will have an invasive surgical procedure to try to alleviate the pain associated with these lower back conditions. 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 low in cellularity. Therefore, its inherent capacity to heal after injury is poor. The clinical rationale of *BRTX-100* is to deliver a high concentration of the patient's own MSCs into the site of pathology to promote healing and relieve pain.

We have developed a mesenchymal stem cell product, *BRTX-100,* derived from autologous (or a person's own) human bone marrow, cultured and formulated to be delivered into a protruding or bulging disc.

In January 2017, we announced that we had submitted an IND application to the FDA to obtain clearance to commence a Phase 2 clinical trial using our lead cell therapy candidate, *BRTX-100*, to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs. In February 2017, we received such clearance from the FDA. We intend to commence such clinical trial during the fourth quarter of 2017.

In addition to developing *BRTX-100*, 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, which includes a clean room facility, to perform the production of cell products (including *BRTX-100*) for use in our clinical trials. We intend to certify the operation of the cleanroom by the third quarter of 2017. 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.

BRTX-100

Our lead therapeutic product*, BRTX-100,* is an autologous hypoxic (low oxygen) cultured mesenchymal stem cell product derived from a 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 delivery of *BRTX-100*, 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 *BRTX-100* 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, *BRTX-100* is expanded under hypoxic conditions for a period of approximately three weeks. This process results in a cell population with enhanced viability and therapeutic potential following injection locally into injured spinal discs. Publications and scientific literature have indicated 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 *BRTX-100* 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 (or a contract laboratory) for culturing and formulation. 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, with an additional two weeks required for quality control testing required to meet product release criteria. We will then send the therapeutic cryopreserved stem cells (*BRTX-100*) in a sterile vial back to the physician's offices where it will be thawed prior to the procedure. The price structure for the procedure and our services has not been

determined and no assurances can be given in this regard. The following illustrates the process.

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License

Pursuant to our license agreement with Regenerative Sciences, LLC, or Regenerative, 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 curved needle device for the administration of specific cells and/or cell products to the disc and/or spine (and other parts of the body). It will be necessary to advance the design of this medical 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 United States and the Cayman Islands. Further, the license agreement requires that Regenerative furnish certain training, assistance and consultation services with regard to the licensed technology.

Animal Study

The efficacy and safety of *BRTX-100* has been tested in a degenerative intervertebral rabbit disc model. In this study, 80 rabbits underwent surgery to create a puncture in the discs. Four weeks post surgery, each rabbit had either contrast, a biomaterial carrier or *BRTX-100* injected into the discs. In order to study the biodistribution and efficacy of *BRTX-100*, the rabbits were evaluated at day 56 and day 120.

The key safety findings of the animal study are as follows:

There was no evidence or observation of gross toxicity related to the administration of *BRTX-100* at either time point. The clinical pathology across both groups and time points were within expected normal historical ranges and under the conditions of the test. No abnormalities (including fractures or overt signs of lumbar disc disease) were identified after review of the radiographic images taken at both endpoints for both groups. No toxicity or adverse finding was evident in the systemic tissues or the discs of animals receiving *BRTX-100*.

There was no detectable presence of human cells (*BRTX-100*) observed at the day 56 interim time point. This is consistent with the proposed mechanism of action that *BRTX-100* acts through a paracrine effect of secreted growth and immunomodulation factors.

The key efficacy findings of the animal study are as follows:

BRTX-100 showed a statistically significant DHI (disc height increase) over the control group at day 120.

BRTX-100 showed a statistically significant improvement in disc histology over the control group at day 120 as graded by a validated histology scale. *BRTX-100* showed a significant improvement in the cellularity and matrix of the disc when compared to the control at day 120.

Clinical Trial

In December 2014, we held a pre-IND meeting with the FDA's 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 the disc program. The FDA representatives identified certain necessary pre-clinical research and data as well as various suggestions to modify the clinical trial design. We believe that these comments and suggestions will not materially impact our plans for a clinical trial. In January 2017, we announced that we had submitted an IND application to the FDA to obtain clearance to commence a Phase 2 clinical trial using our lead cell therapy candidate, *BRTX-100*, to treat chronic lower back pain due to

degenerative disc disease related to protruding/bulging discs. In February 2017, we received such clearance from the FDA. We intend to commence such clinical trial during the fourth quarter of 2017. One of the principal investigators 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 following describes the Phase 2 clinical trial cleared by the FDA:

A Phase 2 Prospective, Double-Blinded, Placebo Controlled, Randomized Study

General

72 patients; randomized 2:1, *BRTX-100* to control

10-20 clinical trial sites

Primary efficacy endpoint at 6 months

Patient follow up at 12 and 24 months

Primary Efficacy Endpoint

Responder endpoint - % of patients that meet the improvement in function and reduction in pain threshold

Improvement in function defined as at least a 30% increase in function based on the Oswestry questionnaires (ODI)

Reduction of pain defined as at least a 30% decrease in pain as measured using the Visual Analogue Scale (VAS)

Additional or Secondary Endpoints

Quality of life assessment

Evolution of affected disc(s) by magnetic resonance imaging (MRI)

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”).

Metabolic Brown Adipose (Fat) Program

Since June 2011, we have been engaging in pre-clinical research efforts with respect to a platform technology utilizing brown adipose (fat) derived stem cells for therapeutic purposes. We have labeled this initiative our *ThermoStem Program*.

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. The pre-clinical *ThermoStem 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. We have had initial success in transplanting the tissue in animals, and we are currently exploring ways to deliver the brown fat tissue into humans. Even though present, BAT mass is very low in healthy adults and even lower in obese populations. Therefore, it may not be sufficient to either naturally impact whole body metabolism, or to be targeted by drugs intended to increase its activity in the majority of the population. Increasing BAT mass is crucial in order to benefit from its metabolic activity and this is what our *ThermoStem Program* seeks to accomplish. We may also identify other naturally occurring and chemically engineered molecules that may enhance brown adipose tissue performance.

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 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.

We are developing a cell-based therapy to target obesity and metabolic disorders using BADSC. Our goal is to develop a bioengineered 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 of 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. We are identifying technology for *in vivo* delivery in small animal models. Having completed our proof of concept using our BAT in small animals, we are currently developing our next generation BAT. It is anticipated that this next version will contain a higher purity of BADSC, which is expected to increase the therapeutic effect compared to our first generation product. In addition, we are exploring the delivery of the therapeutic using encapsulation technology, which will only allow for reciprocal exchange of small molecules between the host circulation and the BAT implant. We expect that encapsulation may present several advantages over our current biological scaffolds, including prevention of any immune response or implant rejection that might occur in an immunocompetent host and an increase in safety by preventing the implanted cells from invading the host tissues and forming tumors. We have developed promising data on the transplantation of human stem cell-derived tissue engineered brown fat into an encapsulation device to be used as a cell delivery system for our metabolic platform program for the treatment of type 2 diabetes, obesity, hyperlipidemia and hypertension. This advancement may lead to successful transplantation of brown fat in humans. By successfully seeding human BADSC into an encapsulation device, we are advancing the development of our cell therapy program to treat metabolic disorders. This data is expected to progress our program to enable transplanted brown adipose cells to effectively maintain or regulate normal metabolism in humans. We are evaluating the next generation of BAT constructs that will first be tested in small animal models. No assurance can be given that this delivery system will be effective *in vivo* in animals or humans. 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.

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In June 2012, we entered into an Assignment Agreement with the University of Utah Research Foundation, or the Foundation, and a Research Agreement with the University of Utah, or the Utah Research Agreement. Pursuant to the Assignment Agreement, which provides for royalty payments, we acquired the rights to two provisional patent applications that relate to human brown fat cell lines. No royalty amounts are payable to date. The applications have been converted to a utility application in the United States and several foreign jurisdictions. Pursuant to the Utah Research Agreement, the University of Utah, or the University, provided research services relating to the identification of brown fat tissue and the development and characterization of brown fat cell lines. The Utah Research Agreement provides that all inventions, discoveries, patent rights, information, data, methods and techniques, including all cell lines, cell culture media and derivatives thereof, are owned by us.

In February 2014, our research with regard to the identification of a population of brown adipose derived stem cells was published in *Stem Cells*, a respected stem cell journal.

In March 2014, we entered into a Research Agreement with Pfizer Inc, or the Pfizer Research Agreement, a global pharmaceutical company. Pursuant to the Pfizer Research Agreement, we were engaged to provide research and development services with regard to a joint study of the development and validation of a human brown adipose (fat) cell model. The Pfizer Research Agreement provided 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, all of which has been received.

In August 2015, we entered into a one year research collaboration agreement with the University of Pennsylvania with regard to the understanding of brown adipose (fat) biology and its role in metabolic disorders. No amounts are payable by or to us pursuant to this agreement.

In September 2015, a United States patent related to the *ThermoStem Program* was issued to us.

Following our research activities, we intend to undertake preclinical studies in order to determine whether our proposed treatment protocol is safe. Such studies are planned to begin by the third quarter of 2017. Following the completion of such studies, if required, we intend to file an IND with the FDA and initiate a clinical trial. 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 laboratory facility, outside core facilities at academic, research or medical institutions, or 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, or 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. In August 2015, a United States patent for the CND was issued to the licensor, Regenerative Sciences, LLC. 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 laboratory in Melville, New York for research purposes and have built a cleanroom within the laboratory for the possible production of cell-based therapies, such as *BRTX-100*, for use in a clinical trial. We intend to certify the operation of the cleanroom by the third quarter of 2017.

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. 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 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 two pending United States patent applications with regard to two patent families. We have been issued a United States patent with regard to one of the two patent families. Patent applications with regard to one patent family have been filed in five foreign jurisdictions (of which one application has become inactive). In addition, a Patent Cooperation Treaty, or PCT, application has been filed with regard to a second patent family and such PCT application has been filed in four foreign jurisdictions. 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-License” above). Regenerative has been issued a patent with regard to its curved needle therapeutic delivery device. Our patent applications and those of Regenerative are currently in prosecution (i.e., we and Regenerative are seeking issued patents). A description of the patent applications and issued patents is set forth below:

Program	**I.D.**	**Jurisdiction**	**Title**
Disc/Spine	13/132,840*	US	Methods and compositions to facilitate repair of avascular tissue
	U.S. Patent No. 9,113,950 B2**	US	Therapeutic delivery device
Metabolic	U.S. Patent No. 9,133,438	US	Brown fat cell compositions and methods
	13/932,468	US	
	2012275335	Australia	
	12743811.7	Europe	
	230237	Israel	
	2014-519026	Japan	
	14/255,595	US	Human brown adipose derived stem cells and uses
	PCT/US2014/034540	Patent Cooperation Treaty	
	2014253920	Australia	
	14729769.1	Europe	
	242150	Israel	
	2016-509105	Japan	

*Patent application filed by licensor, Regenerative Sciences, LLC
**Patent issued to licensor, Regenerative Sciences, LLC

In March 2014, we entered into a Research and Development Agreement with Rohto Pharmaceutical Co., Ltd., a Japanese pharmaceutical company. Pursuant to the Rohto Research and Development Agreement, we were engaged to provide research and development services with regard to stem cells. The Rohto Research and Development Agreement provided 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 (all of which has been earned and received). The Rohto Research and Development Agreement expired in June 2015.

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

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We have secured registrations in the U.S. Patent and Trademark Office for the following trademarks:

THERMOSTEM
STEM CELLUTRITION
STEM PEARLS, and
STEM THE TIDES OF TIME.

We also have federal common law rights in the trademarks, BioRestorative Therapies, *BRTX-100*, and other trademarks used in the conduct of our business that are not registered.

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, non-compete 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. We conduct prior rights searches before launching any new product or service to put us in the best position to avoid claims of infringement.

During the years ended December 31, 2016 and 2015, we incurred $2,883,563 and $2,105,059, respectively, in research and development expenses.

Cosmetic Products

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. No arrangements with regard to the commercial distribution of products that utilize our extract as a cosmetic ingredient are currently in place or are under consideration.

We offer plant derived stem cell cosmetic products under the *Stem Pearls* brand. We have not commenced marketing efforts or generated any significant revenue with regard to *Stem Pearls* products.

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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. Naiyer Imam, 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, 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 with regard to the disc and spine include, among others, Isto Biologics, Harvest Technologies (acquired by Terumo), Celling Biosciences, Mesoblast, Tissue Genesis, Discgenics and Arthrex. Companies that are developing products and therapies to combat obesity, diabetes and other metabolic disorders including through the use of brown fat, include, among others, Pfizer, AstraZeneca, Genentech (acquired by Roche), Eli Lilly, Amgen, Energesis Pharmaceuticals, Sanofi, Novo Nordisk, Johnson & Johnson, Novartis, GlaxoSmithKline, Bristol-Myers Squibb, Mitsubishi Tanabe Pharma, Takeda Pharmaceutical, Vivus, Arena Pharmaceuticals, Teva Pharmaceuticals, Merck, Blu Pharmaceuticals (acquired by PuraCap Pharmaceutical), BioTime, Merz Pharmaceuticals, ViaCyte and Regeneron. 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 their products and therapies to market in competition with those that we are pursuing.

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. Although the FDA has approved several biosimilar products, complex provisions of the law are still being implemented by the FDA and interpreted by the federal courts. As a result, the ultimate impact, implementation, and meaning of the BPCIA are still subject to some uncertainty and FDA actions and court decisions concerning the law could have a material adverse effect on the future commercial prospects for our biological 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.

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 *BRTX-100*. These physicians would include interventional physiatrists (physical medicine physicians), pain management-anesthesiologists, interventional radiologists and neurosurgeons.

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 Service Act, or PHSA, and the Federal Food, Drug, and Cosmetic Act, or FDCA. Stem cells can be regulated under FDA’s Human Cells, Tissues, and Cellular and Tissue-Based Products Regulations, or HCT/Ps, or may also be subject to FDA’s drug, biological product, or medical device regulations, each as discussed below.

Human Cells, Tissues, and Cellular and Tissue-Based Products 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, or 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 an enterprise in the early stages of operations 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. 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 the 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; and

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

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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 notify the FDA 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, or IND, application and an approved new drug application, or 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, or 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.

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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).

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, or 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 investigational device exemption, or IDE, regulations of 21 C.F.R. Part 812. Nonsignificant risk devices are subject to abbreviated requirements that do not require a submission to the 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 the FDA and the 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, or 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 United States 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, or 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 CFR. 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 nonclinical studies that are intended to support FDA submissions 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.

The Federal Trade Commission, or the 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, or the 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.

Federal Regulation of Clinical Laboratories

Congress passed the Clinical Laboratory Improvement Amendments, or CLIA, in 1988, which provided the Centers for Medicare and Medicaid Services, or CMS, authority over all laboratory testing, except research, that is 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, or 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, or HIPAA, included the *Administrative Simplification* provisions that required the Secretary of the Department of Health and Human Services, or 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*, or the Privacy Rule, and the *Security Standards for the Protection of Electronic Protected Health Information*, or 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 (referred to as "covered entities"). The Security Rule establishes a national security standard for safeguarding protected health information that is held or transferred in electronic form (referred to as "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, or 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 (we refer to these regulations as 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 related to the importation of biological material into the United States;
- other laws and regulations administered by the FDA;

other laws and regulations administered by HHS;

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 Statute 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 Administration, or OSHA, regulations and requirements;

the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to "excess benefit transactions" with 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. 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 eleven 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 expires in March 2020; 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.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information

Transactions in our common stock are currently reported under the symbol "BRTX" on the OTCQB market. The following table sets forth the range of high and low bids reported in the over-the-counter market for our common stock. On July 7, 2015, we effected a 1-for-20 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
2015 Calendar Year		
First Quarter	$9.90	$7.00
Second Quarter	$9.70	$6.00
Third Quarter	$12.25	$5.50
Fourth Quarter	$6.09	$2.95

	High	Low
2016 Calendar Year		
First Quarter	$4.45	$2.61
Second Quarter	$4.48	$3.40
Third Quarter	$3.91	$2.71
Fourth Quarter	$3.68	$2.90

Holders

As of March 15, 2017, there were 288 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, 2016, 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, or the Securities Act, as transactions by an issuer not involving any public offering or Section 3(a)(9) of the Securities Act as a security exchanged by an issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. 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, 2015, Quarterly Reports on Form 10-Q for the periods ended March 31, 2016, June 30, 2016 and September 30, 2016 and Current Reports on Form 8-K filed with the Securities and Exchange Commission, and press releases made by us), and we were available to answer questions by prospective investors. We reasonably believe that each of the investors is an accredited investor. The proceeds were used to reduce our working capital deficiency and for other corporate purposes.

Date Issued	Common Stock	Warrants Shares	Exercise Price	Term (Years)	Purchaser(s)	Consideration (1)	
10/10/16	52,658				(2)	$ 78,986	(3)
10/19/16	7,500				(4)	$ 15,000	(5)
10/21/16-12/23/16	193,323	193,323	4.00	5	(2)	$ 579,966	
10/24/16	13,041				(2)	$ 26,212	(6)
11/7/16	10,515				(2)	$ 21,047	(6)
11/22/16	10,874				(2)	$ 21,140	(6)

(1) The value of the non-cash consideration was estimated to be the fair value of our restricted common stock. Since our shares are thinly traded in the open market, the fair value of our equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares.

(2) Accredited investor.

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

(4) Consultant.

(5) Issued in consideration of consulting services.

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

Issuer Purchases of Equity Securities

During the quarter ended December 31, 2016, 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, 2016 and 2015 and for the years ended December 31, 2016 and 2015 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 16. References in this Management's Discussion and Analysis of Financial Condition and Results of Operations to "us," "we," "our," and similar terms refer to BRT. This Annual Report contains forward-looking statements as that term is defined in the federal securities laws. The events described in forward-looking statements contained in this Annual Report may not occur. Generally these statements relate to business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions to be made by us, or projections involving anticipated revenues, earnings or other aspects of our operating results. The words "may," "will," "expect," "believe," "anticipate," "project," "plan," "intend," "estimate," and "continue," and their opposites and similar expressions, are intended to identify forward-looking statements. We caution you that these statements are not guarantees of future performance or events and are subject to a number of uncertainties, risks and other influences, many of which are beyond our control, which may influence the accuracy of the statements and the projections upon which the statements are based. Reference is made to "Factors That May Affect Future Results and Financial Condition" in this Item 7 for a discussion of some of the uncertainties, risks and assumptions associated with these statements.

Overview

We develop therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult (non-embryonic) stem cells. We are currently pursuing our *Disc/Spine Program* with our initial therapeutic product being called *BRTX-100*. We have obtained a license 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. We are also developing 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. A United States patent related to the *ThermoStem Program* was issued in September 2015.

We are developing a patented curved needle device, or CND, that is a needle system to allow access to difficult to locate regions for the delivery or removal of fluids and other substances. We also offer stem cell derived cosmetic and skin care products.

Our offices are located in Melville, New York where we have established a 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, 2016, our accumulated deficit was $41,959,798, our stockholders' deficiency was $5,000,282 and our working capital deficiency was $5,783,184. We have historically only generated 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, 2016 and our forecast for continued operating losses, we require equity and/or debt financing to continue our operations. As of December 31, 2016, our outstanding debt of $2,336,565, together with interest at rates ranging between 0% and 15% per annum, was due on various dates through October 2017. Subsequent to December 31, 2016 and through March 15, 2017, we have received aggregate equity proceeds (including proceeds from the exercise of common stock purchase warrants) and debt proceeds of $945,000 and $200,000, respectively, debt and accrued interest of $325,000 and $9,679, respectively, has been converted into or exchanged for common stock, $89,000 of debt and net short-term advances have been repaid and the due date for the repayment of $322,000 of debt has been extended through April 2017. Giving effect to the above actions, we currently have notes payable aggregating $427,500 which are past due. Based upon our working capital deficiency and outstanding debt, we expect to be able to fund our operations through April 2017. We anticipate that we will require between $8,000,000 and $10,000,000 in financing to commence and complete a Phase 2 clinical trial with regard to our *Disc/Spine Program*. We anticipate that we will require between $20,000,000 and $30,000,000 in further additional funding to complete our clinical trials with regard to our *Disc/Spine Program*. We will also require a substantial amount of additional funding if we determine to establish a manufacturing operation with regard to our *Disc/Spine Program* (as opposed to utilizing a third party manufacturer) and to implement our other programs discussed in "Business", including our metabolic *ThermoStem Program*. 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 are currently seeking several different financing alternatives to support our future operations and are currently in the process of negotiating extensions or discussing conversions to equity with respect to our outstanding indebtedness. If we are unable to obtain such additional financing on a timely basis or, 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

IND Application

In January 2017 we announced that we had submitted an investigational new drug, or IND, application to the U.S. Food and Drug Administration, or the FDA, to obtain clearance to commence a Phase 2 clinical trial using our lead cell therapy candidate, *BRTX-100*, to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs. In February 2017, we received such clearance from the FDA. We intend to commence such clinical trial during the fourth quarter of 2017. See Item 1 ("Business – Disc/Spine Program").

Consolidated Results of Operations

Year Ended December 31, 2016 Compared with Year Ended December 31, 2015

The following table presents selected items in our consolidated statements of operations for the years ended December 31, 2016 and 2015, respectively:

	For the Years Ended, December 31,	
	2016	**2015**
Revenues	$36,355	$628,915
Cost of sales	102	261,504
Gross Profit	36,253	367,411
Operating Expenses		
Marketing and promotion	86,451	168,352
Consulting	1,605,917	1,394,037
Research and development	2,883,563	2,105,059
General and administrative	3,257,579	3,870,325
Total Operating Expenses	7,833,510	7,537,773
Loss From Operations	(7,797,257)	(7,170,362)

Other Income (Expense)		
Interest expense	(221,608)	(263,583)
Amortization of debt discount	(542,336)	(339,443)
Loss on extinguishment of notes payable, net	(58,787)	(35,677)
Warrant modification expense	(28,486)	(114,415)
Gain on settlement of payables	12,182	-
Total Other Expense	(839,035)	(753,118)
Net Loss	$(8,636,292)	$(7,923,480)

Revenues

For the year ended December 31, 2016, we generated $36,000 from royalty revenue in connection with our sublicense agreement and $355 from sales of *Stem Pearls* skincare products. For the year ended December 31, 2015, we generated $609,490 of revenues through the services provided pursuant to our research and development agreements, $19,000 from royalty revenue in connection with our sublicense agreement and $425 from sales of *Stem Pearls* skincare products. The decrease in our revenues for the year ended December 31, 2016 versus 2015 was primarily due to the completion of our obligations under our research and development agreements as of December 31, 2015, and as of the date of this filing there were no new research and development agreements.

Cost of sales

For the year ended December 31, 2016, cost of sales was $102 as compared to $261,504 for 2015. For the year ended December 31 2016, cost of sales consisted of the costs of the underlying *Stem Pearls* skincare products. For the year ended December 31, 2015, cost of sales consisted primarily of the portion of employee salary expense, consultant fees, and laboratory supplies expense related to our research and development agreements. The decrease in our cost of sales for the year ended December 31, 2016 versus 2015 was due to the completion of our obligations under our research and development agreements during 2015.

Gross Profit

For the year ended December 31, 2016, gross profit declined to $36,253 (approximately 100% of revenues) as compared to $367,411 (58% of revenues) for the year ended December 31, 2015, primarily due to completion of obligations under our research and development agreements during 2015.

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, 2016, marketing and promotion expenses decreased by $81,901, or 49%, from $168,352 to $86,451, as compared to the year ended December 31, 2015. The decrease is primarily due to reduced travel activity and associated costs of approximately $79,000.

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

Consulting

Consulting expenses consist of consulting fees and stock-based compensation to consultants. For the year ended December 31, 2016, consulting expenses increased $211,880, or 15%, from $1,394,037 to $1,605,917, as compared to the year ended December 31, 2015. The increase is primarily due to an approximately $180,000 increase in consultant stock-based compensation expense related to options granted to directors and consultants and a $75,000 increase in cash director fees related to the appointment of two additional directors in 2016, partially offset by a decrease of

approximately $43,000 in other cash consulting fees.

Research and development

Research and development expenses include cash and non-cash compensation of (a) our Chief Executive Officer (in part during 2015); (b) our Vice President of Research and Development; (c) our Scientific Advisory Board members; (d) our President, Disc/Spine Division; and (e) laboratory staff 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, 2016, research and development expenses increased by $778,504, from $2,105,059 to $2,883,563, or 37%, as compared to the year ended December 31, 2015. The increase is primarily related to an approximately $560,000 increase in payroll and associated taxes due to salary raises, increased headcount and cash bonuses, an approximately $196,000 increase in costs related to a third party laboratory associated with our disc/spine initiative, and an approximately $76,000 increase in stock-based compensation to our Vice President of Research and Development, President, Disc/Spine Division, and Scientific Advisory Board members, partially offset by an approximately $108,000 decrease due to our Chief Executive Officer no longer devoting time to 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 (through 2015); (b) our Vice President of Research and Development; (c) our President, Disc/Spine Division; and (d) our laboratory staff) as well as corporate support expenses such as legal and professional fees, investor relations and occupancy related expenses. For the year ended December 31, 2016, general and administrative expenses decreased by $612,746, or 16%, from $3,870,325 to $3,257,579, as compared to the year ended December 31, 2015. The decrease is primarily related to decreased professional fees of approximately $965,000, mainly incurred in connection with our 2015 aborted underwritten public offering and a 2015 legal settlement, partially offset by an increase of approximately $326,000 in stock-based compensation to employees and our Chief Executive Officer.

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, 2016, interest expense decreased $41,975, or 16%, to $221,608 as compared to $263,583 during the year ended December 31, 2015. The decrease was due to a reduction in interest-bearing short-term borrowings as compared to the year ended December 31, 2015.

Amortization of debt discount

For the year ended December 31, 2016, amortization of debt discount increased by $202,893 or 60%, to $542,336 as compared to $339,443 during the year ended December 31, 2015. The increase was primarily due to the timing of the recognition of expense related to the beneficial conversion features of convertible notes and the recognition of the debt discount expense.

Loss on extinguishment of notes payable, net

For the year ended December 31, 2016, we recorded a loss on extinguishment of notes payable, net, of $58,787, which is associated with investors' exchange of debt into equity securities, as compared to a loss on extinguishment of notes payable of $35,677 for the year ended December 31, 2015.

Warrant modification expense

During the year ended December 31, 2016, we recorded expense related to the modification of outstanding warrants of $28,486, as compared to expense related to the modification of outstanding warrants of $114,415 for the year ended December 31, 2015.

Gain on settlement of payables, net

During the year ended December 31, 2016, we recorded a gain on settlement of payables, net, of $12,182. We had no such gains during the year ended December 31, 2015.

Liquidity and Capital Resources

Liquidity

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

	December 31, 2016	2015
Cash	$31,822	$166,555
Working Capital Deficiency	$(5,783,184)	$(5,323,179)

Notes Payable (Gross)	$2,336,565	$1,470,083

Availability of Additional Funds

Based upon our working capital and stockholders' deficiency of $5,783,184 and $5,000,282, respectively, as of December 31, 2016, we require additional equity and/or debt financing to continue our operations. These conditions indicate that there is substantial doubt about our ability to continue as a going concern within the next twelve months from the date of this filing.

As of December 31, 2016, our outstanding debt of $2,336,565, together with interest at rates ranging between 0% and 15% per annum, was due on various dates through October 2017. Subsequent to December 31, 2016 and through March 15, 2017, we have received aggregate equity proceeds (including proceeds from the exercise of common stock purchase warrants) and debt proceeds of $945,000 and $200,000, respectively, debt and accrued interest of $325,000 and $9,679, respectively, has been converted into or exchanged for common stock, $89,000 of debt and net short-term advances have been repaid and the due date for the repayment of $322,000 of debt has been extended through April 2017. Giving effect to the above actions, we currently have notes payable aggregating $427,500 which are past due. As of the date of filing, our outstanding debt was as follows:

Maturity Date	Principal Amount
Past Due	$427,500
QE 3/31/2017	20,000
QE 6/30/2017	428,000
QE 9/30/2017	867,000
QE 12/31/2017	437,063
	$2,179,563

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 2017. 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, or GAAP, 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, 2016, 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, 2016 and 2015 in the amounts of $5,002,675 and $3,122,063, respectively. The net cash used in operating activities for the year ended December 31, 2016 was primarily due to cash used to fund a net loss of $8,636,292, adjusted for non-cash expenses in the aggregate amount of $3,464,871, partially offset by $168,745 of cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in 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, 2015 was primarily due to cash used to fund a net loss of $7,923,480, adjusted for non-cash expenses in the aggregate amount of $2,743,141, partially offset by $2,058,276 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, 2016, net cash used in investing activities was $188,764 used for the purchase of medical equipment. During the year ended December 31, 2015, net cash used in investing activities was $483,069 due to $408,069 used for the purchase of medical equipment, leasehold improvements and computer equipment plus $75,000 used to retain the exclusivity of our disc/spine license.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the years ended December 31, 2016 and 2015 was $5,056,706 and $3,679,889, respectively. During the year ended December 31, 2016, $1,345,471 of net proceeds were from debt financings and $3,711,236 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, 2015, $1,382,045 of net proceeds were from debt financings and $2,297,844 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. Our significant estimates and assumptions include the recoverability and useful lives of long-lived assets, the fair value of our equity securities and the valuation allowance related to our deferred tax assets. Certain of our estimates, including the carrying amount of the intangible assets, could be affected by external conditions, including those unique to us and general economic conditions. It is reasonably possible that these external factors could have an effect on our estimates and could cause actual results to differ from those estimates.

Intangible Assets

Intangible assets are comprised of trademarks and licenses with original estimated useful lives of 10 and 17.7 years, 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. While our near term liquidity is tight, historically we have been successful in raising capital as needed (although there can be no assurance that we will continue to be successful in raising capital as needed). We continue to progress our scientific agenda and meet related milestones. We have not identified any impairment losses.

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, or the Plan, were registered on May 27, 2014, we estimate the fair value of the awards granted under the Plan based on the market value of our freely tradable common stock as reported on the OTCQB market. The fair value of our restricted equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares. Awards granted to directors are treated on the same basis as awards granted to employees.

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 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 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. To allow entities additional time to implement systems, gather data and resolve implementation questions, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, in August 2015, to defer the effective date of ASU No. 2014-09 for one year, which is fiscal years beginning after December 15, 2017. We are currently evaluating the impact of the adoption of ASU 2014-09 on our consolidated financial statements or disclosures.

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 explicitly requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist which raise substantial doubt about an entity’s ability to continue as a going concern and to provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and annual and interim periods thereafter, with early adoption permitted. The adoption of this standard did not have a material impact on our financial statement disclosures.

In April 2015, the FASB issued ASU No. 2015-03, “Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs”, or ASU 2015-03. ASU 2015-03 amends the existing guidance to require that debt issuance costs be presented in the balance sheet as a deduction from the carrying amount of the related debt liability instead of as a deferred charge. ASU 2015-03 is effective on a retrospective basis for annual and interim reporting periods beginning after December 15, 2015; earlier adoption is permitted. Additionally, in August 2015, the FASB issued guidance expanding the April 2015 update (ASU No. 2015-15). It states that, given the absence of authoritative guidance within the update, the SEC staff would not object to an entity deferring and presenting debt issuance costs as an asset for revolving lines of credit and subsequently amortizing the deferred debt issuance costs ratably over the term of the arrangement, regardless of whether there are any outstanding borrowings on the line of credit. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years, with early adoption permitted for financial statements that have not been previously issued. Full retrospective application is required. The adoption of this standard did not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842)” (“ASU 2016-02”). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. ASU 2016-02 will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. We are currently evaluating ASU 2016-02 and its impact on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, “Compensation – Stock Compensation (Topic 718)” (“ASU 2016-09”). ASU 2016-09 requires an entity to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, with early adoption permitted. We are currently evaluating ASU 2016-09 and its impact on our consolidated financial statements or disclosures.

In April 2016, the FASB issued ASU 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing” (“ASU 2016-10”). The amendments in this update clarify the following two aspects to Topic 606: identifying performance obligations and the licensing implementation guidance, while retaining the related principles for those areas. The entity first identifies the promised goods or services in the contract and reduces the cost and complexity. An entity evaluates whether promised goods and services are distinct. Topic 606 includes implementation guidance on determining whether an entity’s promise to grant a license provides a customer with either a right to use the entity’s intellectual property (which is satisfied at a point in time) or a right to access the entity’s intellectual property (which is satisfied over time). ASU 2016-10 is effective for fiscal years beginning after December 15, 2017, including interim reporting periods within that reporting period. We are currently evaluating ASU 2016-10 and its impact on our consolidated financial statements or disclosures.

In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments” (“ASU 2016-15”). The new standard will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2017. We will require adoption on a retrospective basis unless it is impracticable to apply, in which case we would be required to apply the amendments prospectively as of the earliest date practicable. We are currently evaluating ASU 2016-15 and its impact on our consolidated financial statements or disclosures.

Off-Balance Sheet Arrangements

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

Factors That May Affect Future Results and Financial Condition

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

Risks Related to Our Business Generally

We have a 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; we believe these conditions indicate that there is substantial doubt about our ability to continue as a going concern within the next twelve months from the date of this filing; 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 limited operating history. Since our inception, we have incurred net losses. As of December 31, 2016, we had a working capital deficiency of $5,783,184 and stockholders' deficiency of $5,000,282. We believe these conditions indicate that there is substantial doubt about our ability to continue as a going concern within the next twelve months from the date of this filing. The report of our independent registered public accounting firm with respect to our financial statements as of December 31, 2016 and 2015 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, 2016 and 2015 and for the years then ended, which are included following Item 16 ("Form 10-K Summary"). Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We will need to obtain a significant amount of financing to initiate and complete our clinical trials and implement our business plan.

Since our inception, we have not generated significant revenues from our operations and have funded our operations through the sale of our equity securities (approximately $14,000,000) and debt securities (approximately $12,000,000). The implementation of our business plan, as discussed in Item 1 ("Business"), 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 and otherwise fund our operations. We anticipate that we will require between $8,000,000 and $10,000,000 in financing to commence and complete a Phase 2 clinical trial with regard to our *Disc/Spine Program.* We anticipate that we will require between $20,000,000 and $30,000,000 in further additional funding to complete our clinical trials using *BRTX-100*. We will also require a substantial amount of additional funding if we determine to establish a manufacturing operation with regard to our *Disc/Spine Program* (as opposed to utilizing a third party manufacturer) and to implement our other programs discussed in Item 1 ("Business"), including our metabolic *ThermoStem Program*. 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. In the event we do not obtain the financing required for the above purposes, 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.

We will need to obtain additional financing to satisfy debt obligations.

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, 2016, our outstanding debt of $2,336,565, together with interest at rates ranging between 0% and 15% per annum, are due on various dates through October 2017. Subsequent to December 31, 2016 and through March 15, 2017, we have received aggregate equity proceeds (including proceeds received from the exercise of common stock purchase warrants) and debt proceeds of $945,000 and $200,000, respectively, debt and accrued interest of $325,000 and $9,679, respectively, has been converted into or exchanged for common stock, $89,000 of debt and short-term advance have been repaid and the due date for the repayment of $322,000 of debt has been extended through April 2017. Giving effect to the above actions, we currently have notes payable aggregating $427,500 which are past due. As of March 15, 2017, the outstanding balance of our debt of $2,179,563, together with accrued interest, was due and payable between on demand and October 2017. 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 2017. 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.

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* metabolic 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 certain license and research and development agreements described in Item 1 (“Business”), 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 have any key-man insurance policies on the lives of any of our executive officers. 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 products and services 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 BRTX-100, 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, *BRTX-100*, is in early stages of development and we only recently received FDA clearance to commence a Phase 2 clinical trial using *BRTX-100* to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs.

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;

the requirement by the FDA that we conduct additional research or studies, and/or to provide additional preclinical data, prior to or in connection with our clinical 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 anticipate that we will not be able to commercialize our *BRTX-100* product for at least five years.

We may experience delays and other difficulties in enrolling a sufficient number of 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.

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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 *BRTX-100* 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 *BRTX-100* 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 current Good Manufacturing Practices, or 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 is 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.

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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 (or a contract laboratory) to provide the cell processing services necessary for clinical production of *BRTX-100* 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 *BRTX-100* 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 *BRTX-100* 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 (which expired in June 2015) 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 Program.* There is no certainty that we will be able to continue to collect brown adipose samples through relationships that we may establish 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 Program.*

We are required to complete a certain milestone or pay a certain royalty amount 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 our license agreement with Regenerative Sciences, LLC, we must complete a certain milestone or pay a certain royalty amount in order to maintain our exclusive rights with regard to the disc/spine technology. No assurances can be given that we will achieve such milestone or have the funds, if necessary, to pay such royalty amount. Any loss of such exclusive rights would have a material adverse effect upon our business, results of operations and financial condition. See Item 1 (“Business - (b) Business - Disc/Spine Program-License").

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 products, 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.

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.

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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 six 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, *BRTX-100* 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 *BRTX-100*, 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. Although the FDA has approved several biosimilar products, complex provisions of the law are still being implemented by the FDA and interpreted by the federal courts. As a result, the ultimate impact, implementation, and meaning of the BPCIA are still subject to some uncertainty and FDA actions and court decisions concerning the law could have a material adverse effect on the future commercial prospects for our biological 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 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 maintain insurance coverage adequate to cover our clinical trials and increase that coverage before commercializing product candidates, if ever. At any time during our clinical trials or after commercialization, if that occurs, 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, result in 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.

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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.

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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 additional patents will be issued to us or, if issued, that such patents 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, or 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 the Patent 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.

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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, Federal Circuit Courts of Appeal, and the Supreme Court. The effects of these decisions are still not known. The first major change is that AIA switches the United States 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 addition the Supreme Court has recently taken more limiting positions as to what constitutes patentable subject matter. As a result, many patents covering what were previously patentable inventions are now determined to cover inventions which are deemed non-statutory subject matter and are now invalid. As a result of this and subsequent opinions by the Court of Appeals for the Federal Circuit, the Patent Office is now applying more stringent limitations to claims in patent applications and is refusing to grant patents in areas of technology where patents were previously deemed available. Therefore there is a risk that we will be unable to acquire patents to cover our products and if such patents are granted they may subsequently be found to be invalid.

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.

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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, the FTC the 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 New York-based laboratory and any treatment centers we may 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. Even if our products are approved, FDA regulation of promotional and manufacturing activities can affect our ability to market a drug, biologic or medical device. These products must 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. 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 fails to comply with the applicable regulations, we will be out of compliance with FDA regulations, which could adversely affect our business. Discovery after FDA 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.

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.

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 may 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.

CMS has authority to implement the Clinical Laboratories Improvement Amendments, or CLIA, program. When we begin laboratory 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.