# 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, 2020**

[ ] **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 **001-37603**

# 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 | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **None** | **Not applicable** | **Not applicable** |

Securities registered pursuant to Section 12(g) of the Act:
**Common Stock, par value $0.0001 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 every Interactive Data File required to be submitted 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 such files). Yes [X] No [ ]

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

| | |
|---|---|
| Large accelerated filer [ ] | Accelerated filer [ ] |
| Non-accelerated filer [X] | Smaller reporting company [X] |
| | Emerging growth company [ ] |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. [ ]

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

As of June 30, 2020, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $159,424 based on the closing sale price as reported on the OTC market.

APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY

PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes [X] No [ ]

As of April 27, 2021, there were 3,175,977,710 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None

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## PART I

### Forward-Looking Statements

This Annual Report contains forward-looking statements as that term is defined in the federal securities laws. The events described in forward-looking statements contained in this Annual Report may not occur. Generally these statements relate to business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions to be made by us, or projections involving anticipated revenues, earnings or other aspects of our operating results. The words "may," "will," "expect," "believe," "anticipate," "project," "plan," "intend," "estimate," and "continue," and their opposites and similar expressions are intended to identify forward-looking statements. We caution you that these statements are not guarantees of future performance or events and are subject to a number of uncertainties, risks and other influences, many of which are beyond our control, that may influence the accuracy of the statements and the projections upon which the statements are based. Factors which may affect our results include, but are not limited to, the risks and uncertainties discussed in Item 7 of this Annual Report ("Management's Discussion and Analysis of Financial Condition and Results of Operations - "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 and Dragonfly design*, *BRTX-100*, *ThermoStem and Stem Pearls*. We also own an allowed trademark application for *BRTX*. 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.

In January 2017, we submitted an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration (the "FDA") to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. In February 2017, we received such authorization from the FDA.

#### Material Events During 2020

In March 2020, our collaboration with the University of Pennsylvania resulted in a publication in *Cell Reports*, a respected peer reviewed journal, with regard to our *ThermoStem Program*.

In March 2020, a United States patent related to our *ThermoStem Program* was issued to us.

In April 2020, a European patent related to our *ThermoStem Program* was issued to us. This European patent was validated in Belgium, France, Germany, Italy, Poland, Spain, Sweden, Switzerland, and the United Kingdom.

In May 2020, an Israeli patent related to our *ThermoStem Program* was issued to us.

During the period from January 1, 2020 through March 19, 2020 (prior to the commencement of the Chapter 11 reorganization discussed below), we received aggregate equity and debt financing of $10,000 and $441,762, respectively.

During the Chapter 11 reorganization proceeding, we received debtor-in-possession financing of $1,189,413 as well as debt financing in the aggregate amount of $3,848,548 at the effective date of our plan of reorganization. We have not received any equity financing since the commencement of our Chapter 11 reorganization proceeding and have not received any debt financing following the effective date of our plan of reorganization.

**Material Events During 2021**

In January 2021, a European patent related to our *ThermoStem Program* was issued to us. This European patent was validated in France, Germany, Italy, Spain, and the United Kingdom.

In March 2021, a United States patent related to our *ThermoStem Program* was issued to us.

In March 2021, a notice of allowance was issued for a separate United States patent application in the *ThermoStem Program*. This application is expected to issue as a United States patent in the next few months.

On March 18, 2021, Nickolay Kukekov, Ph.D. was elected as one of our directors.

**Chapter 11 Reorganization**

On March 20, 2020 (the "Petition Date"), we filed a voluntary petition commencing a case under chapter 11 of title 11 of the U.S. Code in the United States Bankruptcy Court for the Eastern District of New York (the "Bankruptcy Court").

On August 7, 2020 we and Auctus Fund, LLC ("Auctus"), our largest unsecured creditor and a stockholder as of the Petition Date, filed an Amended Joint Plan of Reorganization (the "Plan") and on October 30, 2020, the Bankruptcy Court entered an order (the "Confirmation Order") confirming the Plan, as amended. Amendments to the Plan are reflected in the Confirmation Order. On November 16, 2020 (the "Effective Date"), the Plan became effective.

Reference is made to Item 1.03 of our Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 20, 2020 (https://www.sec.gov/Archives/edgar/data/1505497/000102177120000081/0001021771-20-000081-index.htm) for a description of the Plan, as amended and confirmed by the Confirmation Order, and the events that had occurred as of the filing date, which Item 1.03 is incorporated herein by reference.

Effective as of the Effective Date, as contemplated by the Plan, Mark Weinreb, A. Jeffrey Radov, Paul Jude Tonna and Robert B. Catell resigned as directors of the Company and Mr. Weinreb resigned as our President, Chief Executive Officer and Chairman of the Board.

Effective as of the Effective Date, as contemplated by the Plan, Lance Alstodt was elected President, Chief Executive Officer, Chairman of the Board and a director of the Company and Francisco Silva, our Vice President, Research and Development, was elected a director of the Company. See Item 10 of this Annual Report ("Directors, Executive Officers and Corporate Governance").

**(b) Business**

**General**

We are a life sciences company focused on the development of regenerative medicine products and therapies using cell and tissue protocols, primarily involving adult (non-embryonic) stem cells. Our two core developmental 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 ("MSCs") collected from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complimentary therapeutic to a surgical procedure. The *BRTX-100* production process involves collecting bone marrow and whole blood from a patient, isolating and culturing (in a proprietary method) stem cells from the bone marrow and cryopreserving the cells in an autologous carrier. In an outpatient procedure, *BRTX-100* is to be injected by a physician into the patient's painful 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 highly invasive surgical procedures. We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100* in the treatment of chronic lower back pain arising from degenerative disc disease. We have received such authorization from the FDA. We intend to commence such clinical trial during 2021 (assuming the receipt of necessary funding). See "Disc/Spine Program" below.

- ***Metabolic Program (ThermoStem)***. We are developing a cell-based therapy candidate to target obesity and metabolic disorders using brown adipose (fat) derived stem cells ("BADSC") to generate brown adipose tissue ("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 animals may be responsible for additional caloric burning, as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. See "Metabolic Brown Adipose (Fat) Program" below.

We have also licensed an investigational curved needle device designed to deliver cells and/or other therapeutic products or material to the spine and discs (and other parts of the body). We anticipate that FDA approval or clearance will be necessary for this device prior to commercialization. We do not intend to utilize this device in connection with our contemplated Phase 2 clinical trial with regard to *BRTX-100*. See "Curved Needle Device" below.

The patents and patent applications for the *Disc/Spine Program*, the *ThermoStem Program* and the curved needle device are listed below under "Technology; Research and Development."

**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 more than 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. We also believe that these procedures will be significantly less expensive than the most common surgical procedure alternatives and will compare favorably, over the long-term, to conservative treatment costs which may persist for years.

Accordingly, we have focused our initial developmental efforts on cellular-based therapeutic products and clinical development 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. Upon regulatory approval, 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 undertaken research and development efforts in connection with the development of investigational 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. As a result of these programs, we have obtained five United States patents and seven foreign patents related to research regarding our *ThermoStem Program*, we have obtained licenses for one patent application related to our *Disc/Spine Program* and we have obtained a license for one United States patent related to a curved needle device.

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

We have not generated any significant revenues from our operations. The implementation of our business plan, as discussed below, will require the receipt of sufficient equity and/or debt financing to purchase necessary equipment, technology and materials, fund our research and development efforts, including our contemplated clinical trials, retire our outstanding debt (if such debt is not converted into equity) (see Item 7 of this Annual Report - "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 stockholders and debtholders as well as from other 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 approximately $12,000,000 in financing to complete a Phase 2 clinical trial investigating the use of *BRTX-100* in the treatment of chronic lower back pain arising from degenerative disc disease and that we will require approximately $45,000,000 in further additional funding to complete such clinical trials, as further described in this section (assuming the receipt of no revenues from operations). We will also require a substantial amount of additional funding to implement our other programs described in this section, repay our outstanding debt (assuming such debt is not converted into equity) and fund general operations. 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 debtholders will convert such debt into equity. If we are unable to obtain adequate funding, we may be required to significantly curtail or discontinue our proposed operations. See Item 7 of this Annual Report ("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 a significant amount of financing to initiate and complete our clinical trials and implement our business plan. – We may need to obtain additional financing to satisfy debt obligations. An event of default pursuant to our outstanding debt obligations could trigger an acceleration of the due date of such obligations, including our secured debt.").

***Disc/Spine Program***

*General*

Among the initiatives that we are currently pursuing is our *Disc/Spine Program*, with our initial product candidate 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. The technology is an advanced stem cell culture and injection procedure into the intervertebral disc ("IVD") that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the leg and foot.

Lower back pain is the most common, most disabling, and most costly musculoskeletal ailment faced worldwide. According to a recent market report, of the 250 million American adults, nearly 25 million have chronic lower back pain of which approximately 12 million have been diagnosed with and treated for disc degeneration and approximately 5.6 million have pain caused by a protruding or injured disc. We believe that between 500,000 and 1 million invasive surgical procedures are performed each year to try to alleviate the pain associated with these lower back conditions and that such procedures cost approximately $40 billion. Clinical studies have documented that the source of the pain is most frequently damage to the IVD. This can occur when forces, whether a single load or repetitive microtrauma, exceed the IVD's inherent capacity to resist those loads. Aging, obesity, smoking, lifestyle, and certain genetic factors may predispose one to an IVD injury. Current surgical approaches to back pain are extremely invasive (often altering the spine's biomechanics unfavorably and predisposing it to further disc degeneration) and are associated with unacceptably low success rates (with a second operation occurring 10% to 20% of the time). In addition, current surgical approaches are costly with spinal fusion surgery costing approximately $110,000, discectomy costing approximately $20,000 to $50,000 and disc replacement surgery costing approximately $80,000 to $150,000. Even conservative treatments can be costly, with oral medications costing between $1,000 and $2,000 per year, injection treatments costing approximately $8,000 per year and physical therapy costing approximately $20,000 annually. We anticipate that the cost of a single treatment using BRTX-100 will compare favorably to conservative treatments which may continue for years and will be less expensive than the most common surgical procedures.

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 cultured MSCs into the site of pathology to promote healing and relieve pain.

We have developed a mesenchymal stem cell product candidate, *BRTX-100*, derived from autologous (or a person's own) human bone marrow, cultured and formulated, in a proprietary method, specifically for introduction into a painful lumbar disc. As described below under "*BRTX-100*" and "*Production and Delivery*," *BRTX-100* is a hypoxic (low oxygen) stem cell product. In order to enhance the survivability of our bone marrow-derived MSCs in the avascular environment of the damaged disc, *BRTX-100* is designed to expand under hypoxic conditions. This process is intended to result in a large cell count population with enhanced viability and therapeutic potential following injection into the injured disc.

We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We received such authorization from the FDA in February 2017. We intend to commence such clinical trial during 2021 (assuming the receipt of necessary funding).

In addition to developing *BRTX-100*, we may also seek to sublicense the technology to a strategic third party, who may assist in gaining FDA approval for a lumbar disc indication, or third parties for use in connection with cellular-based developmental 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 (possibly including *BRTX-100*) for use in our clinical trials, for third party cell products or for general research purposes. We may also use this laboratory to develop our pipeline of future products and expand our stem cell-related IP. See "Laboratory" and "Technology; Research and Development" below.

*BRTX-100*

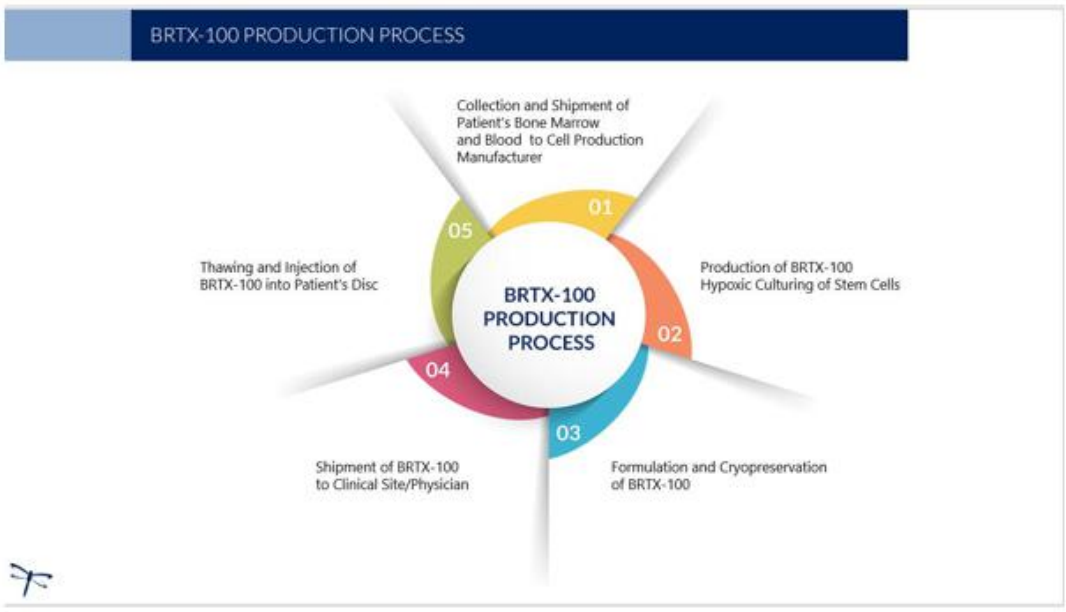
Our lead product candidate, *BRTX-100*, is an autologous hypoxic (low oxygen) cultured mesenchymal stem cell product derived from a patient's own bone marrow and formulated with a proprietary biomaterial carrier (platelet lysate) to increase potency, viability and survivability. We have designed the cryopreserved sterile cellular product candidate to be provided in vials for injection into painful lumbar discs. We anticipate the product candidate will be delivered using a standard 20 gauge 3.5 inch introducer needle and a 25 gauge 6 inch needle that will extend into the disc center upon delivery. Upon regulatory approval, we plan to provide training to medical practitioners with regard to the approved injection procedure. It is anticipated that the delivery of the product candidate will be a 30 minute procedure.

Mesenchymal stem cells 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 designed to expand under hypoxic conditions for a period of approximately three weeks. This process is intended to result in an approximate 40 million cell count 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 properties and improved impacts upon circulation and vascular formation compared to MSCs cultured under normoxic (normal oxygen) conditions.

In August 2018, the *Journal of Translational Medicine* published the results of our study evaluating the benefits of long-term hypoxic culturing of human bone marrow-derived MSCs.

*Production and Delivery*

The production of our product candidate, *BRTX-100*, begins with the physician collecting bone marrow from the patient under 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 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. We anticipate that 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 undergo a controlled thaw prior to the procedure. The price structure for the procedure and our services has not been determined and no assurances can be given as to the effect that such price structure will have on the marketability of such procedure and services. The following illustrates the process:




*License*

Pursuant to our license agreement with Regenerative Sciences, LLC ("Regenerative") that became effective in April 2012 (the "Regenerative License Agreement") 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 our developmental program involving disc and spine conditions, including protruding or painful discs and the treatment of avascular zones. The investigational 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 leg and foot. Pursuant to the Regenerative License Agreement, we have also obtained a worldwide, exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain investigational 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 investigational 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 Regenerative License Agreement currently provides for the requirement that we complete our Phase 2 clinical trial by a certain date (which we believe to be February 2022) in order to maintain the exclusive nature of the licenses. The Regenerative License Agreement also provides for a royalty-bearing sublicense of certain aspects of the technology to Regenerative for use for certain purposes, including in the United States and the Cayman Islands. Further, the Regenerative License Agreement requires that Regenerative furnish certain training, assistance and consultation services with regard to the licensed technology. The patents that are the subject of the Regenerative License Agreement have been assigned to Regenexx, LLC which we have been advised is an affiliate of Regenerative.

*Animal Study*

The efficacy and safety of our product candidate, *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*

We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We have received such authorization from the FDA. We intend to commence such clinical trial during 2021 (assuming the receipt of necessary funding).

The following describes the Phase 2 clinical trial authorized by the FDA:

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

- General
  - 99 patients; randomized 2:1, *BRTX-100* to control, 40 million cells/dose
  - 10-20 clinical trial sites
  - Primary efficacy endpoint at 12 months
  - Patient safety and efficacy follow up at 24 months
  - Included subjects must have only one symptomatic diseased disc
  - Included subjects must have current diagnosis of chronic lumbar disc disease typical pain with degeneration of a single disc confirmed by history, exam, radiography, or other acceptable means
  - Included subjects must have exhausted previous conservative non-operative therapies

- 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

  - Clinical response at 12 months
  - Changes from baseline in pain as assessed with the VAS score and ODI at weeks 2, 12, 26, 52 and 104
  - Changes from baseline in function as assessed with the ODI at weeks 2, 12, 26, 52 and 104
  - Changes from baseline in function as assessed by Roland Morris Disability Questionnaire (RMDQ) at weeks 26, 52 and 104
  - Changes from baseline function as assessed by Functional Rating Index (FRI) at weeks 12, 52 and 104
  - Changes from baseline Quality of Life assessment (SF-12 questionnaire) scores at weeks 2, 12, 26, 52 and 104

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 of this Annual Report ("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.").

As an alternative to undertaking the Phase 3 clinical trial ourselves, we may explore the licensing of our rights with respect to our product candidate, *BRTX-100*, to a strategic partner. Such an arrangement could possibly eliminate or significantly reduce the need to raise the substantial capital needed to commence and complete the clinical trials and undertake the commercialization of *BRTX-100* and would provide licensing-related revenue to us. No assurance can be given that any licensing agreement will be entered into, whether upon commercially reasonable terms or otherwise.

*Defined Health Report*

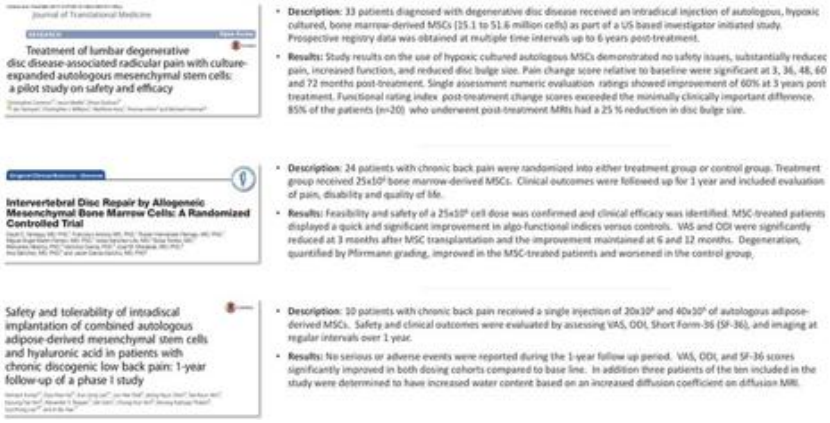
In March 2018, we engaged Defined Health, a business development and strategy consulting firm, to conduct an independent review of *BRTX-100*. Defined Health has worked with many of the leading companies in the pharmaceutical, biotech and healthcare industries for over 25 years.

The review was intended to collect informed, independent opinions regarding *BRTX-100* among key opinion leaders ("KOLs") (i.e., orthopedic surgeons specializing in back and spine surgery with experience in stem cell therapy), who, upon studying applicable clinical material, could offer opinions regarding the future therapeutic potential of *BRTX-100*.

As noted in the Defined Health report, the KOLs indicated that stem cell therapies have great potential to treat chronic lumbar disc disease and other therapeutic areas. The KOLs reacted positively to the value proposition of our product candidate, *BRTX-100*, and were optimistic that the clinical data presented to date is likely to be mirrored in future clinical investigations. Given the opportunity, the KOLs indicated that they would likely participate in a clinical trial should it be offered at their center and that they would recommend the study to appropriately eligible patients. The report indicated that, if *BRTX-100* were to be granted FDA approval, the KOLs anticipate that it would be integrated into the standard of care for eligible chronic lumbar disc disease patients.

*Similar Therapies*

Human data from studies of therapies comparative to *BRTX-100* have shown reduced pain, increased function, and an absence of significant safety issues with a durable response, as shown below:




*Impact on Public Health*

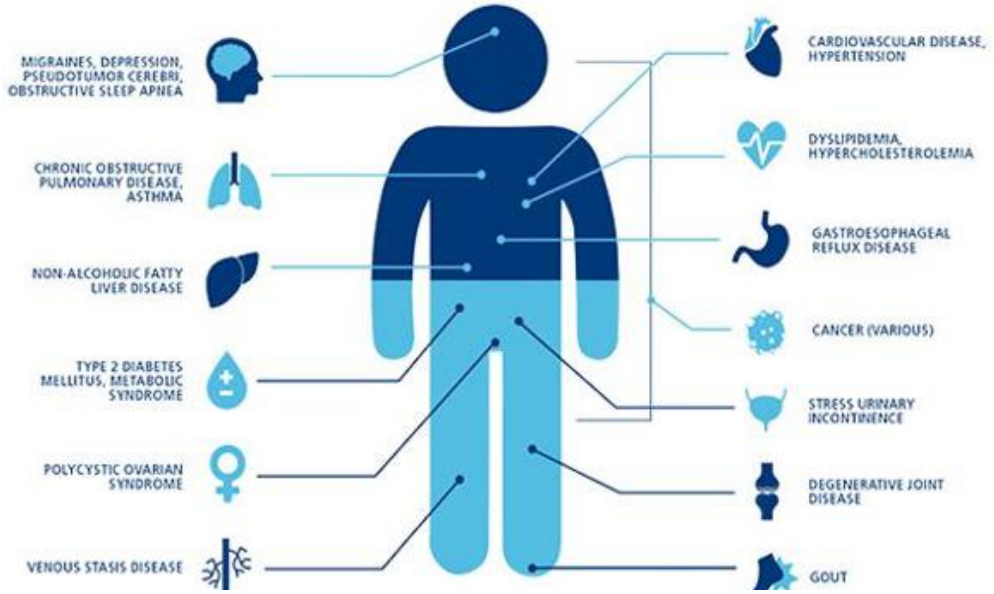
The United States is the world's leading consumer of hydrocodone (99%) and oxycodone (83%) and leads the world in per capital consumption of such drugs (twice as much as second ranked Canada). Each year 42,000 Americans die from overdoses and in 2012 there were enough pain prescriptions in the United States for every adult to obtain a bottle of pills.

Total annual healthcare and lost productivity costs in the United States related to pain, including headache, back pain and neck pain, are estimated to be $600 billion, which is twice the annual costs related to heart disease and greater than the combined annual costs related to cancer and diabetes.

**Metabolic Brown Adipose (Fat) Program**

Since June 2011, we have been engaging in pre-clinical research efforts with respect to an investigational platform technology utilizing brown adipose (fat) derived stem cells ("BADSCs") 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 construct) treatment for metabolic disease, such as type 2 diabetes, obesity, hypertension and other metabolic disorders, as well as cardiac deficiencies. The diseases, disorders and syndromes that may be targeted by our *ThermoStem* Program are as follows:




We have had initial success in transplanting the brown adipose tissue construct in animals, and we are currently exploring ways to deliver 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 biologics and chemically engineered molecules that may enhance brown adipose tissue performance and activity.

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. White and brown adipose tissues are found in mammals. White adipose tissue's 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 product candidate to target obesity and metabolic disorders using BADSCs. Our goal is to develop a bioengineered implantable brown adipose tissue construct 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 BADSCs onto 3-dimensional biological scaffolds. Pre-clinical animal models of diet-induced obesity, that were transplanted with differentiated BADSCs supported by a biological scaffold, presented significant reductions in weight and blood glucose levels compared to scaffold only 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 and a greater percent of functional brown adipocytes, 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. We have developed promising data on the loading 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. 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.

In June 2012, we entered into an Assignment Agreement with the University of Utah Research Foundation (the "Foundation") and a Research Agreement with the University of Utah (the "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 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 2019, we entered into a Services Agreement with the University of Utah pursuant to which the university has been retained to provide research services with regard to the *ThermoStem Program*. Pursuant to this agreement, we will initiate preclinical models to study the efficacy of our generation 2 encapsulated brown adipose tissue construct.

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., a global pharmaceutical company ("Pfizer"). Pursuant to the Research Agreement with Pfizer, 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 cell model. The Research Agreement with Pfizer 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 biology and its role in metabolic disorders. In September 2018, we entered into a one year material transfer agreement with the University of Pennsylvania pursuant to which the university was provided access to our proprietary brown adipose tissue cells for research purposes. No amounts were payable by or to us pursuant to either agreement.

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

In April 2017, an Australian patent related to the *ThermoStem Program* was issued to us.

In December 2017, a Japanese patent related to the *ThermoStem Program* was issued to us.

In January 2019, a United States patent related to the *ThermoStem Program* was issued to us.

In October 2019, an Australian patent related to the *ThermoStem Program* was issued to us.

In October 2019, an Israeli patent related to the *ThermoStem Program* was issued to us.

In March 2020, a United States patent related to our *ThermoStem Program* was issued to us.

In March 2020, our collaboration with the University of Pennsylvania resulted in a publication in *Cell Reports*, a respected peer reviewed journal, with regard to our *ThermoStem Program*.

In April 2020, a European patent related to our *ThermoStem Program* was issued to us. This European patent was validated in Belgium, France, Germany, Italy, Poland, Spain, Sweden, Switzerland, and the United Kingdom.

In May 2020, an Israeli patent related to our *ThermoStem Program* was issued to us.

In January 2021, a European patent related to our *ThermoStem Program* was issued to us. This European patent was validated in France, Germany, Italy, Spain, and the United Kingdom.

In March 2021, a United States patent related to our *ThermoStem Program* was issued to us.

In March 2021, a notice of allowance was issued for a separate United States patent application in the *ThermoStem Program*. This application is expected to issue as a United States patent in the next few months.

We have completed proof of concept preclinical animal studies using our first generation brown adipose derived stem cells. We intend to undertake additional preclinical animal studies in order to optimize delivery and explore the feasibility of targeting additional indications. Such studies are planned to begin by the third quarter of 2021 (assuming the receipt of necessary financing). Following the completion of such studies, we intend to file an IND with the FDA and initiate a clinical trial. See "Government Regulation" below and Item 7 of this Annual Report ("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 an investigational curved needle device ("CND") that is a needle system with a curved inner cannula to allow access to difficult-to-locate regions for the delivery or removal of fluids and other substances. The investigational 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 is designed to rely 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 investigational 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 investigational device may also have more general use applications. In August 2015, a United States patent for the CND was issued to the licensor, Regenerative. We anticipate that FDA approval or clearance will be necessary for the investigational CND prior to commercialization. We do not intend to utilize the CND in connection with our contemplated Phase 2 clinical trial with regard to *BRTX-100*. See "Government Regulation" below and Item 7 of this Annual Report ("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 product candidates, such as *BRTX-100*, for use in a clinical trial, for third party cell products or general research purposes.

As operations grow, our plans include the expansion of our laboratory to perform cellular characterization and culturing, protocol and stem cell-related IP development, translational research and therapeutic outcome analysis. As we develop our business and our stem cell product candidates and obtain regulatory approval, 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 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 designed to enhance cellular growth and regeneration for the purpose of improving pre-treatment and post-treatment outcomes.

In our *Disc/Spine Program*, two patent applications have been filed with regard to technology that is the subject of the Regenerative License Agreement (see "Disc/Spine Program-License" above). Regenerative has been issued a patent from one of these applications with regard to its curved needle therapeutic delivery device. The other application remains pending. The patents that are the subject of the Regenerative License Agreement have been assigned to Regenexx, LLC which we have been advised is an affiliate of Regenerative.

In our *ThermoStem Program*, we have two pending United States patent applications and five United States patents within three patent families. With regards to the first patent family in the *ThermoStem Program*, patent applications have been filed in five foreign jurisdictions (of which four applications have been granted as foreign patents and one application, which is not listed in the table below, has lapsed). With regards to the second patent family in the *ThermoStem Program*, patent applications have been filed in four foreign jurisdictions (of which three applications have been granted as foreign patents). With regards to the third patent family in the *ThermoStem Program*, a U.S. application and PCT application have been filed.

Our patent applications and those of Regenexx, LLC are currently in prosecution (i.e., we and Regenexx, LLC are seeking issued patents). A description of the active patent applications and issued patents is set forth in the table below:

| Program | Patent Family | I.D. | Jurisdiction | Title |
|---|---|---|---|---|
| *Disc/Spine (brtxDisc)* | 1 | 16/441,897* | US | Methods and compositions to facilitate repair of avascular tissue |
| | 1 | U.S. Patent No. 9,113,950 B2** | US | Therapeutic delivery device |
| *Metabolic (ThermoStem)* | 2 | U.S. Patent No. 9,133,438 | US | Brown fat cell compositions and methods |
| | 2 | U.S. Patent No. 10,597,638 | US | |
| | 2 | 15/910,625*** | US | |
| | 2 | AU Patent No. 2012275335 | Australia | |
| | 2 | EP Patent No. 2726603 (validated in Belgium, France, Germany, Italy, Poland, Spain, Sweden, Switzerland, and the United Kingdom) | Europe | |
| | 2 | IL Patent No. 230237 | Israel | |
| | 2 | JP Patent No. 6243839 | Japan | |
| | 3 | U.S. Patent No. 10,167,449 | US | Human brown adipose derived stem cells and uses |
| | 3 | U.S. Patent No. 10,941,383 | US | |
| | 3 | 17/165,074 | US | |
| | 3 | AU Patent No. 2014253920 | Australia | |
| | 3 | 2019240634 | Australia | |
| | 3 | EP Patent No. 2986714 (validated in France, Germany, Italy, Spain, and the United Kingdom) | Europe | |
| | 3 | 20204990.4 | Europe | |
| | 3 | IL Patent No. 242150 | Israel | |
| | 3 | 274995 | Israel | |
| | 3 | 2016-509105 | Japan | |
| | 3 | 2019-95972 | Japan | |
| | 4 | 16/862,226 | US | Non-naturally occurring three-dimensional (3D) brown adipose-derived stem cell aggregates, and methods of generating and using the same |
| | 4 | PCT/US2020/030520 | PCT | |

*Patent application filed by licensor assignee, Regenexx, LLC
**Patent issued to licensor assignee, Regenexx, LLC
***Application has been allowed, but not yet issued as a US patent.

In March 2014, we entered into a Research and Development Agreement with Rohto Pharmaceutical Co., Ltd., a Japanese pharmaceutical company ("Rohto"). Pursuant to the Research and Development Agreement with Rohto, we were engaged to provide research and development services with regard to stem cells.

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

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

- 

- BRTX-100
- THERMOSTEM
- STEM PEARLS

We own an allowed application in the U.S. Patent and Trademark Office for the trademark *BRTX*. The *Dragonfly Logo* is also registered with the U.S. Copyright Office.

We also have federal common law rights in the trademark *BioRestorative Therapies* and other trademarks and trade names 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.

During the years ended December 31, 2020 and 2019, we incurred $876,829 and $1,722,338, respectively, in research and development expenses.

**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. The Scientific Advisory Board has established a Disc Advisory Committee which focuses on matters relating to our *Disc/Spine Program*. Our Scientific Advisory Board members are Dr. Wayne Marasco (Chairman), Dr. Naiyer Imam, Dr. Wayne Olan, Dr. Joy Cavagnaro, Dr. Jason Lipetz, Dr. Harvinder Sandhu, Dr. Christopher Plastaras and Dr. Gerard A. Malanga. The Disc Advisory Committee members are Dr. Lipetz (Chairman), Dr. Olan, Dr. Sandhu, Dr. Plastaras and Dr. Malanga. See Item 10 of this Annual Report ("Directors, Executive Officers and Corporate Governance–Scientific Advisors") for a listing of the principal positions for Drs. Marasco, Imam, Olan, Cavagnaro, Lipetz, Sandhu, Plastaras and Malanga.

**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.

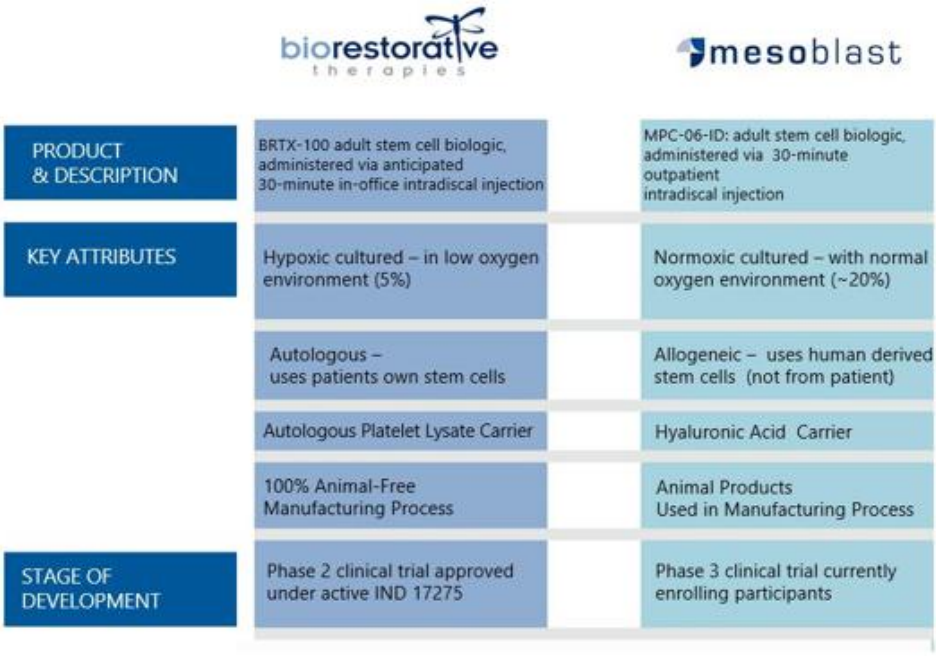
Companies working in the area of regenerative medicine with regard to the disc and spine include, among others, Mesoblast, SpinalCyte, DiscGenics and Isto Biologics. Companies that are developing products and therapies to combat obesity and diabetes, including through the use of brown fat, include, among others, Novo Nordisk, Sanofi, Merck, Eli Lilly, Roche, Pfizer 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 (the "BPCIA"), an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. For the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and the proposed biosimilar product. Interchangeability requires that a product is biosimilar to the reference product, and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years following approval of the reference product, and it may not be approved by the FDA until 12 years after the original branded product is approved under a biologics license application ("BLA").

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.

Set forth below is a comparison of *BRTX-100* to Mesoblast's adult stem cell biologic:




We believe that *BRTX-100* has competitive advantages to Mesoblast's product for the following reasons:

- The use of autologous cells results in low to no risk of rejection, greater safety profile (introduction of viral/genetic) and streamlined regulatory path
- Hypoxic culturing creates increased cell proliferation, greater plasticity, increased paracrine effect and increased cell survival after application
- Autologous platelet lysate provides growth factors that interact with the cells, allowing for better cell survival
- Low to no risk of safety concerns related to immunological and zoonotic (animal to human) transmission
- Strong runway for value creation with successful clinical results

**Customers**

Upon regulatory approval, our cell product candidates 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* upon regulatory approval. 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 FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, approval, manufacture, distribution and marketing of medical products, including drugs, biologics, and medical devices. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, post-approval monitoring, advertising, promotion, sampling and import and export of medical products. 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 ("PHSA") and the Federal Food, Drug, and Cosmetic Act ("FDCA"). Stem cells can be regulated under the FDA's Human Cells, Tissues, and Cellular and Tissue-Based Products Regulations ("HCT/Ps") or may also be subject to the FDA's drug, biologic, 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 ("CFR") (the "HCT/P Regulations"), 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 define 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." The HCT/P Regulations strictly constrain the types of products that may be regulated solely as HCT/P. 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 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 the HCT/P Regulations. 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. In July 2020, the FDA issued an updated guidance document entitled "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use" that provides additional guidance on how FDA interprets the HCT/P Regulations, particularly the definition of the terms "minimally manipulated" and "homologous use." In the guidance, FDA stated it will exercise enforcement discretion until May 31, 2021 for products that do not comply with the HCT/P Regulations. After that date, manufacturers of products marketed as HCT/Ps that do not comply with the HCT/P Regulations will be subject to immediate FDA enforcement action. If we are not regulated solely under the HCT/P Regulations, 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 past 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.

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 in certain situations.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practice ("GLP") or other applicable regulations;

- submission of an IND, which allows clinical trials to begin unless the FDA objects within 30 days;

- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use or uses conducted in accordance with FDA regulations and Good Clinical Practices ("GCP"), which are international ethical and scientific quality standards meant to ensure that the rights, safety and well-being of trial participants are protected and that the integrity of the data is maintained;

- registration of clinical trials of FDA-regulated products and certain clinical trial information;

- preparation and submission to the FDA of a new drug application ("NDA"), in the case of a drug or BLA in the case of a biologic;

- review of the product by an FDA advisory committee, where appropriate or if applicable;

- satisfactory completion of pre-approval inspection of manufacturing facilities and clinical trial sites at which the product, or components thereof, are produced to assess compliance with Good Manufacturing Practice, or cGMP, requirements and of selected clinical trial sites to assess compliance with GCP requirements; and

- FDA approval of an NDA or BLA which must occur before a drug or biologic can be marketed or sold.

Approval of an 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. 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.

For purposes of an NDA or BLA approval by the FDA, human clinical trials are typically conducted in the following phases (which may overlap):

- Phase 1: The investigational product is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. These trials may also provide early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product's pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

- Phase 2: These clinical trials are conducted in a limited number of human subjects in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the investigational product for specific targeted diseases and to determine dosage tolerance and dosage levels. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

- Phase 3: Phase 3 clinical trials are undertaken after Phase 2 clinical trials demonstrate that a dosage range of the investigational product appears effective and has a tolerable safety profile. The Phase 2 clinical trials must also provide sufficient information for the design of Phase 3 clinical trials. Phase 3 clinical trials are conducted to provide statistically significant evidence of clinical efficacy and to further test for safety risks in an expanded human subject population at multiple clinical trial sites. These clinical trials are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk profile of the investigational product and to provide an adequate basis for product labeling and approval by the FDA. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of an investigational drug or biologic.

All clinical trials must be conducted in accordance with FDA regulations, GCP requirements and their protocols in order for the data to be considered reliable for regulatory purposes. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. These government regulations may delay or prevent approval of product candidates for a considerable period of time and impose costly procedures upon our business operations.

The FDA may require, or companies may pursue, additional clinical trials, referred to as Phase 4 clinical trials, after a product is approved. Such trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has authority to require sponsors to conduct post-marketing trials to specifically address safety issues identified by the agency.

Under the Pediatric Research Equity Act ("PREA"), certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act ("FDASIA") amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration submit an initial Pediatric Study Plan ("PSP") within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA, or an NDA or BLA supplement, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs.

Drug and biological products must also comply with applicable requirements, including monitoring and recordkeeping activities, manufacturing requirements, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling, or off-label use, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may, in their independent professional medical judgment, prescribe legally available drugs for off-label uses, manufacturers typically may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling, or changes of the site of manufacture, are often subject to the approval of the FDA and other regulators, who may or may not grant approval or may include a lengthy review process.

In the event that the FDA does not regulate our product candidates 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 product candidates, there is no assurance as to whether or when we will receive FDA approval of the product candidate. 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.

In addition, even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution or use, or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product, including safety labeling or imposition of a Risk Evaluation and Mitigation Strategy ("REMS"), the requirement to conduct post-market studies or clinical trials or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our products, or obtaining approval but for significantly limited use, would harm our business. Further, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

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.

*FDA Expedited Review Programs*

The FDA is authorized to expedite the review of NDAs and BLAs in several ways. Under the Fast Track program, the sponsor of a drug or biologic product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Drug and biologic products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied.

In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track NDA or BLA before the application is complete, a process known as rolling review.

Any product submitted to the FDA for marketing, including under a Fast Track program, may also be eligible for the following other types of FDA programs intended to expedite development and review:

- Breakthrough therapy designation. To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review, and rolling review.

- Priority review. A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA aims to complete its review of priority review applications within six months as opposed to ten months for standard review.

- Accelerated approval. Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

Fast Track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Further, with the passage of the 21st Century Cures Act (the “Cures Act”) in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine advanced therapy (“RMAT”) (which may include a cell therapy) that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. The benefits of a RMAT designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

*Medical Device Regulation*

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

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

Class II devices are subject to the General Controls as well as certain Special Controls such as 510(k) premarket notification. Class III devices are subject to the highest degree of regulatory scrutiny and typically include life supporting and life sustaining devices and implants. They are subject to the General Controls and Special Controls that include a premarket approval application ("PMA"). "New" devices are automatically regulated as Class III devices unless they are shown to be low risk, in which case they may be subject to de novo review to be moved to Class I or Class II. Clinical research of an investigational device is subject to the FDA's Investigational Device Exemption ("IDE") regulations. 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 cGMP regulations. These cGMPs and related 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.

*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 (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 (the "FTCA"). 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 ("CLIA") in 1988, which provided the Centers for Medicare and Medicaid Services ("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 ("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. To the extent that our business activities require CLIA certification, we intend to obtain and maintain such certification. If we are subject to CLIA, 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. If any of these events were to occur, it could impact our business operations.

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

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information on certain types of individuals and organizations. In addition, certain state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other and from HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts. Further, we may need to also comply with 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.

The Department of Health and Human Services ("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.

*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 False Claims Act ("FCA");
- the federal Anti-Kickback Statute ("AKS") 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 ("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);
- state and other federal laws addressing the privacy of health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare professionals and other potential referral sources, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Violation of any of the laws described above or any other governmental laws and regulations may result in penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs and imprisonment. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products.

*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 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 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 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, Suite One, 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 five 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 of this Annual Report ("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, Suite One, Melville, New York. We occupy 6,800 square feet of space at the premises pursuant to a lease that expires in December 2024. The lease provides for an annual base rental during the five year period ending in December 2024 ranging between $153,748 and $173,060. Our premises are suitable and adequate for our current operations.

**ITEM 3. LEGAL PROCEEDINGS**.

Not applicable. See, however, Item 1 of this Annual Report ("Business – Business Development – Chapter 11 Reorganization") for a discussion of a voluntary petition filed by us in March 2020 commencing a case under chapter 11 of title 11 of the U.S. Code in the United States Bankruptcy Court for the Eastern District of New York. The Amended Joint Plan of Reorganization filed in connection with the proceeding became effective on November 16, 2020.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

## PART II

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

**Market Information**

Transactions in our common stock are currently reported under the symbol "BRTX" on the OTC markets. Any over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

**Holders**

As of April 27, 2021, there were 367 record holders of our shares of common stock.

**Dividends**

Not applicable.

**Recent Sales of Unregistered Securities**

During the three months ended December 31, 2020, 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 (the "Securities Act"), as transactions by an issuer not involving any public offering or Section 1145 of the Bankruptcy Code as a security exchanged by an issuer for a claim against the issuer in a bankruptcy plan of reorganization. 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, 2018, Quarterly Reports on Form 10-Q for the periods ended March 31, 2019, June 30, 2019 and September 30, 2019 and Current Reports on Form 8-K filed with the Securities and Exchange Commission, press releases made by us and information contained in filings with the bankruptcy court), 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.

| | | Warrants | | | | |
|---|---|---|---|---|---|---|
| Date Issued | Common Stock | Shares | Exercise Price | Term (Years) | Purchaser(s) | Consideration[1] |
| 11/16/2020 | 1,049,726,797 | - | - | - | (2) | $ 14,381,259(4) |
| 11/16/2020 | - | 9,453,802,480 | $ 0.0005 | 5.00 | (2) | $ 2,565,699(3) |
| 11/16/2020 | - | 4,726,901,240 | $ 0.001 | 5.00 | (2) | $ 1,282,849(3) |
| 10/20/2020 | 81,796,200 | - | - | - | (2) | $ 1,382,356(5) |
| 12/21/2020 | 136,000,000 | - | - | - | (2) | $ 775,200(5) |

(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 sale prices of both restricted shares and freely tradeable shares.
(2) Accredited investor.
(3) Issued in connection with the issuance of Secured Convertible Notes pursuant to the Plan.
(4) Issued in exchange for allowed unsecured claims pursuant to the Plan.
(5) Issued on a cashless net exercise basis pursuant to the exercise of warrants.

**Issuer Purchases of Equity Securities**

During the quarter ended December 31, 2020, 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 consolidated results of operations and financial condition of BioRestorative Therapies, Inc. and its subsidiary as of December 31, 2020 and 2019 and for the years ended December 31, 2020 and 2019 should be read in conjunction with our financial statements and the notes to those financial statements that are included elsewhere in this Annual Report following Item 16 ("Form 10-K Summary"). References in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" to "us," "we," "our," and similar terms refer to BioRestorative Therapies, Inc.. 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 that may 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 investigational therapeutic product being called *BRTX-100*. We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We have received such authorization from the FDA. We intend to commence such clinical trial during 2021 (assuming the receipt of necessary funding). We have obtained a license to use technology for investigational 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 leg and foot. We are also developing our *ThermoStem Program*. This pre-clinical program involves the use of brown adipose (fat) in connection with the cell-based treatment of type 2 diabetes and obesity as well as hypertension, other metabolic disorders and cardiac deficiencies. United States patents related to the *ThermoStem Program* were issued in September 2015, January 2019, March 2020 and March 2021; a notice of allowance was also issued in March 2021 for a separate United States patent application in the *ThermoStem* Program and is expected to issue in the next few months; Australian patents related to the *ThermoStem Program* were issued in April 2017 and October 2019; a Japanese patent related to the *ThermoStem Program* was issued in December 2017; Israeli patents related to the *ThermoStem Program* were issued in October 2019 and May 2020; and European patents related to the *ThermoStem Program* were issued in April 2020 and January 2021.

We have licensed a patented curved needle device that is a needle system designed to deliver cells and/or other therapeutic products or materials to the spine and discs or other potential sites. We anticipate that FDA approval or clearance will be necessary for this device prior to commercialization. We do not intend to utilize this device in connection with our contemplated Phase 2 clinical trial with regard to *BRTX-100*.

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, 2020, our accumulated deficit was $89,842,833 and our stockholders' deficit was $1,331,492. We have historically only generated a modest amount of revenue, and 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 forecast for continued operating losses, as of December 31, 2020, we required equity and/or debt financing to continue our operations. As of December 31, 2020, our outstanding debt of $9,637,102, together with interest at rates ranging between 5% and 7% per annum, was due on November 16, 2023. As of December 31, 2020, the outstanding debt amount of $9,637,102 did not include $657,598 of estimated DIP and Plan costs associated with the DIP Funding and the Plan (the "Auctus Costs"). As of December 31, 2020, the Auctus Costs were not finalized and, of which, $500,000 and $157,598 are recorded in debt discount and accrued expenses, respectively, on the consolidated balance sheets.

As discussed in Item 1 of this Annual Report ("Business – Business Development"), on March 20, 2020, we filed a voluntary petition commencing a case under chapter 11 of title 11 of the U.S. Code in the United States Bankruptcy Court for the Eastern District of New York. On October 30, 2020, the Bankruptcy Court entered an order confirming the plan of reorganization and, on November 16, 2020, the plan became effective. As a result of the confirmed plan of reorganization $14,796,000 in outstanding debt and liabilities were exchanged for (i) shares of common stock, (ii) new convertible debt or (iii) new convertible debt and warrants to purchase common stock.

We anticipate that we will require approximately $12,000,000 in financing to complete a Phase 2 clinical trial with regard to our *Disc/Spine Program*. We anticipate that we will require approximately $45,000,000 in further additional funding to complete such clinical trials (assuming the receipt of no revenues). We will also require a substantial amount of additional funding to implement our other programs described in Item 1 of this Annual Report ("Business"), including our metabolic ThermoStem Program, repay our outstanding debt (assuming such debt is not converted into equity) and fund general operations. 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. The plan of reorganization provides that, at such time as we are current in our periodic SEC filings (which will be the case upon the filing of this Annual Report), subject to certain customary conditions, Auctus Fund, LLC ("Auctus"), which provided debtor-in-possession ("DIP") financing to us during the reorganization process, is to provide a loan to us, as needed, in an amount equal to $3,500,000 less the sum of the DIP loans previously made by Auctus to us (inclusive of accrued interest, of $1,226,901) and the DIP costs incurred by Auctus as the DIP lender. In addition, Auctus and others provided debt financing in the aggregate principal amount of $3,848,548 at the effective date of our plan of reorganization. If we are unable to obtain such financing on a timely basis or other required financing as needed, we may have to curtail our development, marketing and promotional activities, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately we could be forced to discontinue our operations and liquidate. See "Liquidity and Capital Resources" below.

**Consolidated Results of Operations**

***Year Ended December 31, 2020 Compared with Year Ended December 31, 2019***

The following table presents selected items in our consolidated statements of operations for the year ended December 31, 2020 and 2019, respectively:

| | For The Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| **Revenues** | $ 77,000 | $ 130,000 |
| | | |
| **Operating Expenses:** | | |
| Marketing and promotion | 28,281 | 321,280 |
| Consulting | 137,250 | 1,912,683 |
| Research and development | 876,829 | 1,722,338 |
| General and administrative | 1,786,716 | 4,605,704 |
| Total Operating Expenses | 2,829,076 | 8,562,005 |
| Loss From Operations | (2,752,076) | (8,432,005) |
| | | |
| **Other (Expense) Income:** | | |
| Interest expense | (362,041) | (1,467,952) |
| Amortization of debt discount | (1,278,104) | (3,671,087) |
| Loss on extinguishment of notes payable, net | (658,152) | (1,895,116) |
| Change in fair value of derivative liabilities | (2,141,069) | 788,970 |
| Reorganization items, net | (4,081,245) | - |
| Other income | - | 29,300 |
| Total Other Expense | (8,520,611) | (6,215,885) |
| **Net Loss** | $ (11,272,687) | (14,647,890) |

*Revenues*

For the years ended December 31, 2020 and 2019, we generated $77,000 and $130,000, respectively, of royalty revenue in connection with our sublicense agreement.

*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, 2020, marketing and promotion expenses decreased by $292,999, or 91%, from $321,280 to $28,281 as compared to the year ended December 31, 2019, due to the Company's reduced spending on marketing prior to and during the Company's Chapter 11 reorganization.

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, 2020, consulting expenses decreased by $1,775,433, or 93%, from $1,912,683 to $137,250, as compared to the year ended December 31, 2019, due to the Company's reduced usage of consultants prior to and during the Company's Chapter 11 reorganization.

*Research and development*

Research and development expenses include cash and non-cash compensation of (a) our Vice President of Research and Development; (b) our Scientific Advisory Board members; and (c) 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, 2020, research and development expenses decreased by $845,509, or 49%, from $1,722,338 to $876,829, as compared to the year ended December 31, 2019. The decrease was primarily a result of the Company's reduced spending on research and development prior to and during the Company's Chapter 11 reorganization.

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 our Vice President of Research and Development and our laboratory staff), as well as corporate expenses such as legal and professional fees, investor relations and occupancy related expenses. For the year ended December 31, 2020, general and administrative expenses decreased by $2,818,988, or 61%, from $4,605,704 to $1,786,716, as compared to the year ended December 31, 2019. The decrease is primarily due to the Company's reduced incurrence of general and administrative expenses prior to and during the Company's Chapter 11 reorganization.

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, 2020, interest expense decreased $1,105,911, or 75%, as compared to the year ended December 31, 2019. The decrease was due to the prepetition outstanding notes payable being reclassified to liabilities subject to compromise at the Petition Date and, as a result, pursuant to ASC 852, *Reorganizations*, the Company did not accrue any new interest related to these notes. Certain of these notes were converted into shares of the Company's common stock at November 16, 2020. All new accrued interest was related to secured and unsecured convertible notes payable that resulted from the Plan.

*Amortization of debt discount*

For the year ended December 31, 2020, amortization of debt discount decreased $2,392,983, or 65%, as compared to the year ended December 31, 2019. The decrease was primarily due to the prepetition outstanding notes payable being reclassified to liabilities subject to compromise at the Petition Date and as a result, pursuant to ASC 852, *Reorganizations*, the remaining debt discount was written off to reorganization items on the consolidated statements of operations.

*Loss on extinguishment of notes payable, net*

For the year ended December 31, 2020, we recorded a loss on extinguishment of notes payable, net, of $658,152, as compared to a loss on extinguishment of notes payable, net of $1,895,116 for the year ended December 31, 2019. The decrease is associated with debtholders' exchanges of debt into equity securities.

*Change in fair value of derivative liabilities*

For the year ended December 31, 2020, we recorded a loss related to the change in fair value of derivative liabilities of $2,141,069 due to the decrease in time value of embedded conversion options within certain convertible notes payable, as compared to a gain related to the change in fair value of derivative liabilities of $788,970 for the year ended December 31, 2019.

*Reorganization items, net*

Reorganization items, net consists primarily of costs associated the post-petition Chapter 11 bankruptcy. For the year ended December 31, 2020, reorganization items, net decreased $4,081,245, or 100%, as compared to the year ended December 31, 2019. The decrease was due to, pursuant to ASC 852, *Reorganizations*¸ legal fees associated with the Chapter 11 reorganization, the write-off of the outstanding debt discount at the date of the bankruptcy, the exchange of common stock and unsecured convertible debt for allowable claims, and the write-off of derivative liabilities related to the convertible notes included in the Chapter 11 reorganization allowable claims.

**Liquidity and Capital Resources**

***Liquidity***

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

| | December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Cash | $ 3,064,610 | $ 1,664 |
| Working Capital (Deficiency) | $ 2,142,227 | $ (13,651,716) |
| Notes Payable (Gross) | $ 9,637,102 | $ 8,393,327 |

***Availability of Additional Funds***

Based upon our accumulated deficit and stockholders' deficit as of December 31, 2020 of $89,842,833 and $1,331,492, respectively, along with our forecast for continued operating losses and our need for financing to fund our contemplated clinical trials, as of such date, we required additional equity and/or debt financing to continue our operations.

As of December 31, 2020, our outstanding debt of $9,637,102, together with interest at rates ranging between 5% and 7% per annum, was due on November 16, 2023. As of December 31, 2020, the outstanding debt amount of $9,637,102 did not include $657,598 of estimated DIP and Plan costs associated with the DIP Funding and the Plan (the "Auctus Costs"). As of December 31, 2020, the Auctus Costs were not finalized and, of which, $500,000 and $157,598 are recorded in debt discount and accrued expenses, respectively, on the consolidated balance sheets.

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. We have granted a security interest in all of our assets to certain lenders, including Auctus, in connection with our Chapter 11 plan of reorganization. This may impede our ability to raise additional debt financing. In addition, future 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 have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. 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.

The following events have mitigated the above factors with regards to our ability to continue as a going concern: (i) as part of our Chapter 11 reorganization approximately $14,700,000 in outstanding debt and other liabilities were exchanged for (a) shares of common stock, (b) new convertible notes with three year terms or (c) new convertible notes with three year terms and warrants to purchase shares of common stock; (ii) we secured DIP financing during our Chapter 11 reorganization in the aggregate amount of $1,189,413, and $3,848,548 in debt financing as part of our Chapter 11 reorganization to sustain operations; and (iii) pursuant to the plan of reorganization, Auctus is required to loan to us, as needed and subject to our becoming current in our SEC reporting obligations (which will be the case upon the filing of this Annual Report), an additional amount equal to $3,500,000, less the amount of Auctus' DIP financing ($1,226,901, inclusive of accrued interest) and its DIP costs. As a result of the above, we have sufficient cash to fund operations for the twelve months subsequent to the filing date. In addition, the Company will need to obtain further funding of at least $12,000,000 to commence and complete a Phase 2 clinical study of the use of *BRTX-100*.

During the years ended December 31, 2020 and 2019, our sources and uses of cash were as follows:

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

We experienced negative cash flows from operating activities for the years ended December 31, 2020 and 2019 in the amounts of $1,964,265 and $6,918,734, respectively. The net cash used in operating activities for the year ended December 31, 2020 was primarily due to cash used to fund a net loss of $11,272,687, adjusted for non-cash expenses in the aggregate amount of $8,736,072 and partially offset by $572,350 of cash generated by changes in the levels of operating assets and liabilities, primarily as a result of increases in accrued expenses. The net cash used in operating activities for the year ended December 31, 2019 was primarily due to cash used to fund a net loss of $14,647,890, adjusted for non-cash expenses in the aggregate amount of $7,189,303 and partially offset by $539,853 of cash generated by changes in the levels of operating assets and liabilities, primarily as a result of increases in accrued interest, expenses, and other current liabilities, partially offset by an increase in accounts payable.

***Net Cash Used in Investing Activities***

During the years ended December 31, 2020 and 2019, cash used in investing activities was $- and $35,631, respectively.

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

Net cash provided by financing activities during the years ended December 31, 2020 and 2019 was $5,027,211 and $6,838,505, respectively. During the year ended December 31, 2020, $5,517,211 of net proceeds were from debt financings. During the year ended December 31, 2019, $10,888,339 of net proceeds were from debt financings, $1,658,500 of net proceeds were from equity financings, partially offset by $5,708,334 of repayments on debt financings and prepayment premiums.

We anticipate that the costs to complete our Phase 2 clinical trials with regard to our Disc/Spine Program will be at least $12,000,000. In addition, we anticipate approximately $45,000,000 in additional funding will be needed to complete the clinical trials using BRTX-100 (assuming the receipt of no revenues). As noted above in "Availability of Additional Funds" we secured additional funding as part of Chapter 11 reorganization in the aggregate amount of $5,037,961 as well as approximately $14,700,000 in outstanding debt and other liabilities being exchanged for (a) shares of common stock, (b) new convertible notes with three year terms or (c) new convertible notes with three year terms and warrants to purchase shares of common stock. Additionally, pursuant to the plan of reorganization, Auctus is required to loan to us, as needed and subject to our becoming current in our SEC reporting obligations (which will be the case upon the filing of this Annual Report), an additional amount equal to $3,500,000, less the amount of Auctus' DIP financing ($1,226,901, inclusive of accrued interest) and its DIP costs. As a result of the above, we have sufficient cash to fund operations for the twelve months subsequent to the filing date.

**Critical Accounting Policies and Estimates**

*Use of Estimates*

The preparation of financial statements in conformity with U.S. 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 common stock, stock-based compensation, warrants issued in connection with notes payable, derivative liabilities 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 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, or 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, or 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 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 OTC. 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.

*Derivative Financial Instruments*

We evaluate our convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with Topic 815 of the Financial Accounting Standards Board ("FASB") ASC. The accounting treatment of derivative financial instruments requires that we record embedded conversion options ("ECOs") and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. Conversion options are recorded as a discount to the host instrument and are amortized as amortization of debt discount on the consolidated financial statements over the life of the underlying instrument. We reassess the classification of our derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification.

The Multinomial Lattice Model and Black-Scholes Model were used to estimate the fair value of the ECOs of convertible notes payable, the warrants, and stock options that are classified as derivative liabilities on the consolidated balance sheets. The models include subjective input assumptions that can materially affect the fair value estimates. The expected volatility is estimated based on the actual volatility during the most recent historical period of time equal to the weighted average life of the instruments.

**Recently Issued Accounting Pronouncements**

See Note 3 to our consolidated financial statements for the years ended December 31, 2020 and 2019 included elsewhere in this Annual Report following Item 16 ("Form 10-K Summary").

**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; as of December 31, 2020, we had a stockholders' deficiency.***

We have a limited operating history. Since our inception, we have incurred net losses. As of December 31, 2020, we had a working capital of $2,142,229 and a stockholders' deficit of $1,331,492. On October 30, 2020, the Bankruptcy Court confirmed the plan of reorganization pursuant to the Chapter 11 Case (the "Plan of Reorganization") and on November 16, 2020, the Plan of Reorganization became effective.

***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 and debt securities. The implementation of our business plan, as discussed in Item 1 of this Annual Report ("Business"), will require the receipt of sufficient equity and/or debt financing to purchase necessary equipment, technology and materials, fund our clinical trials and other research and development efforts, retire our outstanding debt and otherwise fund our operations. We anticipate that we will require approximately $12,000,000 in financing to complete a Phase 2 clinical trial using *BRTX-100*. We anticipate that we will require approximately $45,000,000 in further additional funding to complete our clinical trials using *BRTX-100* (assuming the receipt of no revenues). We will also require a substantial amount of additional funding to implement our other programs described in Item 1 of this Annual Report ("Business"), including our metabolic *ThermoStem Program*, repay our outstanding debt (assuming such debt is not converted into equity) and fund general operations. We received debtor-in-possession ("DIP") funding of $1,189,413 during the Chapter 11 Case and debt financing of $3,848,548 on the effective date of the Chapter 11 Case. The Plan of Reorganization provides for additional debt funding of $3,500,000 (less our DIP funding obligation, including accrued interest, of $1,226,901 at the effective date of the Chapter 11 Case, less DIP costs incurred by the DIP lender) as needed, from our DIP lender upon our becoming current in our SEC periodic report filings (which will be the case upon the filing of this Annual Report). Such additional funding from the DIP lender, if received, will not be sufficient to satisfy our needs. 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 may need to obtain additional financing to satisfy debt obligations. An event of default pursuant to our outstanding debt obligations could trigger an acceleration of the due date of such obligations, including our secured debt.***

As described in this 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, 2020, our outstanding debt of $9,634,104, together with interest at rates ranging between 5% and 7% per annum, was due on November 16, 2023. As of December 31, 2020, the outstanding debt amount of $9,637,102 did not include $657,598 of estimated DIP and Plan costs associated with the DIP Funding and the Plan (the "Auctus Costs"). As of December 31, 2020, the Auctus Costs were not finalized and, of which, $500,000 and $157,598 are recorded in debt discount and accrued expenses, respectively, on the consolidated balance sheets. The DIP lender is required, pursuant to the Plan of Reorganization as discussed above, to lend us an additional $3,500,000 (less our DIP funding obligation, including accrued interest, of $1,226,901 at the effective date of the Chapter 11 Case, less the DIP costs incurred by the DIP lender), as needed. Although our outstanding debt is repayable on November 16, 2023 (unless sooner converted into equity), an event of default pursuant to the secured and unsecured promissory notes evidencing such indebtedness could trigger an acceleration of the due dates of all of the notes. We do not have the financial resources to satisfy such debt obligations. Since the repayment of a substantial portion of our outstanding debt is secured by a security interest in all of our assets, in the event of a default, and foreclosure upon our assets, we could be forced to cease operations and liquidate.

***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 securities an unsuitable investment for many investors.

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

Except for a certain license agreement with Regenerative Sciences, LLC described in Item 1 of this Annual Report ("Business – Disc/Spine Program - License"), 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 Lance Alstodt, our Chief Executive Officer. We rely upon him for strategic business decisions and guidance. We are also dependent on the performance of Francisco Silva, our Vice President of Research and Development. Each of Messrs. Alstodt and Silva is subject to an employment agreement with us. We do not have any key-man insurance policies on the lives of either 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. Alstodt 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.

***The impact of COVID-19 and related risks could materially affect our results of operations and prospects.***

Beginning in March 2020, the global pandemic related to the novel coronavirus COVID-19 began to impact the global economy. Because of the size and breadth of this pandemic, all of the direct and indirect consequences of COVID-19 are not yet known and may not emerge for some time. Risks presented by the ongoing effects of COVID-19 include, among others, the following:

*Clinical Trials.* We anticipate that the COVID-19 pandemic may negatively impact our contemplated clinical trials. Due to the worldwide efforts being taken to combat COVID-19 and the increased clinical work being done in this respect, we believe that it may be difficult for certain needed laboratory supplies, equipment and other materials to be obtained in order to conduct our clinical trials. We also anticipate that, due to a fear of COVID-19 transmission, there may be a hesitancy on the part of certain individuals to become clinical trial participants. We hope that these possible negative effects will lessen as more of the population becomes vaccinated; however, the impact that the vaccinations will have is uncertain at this time.

*Adverse Legislative and/or Regulatory Action.* Federal, state and local government actions to address and contain the impact of COVID-19 may adversely affect us. For example, we may be subject to legislative and/or regulatory action that negatively impacts the manner in which the clinical trials may be conducted.

*Operational Disruptions and Heightened Cybersecurity Risks.* Our operations could be disrupted if key members of our senior management or a significant percentage of our workforce are unable to continue to work because of illness, government directives or otherwise. In addition, in connection with increased remote working arrangements, we face a heightened risk of cybersecurity attacks or data security incidents and are more dependent on internet and telecommunications access and capabilities.

***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 have not yet commenced 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; the 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 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 ("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 raise 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 ("GCP") requirements, or applicable regulatory guidelines in other countries;

- delays in having patients qualify for or complete participation in a study or return for post-treatment follow-up;

- patients dropping out of a study;

- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- transfer of manufacturing processes from any academic collaborators to larger-scale facilities operated by either a contract manufacturing organization ("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;

- 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; and

- failure to raise sufficient funds to complete our clinical trials.

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, 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 candidate 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.

***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 our product candidate, *BRTX-100*, or any of our other product candidates in development. Since our Company lacks significant experience in completing clinical trials and bringing a drug through commercialization, we have hired outside consultants with such experience. Clinical trials for *BRTX-100* and other product candidates 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, the failure of study sites and/or investigators in our clinical research program to comply with GCP requirements, or our failure, or the failure of our contract manufacturers, to comply with current 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;
- treatment candidates demonstrating significant safety signals; and/or
- inability to continue to fund clinical trials or to find a partner to fund the 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 composition of the cell population varies from patient to patient. Such variability in the number and composition of these cells could adversely affect our ability to manufacture autologous cell therapies in a cost-effective or profitable manner and meet acceptable product release specifications for use in a clinical trial or, if approved, for commercial sale. As a consequence, the development and regulatory approval process for autologous cell therapy products could be delayed or may never be completed.

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

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

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

The successful development of cellular based products is highly uncertain. Product candidates that appear promising in preclinical and early 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. Positive preclinical data may not continue or occur for future subjects in our clinical studies and may not be repeated or observed in ongoing or future studies involving our product candidates. Furthermore, our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical studies. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

***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.

***Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate, and the approval may be for a narrower indication than we seek.***

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions or conditions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, contraindications or a Risk Evaluation and Mitigation Strategy (“REMS”). These regulatory authorities may require warnings or precautions with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims or allow the promotional claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations and prospects.

***We may never obtain FDA approval for any of our product candidates in the United States and, even if we do, we may never obtain approval for or commercialize any of our product candidates in any foreign jurisdiction, which would limit our ability to realize our full market potential.***

In order to eventually market any of our product candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements regarding safety and efficacy on a jurisdiction-by-jurisdiction basis. Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, preclinical studies and clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The foreign regulatory approval process involves similar risks to those associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, nor have we attempted to obtain such approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products may be unrealized.

***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.***

We use brown adipose (fat) tissue 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 any relationships that we have, have had or may establish with potential sources of brown adipose tissue. The inability to procure brown fat tissue would have a material adverse effect upon our ability to advance our *ThermoStem Program.*

***We are required to complete a certain milestone 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 our Phase 2 clinical trial by a certain date (which we believe to be February 2022) in order to maintain our exclusive rights with regard to the disc/spine technology. We will not be able to achieve such milestone. Any loss of such exclusive rights would have a material adverse effect upon our business, results of operations and financial condition. See "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.

***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. To date, such efforts have not been successful.

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

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

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

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

Our business plan has been focused historically 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 and have hired FDA consultants, 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.***

The enactment of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated regulatory pathway for the approval of products demonstrated to be biosimilar, or "highly similar," to or "interchangeable" with an FDA-approved innovator (original) biologic product. 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 ("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 approve biosimilar applicants for other reference products that no longer have such exclusivity, thus potentially creating the opportunity for greater competition sooner than anticipated. 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.

***The FDA's regulation of regenerative medicine products remains unpredictable and we are not certain what impact this will have on the potential approval of our products.***

The FDA's regulation of therapies derived from stem cell products and technologies is evolving and may continue to evolve. In December 2016, the 21st Century Cures Act (the "Cures Act") was signed into law in the United States to advance access to medical innovations. Among other things, the Cures Act established a new FDA regenerative medicine advanced therapy ("RMAT") designation. This designation offers a variety of benefits to product candidates, including enhanced FDA support during clinical development, priority review on application filing, accelerated approval based on potential surrogate endpoints, and the potential use of patient registry data and other forms of real world evidence for post-approval confirmatory studies. There is no certainty that any of our product candidates will receive RMAT designation or any other type of expedited review program designation from the FDA. In any event, the receipt of an FDA RMAT designation or other expedited review program designation may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA.

***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.

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

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

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

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

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

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

Market acceptance and sales of our product candidates may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our product candidates, as well as levels at which these payors pay directly for our product candidates, where applicable, could affect whether we are able to successfully commercialize these products. We cannot guarantee that reimbursement will be available for any of our product candidates. We also cannot guarantee that coverage or reimbursement amounts will not reduce the demand for, or the price of, our product candidates.

If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize our products. The Patient Protection and Affordable Care Act ("PPACA") and other health reform proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union (the "EU"), the pricing of drugs and biologics is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to government control, we may not be able to generate revenue, attain profitability or commercialize our products.

In addition, third-party payors are increasingly limiting both coverage and the level of reimbursement of new drugs and biologics. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly-approved drugs and biologics. If we are unable to obtain adequate levels of reimbursement for our product candidates, our ability to successfully market and sell our product candidates will be harmed.

***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 based on our or our licensor's pending applications 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 ("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 (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 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 also rely, in part, on confidentiality agreements with our partners, employees, advisors, vendors, and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or that we will have adequate remedies for any breach, or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

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

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

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

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

The Leahy-Smith America Invents Act ("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.

***Risks Related to Government Regulation***

***Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory oversight.***

Our product candidates for which we obtain regulatory approval will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates also may be subject to a REMS or the specific obligations imposed as a condition for marketing authorization by equivalent authorities in a foreign jurisdiction, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, in the United States, the holder of an approved new drug application (“NDA”) or BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA or BLA. The holder of an approved NDA or BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with the Federal Food, Drug and Cosmetic Act (“FDCA”) and implementing regulations and are subject to FDA oversight and post-marketing reporting obligations, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities may be subject to payment of application and program fees and are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA, BLA or foreign marketing application. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or if a regulatory authority disagrees with the promotion, marketing or labeling of our product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements for any product candidate following approval, a regulatory authority may:

- issue a warning or untitled letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;

- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise demand or require the withdrawal or recall of the product from the market;
- refuse to permit the import or export of products;
- request and publicize a voluntary recall of the product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government enforcement action or investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and adversely affect our business, financial condition, results of operations and prospects.

***We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

In the United States, the research, manufacturing, distribution, sale, and promotion of drugs and biologic products are subject to regulation by various federal, state, and local authorities, including the FDA, the Centers for Medicare and Medicaid Services ("CMS"), other divisions the Department of Health and Human Services ("HHS") (e.g., the Office of Inspector General), the United States Department of Justice offices of the United States Attorney, the Federal Trade Commission and state and local governments. Our operations are directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including the federal Anti-Kickback Statute ("AKS"), the federal civil and criminal False Claims Act ("FCA"), the Physician Payments Sunshine Act and regulations and equivalent provisions in other countries. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business.

State and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the AKS. Enforcement agencies also continue to pursue novel theories of liability under these laws. Government agencies have recently increased regulatory scrutiny and enforcement activity with respect to programs supported or sponsored by pharmaceutical companies, including reimbursement and co-pay support, funding of independent charitable foundations and other programs that offer benefits for patients. Several investigations into these programs have resulted in significant civil and criminal settlements.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert the attention of our management from operating our business.

Further, in the event we determine to operate in foreign jurisdictions, including conducting clinical trials, we will need to comply with the United States Foreign Corrupt Practices Act of 1977 (the "FCPA"). The FCPA prohibits a corporation, including its subsidiaries, third-party contractors, distributors, consultants and employees, from corruptly making or offering to make payments to foreign officials for the purpose of obtaining or enhancing business. Under the law, "foreign officials" include employees of health systems operated by government entities. The FCPA also establishes specific record-keeping and internal accounting controls. Violations of the FCPA can result in the imposition of civil penalties or criminal prosecution. Failure to comply with the FCPA will adversely affect our business.

In addition to the FCPA, we will also need to comply with the foreign government laws and regulations of each individual country in which any therapy centers that we may establish 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 stem cell and cell therapy 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, there can be no guarantee that laws and regulations will not be implemented, amended and/or reinterpreted in a way that will negatively affect our business. Likewise, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all such healthcare laws and regulations. Failure to comply with such healthcare laws and regulations, as well as the costs associated with such compliance or with enforcement of such healthcare laws and regulations, may have a material adverse effect on our operations or may require restructuring of our operations or impair our ability to operate profitably.

***Our current and future employees, consultants and advisors and our future principal investigators, medical institutions and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk of fraud or other misconduct by our current and future employees, consultants and advisors and our future principal investigators, medical institutions and commercial partners, including contract laboratories, and CROs. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us.

We currently do not and in the future may not independently conduct all aspects of our product candidate research and preclinical and clinical testing and product candidate manufacturing. If we rely on third parties, including CROs, medical institutions, and contract laboratories to monitor and manage data for our ongoing preclinical and clinical programs, we will still maintain responsibility for ensuring their activities are conducted in accordance with the applicable study protocol, legal, regulatory and scientific standards. We and our third-party vendors will be required to comply with current cGMP, GCP, and Good Laboratory Practice (“GLP”) requirements, which are a collection of laws and regulations enforced by the FDA, the EU and comparable foreign authorities for all of our product candidates in clinical development.

In addition, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation.

The precautions we take to detect and prevent employee and third-party misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

***The failure to receive regulatory approvals for our cell therapy product candidates would likely have a material and adverse effect on our business and prospects.***

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

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

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

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

- third-party clinical investigators do not perform the clinical trials on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices required by the FDA and other regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or other regulatory authorities reveal violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit use of some or all of the data in support of marketing applications; or
- the FDA or one or more institutional review boards suspends or terminates the trial at an investigational site, or precludes enrollment of additional subjects.

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

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

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

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

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

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

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

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

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

Furthermore, there has been a trend in recent years towards reductions in overall funding for Medicare, Medicaid and other federal health care programs. There has also been an increase in the number of people who are not eligible for or enrolled in Medicare, Medicaid or other governmental programs. The reduced funding of governmental programs could have a negative impact on the demand for our services to the extent it relates to products and services which are reimbursed by government and private payors.

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

The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the United States, the PPACA was signed into law in 2010 under the Obama administration. By implementing comprehensive reforms, the law seeks to, among other things, increase access to healthcare for the uninsured and control the escalation of healthcare expenditures within the economy. While we do not believe this law will have a direct impact on our business, the law requires the adoption of various implementing regulations, which may have unintended consequences or indirectly impact our business.

In addition, other legislative changes have been adopted since the PPACA was enacted. These changes include aggregate reductions in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, following passage of the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In the past two years, Congress has considered additional reductions in Medicare reimbursement for drugs and devices as part of legislation to reduce the budget deficit. Similar legislation could be enacted in the future. The Medicare regulations and interpretive determinations that determine how drugs, devices and services are covered and reimbursed also are subject to change. These laws may result in additional reductions in Medicare and other health care funding, which could impact our business.

Healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and decreased reimbursement. Under the Trump administration, Congress passed certain legislation to alter the PPACA. In addition, Congress and select states have proposed legislation to alter and/or repeal the PPACA and/or transform certain aspects of existing federal and state health programs. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. It is difficult to predict how enforcement initiatives under the PPACA and/or additional legislation or regulation enacted in the future may impact our business. If the PPACA and/or additional legislation or regulation enacted in the future cause such unintended consequences or indirect impact, they could have a material adverse effect on our business, financial condition and results of operations.

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

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

These exemptions could allow our competitors to make sales in the EU without having obtained a marketing authorization and without undergoing the expense of clinical trials, especially if those competitors have cell processing facilities in the relevant EU member state. Similarly, certain hospitals may be able to compete with us on the basis of these rules.

***Risks Related to and Our Common Stock***

***We pay no dividends.***

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

***There is no assurance that an active trading market for our securities will be sustained.***

No assurance can be given that an active market for our shares will be sustained. In addition, although there have been market makers in our common stock, we cannot assure that these market makers will continue to make a market in our securities or that other factors outside of our control will not cause them to stop market making in our securities. Making a market in securities involves maintaining bid and ask quotations and being able to effect transactions in reasonable quantities at those quoted prices, subject to various securities laws and other regulatory requirements. Furthermore, the maintenance of a public trading market depends upon the existence of willing buyers and sellers, the presence of which is not within our control or that of any market maker. Market makers are not required to maintain a continuous two-sided market, are required to honor firm quotations for only a limited number of securities, and are free to withdraw firm quotations at any time. Even with a market maker, factors such as our past losses from operations and the small size of our company mean that there can be no assurance that an active and liquid market for our securities will be sustained or that stockholders will be able to resell their securities at any price.

***Stockholders who hold unregistered shares of our common stock are subject to resale restrictions pursuant to Rule 144 due to our former status as a "shell company."***

We previously were a "shell company" pursuant to Rule 144, promulgated under the Securities Act ("Rule 144"), and, as such, sales of our securities pursuant to Rule 144 cannot be made unless, among other things, we continue to remain subject to Section 13 or 15(d) of the Exchange Act, and we file all of our required periodic reports with the SEC under the Exchange Act. Because our unregistered securities cannot be sold pursuant to Rule 144 unless we continue to meet such requirements, any unregistered securities we sell in the future or issue to consultants or employees, in consideration for services rendered or for any other purpose, will have no liquidity unless we continue to comply with such requirements. As a result, it may be more difficult for us to obtain financing to fund our operations and pay our consultants and employees with our securities instead of cash.

***We have incurred, and will continue to incur, increased costs as a result of being an SEC reporting company.***

The Sarbanes-Oxley Act of 2002, as well as a variety of related rules implemented by the SEC, have required changes in corporate governance practices and generally increased the disclosure requirements of public companies. As a reporting company, we incur significant legal, accounting and other expenses in connection with our public disclosure and other obligations. Based upon SEC regulations currently in effect, we are required to establish, evaluate and report on our internal control over financial reporting. We believe that compliance with the myriad of rules and regulations applicable to reporting companies and related compliance issues will continue to require a significant amount of time and attention from our management.

***Our stock prices may fluctuate significantly and be highly volatile and this may make it difficult for a stockholder to resell our securities at the volume, prices and times the stockholder finds attractive.***

The market price of our common stock may be subject to significant fluctuations and be highly volatile, which may make it difficult for a stockholder to resell our securities at the volume, prices and times the stockholder finds attractive. There are many factors that will impact our stock price and trading volume, including, but not limited to, the factors listed above under "Risks Related to Our Business Generally," "Risks Related to Our Cell Therapy Product Development Efforts," "Risks Related to Our Intellectual Property," "Risks Related to Government Regulation" and "Risks Related to Our Common Stock".

Stock markets, in general, experience significant price and volume volatility, and the market price of our securities may continue to be subject to such market fluctuations that may be unrelated to our operating performance and prospects. Increased market volatility and fluctuations could result in a substantial decline in the market price of our securities.

***There may be significant future issuances or resales of our common stock which may materially and adversely dilute stockholders' ownership interest and affect the market price of our securities.***

We have authorization to issue up to 300,000,000,000 shares of common stock of which, as of April 27, 2021, 3,175,977,710 shares were issued and outstanding. We are not restricted from issuing additional shares of our common stock in the future, including securities convertible into, or exchangeable or exercisable for, shares of our common stock. Pursuant to the Plan of Reorganization, we issued warrants for the purchase of an aggregate of 15,226,346,970 shares of our common stock. In addition, pursuant to the Plan of Reorganization, we issued or will be issuing convertible notes in the aggregate estimated principal amount of $11,794,700. Such notes are or will be convertible into shares of our common stock at prices related to the market price of our common stock at the time of conversion. Our issuance of additional shares of common stock in the future will dilute the ownership interests of our then existing stockholders.

Pursuant to the Plan of Reorganization, an aggregate of 1,049,726,797 shares of common stock were issued to holders of unsecured claims. Such shares are freely tradeable in the public market, except for shares held by affiliates.

We have effective registration statements on Form S-8 under the Securities Act registering an aggregate of 19,955,000 shares of our common stock issuable under our 2010 Equity Participation Plan (the "2010 Plan"). As of April 27, 2021, options to purchase 4,879,617 shares of our common stock were outstanding under the 2010 Plan. In addition, as of such date, 45,000 shares of common stock were issued as stock grants pursuant to the 2010 Plan. The 2010 Plan terminated on November 17, 2020 and accordingly no further grants may be made under the 2010 Plan.

Immediately following the filing of this Annual Report, we intend to file a registration statement on Form S-8 under the Securities Act registering 4,700,000,000 shares of our common stock issuable under our 2021 Stock Incentive Plan (the "2021 Plan"). As of April 27, 2021, options to purchase 2,347,835,948 shares of our common stock were outstanding under the 2021 Plan. In addition, as of such date, 1,173,917,974 restricted stock units were outstanding under the 2021 Plan. All of such options and restricted stock units are held by our senior management team, Messrs. Alstodt and Silva.

The shares issuable pursuant to the registration statements on Form S-8 will be freely tradable in the public market, except for shares held by affiliates. We intend to include a resale prospectus in our registration statement on Form S-8 with regard to the 2021 Plan covering the resale of the shares issuable to Messrs. Alstodt and Silva upon their exercise of the above described options and the vesting of the above described RSUs. The resale of such shares will be currently subject to the volume limitations imposed by Rule 144.

The sale of a substantial number of shares of our common stock or securities convertible into, or exchangeable or exercisable for, shares of our common stock, whether directly by us in future offerings or by our existing stockholders in the secondary market, the perception that such issuances or resales could occur or the availability for future issuances or resale of shares of our common stock or securities convertible into, or exchangeable or exercisable for, shares of our common stock could materially and adversely affect the market price of our securities and our ability to raise capital through future offerings of equity or equity-related securities on attractive terms or at all.

In addition, our Board of Directors is authorized to designate and issue preferred stock without further stockholder approval, and we may issue other equity and equity-related securities that are senior to our common stock in the future for a number of reasons, including, without limitation, to support operations and growth, and to comply with any future changes in regulatory standards.

***Anti-takeover provisions and the regulations to which we may be subject may make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to our securityholders.***

We are incorporated in Delaware. Anti-takeover provisions in Delaware law and our certificate of incorporation and bylaws could make it more difficult for a third party to acquire control of us and may prevent stockholders from receiving a premium for their securities. Our certificate of incorporation provides that our Board of Directors may issue up to 20,000,000 shares of preferred stock, in one or more series, without stockholder approval and with such terms, preferences, rights and privileges as the Board of Directors may deem appropriate. These provisions and other factors may hinder or prevent a change in control, even if the change in control would be perceived as beneficial to, or sought by, our other stockholders.

***Our common stock is classified as a "penny stock;" the restrictions of the penny stock regulations of the SEC may result in less liquidity for our common stock.***

The SEC has adopted regulations which define a "penny stock" to be any equity security that has a market price (as therein defined) of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. Unless exempt, the rules require the delivery, prior to any transaction involving a penny stock by a retail customer, of a disclosure schedule prepared by the SEC relating to the penny stock market. Disclosure is also required to be made about commissions payable to both the broker/dealer and the registered representative and current quotations for the securities. Finally, monthly statements are required to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Our common stock is classified as a penny stock. As a result of the penny stock restrictions, brokers or potential investors may be reluctant to trade in our securities, which may result in less liquidity for our securities.

***Substantial future sales of shares of our common stock in the public market could cause our stock price to fall.***

Shares of our common stock that we have issued or are issuable upon the exercise of warrants or upon the conversion of convertible debt may be covered by registration statements which permit the public sale of stock. Other holders of shares of common stock that we have issued, including shares issuable upon the exercise of warrants and the conversion of convertible debt, may be entitled to dispose of their shares subject to the requirements of Rule 144 or other applicable exemption from registration under the Securities Act. Pursuant to the Plan of Reorganization, the shares of our common stock issuable pursuant to the conversion of convertible promissory notes in the aggregate principal amount of $3,644,279 are subject to certain lock-up restrictions over the 180 day period following the November 16, 2020 effective date of the Plan of Reorganization. As those lock-up restrictions expire during said 180 day period, the shares of common stock issuable pursuant to the conversion of such notes will become eligible for resale in the open market (subject to Rule 144 volume limitations applicable to affiliates), resulting in more shares eligible for sale and potentially causing sales in the market to increase and our stock price to decline. In addition, effective February 17, 2021, certain lock-up restrictions imposed by the Plan of Reorganization with regard to the resale of the 1,049,726,797 shares of common stock issued to holders of unsecured claims expired. The unrestricted eligibility of such shares for resale in the open market (subject to Rule 144 volume limitations applicable to affiliates) could also have a negative effect upon our stock price. Additional sales of a substantial number of our shares of our common stock in the public market, or the perception that sales could occur, could have a material adverse effect on the price of our stock.

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

Not applicable.

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

The financial statements required by this Item 8 of this Annual Report are included in this Annual Report following Item 16 ("Form 10-K Summary"). As a smaller reporting company, we are not required to provide supplementary financial information.

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

None.

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

**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives.

Under the supervision and with the participation of our management, including our principal executive officer, who is also our principal financial officer, we are required to perform an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Exchange Act, as of December 31, 2020. Management has not completed such evaluation and, as such, has concluded that our disclosure controls and procedures were not effective to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive officer, who is also our principal financial officer, as appropriate to allow timely decisions regarding required disclosures. As a result of the material weakness in internal controls over financial reporting described below, we concluded that our disclosure controls and procedures as of December 31, 2020 were not effective.

**Management's Annual Report on Internal Control Over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed under the supervision of our principal executive and principal financial officer and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with GAAP.

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

**Material Weaknesses in Internal Control over Financial Reporting**

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the framework established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that our internal control over financial reporting as of December 31, 2020 was not effective.

A material weakness, as defined in the standards established by the Sarbanes-Oxley is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

The ineffectiveness of our internal control over financial reporting was due to the following material weaknesses:

- Inadequate segregation of duties due to limited personnel consistent with control objectives;
- Adherence to formal policies and procedures post-bankruptcy; and
- Lack of risk assessment procedures on internal controls to detect financial reporting risks on a timely manner.

**Management's Plan to Remediate the Material Weakness**

Management has been implementing and continues to implement measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented, and operating effectively. The remediation actions include:

- New management personnel, including our new principal executive officer, who is executing on our business plan moving forward and analyzing new controls;
- Identify gaps in our skills base and the expertise of our staff required to meet the financial reporting requirements of a public company; and
- Engagement of external financial consulting firm in the fourth quarter of 2020 to assist us with our financial reporting, financial operations and internal controls moving forward.

Management will continue to monitor and evaluate the effectiveness of our internal controls and procedures over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements, as necessary and as funds allow.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that exempt smaller reporting companies from this requirement.

**Changes in Internal Control Over Financial Reporting**

Other than described above there have been no changes in our internal control over financial reporting that occurred during our fourth quarter of 2020 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**.

None.

## PART III

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

**Directors and Executive Officers**

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

| Name | Age | Positions Held |
|---|---|---|
| Lance Alstodt | 50 | Chief Executive Officer, President and Chairman of the Board |
| Francisco Silva | 46 | Vice President of Research and Development, Secretary and Director |
| Nickolay Kukekov, Ph.D. | 47 | Director |

**Lance Alstodt**

Lance Alstodt has served as our Chief Executive Officer, President and Chairman of the Board since November 2020. He served as our Executive Vice President and Chief Strategy Officer from October 2018 to February 2020. Since 2013, Mr. Alstodt has served as Chief Executive Officer of MedVest Consulting Corporation, an advisory and capital firm that focuses exclusively on the healthcare industry. Prior to MedVest, he was an investment banker with over 23 years of experience with respect to healthcare investment banking, including mergers and acquisitions. From 2011 to 2013, Mr. Alstodt was a Managing Director at Leerink Partners where he helped lead its medical technology sector. From 2009 to 2011, he was a Managing Director and Head of Medical Technology at Oppenheimer & Co. From 2000 to 2009, Mr. Alstodt was a Managing Director in the Healthcare Group and Global Mergers and Acquisitions Group at Bank of America Merrill Lynch. He previously spent seven years as a Vice President in the Global Mergers and Acquisitions Group at J.P. Morgan Chase, where he worked extensively on acquisitions, leveraged buyouts, private and public financings, exclusive sales and general advisory assignments. Mr. Alstodt received a degree in Economics from the State University of New York at Albany, with a secondary concentration in Finance and Marketing. We believe that Mr. Alstodt's executive-level management experience with us and other healthcare businesses and his extensive experience in the investment banking field relating to the healthcare sector give him the qualifications to serve as one of our directors.

**Francisco Silva**

Francisco Silva has served as our Vice President of Research and Development since March 2013, having also previously served in such position from April 2011 until March 2012. Mr. Silva was elected our Secretary and a director in November 2020. He served as our Research Scientist from March 2012 to June 2012 and as our Chief Scientist from June 2012 to March 2013. From 2007 to 2011, Mr. Silva served as Chief Executive Officer of DV Biologics LLC, and as President of DaVinci Biosciences, LLC, companies engaged in the commercialization of human based biologics for both research and therapeutic applications. From 2003 to 2007, Mr. Silva served as Vice President of Research and Development for PrimeGen Biotech LLC, a company engaged in the development of cell based platforms. From 2002 to 2003, he was a Research Scientist with PrimeGen Biotech and was responsible for the development of experimental designs that focused on germ line reprogramming stem cell platforms. Mr. Silva has taught courses in biology, anatomy and advanced tissue culture at California State Polytechnic University. He has obtained a number of patents relating to stem cells and has had numerous articles published with regard to stem cell research. Mr. Silva graduated from California State Polytechnic University with a degree in Biology. He also obtained a Graduate Presidential Fellowship and MBRS Fellowship from California State Polytechnic University. We believe that Mr. Silva's executive-level management experience with us since April 2011 and his extensive knowledge of the science related to our business give him the qualifications to serve as one of our directors.

**Nickolay Kukekov, Ph.D.**

Nickolay Kukekov, Ph.D. has served as one of our directors since March 2021. For more than the past fifteen years, Dr. Kukekov has held a number of healthcare investment banking positions. He has served as Senior Managing Director of Paulson Investment Company, LLC since 2020. From 2012 to 2020, Dr. Kukekov was a founding partner of Highline Research Advisors LLC. He served as a Managing Director of Summer Street Research Partners from 2010 to 2012. From 2007 to 2009, Dr. Kukekov was a Managing Director of Paramount Capital. He served as a Vice President of Rodmen & Renshaw from 2006 to 2007. He serves as a director of Brain Scientific, Inc. and Omnia Wellness Inc. whose shares are publicly traded. Dr. Kukekov received a Bachelor of Arts degree in molecular, cellular and developmental biology from the University of Colorado at Boulder and a Ph.D. in neuroscience from Columbia University College of Physicians and Surgeons. We believe that Dr. Kukekov's extensive experience in the investment banking field relating to the healthcare sector and his strong background in regenerative medicine give him the qualifications to serve as one of our directors.

**Scientific Advisors**

**Scientific Advisory Board**

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

| Name | Principal Positions |
|---|---|
| Wayne Marasco, M.D., Ph.D.<br>Chairman | Professor, Department of Cancer Immunology & AIDS, Dana-Farber Cancer Institute;<br>Professor of Medicine, Harvard Medical School;<br>Principal Faculty Member, Harvard Stem Cell Institute |
| Naiyer Imam, M.D. | Chairman and President, First Medicine, Inc., an international telemedicine corporation dedicated to virtual physician services and chronic disease management |
| Wayne J. Olan, M.D. | Director, Interventional and Endovascular Neurosurgery;<br>Associate Professor, Neurosurgery and Radiology, George Washington University Medical Center;<br>Consulting Physician, Department of Radiology, National Institutes of Health |
| Joy Cavagnaro, Ph.D., DABT, RAC | President and Founder, Access BIO, L.C.; Fellow, Academy of Toxicological Sciences and the Regulatory Professional Society;<br>Formerly Senior Pharmacologist and Director of Quality Assurance, Food and Drug Administration's Center for Biologics Evaluation and Research |
| Jason Lipetz, M.D.<br>Chairman, Disc Advisory Committee | Founder, Long Island Spine Rehabilitation Medicine;<br>Chief of Spine Medicine, Northwell Health Spine Center;<br>Assistant Professor of Rehabilitation Medicine, Hofstra University School of Medicine |
| Harvinder Sandhu, M.D. | Orthopedic Spine Surgeon, Hospital for Special Surgery;<br>Formerly Chief of Spinal Surgery Service, UCLA Medical Center |
| Christopher Plastaras, M.D. | Clinical Director of Musculoskeletal Spine and Sports Rehabilitation Medicine and Physiatrist, MossRehab;<br>Formerly Director of The Penn Spine and Rehabilitation Center;<br>Formerly Director of Spine, Sports and Musculoskeletal Medicine Fellowship, University of Pennsylvania |
| Gerard A. Malanga, M.D. | Founder, Partner and Physiatrist, New Jersey Sports Medicine, LLC and New Jersey Regenerative Institute;<br>Chair, American Academy of Physical Medicine and Rehabilitation Task Force on Regenerative Medicine;<br>President Elect, Interventional Orthopedic Foundation |

**Family Relationships**

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

**Term of Office**

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

| Name | Class | Term Expires |
|---|---|---|
| Lance Alstodt | III | 2023 |
| Francisco Silva | II | 2022 |
| Nickolay Kukekov | I | 2021 |

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

**Audit Committee**

The Audit Committee of the Board of Directors is responsible for overseeing our accounting and financial reporting processes and the audits of our financial statements. The sole member of the Audit Committee is Dr. Kukekov.

**Audit Committee Financial Expert**

We do not currently have an "audit committee financial expert," as that is defined in Item 407(d)(5) of Regulation S-K, as we are in the process of reconstituting our Board of Directors following our Chapter 11 reorganization.

**Delinquent Section 16(a) Beneficial Ownership Reports**

Section 16 of the Exchange Act requires that reports of beneficial ownership of common stock and changes in such ownership be filed with the Securities and Exchange Commission by Section 16 "reporting persons," including directors, certain officers, holders of more than 10% of the outstanding common stock and certain trusts of which reporting persons are trustees. We are required to disclose in this Annual Report each reporting person whom we know to have failed to file any required reports under Section 16 on a timely basis during the fiscal year ended December 31, 2020. To our knowledge, based solely on a review of copies of Forms 3, 4 and 5 filed with the Securities and Exchange Commission, during the fiscal year ended December 31, 2020, our officers, directors and 10% stockholders complied with all Section 16(a) filing requirements applicable to them.

**Code of Ethics for Senior Financial Officers**

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

**ITEM 11. EXECUTIVE COMPENSATION**.

**Summary Compensation Table**

The following Summary Compensation Table sets forth all compensation earned in all capacities during the fiscal years ended December 31, 2020 and 2019 by (i) each of our then principal executive officers, and (ii) our most highly compensated executive officer, other than our then principal executive officers, who was serving as an executive officer as of December 31, 2020 and whose total compensation for the 2020 fiscal year, as determined by Regulation S-K, Item 402, exceeded $100,000 (the individuals falling within categories (i) and (ii) are collectively referred to as the "Named Executive Officers"):

| Name and Principal Position | Year | Salary | All Other Compensation | Total |
|---|---|---|---|---|
| Lance Alstodt | 2020 | $ 64,317 | $ - | $ 64,317 |
| Chief Executive Officer [1] | 2019 | $ 350,000 | $ - | $ 350,000[2] |
| Francisco Silva | 2020 | $ 207,553 | $ - | $ 207,553 |
| VP, Research and Development | 2019 | $ 287,500 | $ - | $ 287,500[3] |
| Mark Weinreb | 2020 | $ 179,172 | $ - | $ 179,172[4] |
| Chief Executive Officer [5] | 2019 | $ 369,952 | $ 2,400[6] | $ 372,352[6] |

(1) Mr. Alstodt served as our Executive Vice President and Chief Strategy Officer from October 15, 2018 through February 24, 2020. Mr. Alstodt has been serving as our President, Chief Executive Officer and Chairman of the Board since November 16, 2020.

(2) Of the aggregate $350,000 earned cash compensation during 2019, $340,860 was paid in cash during 2019. Accrued compensation of $9,140 at December 31, 2019 was settled in our bankruptcy case.

(3) Of the aggregate $287,500 earned cash compensation during 2019, $263,660 was paid in cash during 2019. Accrued compensation of $23,840 at December 31, 2019 was settled in our bankruptcy case.

(4) Of the aggregate $179,172 earned cash compensation during 2020, $172,672 was paid in cash during 2020. The remaining $6,500 in earned compensation was settled in our bankruptcy case.

(5) Mr. Weinreb resigned as our President, Chief Executive Officer and Chairman of the Board in November 2020.

(6) Of the aggregate $372,352 earned cash compensation during 2019, $335,852 was paid in cash during 2019. The remaining $36,500 in earned compensation was settled in our bankruptcy case. All Other Compensation represents an automobile allowance paid to Mr. Weinreb in 2019.

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

The following table provides information on outstanding equity awards as of December 31, 2020 to the Named Executive Officers:

| | Option Awards | | | | | Stock Awards | | | |
|---|---|---|---|---|---|---|---|---|---|
| Name | Number of securities underlying unexercised options exercisable | Number of securities underlying unexercised options unexercisable | Equity incentive plan awards: Number of securities underlying unexercised unearned options | Option exercise price | Option expiration date | Number of shares or units of stock that have not vested | Market value of shares of units that have not vested | Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested | Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested |
| Lance Alstodt | 500,000 | - | - | $ 1.42 | 2/24/2021 | - | $ - | - | $ - |
| Francisco Silva | 4,000 | - | - | $ 4.70 | 4/4/2021 | - | $ - | - | $ - |
| Francisco Silva | 150 | - | - | $ 4.70 | 6/23/2021 | - | $ - | - | $ - |
| Francisco Silva | 1,000 | - | - | $ 4.70 | 11/16/2021 | - | $ - | - | $ - |
| Francisco Silva | 2,000 | - | - | $ 4.70 | 2/10/2022 | - | $ - | - | $ - |
| Francisco Silva | 4,500 | - | 3,000(1) | $ 4.70 | 5/2/2022 | - | $ - | - | $ - |
| Francisco Silva | 4,000 | - | - | $ 4.70 | 12/7/2022 | - | $ - | - | $ - |
| Francisco Silva | 5,000 | - | - | $ 4.70 | 10/4/2023 | - | $ - | - | $ - |
| Francisco Silva | 12,500 | - | - | $ 4.70 | 2/18/2024 | - | $ - | - | $ - |
| Francisco Silva | 2,000 | - | - | $ 4.70 | 3/12/2024 | - | $ - | - | $ - |
| Francisco Silva | 37,500 | - | - | $ 4.70 | 10/23/2024 | - | $ - | - | $ - |
| Francisco Silva | 25,000 | - | - | $ 4.70 | 9/4/2025 | - | $ - | - | $ - |
| Francisco Silva | 60,000 | - | - | $ 3.73 | 6/10/2026 | - | $ - | - | $ - |
| Francisco Silva | 80,000 | - | - | $ 2.80 | 7/12/2027 | - | $ - | - | $ - |
| Francisco Silva | 66,667 | 33,333(2) | - | $ 1.23 | 10/29/2028 | - | $ - | - | $ - |
| Mark Weinreb | 50,000 | - | - | $ 4.70 | 2/10/2022 | - | $ - | - | $ - |
| Mark Weinreb | 20,000 | - | - | $ 4.70 | 12/7/2022 | - | $ - | - | $ - |
| Mark Weinreb | 12,500 | - | - | $ 4.70 | 10/4/2023 | - | $ - | - | $ - |
| Mark Weinreb | 50,000 | - | - | $ 4.70 | 2/18/2024 | - | $ - | - | $ - |
| Mark Weinreb | 150,000 | - | - | $ 4.70 | 10/23/2024 | - | $ - | - | $ - |
| Mark Weinreb | 208,000 | - | - | $ 4.70 | 9/4/2025 | - | $ - | - | $ - |
| Mark Weinreb | 275,000 | - | - | $ 3.73 | 6/10/2026 | - | $ - | - | $ - |
| Mark Weinreb | 275,000 | - | - | $ 3.35 | 6/23/2027 | - | $ - | - | $ - |
| Mark Weinreb | 275,000 | - | - | $ 1.23 | 10/29/2028 | - | $ - | - | $ - |

(1) Option is exercisable commencing on the date (provided that such date is during Mr. Silva's employment with us), if any, on which either (i) the FDA approves a biologics license application made by us with respect to any biologic product or (ii) a 510(k) Premarket Notification submission is made by us to the FDA with respect to a certain device.

(2) Option is exercisable on October 29, 2021.

**Employment Agreements**

*Lance Alstodt*

2018 Employment Agreement

Effective October 15, 2018, we entered into an at will employment agreement with Lance Alstodt, our then Executive Vice President and Chief Strategy Officer. Pursuant to the employment agreement, Mr. Alstodt was entitled to receive a base annual salary of $350,000. Effective January 1, 2020, his salary was $46,800 per annum (in connection with a salary reduction program for senior management). In addition, pursuant to the employment agreement, Mr. Alstodt was entitled to receive an annual bonus of up to 30% of his annual salary based on the satisfaction of certain performance goals, as determined by our Compensation Committee. Such goals were not satisfied for 2019 (the first year of bonus eligibility). The employment agreement also

provided for the payment of six months severance under certain circumstances. Mr. Alstodt's employment with us as Executive Vice President and Chief Strategy Officer ended effective February 24, 2020. Based upon such termination of employment, Mr. Alstodt was entitled to receive six months severance based upon his salary of $350,000 per annum. Such amount was considered an unsecured claim in our Chapter 11 Case and Mr. Alstodt received shares of our common stock in exchange for such claim in a manner consistent with other unsecured creditors.

2021 Employment Agreement

Effective November 16, 2020, Mr. Alstodt was elected our Chief Executive Officer, President and Chairman of the Board. On March 18, 2021, we entered into an employment agreement with Mr. Alstodt which provides for a term ending on March 18, 2026. Pursuant to the employment agreement, Mr. Alstodt is entitled to receive initially an annual salary of $250,000. Mr. Alstodt's annual salary will increase by $50,000 per year. In addition, in the event certain performance goals are met, Mr. Alstodt's salary will increase by $150,000. Concurrently with the execution of the employment agreement, we granted to Mr. Alstodt pursuant to the 2021 Plan (i) a ten year option for the purchase of 1,173,917,974 shares of our common stock at an exercise price if $0.0119 per share and (ii) 586,958,987 restricted stock units ("RSUs"). The option vests to the extent of 50% thereof on the date of grant and 25% thereof on each of the first and second anniversaries of the date of grant. The RSUs vest in three equal annual installments on the first, second and third anniversaries of the date of grant. In the event that Mr. Alstodt's employment is terminated by us without "cause", or Mr. Alstodt terminates his employment for "good reason" (each as defined in the employment agreement), Mr. Alstodt will be entitled to receive severance in an amount up to one times his then annual base salary. If Mr. Alstodt's employment with us is terminated without cause, the option granted to Mr. Alstodt will vest and become exercisable and such option will remain exercisable until its expiration date notwithstanding such termination of employment with us. In addition, the RSU's granted to Mr. Alstodt will vest in the event of the termination of his employment without cause. Further, in the event of a change in control (as defined in the 2021 Plan), 50% of the unvested RSUs shall vest as of the date of the change in control and the remainder shall vest upon the earlier of the one year anniversary of the change in control or the date on which the RSU was scheduled to vest, subject to earlier vesting in the event Mr. Alstodt's employment is terminated without cause.

*Francisco Silva*

2018 Employment Agreement

Effective April 5, 2011, we entered into an at will employment agreement with Francisco Silva, our Vice President of Research and Development. The employment agreement, as amended, provides for a salary of $287,500 per annum except that, between January 1, 2020 and March 19, 2020, Mr. Silva's salary was $46,800 per annum (in connection with a salary reduction program for senior management) and between April 16, 2020 and November 15, 2020 (during the Chapter 11 Case), his salary was $200,000 per annum. Mr. Silva is currently receiving a salary of $225,000 per annum. In addition, pursuant to the employment agreement, as amended, Mr. Silva is entitled to receive an annual bonus of up to 20% of his annual salary based on the satisfaction of certain performance goals, as determined by our Compensation Committee. Mr. Silva satisfied such goals in part for 2018 and received a bonus of $23,000. Such goals were not satisfied for 2019. Further, pursuant to the employment agreement, as amended, in the event that Mr. Silva's employment with us is terminated without cause, Mr. Silva would be entitled to receive severance in an amount equal to 50% of his then annual base salary.

2021 Employment Agreement

On March 18, 2021, we and Mr. Silva entered into an employment agreement which provides for a term ending on March 18, 2026. Pursuant to the employment agreement, Mr. Silva is entitled to receive initially an annual salary of $225,000. Mr. Silva's annual salary will increase by $50,000 per year. In addition, in the event certain performance goals are met, Mr. Silva's salary will increase by $150,000. Concurrently with the execution of the employment agreement we granted to Mr. Silva pursuant to the 2021 Plan (i) a ten year option for the purchase of 1,173,917,974 shares of our common stock at an exercise price of $0.0119 per share and (ii) 586,958,987 RSUs. The option vests to the extent of 50% thereof on the date of grant and 25% thereof on each of the first and second anniversaries of the date of grant. The RSUs vest in three equal annual installments on the first, second and third anniversaries of the date of grant. In the event that Mr. Silva's employment is terminated by us without "cause", or Mr. Silva terminates his employment for "good reason" (each as defined in the employment agreement), Mr. Silva will be entitled to receive severance in an amount up to one times his then annual base salary. If Mr. Silva's employment with us is terminated without cause, the option granted to Mr. Silva will vest and become exercisable and such option will remain exercisable until its expiration date notwithstanding such termination of employment with us. In addition, the RSU's granted to Mr. Silva will vest in the event of the termination of his employment without cause. Further, in the event of a change in control (as defined in the 2021 Plan), 50% of the unvested RSUs shall vest as of the date of the change in control and the remainder shall vest upon the earlier of the one year anniversary of the change in control or the date on which the RSU was scheduled to vest, subject to earlier vesting in the event Mr. Silva's employment is terminated without cause.

*Mark Weinreb*

In March 2015, we entered into an employment agreement with Mark Weinreb, our then Chief Executive Officer, President and Chairman of the Board. Pursuant to the employment agreement, which expired on September 30, 2020, Mr. Weinreb was entitled to receive a salary of $400,000 per annum, except that, between January 1, 2020 and March 19, 2020, his salary was $46,800 per annum (in connection with a salary reduction program for senior management) and between April 16, 2020 and November 15, 2020 (during the Chapter 11 Case), his salary was $200,000 per annum. Mr. Weinreb was entitled to receive an annual bonus for 2018 and 2019 of up to 50% of his annual base salary in the event certain performance goals, as determined by our Compensation Committee, were satisfied. Such goals were not satisfied for such years. Pursuant to the employment agreement, Mr. Weinreb was entitled to receive severance in an amount equal to one time his then annual base salary (but not less than $400,000) and certain benefits, plus $100,000 (in lieu of bonus) in the event that, within three months of the expiration date of his agreement, his employment was terminated by us without "cause" or if Mr. Weinreb terminated his employment for any reason. Further, in the event that Mr. Weinreb's employment was terminated by us without "cause", or Mr. Weinreb terminated his employment for "good reason", following a "change in control" (as defined in the employment agreement), Mr. Weinreb would have been entitled to receive severance in an amount equal to one and one-half times his then annual base salary (but not less than $400,000 in annual base salary) and certain benefits, plus $300,000 (in lieu of bonus). Pursuant to the employment agreement, with respect to options granted to Mr. Weinreb during the term of his employment with us, such options would vest and become exercisable if Mr. Weinreb was entitled to receive severance based upon a termination of his employment as set forth above. In addition, pursuant to the employment agreement, to the extent that an option granted to Mr. Weinreb during his term of his employment with us became exercisable (whether due to the passage of time or otherwise), such option would remain exercisable until its expiration date notwithstanding any termination of employment with us. Mr. Weinreb resigned his employment with us on November 16, 2020, the effective date of the Chapter 11 reorganization. Based upon such termination of employment, Mr. Weinreb was entitled to receive his severance of $400,000 and certain benefits plus $100,000, and the option accelerations as discussed above. The severance amount was generally considered an unsecured claim in our Chapter 11 Case and Mr. Weinreb received shares of our common stock in exchange for such claim in a manner consistent with other unsecured creditors.

## DIRECTOR COMPENSATION

The following table sets forth certain information concerning the compensation of our then non-employee directors for the fiscal year ended December 31, 2020:

| Name | Fees Earned or Paid in Cash | Stock Awards | Option Awards | Non-Equity Incentive Plan Compensation | Nonqualified Deferred Compensation Earnings | All Other Compensation | Total |
|---|---|---|---|---|---|---|---|
| Robert B. Catell[1] | $ - | $ - | $ -[2] | $ - | $ - | $ - | $ - |
| John M. Desmarais[3] | $ - | $ - | $ -[4] | $ - | $ - | $ - | $ - |
| A. Jeffrey Radov[5] | $ - | $ - | $ -[6] | $ - | $ - | $ - | $ - |
| Charles S. Ryan[7] | $ - | $ - | $ -[8] | $ - | $ - | $ - | $ - |
| Paul Jude Tonna[9] | $ - | $ - | $ -[10] | $ - | $ - | $ - | $ - |

(1) Mr. Catell resigned as a director effective November 16, 2020.

(2) As of December 31, 2020. Mr. Catell held options for the purchase of 219,000 shares of common stock.

(3) Mr. Desmarais resigned as a director effective January 10, 2020.

(4) As of December 31, 2020, Mr. Desmarais held options for the purchase of 225,000 shares of common stock.

(5) Mr. Radov resigned as a director effective November 16, 2020.

(6) As of December 31, 2020, Mr. Radov held options for the purchase of 566,000 shares of common stock.

(7) Dr. Ryan resigned as a director effective January 10, 2020.

(8) As of December 31, 2020, Dr. Ryan held options for the purchase of 231,000 shares of common stock.

(9) Mr. Tonna resigned as a director effective November 16, 2020.

(10) As of December 31, 2020, Mr. Tonna held options for the purchase of 364,000 shares of common stock.

Each of Messrs. Catell, Desmarais, Radov and Tonna and Dr. Ryan, our then non-employee directors, was entitled to receive, as compensation for his services as a director, $30,000 per annum plus $10,000 per annum for all committee service, in each case payable quarterly (subject to our cash needs). Our non-employee directors also received stock options, from time to time, in consideration of their services. There is no arrangement in place for compensation of our only current non-employee director, Dr. Kukekov.

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

**Principal Stockholders**

The following table sets forth certain information regarding the beneficial ownership of our common stock, as of April 27, 2021, known by us, through transfer agent records and reports filed with the SEC, to be held by: (i) each person who beneficially owns 5% or more of the shares of common stock then outstanding; (ii) each of our directors; (iii) each of our Named Executive Officers (as defined above); and (iv) all of our directors and executive officers as a group.

The information in this table reflects "beneficial ownership" as defined in Rule 13d-3 of the Exchange Act. To our knowledge, and unless otherwise indicated, each stockholder has sole voting power and investment power over the shares listed as beneficially owned by such stockholder, subject to community property laws where applicable. Percentage ownership is based on 3,175,977,710 shares of common stock outstanding as of April 27, 2021.

| Beneficial Owner | Number of Shares Beneficially Owned | Approximate Percent of Class |
|---|---|---|
| Lance Alstodt | 605,670,653(1) | 16.1% |
| Francisco Silva | 595,703,049(2) | 15.8% |
| Nickolay Kukekov | 0 | - |
| Mark Weinreb | 1,395,500(3) | * |
| All directors and executive officers as a group (3 persons) | 1,201,373,702(1)(2) | 27.6% |

* Less than 1%

(1)Includes 586,958,987 shares of common stock issuable upon the exercise of a currently exercisable option.

(2)Includes 587,259,304 shares of common stock issuable upon the exercise of currently exercisable options and 12,116 shares of common stock held by Mr. Silva in a retirement account.

(3)Includes 1,315,500 shares of common stock issuable upon the exercise of currently exercisable options.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table sets forth information as of December 31, 2020 with respect to compensation plans (including individual compensation arrangements) under which our common stock are authorized for issuance, aggregated as follows:

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

**EQUITY COMPENSATION PLAN INFORMATION**

| | Number of securities to be issued upon exercise of outstanding options (a) | Weighted-average exercise price of outstanding options (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---|---|---|---|
| Equity compensation plans approved by security holders | 4,859,617 | $ 0.98 | 5,095,383 |
| Total | 4,859,617 | $ 0.98 | 5,095,383 |

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

In July 2019, we, John Desmarais, one of our then non-employee directors and principal stockholders, and Tuxis Trust, a trust for which Mr. Desmarais and his wife serve as the trustees and which was established for the benefit of Mr. Desmarais' immediate family, agreed that the outstanding principal amounts of promissory notes held by Desmarais and Tuxis Trust in the amounts of $175,000 and $500,000, respectively, together with accrued interest, would be exchanged for shares of common stock and warrants, as described below, concurrently with a certain public offering of our securities. The exchange price was to equal 75% of the public offering price of the securities sold by us. The number of shares of common stock issuable pursuant to the warrants to be issued to Mr. Desmarais and Tuxis Trust was to be in the same ratio to the number of shares of common stock issued upon exchange of their indebtedness as the number of shares of common stock subject to the public warrants bore to the number of shares of common stock issued as part of any units of common stock and warrants offered by us. The exercise price of the warrants was to be 125% of the exchange price and the term of the warrants was to be the same term as the public warrants. Concurrently with the exchange, the exercise prices of outstanding warrants held by Mr. Desmarais and Tuxis Trust for the purchase of an aggregate of 1,377,842 shares of common stock were to be reduced from between $1.50 and $4.00 per share to $0.75 per share and the expiration dates of such warrants were to be extended from between December 31, 2019 and March 1, 2022 to December 31, 2023. Concurrently with the exchange, Mr. Desmarais and Tuxis Trust were to release the security interest they held in our equipment and intellectual property with respect to the payment of the notes. The public offering contemplated by the exchange agreement did not occur.

In February 2019, we borrowed $450,000 from Harvey P. Alstodt and Melody Alstodt. The convertible promissory note issued to them provided for the payment of the principal amount, together with interest at the rate of 15% per annum, six months from the date of issuance. The note was convertible, at the option of the lenders, into shares of our common stock at a conversion price of $0.60 per share, subject to adjustment, and a five year warrant for the purchase of a number of shares equal to the number of shares issued upon the conversion of the principal amount of the note. The warrant provided for an exercise price of $0.80 per share, subject to adjustment. The lenders are the parents of Lance Alstodt, our then Executive Vice President and Chief Strategy Officer and currently our President, Chief Executive Officer and Chairman of the Board.

In August 2019, the Alstodts agreed to an extension of the maturity date of the note to September 30, 2019 and that the outstanding principal amount of the note, together with accrued interest, would be exchanged for shares of common stock and warrants concurrently with a certain public offering of our securities. The exchange price was to be equal to the lesser of (i) 75% of the public offering price of the units offered by us and (ii) $0.60 per share. The number of shares of common stock issuable pursuant to the warrant to be issued to the Alstodts was to be equal to the number of shares of common stock issued upon conversion of the principal amount of the note. The exercise price of the warrant was to be equal to the lesser of (i) 125% of the exchange price or (ii) $0.80 per share. The term of the warrant was to be five years. The public offering contemplated by the exchange agreement did not occur.

In March 2019, our Board of Directors reduced the exercise price of outstanding options for the purchase of an aggregate of 4,631,700 shares of our common stock (with exercise prices ranging between $1.00 and $4.70 per share) to $0.75 per share, which was the closing price for our common stock on the day prior to the determination, as reported by the OTCQB. The exercise price reduction related to options held by, among others, our Named Executive Officers and directors with respect to the following number of shares: (i) Mark Weinreb, our then President, Chief Executive Officer and Chairman of the Board: 1,319,500 shares, (ii) A. Jeffrey Radov, one of our then directors: 566,000 shares, (iii) Paul Jude Tonna, one of our then directors: 364,000 shares, (iv) Dr. Charles S. Ryan, one of our then directors: 256,000 shares, (v) Mr. Desmarais: 250,000 shares, (vi) Robert B. Catell, one of our then directors: 219,000 shares, (vii) Mr. Alstodt: 500,000 shares; and (viii) Francisco Silva, our Vice President of Research and Development: 340,650 shares.

In May 2019, we issued 1,111,111 shares of our common stock to Dale Broadrick, one of our then principal stockholders, at a purchase price of $0.45 per share. In consideration thereof, we issued to Mr. Broadrick a five year warrant for the purchase of 555,556 shares of our common stock at an exercise price of $0.85 per share and a one year warrant for the purchase of 555,555 shares of our common stock at an exercise price of $0.70 per share.

In October 2019, we issued 3,333,333 shares of our common stock to Mr. Broadrick at a purchase price of $0.15 per share. In consideration thereof, we issued to Mr. Broadrick a five year warrant for the purchase of 3,333,333 shares of our common stock at an exercise price of $0.20 per share. In addition, in consideration thereof, we reduced the exercise prices of outstanding warrants held by Mr. Broadrick for the purchase of 1,055,556 and 1,055,555 shares of our common stock from $0.70 and $0.85 per share, respectively, to $0.15 per share and extended the expiration dates of warrants held by Mr. Broadrick for the purchase of 500,000 and 555,555 shares of our common stock from February 19, 2020 and May 7, 2020, respectively, to February 19, 2024 and May 7, 2024, respectively.

In December 2019, we agreed that the exercise price of warrants held by Mr. Broadrick for the purchase of an aggregate of 5,444,444 shares of our common stock was reduced to the lesser of (i) $0.03 per share or (ii) 80% of fair market value at the time of exercise of the particular warrant, but in no event less than $0.01 per share (subject to adjustment for stock splits, reverse stock splits, recapitalizations and similar events).

**Director Independence**

**Board of Directors**

Our Board of Directors is currently comprised of Lance Alstodt (Chair), Francisco Silva and Nickolay Kukekov. Dr. Kukekov is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

**Audit Committee**

Dr. Kukekov is the sole member of our Board's Audit Committee. Dr. Kukekov is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market and Rule 10A-3(b)(1) under the Exchange Act.

**Nominating Committee**

Dr. Kukekov is the sole member of our Board's Nominating Committee. Dr. Kukekov is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

**Compensation Committee**

Dr. Kukekov is the sole member of our Board's Compensation Committee. Dr. Kukekov is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Friedman LLP has served as our independent registered public accountants for the years ended December 31, 2020 and 2019.

The following is a summary of the fees billed or expected to be billed to us by Friedman LLP, our independent registered public accountants, for professional services rendered with respect to the fiscal years ended December 31, 2020 and 2019 and by Marcum LLP, our former independent registered public accountants, for professional services rendered with respect to the fiscal year ended December 31, 2019:

| | Friedman LLP | | Marcum LLP |
|---|---|---|---|
| | 2020 | 2019 | 2019 |
| Audit fees (1) | $ 80,000 | $ 45,000 | $ 92,000 |
| Audit-related fees (2) | - | - | - |
| Tax fees (3) | - | - | 11,000 |
| All other fees (4) | - | - | - |
| | $ 80,000 | $ 45,000 | $ 103,000 |

(1) Audit Fees consist of fees billed and expected to be billed for services rendered for the audit of our consolidated financial statements for the fiscal years ended December 31, 2020 and 2019 and, with respect to Marcum, the review of our condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q and in connection with the filing of Forms S-1 and S-8 registration statements.

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

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

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

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

## PART IV

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

| Exhibit No. | |
|---|---|
| 2.1 | Order of the Bankruptcy Court for the Eastern District of New York Confirming Amended Joint Plan of Reorganization of BioRestorative Therapies, Inc., and Auctus Fund, LLC (the "Plan of Reorganization"), incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is identified as Exhibit 2.1 |
| 2.2 | Amended Disclosure Statement with respect to the Plan of Reorganization, together with exhibits thereto, including the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is identified as Exhibit 2.2 |
| 2.3 | Plan Supplement to the Plan of Reorganization, together with forms of Secured Convertible Note, Unsecured Convertible Note, Class A Warrant, Class B Warrant, Intercreditor Agreement and Security Agreement attached as exhibits thereto, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is identified as Exhibit 2.3. |
| 3.1 | Certificate of Incorporation, as amended, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2019, wherein such document is identified as Exhibit 2.3. |
| 3.2 | Bylaws, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated December 19, 2014, wherein such document is identified as Exhibit 3.4 |
| 10.1 | 2010 Equity Participation Plan, as amended, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2019, wherein such document is identified as Exhibit 10.1 |
| 10.2 | Stock Option Agreement, dated April 5, 2011, between Stem Cell Assurance, Inc. (now BioRestorative Therapies, Inc.) and Francisco Silva, incorporated by reference to the registrant's Form 10, wherein such document is identified as Exhibit 10.24 |
| 10.3 | License Agreement, dated as of January 27, 2012, between Regenerative Sciences, LLC and BioRestorative Therapies, Inc. ("License Agreement"), incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 10.44 |
| 10.4 | Amendment to License Agreement, dated March 21, 2012, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 10.45 |
| 10.5 | Amendment to License Agreement, dated November 30, 2015, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, wherein such document is identified as Exhibit 10.20 |
| 10.6 | Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 10.46 |
| 10.7 | Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 10.49 |
| 10.8 | Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2012, wherein such document is identified as Exhibit 10.58 |
| 10.9 | Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2012, wherein such document is identified as Exhibit 10.61 |
| 10.10 | Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.59 |
| 10.11 | Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.62 |

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|---|---|
| 10.12 | Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.64 |
| 10.13 | Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.67 |
| 10.14 | Stock Option Agreement, dated as of March 12, 2014, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.70 |
| 10.15 | Lease, dated as of August 25, 2014, between BioRestorative Therapies, Inc. and 50 Republic Road, LLC, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated August 25, 2014, wherein such document is identified as Exhibit 99.1 |
| 10.16 | Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.65 |
| 10.17 | Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.67 |
| 10.18 | Stock Option Agreement, dated as of September 4, 2015, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Amendment No. 1 to Form S-1 Registration Statement (Registration No. 333-204672), wherein such document is identified as Exhibit 10.77 |
| 10.19 | Stock Option Agreement, dated as of September 4, 2015, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Amendment No. 1 to Form S-1 Registration Statement (Registration No. 333-204672), wherein such document is identified as Exhibit 10.80 |
| 10.20 | Stock Option Agreement, dated as of June 10, 2016, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2016, wherein such document is identified as Exhibit 10.59 |
| 10.21 | Stock Option Agreement, dated as of June 10, 2016, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2016, wherein such document is identified as Exhibit 10.60 |
| 10.22 | Stock Option Agreement, dated as of June 23, 2017, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.73 |
| 10.23 | Stock Option Agreement, dated as of July 12, 2017, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.76 |
| 10.24 | Stock Option Agreement, dated as of October 29, 2018, between BioRestorative Therapies, Inc., and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.94 |
| 10.25 | Stock Option Agreement, dated as of October 29, 2018, between BioRestorative Therapies, Inc., and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.96 |
| 10.26 | Lease Amendment, dated as of June 4, 2019, between 50 Republic Road, LLC and BioRestorative Therapies, Inc., incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2019, wherein such document is identified as Exhibit 10.37 |
| 10.27 | Form of Secured Convertible Note issued pursuant to Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit A to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3 |
| 10.28 | Form of Unsecured Convertible Note issued pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit B to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3 |
| 10.29 | Form of Class A Warrant issued pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit C to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3 |
| 10.30 | Form of Class B Warrant issued pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit D to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3 |
| 10.31 | Form of Intercreditor Agreement entered into pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit E to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3 |

| | |
|---|---|
| 10.32 | Form of Security Agreement entered into pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit F to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3 |
| 10.33 | BioRestorative Therapies, Inc. 2021 Stock Incentive Plan, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.1 |
| 10.34 | Employment Agreement, dated as of March 18, 2021, by and between BioRestorative Therapies, Inc. and Lance Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.2 |
| 10.35 | Employment Agreement, dated as of March 18, 2021, by and between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.3 |
| 10.36 | Non-Qualified Stock Option Award Agreement, dated as of March 18, 2021, between BioRestorative Therapies, Inc. and Lance Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.4 |
| 10.37 | Non-Qualified Stock Option Award Agreement, dated as of March 18, 2021, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.5 |
| 10.38 | Restricted Stock Unit Award Agreement, dated as of March 18, 2021, between BioRestorative Therapies, Inc. and Lance Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.6 |
| 10.39 | Restricted Stock Unit Award Agreement, dated as of March 18, 2021, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.7 |
| 14 | Code of Ethics, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 14 |
| 21 | Subsidiaries, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 21 |
| 23 | Independent Registered Public Accounting Firm's Consent* |
| 31.1 | Principal Executive Officer Certification* |
| 31.2 | Principal Financial Officer Certification* |
| 32 | Section 1350 Certification** |

| | |
|---|---|
| 101.INS | XBRL Instance Document * |
| 101.SCH | XBRL Schema Document * |
| 101.CAL | XBRL Calculation Linkbase Document* |
| 101.DEF | XBRL Definition Linkbase Document* |
| 101.LAB | XBRL Label Linkbase Document* |
| 101.PRE | XBRL Presentation Linkbase Document* |

* Filed herewith
** Furnished herewith

**ITEM 16. FORM 10-K SUMMARY**.

Not applicable

## SIGNATURES

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

**BIORESTORATIVE THERAPIES, INC.**

Dated: April 29, 2021

By: */s/ Lance Alstodt*
Lance Alstodt
Chief Executive Officer

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

| Signature | Capacity | Date |
|---|---|---|
| */s/ Lance Alstodt*<br>Lance Alstodt | Chief Executive Officer, President, Chairman of the Board and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer) | April 29, 2021 |
| */s/ Francisco Silva*<br>Francisco Silva | Vice President, Research and Development and Director | April 29, 2021 |
| */s/ Nickolay Kukekov*<br>Nickolay Kukekov | Director | April 29, 2021 |

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

**BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY**
**CONSOLIDATED FINANCIAL STATEMENTS**

TABLE OF CONTENTS

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Shareholders of BioRestorative Therapies, Inc. & Subsidiary.

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of BioRestorative Therapies, Inc. & Subsidiary (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

**Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the board of directors and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

***Valuation of Intangible Asset***

*Description of the Matter*

As described in Note 3 of the consolidated financial statements, the Company records its intangible asset at cost and amortizes the asset over an estimated useful life using the straight-line method, which is determined by identifying the period over which the cash flows from the assets are expected to be generated. The Company reviews long-lived assets, including definite-lived intangible assets, for impairment whenever events or circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets are determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to the carrying amount. If the operation is determined to be unable to recover the carrying amount of its assets, then these assets are written down first, followed by other long-lived assets of the operation to fair value.

*How We Addressed the Matter in Our Audit*

We evaluated management's assessment of impairment. We evaluated the Company's current performance, and reviewed forecasted information. We assessed the reasonableness of the forecasted operating results. The testing included inquiries with management, testing of management's qualitative assessment of impairment and indicators, and comparison of prior period forecasts to actual results.

***Liquidity – Assessing the Company's Ability to Continue as a Going Concern***

*Description of the Matter*

As described in Note 2 of the consolidated financial statements, the Company has adequate cash on hand, which will provide sufficient liquidity to finance the operating activities of the Company for twelve months from the issuance of these consolidated financial statements. We determined that the Company's ability to continue as a going concern is a critical audit matter due to significant management's judgments and assumptions used in estimating future cash flows.

*How We Addressed the Matter in Our Audit*

We reviewed forecasted information, assessed reasonableness of the forecasted operating results and uses and sources of cash used in management's assessment. This testing included inquiries with management, comparison of prior period forecasts to actual results, assessment of available financing, consideration of positive and negative evidence impacting management's forecasts, market and industry factors.

*/s/ Friedman LLP*

We have served as the Company's auditor since 2020.
Marlton, New Jersey
April 29, 2021

**BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY**
**CONSOLIDATED BALANCE SHEETS**

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **ASSETS** | | |
| **Current Assets:** | | |
| Cash | $ 3,064,610 | $ 1,664 |
| Accounts receivable | 17,000 | 32,000 |
| Prepaid expenses | 105,407 | 35,199 |
| **Total Current Assets** | 3,187,017 | 68,863 |
| Equipment, net | 21,914 | 68,402 |
| Right of use asset | 473,849 | 589,894 |
| Intangible assets, net | 664,268 | 739,164 |
| **Total Assets** | $ 4,347,048 | $ 1,466,323 |
| **LIABILITIES AND STOCKHOLDERS' DEFICIT** | | |
| **Current Liabilities:** | | |
| Accounts payable | $ 118,851 | $ 1,954,427 |
| Accrued expenses and other current liabilities | 718,259 | 2,921,164 |
| Accrued interest | 49,307 | 697,658 |
| Lease liability | 158,371 | 85,465 |
| Notes payable, net of debt discount of $- and $1,247,422, respectively | - | 7,145,906 |
| Derivative liabilities | - | 915,959 |
| **Total Current Liabilities** | 1,044,788 | 13,720,579 |
| Lease liability, net of current portion | 363,519 | 521,890 |
| Notes payable, net of debt discount of $5,366,869 | 4,270,233 | - |
| **Total Liabilities** | 5,678,540 | 14,242,469 |
| **Commitments and Contingencies** | | |
| **Stockholders' Deficit:** | | |
| Preferred stock, $0.01 par value; Authorized, 20,000,000 shares; none issued and outstanding at December 31, 2020 and December 31, 2019 | - | - |
| Common stock, $0.0001 par value; Authorized, 300,000,000,000 shares; Issued and outstanding 2,862,174,380 and 77,851,633, respectively | 286,220 | 7,787 |
| Additional paid in capital | 88,225,121 | 65,786,213 |
| Accumulated deficit | (89,842,833) | (78,570,146) |
| **Total Stockholders' Deficit** | (1,331,492) | (12,776,146) |
| **Total Liabilities and Stockholders' Deficit** | $ 4,347,048 | $ 1,466,323 |

The accompanying notes are an integral part of these consolidated financial statements.

**BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY**
**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | For the Years Ended | |
|---|---|---|
| | **December 31, 2020** | **December 31, 2019** |
| Revenues | $ 77,000 | $ 130,000 |
| Operating expenses: | | |
| Marketing and promotion | 28,281 | 321,280 |
| Consulting | 137,250 | 1,912,683 |
| Research and development | 876,829 | 1,722,338 |
| General and administrative | 1,786,716 | 4,605,704 |
| Total operating expenses | 2,829,076 | 8,562,005 |
| Loss from operations | (2,752,076) | (8,432,005) |
| Other expense: | | |
| Interest expense | (362,041) | (1,467,952) |
| Amortization of debt discount | (1,278,104) | (3,671,087) |
| Loss on extinguishment of notes payable, net | (658,152) | (1,895,116) |
| Change in fair value of derivative liabilites | (2,141,069) | 788,970 |
| Reorganization items, net | (4,081,245) | - |
| Other income | - | 29,300 |
| Total other expense | (8,520,611) | (6,215,885) |
| Net loss | $ (11,272,687) | $ (14,647,890) |
| Net Loss Per Share | | |
| - Basic and Diluted | $ (0.01) | $ (0.66) |
| Weighted Average Number of Common Shares Outstanding | | |
| - Basic and Diluted | 1,578,818,497 | 22,277,350 |

The accompanying notes are an integral part of these consolidated financial statements.

**BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT**

| | Common Stock | | Additional Paid-in | Accumulated | Total Shareholders' |
|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Deficit |
| **Balance at January 1, 2020** | 77,851,633 | $ 7,787 | $ 65,786,213 | $ (78,570,146) | $ (12,776,146) |
| Shares and warrants issued for cash | 1,000,000 | 100 | 9,900 | - | 10,000 |
| Shares issued in exchange of notes payable and accrued interest | 1,515,799,750 | 151,580 | 2,407,352 | - | 2,558,932 |
| Shares issued in satisfaction of bankruptcy allowable claims | 1,049,726,797 | 104,973 | 14,276,286 | - | 14,381,259 |
| Shares issued in cashless exercise of warrants | 217,796,200 | 21,780 | (21,780) | - | - |
| Fair market value of beneficial conversion feature and warrants issued convertible notes payable instruments | - | - | 5,075,449 | - | 5,075,449 |
| Stock-based compensation: | | | | | |
| - options | - | - | 691,701 | - | 691,701 |
| Net loss | - | - | - | (11,272,687) | (11,272,687) |
| **Balance as of December 31, 2020** | 2,862,174,380 | $ 286,220 | $ 88,225,121 | $ (89,842,833) | $ (1,331,492) |
| **Balance at January 1, 2019** | 11,728,394 | $ 1,175 | $ 55,280,043 | $ (63,922,256) | $ (8,641,038) |
| Shares and warrants issued for cash | 5,663,301 | 566 | 254,346 | - | 254,912 |
| Shares issued in satisfaction of accrued consulting services | 10,000 | 1 | 7,199 | - | 7,200 |
| Shares issued in exchange for notes payable and accrued interest | 60,296,065 | 6,029 | 5,715,331 | - | 5,721,360 |
| Shares issued and recorded as debt discount in connection with a note payable issuances and extensions | 78,873 | 8 | 61,212 | - | 61,220 |
| Reclassification of derivative liabilities to equity | - | - | 2,809,565 | - | 2,809,565 |
| Stock-based compensation: | | | | | |
| - common stock | 75,000 | 8 | 29,992 | - | 30,000 |
| - options and warrants | - | - | 1,628,525 | - | 1,628,525 |
| Net loss | - | - | - | (14,647,890) | (14,647,890) |
| **Balance as of December 31, 2019** | 77,851,633 | $ 7,787 | $ 65,786,213 | $ (78,570,146) | $ (12,776,146) |

The accompanying notes are an integral part of these consolidated financial statements.

**BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | Years Ended | |
|---|---|---|
| | **December 31, 2020** | **December 31, 2019** |
| Cash flows from operating activities: | | |
| Net Loss | $ (11,272,687) | $ (14,647,890) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Amortization of debt discount | 1,278,105 | 3,671,087 |
| Accretion of interest expense | 2,810,973 | 548,026 |
| Depreciation and amortization | 121,384 | 217,359 |
| Stock-based compensation | 691,701 | 1,658,524 |
| Loss on extinguishment of note payables, net | 658,152 | 1,895,116 |
| Gain on settlement of payables | - | (29,300) |
| Reorganization items, net | 527,455 | - |
| Change in fair value of derivative liabilities | 2,141,069 | (788,970) |
| Professional fees paid for services related to bankruptcy proceedings | 476,653 | - |
| Non-cash effect of right of use asset | 30,580 | 17,461 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 15,000 | (3,000) |
| Security deposit | - | 22,100 |
| Prepaid assets and other current assets | (70,208) | (735) |
| Accounts payable | 84,631 | 97,099 |
| Accrued interest, expenses and other current liabilities | 542,927 | 424,389 |
| Net cash used in operating activities | (1,964,265) | (6,918,734) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | - | (35,631) |
| Net cash used in investing activities | - | (35,631) |
| Cash flows from financing activities: | | |
| Proceeds from notes payable | 4,290,310 | 10,888,339 |
| Payments on notes payable - principal | - | (4,894,604) |
| Payments on notes payable - prepayment premiums | - | (813,730) |
| Proceeds from DIP financiing | 1,226,901 | - |
| Financing costs | (500,000) | - |
| Sales of common stock and warrants for cash | 10,000 | 1,658,500 |
| Net cash provided by financing activities | 5,527,211 | 6,838,505 |
| Net increase (decrease) in cash and cash equivalents | 3,062,946 | (115,859) |
| Cash and cash equivalents - beginning of year | 1,664 | 117,523 |
| Cash and cash equivalents - end of year | $ 3,064,610 | $ 1,664 |
| Supplemental cash flow information: | | |
| Cash paid for: | | |
| Interest | $ - | $ 355,326 |
| Non-cash investing and financing activities: | | |
| Shares issued and recorded as debt discount in connection with notes payable issuances and extensions | $ - | $ 61,220 |
| Shares issued in exchange for notes payable and accrued interest | $ 2,558,932 | $ 5,721,360 |
| Shares and warrants issued in satisfaction of accrued consulting services | $ - | $ 7,200 |
| Shares issued in satisfaction of bankruptcy allowable claims | $ 14,381,259 | $ - |
| Reclassification of derivative liabilities to equity | $ - | $ 2,809,565 |
| Bifurcated embedded conversion options and warrants recorded as derivative liability and debt discount | $ 2,377,818 | $ 5,216,650 |
| Fair market value of beneficial conversion feature and warrants issued convertible notes payable instruments | $ 5,075,449 | $ - |
| Sale of warrants recorded as derivative liabilities | $ 10,000 | $ 1,403,588 |
| Write of use asset and lease liability recorded upon adoption of ASC 842 | $ - | $ 638,246 |

The accompanying notes are an integral part of these consolidated financial statements.

## NOTE 1 – ORGANIZATION AND BUSINESS OPERATIONS

*Corporate History*

BioRestorative Therapies, Inc. has one wholly-owned subsidiary, Stem Pearls, LLC ("Stem Pearls"). BioRestorative Therapies, Inc. and its subsidiary are referred to collectively as "BRT" or the "Company".

On March 20, 2020 (the "Petition Date"), the Company filed a voluntary petition commencing a case (the "Chapter 11 Case") under chapter 11 of title 11 of the U.S. Code in the United States Bankruptcy Court for the Eastern District of New York (the "Bankruptcy Court").

On August 7, 2020 the Company and Auctus Fund, LLC ("Auctus"), the Company's largest unsecured creditor and a stockholder as of the Petition Date, filed an Amended Joint Plan of Reorganization (the "Plan") and on October 30, 2020, the Bankruptcy Court entered an order (the "Confirmation Order") confirming the Plan, as amended. Amendments to the Plan are reflected in the Confirmation Order. On November 16, 2020 (the "Effective Date"), the Plan became effective. See Note 7 – Notes Payable – Chapter 11 Reorganization.

*Business Operations*

BRT develops therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. BRT's website is at www.biorestorative.com. BRT is currently developing a Disc/Spine Program referred to as "brtxDISC". Its lead cell therapy candidate, *BRTX-100*, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells collected from the patient's bone marrow. The product is intended to be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complimentary therapeutic to a surgical procedure. BRT is also engaging in research efforts with respect to a platform technology utilizing brown adipose (fat) for therapeutic purposes to treat type 2 diabetes, obesity and other metabolic disorders and has labeled this initiative its ThermoStem Program. Further, BRT has licensed a patented curved needle device that is a needle system designed to deliver cells and/or other therapeutic products or material to the spine and discs or other potential sites.

## NOTE 2 – LIQUIDITY

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. For the year ended December 31, 2020, the Company had a loss from operations of approximately $2,752,000 and negative cash flows from operations of approximately $1,964,000. The Company's operating activities consume the majority of its cash resources. The Company anticipates that it will continue to incur operating losses as it executes its development plans for 2021, as well as other potential strategic and business development initiatives. In addition, the Company has had and expects to have negative cash flows from operations, at least into the near future. The Company has previously funded, and plans to continue funding, these losses primarily through additional infusions of cash from equity and debt financing.

The Company believes the following has been able to mitigate the above factors with regards to its ability to continue as a going concern: (i) as part of its Chapter 11 reorganization approximately $14,700,000 in outstanding debt and other liabilities were exchanged for (a) shares of common stock, (b) new convertible notes or (c) new convertible notes and warrants to purchase shares of common stock; (ii) the Company secured DIP financing during its Chapter 11 Case in the amount of $1,189,413, as well as an aggregate amount of $3,848,548 in debt financing from Auctus and others as part of the Company's Chapter 11 reorganization, to sustain operations; and (iii) pursuant to the plan of reorganization, Auctus is required to loan to the Company, as needed and subject to the Company becoming current in its SEC reporting obligations, an additional amount equal to $3,500,000, less the amount of Auctus' DIP financing ($1,226,901, inclusive of accrued interest) and its DIP costs not to exceed approximately $650,000. As a result of the above, and cash on hand of approximately $2,455,935 as of April 19, 2021, the Company believes it has sufficient cash to fund operations for the twelve months subsequent to the filing date. In addition, the Company is seeking further funding to commence and complete a Phase 2 clinical study of the use of *BRTX-100*.

Current funds on hand will not be sufficient to enable the Company to fully complete its development activities or attain profitable operations. If the Company is unable to obtain such additional financing on a timely basis the Company may have to curtail its development, marketing and promotional activities, which would have a material adverse effect on the Company's business, financial condition and results of operations, and ultimately the Company could be forced to discontinue its operations and liquidate.

**NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Basis of Presentation*

The accompanying audited consolidated financial statements have been prepared in accordance with GAAP. The summary of significant accounting policies presented below is designed to assist in understanding the Company's consolidated financial statements. Such consolidated financial statements and accompanying notes are the representations of Company's management, who is responsible for their integrity and objectivity.

*Principles of Consolidation*

These consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary Stem Pearls. Intercompany accounts and transactions have been eliminated upon consolidation.

*Chapter 11 Cases*

**Chapter 11 Accounting**

The consolidated financial statements included herein have been prepared as if we were a going concern and in accordance with Accounting Standards Codification ("ASC") 852, *Reorganizations*.

Weak industry conditions in 2019 negatively impacted the Company's results of operations and cash flows and may continue to do so in the future. In order to decrease the Company's indebtedness and maintain the Company's liquidity levels sufficient to meet its commitments, the Company undertook a number of actions, including minimizing capital expenditures and further reducing its recurring operating expenses. The Company believed that even after taking these actions, it would not have sufficient liquidity to satisfy its debt service obligations and meet its other financial obligations. On March 20, 2020 (the "Petition Date"), the Company filed a voluntary petition commencing a case under chapter 11 of title 11 of the U.S. Code in the United States Bankruptcy Court for the Eastern District of New York. On August 7, 2020, the Company and Auctus, the Company's largest unsecured creditor and a stockholder as of the Petition Date, filed an Amended Joint Plan of Reorganization (the "Plan"). On November 16, 2020 (the "Effective Date"), the Plan became effective.

**Reorganization Items, Net**

The Company incurred costs after the Petition Date associated with the reorganization, primarily unamortized debt discount, exchange of common stock and unsecured convertible notes for allowable claims and post-petition professional fees. In accordance with applicable guidance, costs associated with the bankruptcy proceedings have been recorded as reorganization items, net within the accompanying consolidated statements of operations for the year ended December 31, 2020. Reorganization items, net for the year ended December 31, 2020, was $(4,081,245), representing cash used in operating activities.

Reorganization items, net for the year ended December 31, 2020, consisted of the following:

| | Year Ended December 31, 2020 |
|---|---|
| Professional fees | $ (476,652) |
| Write-off of derivative liability | 4,375,231 |
| Default interest and penalties | (864,125) |
| Exchange of common stock for allowable claims | (3,047,417) |
| Exchange of secured convertible debt for allowable claims | (1,488,172) |
| Unamortized debt discount on convertible notes | (2,580,110) |
| Total reorganization items, net | $ (4,081,245) |

*Use of Estimates*

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity-based transactions, revenue and expenses and disclosure of contingent liabilities at the date of the consolidated financial statements. The Company bases its estimates and assumptions on historical experience, known or expected trends and various other assumptions that it believes to be reasonable. As future events and their effects cannot be determined with precision, actual results could differ from these estimates which may cause the Company's future results to be affected.

The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of the accompanying consolidated financial statements. Significant estimates include the carrying value of intangible assets, deferred tax asset and valuation allowance, estimated fair value of derivative liabilities stemming from convertible debt securities, and assumptions used in the Black-Scholes-Merton pricing model, such as expected volatility, risk-free interest rate, and expected divided rate.

*Concentrations*

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. As of December 31, 2020 and 2019, the Company had approximately $2,815,000 and $-, respectively, in excess of the FDIC insured limit.

The royalties related to the Company's sublicense comprised all of the Company's revenue during the years ended December 31, 2020 and 2019. See "Revenue" below.

During the years ended December 31, 2020 and 2019, 84% and 30% of the Company's debt financings were from one lender.

*Revenue*

The Company accounts for revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, which the Company adopted beginning on January 1, 2019, utilizing the modified retrospective method. The approach was applied to contracts that were in process as of January 1, 2019. The adoption of ASC Topic 606 did not have an impact on the Company's reported revenue or contracts in process at January 1, 2019. The reported results for the fiscal year 2019 reflect the application of ASC Topic 606.

The Company derives all of its revenue pursuant to a license agreement between the Company and a stem cell treatment company ("SCTC") entered into in January 2012, as amended in November 2015. Pursuant to the license agreement, the SCTC granted to the Company a license to use certain intellectual property related to, among other things, stem cell disc procedures and the Company has granted to the SCTC a sublicense to use, and the right to sublicense to third parties the right to use, in certain locations in the United States and the Cayman Islands, certain of the licensed intellectual property. In consideration of the sublicenses, the SCTC has agreed to pay the Company royalties on a per disc procedure basis.

The Company's contracted transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The Company's contracts have a single performance obligation which is not separately identifiable from other promises in the contracts and is, therefore, not distinct. The Company's performance obligation is satisfied upon the transfer of risk of loss to the customer. All sales have fixed pricing and there are currently no variable components included in the Company's revenue. The timing of the Company's revenue recognition may differ from the timing of receiving royalty payments. A receivable is recorded when revenue is recognized prior to receipt of a royalty payment and the Company has an unconditional right to the royalty payment. Alternatively, when a royalty payment precedes the provision of the related services, the Company records deferred revenue until the performance obligations are satisfied. During the years ended December 31, 2020 and 2019, the Company recognized $77,000 and $130,000, respectively, of revenue related to the Company's sublicenses.

**Practical Expedients**

As part of ASC Topic 606, the Company has adopted several practical expedients including:

- Significant Financing Component – the Company does not adjust the promised amount of consideration for the effects of a significant financing component since the Company expects, at contract inception, that the period between when the Company transfers a promised good or service to the customer and when the customer pays for that good or service will be one year or less.
- Unsatisfied Performance Obligations – all performance obligations related to contracts with a duration for less than one year, the Company has elected to apply the optional exemption provided in ASC Topic 60 and therefore, is not required to disclose the aggregate amount of transaction price allocated to performance obligations that are unsatisfied or partially satisfied at the end of the reporting period.
- Right to Invoice – the Company has a right to consideration from a customer in an amount that corresponds directly with the value to the customer of the Company's performance completed to date the Company may recognize revenue in the amount to which the entity has a right to invoice.

Contract Modifications

There were no contract modifications during the years ended December 31, 2020 and 2019. Contract modifications are not routine in the performance of the Company's contracts.

*Cash*

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. There were no cash equivalents as of December 31, 2020 or 2019.

*Accounts Receivable*

Accounts receivable are reported at their outstanding unpaid principal balances net of allowances for doubtful accounts. The Company periodically assesses its accounts and other receivables for collectability on a specific identification basis. The Company provides for allowances for doubtful receivables based on management's estimate of uncollectible amounts considering age, collection history, and any other factors considered appropriate. The Company writes off accounts receivable against the allowance for doubtful accounts when a balance is determined to be uncollectible. The Company did not record an allowance for doubtful accounts as of December 31, 2020 and 2019, respectively.

*Property and Equipment*

Property and equipment are recorded at cost. Depreciation is computed using straight-line method over the estimated useful lives of the related assets, generally three to fifteen years. Expenditures that enhance the useful lives of the assets are capitalized and depreciated. Computer equipment costs are capitalized, as incurred, and depreciated on a straight-line basis over a range of 3 – 5 years.

Leasehold improvements are amortized over the lesser of (i) the useful life of the asset, or (ii) the remaining lease term. Maintenance and repairs are charged to expense as incurred. The Company capitalizes cost attributable to the betterment of property and equipment when such betterment extends the useful life of the assets. At the time of retirement or other disposition of property and equipment, the cost and accumulated depreciation will be removed from the accounts and the resulting gain or loss, if any, will be reflected in operations.

*Impairment of Long-Lived Assets*

The Company reviews long-lived assets, including definite-lived intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to the carrying amount. If the operation is determined to be unable to recover the carrying amount of its assets, then these assets are written down first, followed by other long-lived assets of the operation to fair value. Fair value is determined based on discounted cash flows or appraised values, depending on the nature of the assets. For the years ended December 31, 2020 and 2019, we determined that there was no impairment charge for our intangible assets.

*Intangible Assets*

The Company records its intangible assets at cost in accordance with Accounting Standards Codification ("ASC") 350, Intangibles – Goodwill and Other. Definite lived intangible assets are amortized over their estimated useful life using the straight-line method, which is determined by identifying the period over which the cash flows from the asset are expected to be generated.

*Advertising and Marketing Costs*

The Company expenses advertising and marketing costs as they are incurred. Advertising and marketing expenses were $28,281 and $321,280 for the years ended December 31, 2020 and 2019, respectively, and are recorded in marketing and promotion on the statement of operations.

*Fair Value Measurements*

As defined in ASC 820, "Fair Value Measurements and Disclosures," fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The Company utilizes market data or assumptions that market participants would use in pricing the asset or liability, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated, or generally unobservable. ASC 820 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurement) and the lowest priority to unobservable inputs (level 3 measurement). This fair value measurement framework applies at both initial and subsequent measurement.

Level 1: Quoted prices are available in active markets for identical assets or liabilities as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis. Level 1 primarily consists of financial instruments such as exchange-traded derivatives, marketable securities and listed equities.

Level 2: Pricing inputs are other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reported date. Level 2 includes those financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including quoted forward prices for commodities, time value, volatility factors and current market and contractual prices for the underlying instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace throughout the full term of the instrument, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace. Instruments in this category generally include non-exchange-traded derivatives such as commodity swaps, interest rate swaps, options and collars.

Level 3: Pricing inputs include significant inputs that are generally less observable from objective sources. These inputs may be used with internally developed methodologies that result in management's best estimate of fair value.

See Note 9 – Derivative Liabilities for additional details regarding the valuation technique and assumptions used in valuing Level 3 inputs.

*Fair Value of Financial Instruments*

The carrying value of cash, accounts receivable, accounts payable and accrued expenses, and other current liabilities approximate their fair values based on the short-term maturity of these instruments. The carrying amount of notes approximate the estimated fair value for these financial instruments as management believes that such notes constitute substantially all of the Company's debt and interest payable on the notes approximates the Company's incremental borrowing rate.

*Net Loss per Common Share*

Net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. All vested outstanding options and warrants are considered potential common stock. The dilutive effect, if any, of stock options and warrants are calculated using the treasury stock method. All outstanding convertible notes are considered common stock at the beginning of the period or at the time of issuance, if later, pursuant to the if-converted method. Since the effect of common stock equivalents is anti-dilutive with respect to losses, options, warrants, and convertible notes have been excluded from the Company's computation of net loss per common share for the years ended December 31, 2020 and 2019.

The following table summarizes the securities that were excluded from the diluted per share calculation because the effect of including these potential shares was antidilutive due to the Company's net loss position even though the exercise price could be less than the average market price of the common shares:

| | Year Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Options | 4,859,617 | 4,879,617 |
| Warrants | 15,002,388,203 | 8,379,177 |
| Convertible notes | 436,307,132(1) | 501,549,663(2) |
| Total | 15,675,232,655 | 514,808,457 |

(1) As of December 31, 2020 all of the convertible notes had variable conversion prices and the shares issuable were estimated based on the market conditions. Pursuant to the note agreements, there were 52,292,375,355 shares of common stock reserved for future note conversions as of December 31, 2020.

(2) As of December 31, 2019 many of the convertible notes had variable conversion prices and the shares issuable were estimated based on the market conditions. Pursuant to the note agreements, there were 225,023,100 shares of common stock reserved for future note conversions as of December 31, 2019.

*Stock-Based Compensation*

The Company applies the provisions of ASC 718, Compensation—Stock Compensation ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees, including employee stock options, in the statements of operations.

For stock options issued to employees and members of the board of directors for their services, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are recorded as they are incurred as opposed to being estimated at the time of grant and revised.

Pursuant to ASU 2018-07 Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, the Company accounts for stock options issued to non-employees for their services in accordance ASC 718. The Company uses valuation methods and assumptions to value the stock options that are in line with the process for valuing employee stock options noted above.

Since the shares underlying the Company's 2010 Equity Participation Plan (the "Plan") are registered, the Company estimates the fair value of the awards granted under the Plan based on the market value of its freely tradable common stock as reported on the OTCQB market. On February 3, 2020, the Company was advised by OTC Markets Group that, based upon the closing bid price of the Company's common stock being less than $0.001 per share for five consecutive trading days, the Company's common stock was moved from the OTCQB Market to the Pink Market effective at market open on February 10, 2020. The fair value of the Company's restricted equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares. Awards granted to directors are treated on the same basis as awards granted to employees. Upon the exercise of an option or warrant, the Company issues new shares of common stock out of its authorized shares.

*Convertible Instruments*

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

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

*Income Taxes*

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets, including tax loss and credit carry forwards, and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The Company utilizes ASC 740, "Income Taxes," which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. A valuation allowance is recorded when it is "more likely-than-not" that a deferred tax assets will not be realized.

For uncertain tax positions that meet a "more likely than not" threshold, the Company recognizes the benefit of uncertain tax positions in the consolidated financial statements. The Company's practice is to recognize interest and penalties, if any, related to uncertain tax positions in income tax expense in the consolidated statements of operations.

*Derivative Financial Instruments*

The Company evaluates its convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with Topic 815 of the Financial Accounting Standards Board ("FASB") ASC. The accounting treatment of derivative financial instruments requires that the Company record embedded conversion options ("ECOs") and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. Conversion options are recorded as a discount to the host instrument and are amortized as amortization of debt discount on the consolidated financial statements over the life of the underlying instrument. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification.

The Multinomial Lattice Model and Black-Scholes Model were used to estimate the fair value of the ECOs of convertible notes payable, the warrants, and stock options that are classified as derivative liabilities on the consolidated balance sheets. The models include subjective input assumptions that can materially affect the fair value estimates. The expected volatility is estimated based on the actual volatility during the most recent historical period of time equal to the weighted average life of the instruments.

*Sequencing Policy*

Under ASC 815-40-35 ("ASC 815"), the Company has adopted a sequencing policy, whereby, in the event that reclassification of contracts from equity to assets or liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares as a result of certain securities with a potentially indeterminable number of shares, shares will be allocated on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest grants receiving the first allocation of shares. Pursuant to ASC 815, issuances of securities to the Company's employees and directors, or to compensate grantees in a share-based payment arrangement, are not subject to the sequencing policy.

*Leases*

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The standard requires all leases that have a term of over 12 months to be recognized on the balance sheet with the liability for lease payments and the corresponding right-of-use asset initially measured at the present value of amounts expected to be paid over the term. Recognition of the costs of these leases on the income statement will be dependent upon their classification as either an operating or a financing lease. Costs of an operating lease will continue to be recognized as a single operating expense on a straight-line basis over the lease term. Costs for a financing lease will be disaggregated and recognized as both an operating expense (for the amortization of the right-of-use asset) and interest expense (for interest on the lease liability). This standard, which the Company adopted on January 1, 2019, was applied on a modified retrospective basis to leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The adoption of ASU 2016 - 02 did not have a material impact on the Company's financial statements and related disclosures.

A lease is defined as a contract that conveys the right to control the use of identified property, plant or equipment for a period of time in exchange for consideration. On January 1, 2019, the Company adopted ASC 842 and it primarily affected the accounting treatment for operating lease agreements in which the Company is the lessee.

In accordance with ASC 842, *Leases*, the Company recognized a right-of-use ("ROU") asset and corresponding lease liability on its balance sheets for its office space lease agreement. See Note 12 for further discussion, including the impact on the Company's financial statements and related disclosures.

ROU assets include any prepaid lease payments and exclude any lease incentives and initial direct costs incurred. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The lease terms may include options to extend or terminate the lease if it is reasonably certain that the Company will exercise that option.

Leases in which the Company is the lessee are comprised of office rental. All of the leases are classified as operating leases. The Company has a lease agreement for office space with a remaining term of four years as of December 31, 2020.

*Recent Accounting Pronouncements*

All newly issued but not yet effective accounting pronouncements have been deemed to be not applicable or immaterial to the Company.

**NOTE 4 – PROPERTY AND EQUIPMENT**

Property and equipment consists of the following:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Medical equipment | $ 352,133 | $ 352,133 |
| Furniture and fixtures | 123,487 | 123,487 |
| Computer software and equipment | 107,648 | 107,648 |
| Office equipment | 12,979 | 12,979 |
| Leasehold improvements | 304,661 | 304,661 |
| | 900,908 | 900,908 |
| Less: accumulated depreciation | (878,994) | (832,506) |
| Property and equipment, net | $ 21,914 | $ 68,402 |

Total depreciation expense for the years ended December 31, 2020 and 2019 was $46,488 and $142,465, respectively. Depreciation expense is reflected in general and administrative expenses and research and development expenses in the consolidated statement of operations.

**NOTE 5 – INTANGIBLE ASSETS**

The Company is a party to a license agreement with the SCTC (as amended) (the “SCTC Agreement”). Pursuant to the SCTC Agreement, the Company obtained, among other things, a worldwide, exclusive, royalty-bearing license from the SCTC to utilize or sublicense a certain medical device patent for the administration of specific cells and/or cell products to the disc and/or spine (and other parts of the body) and a worldwide (excluding Asia and Argentina), exclusive, royalty-bearing license to utilize or sublicense a certain method for culturing cells. Pursuant to the license agreement with the SCTC, unless certain performance milestones had been or are satisfied, the Company would have been required to pay to the SCTC $150,000 by April 2017 and an additional $250,000 by April 2019 in order to maintain its exclusive rights with regard to the disc/spine technology. In February 2017, the Company received authorization from the Food and Drug Administration (the “FDA”) to proceed with a Phase 2 clinical trial. Based upon such authorization, the Company has satisfied a performance milestone such that the Company was not required to pay to the SCTC a minimum amount of $150,000 by April 2017 to retain exclusive rights with regard to the disc/spine technology. In addition, the Company believes that it has until February 2022 to complete the Phase 2 clinical trial in order to satisfy the final performance milestone such that the Company was not required to pay the additional $250,000 by April 2019 pursuant to the SCTC Agreement to maintain its exclusive rights.

Intangible assets consist of the following:

| | Patents and Trademarks | Licenses | Accumulated Amortization | Total |
|---|---|---|---|---|
| Balance as of January 1, 2019 | $ 3,676 | $ 1,301,500 | $ (491,117) | $ 814,059 |
| Amortization expense | - | - | (74,895) | (74,895) |
| Balance as of December 31, 2019 | 3,676 | 1,301,500 | (566,012) | 739,164 |
| Amortization expense | - | - | (74,896) | (74,896) |
| Balance as of December 31, 2020 | $ 3,676 | $ 1,301,500 | $ (640,908) | $ 664,268 |
| Weighted average remaining amortization period at December 31, 2020 (in years) | - | 8.9 | | |

Amortization of intangible assets consists of the following:

| | Patents and Trademarks | Licenses | Accumulated Amortization |
|---|---|---|---|
| Balance as of January 1, 2019 | $ 2,944 | $ 488,173 | $ 491,117 |
| Amortization expense | 368 | 74,527 | 74,895 |
| Balance as of December 31, 2019 | 3,312 | 562,700 | 566,012 |
| Amortization expense | 364 | 74,531 | 74,895 |
| Balance as of December 31, 2020 | $ 3,676 | $ 637,231 | $ 640,907 |

**NOTE 6 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES**

Accrued expenses and other current liabilities consist of:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Accrued payroll | $ - | $ 152,308 |
| Accrued research and development expenses | - | 806,175 |
| Accrued general and administrative expenses | 60,661 | 1,392,743 |
| Accrued director compensation | - | 557,500 |
| Deferred rent | - | 12,438 |
| Accrued DIP and Plan costs related to DIP Funding and Plan | 657,598(1) | - |
| Total accrued expenses | $ 718,259 | $ 2,921,164 |

(1) Amount represents DIP and Plan costs associated with the Auctus DIP Funding and the Plan. As of December 31, 2020, these amounts were note finalized and, as a result, were recorded as accrued expenses in the consolidated balance sheets. Subsequent to December 31, 2020, upon finalization, the amount representing the costs associated with the DIP Funding and the Plan will be converted into a Secured Convertible Note.

**NOTE 7 – NOTES PAYABLE & CHAPTER 11 REORGANIZATION**

A summary of the notes payable activity during the years ended December 31, 2020 and 2019 is presented below:

| | Related Party Notes | Convertible Notes | Other Notes | Debt Discount | Total |
|---|---|---|---|---|---|
| Outstanding, December 31, 2018 | $ 720,000 | $ 4,309,415 | $ 132,501 | $ (1,012,363) | $ 4,149,553 |
| Issuances | 635,000 | 9,913,339 | 340,000 | - | 10,888,339 |
| Exchanges for equity | - | (2,637,323) | - | 634,525 | (2,002,798) |
| Repayments | (70,000) | (4,817,105) | (7,500) | 428,939 | (4,465,666) |
| Extinguishment of notes payable | - | - | (148,014) | 6,196 | (141,818) |
| Recognition of debt discount | - | - | - | (5,523,830) | (5,523,830) |
| Accretion of interest expense | - | - | - | 548,026 | 548,026 |
| Accrued interest reclassified to notes payable principal | - | - | 23,013 | - | 23,013 |
| Amortization of debt discount | - | - | - | 3,671,087 | 3,671,087 |
| Outstanding, December 31, 2019 | 1,285,000 | 6,768,326 | 340,000 | (1,247,420) | 7,145,906 |
| Issuances | 353,762 | 3,936,548 | - | - | 4,290,310 |
| Third-party purchases | (287,041) | 287,041 | - | - | - |
| Exchanges for equity | - | (813,393) | - | 253,654 | (559,739) |
| Exchanged for equity pursuant to Chapter 11 Plan | (998,139) | (3,592,395) | (340,000) | - | (4,930,534) |
| Secured and Unsecured convertible notes payable exchanged pursuant to Chapter 11 Plan, net | (353,582) | 3,050,975 | - | - | 2,697,393 |
| Recognition of debt discount | - | - | - | (8,534,245) | (8,534,245) |
| Accretion of interest expense | - | - | - | 2,886,036 | 2,886,036 |
| Amortization of debt discount | - | - | | 1,275,106 | 1,275,106 |
| Outstanding, December 31, 2020 | $ - | $ 9,637,102 | $ - | $ (5,366,869) | $ 4,270,233 |

*Chapter 11 Reorganization*

On March 20, 2020, the Company filed a voluntary petition commencing a case under chapter 11 of title 11 of the U.S. Code in the United States Bankruptcy Court for the Eastern District of New York. On August 7, 2020, the Company and Auctus, the Company's largest unsecured creditor and a stockholder as of the Petition Date, filed an Amended Joint Plan of Reorganization (the "Plan"). Pursuant to the Bankruptcy, for any outstanding principal and interest at the date of the Company's Chapter 11 petition (except for creditors who provided additional debt financing in connection with the Bankruptcy), 100 shares of the Company's common stock were issued for each dollar of allowed claim, with such shares subject to leak-out restrictions prohibiting the holder from selling, without the consent of the Company, more than 33% of the issued shares during each of the three initial 30 day periods following the Effective Date. As a result of the Chapter 11 petition, the conversion rights for the notes described in this Note 7 – Notes Payable – Convertible Notes – Embedded Conversion Options and Note Provisions were rescinded and were subject to the conversion rights outlined above. As a result of the Chapter 11 reorganization, pursuant to ASC 852, *Reorganizations*, the Company has recorded all prepetition liabilities at the expected allowable claim amounts as of December 31, 2020. This resulted in the Company amortizing the remaining debt discount of $2,580,110 to reorganization items on the consolidated statements of operations.

On October 30, 2020, the Bankruptcy Court entered an order (the "Confirmation Order") confirming the Plan, as amended. Amendments to the Plan are reflected in the Confirmation Order. On November 16, 2020 (the "Effective Date"), the Plan became effective.

The material features of the Plan, as amended and confirmed by the Confirmation Order, are as follows:

i. Treatment of the financing to the Company by Auctus of up to $7,000,000 which Auctus has provided or committed to provide consisting of the debtor-in-possession loans made to the Company by Auctus during the Chapter 11 Case (the "DIP Funding") and additional funding as described below.

ii. Auctus has provided $3,500,000 in funding to the Company (the "Initial Auctus Funding") and is to provide, subject to certain conditions, additional funding to the Company, as needed, in an amount equal to $3,500,000, less the sum of the debtor-in-possession loans made to the Company by Auctus during the Chapter 11 Case (inclusive of accrued interest) (approximately $1,227,000 as of the Effective Date) and the costs incurred by Auctus as the debtor-in-possession lender (the "DIP Costs"). As of December 31, 2020, the DIP Costs and additional Plan costs were not finalized and recorded. The DIP Costs and the additional Plan costs in the aggregate are estimated to total $657,598, of which $500,000 and $157,598 were recorded in debt discount and accrued expenses, respectively, on the consolidated balance sheets. In addition, four other persons and entitles (collectively, the "Other Lenders") who held allowed general unsecured claims provided funding to the Company in the aggregate amount of approximately $348,000 (the "Other Funding" and together with the Initial Auctus Funding, the "Funding"). In consideration of the Funding, the Company has issued the following:

a. Secured convertible notes of the Company (each, a "Secured Convertible Note") in the principal amount equal to the Funding; the payment of the Secured Convertible Notes is secured by the grant of a security interest in substantially all of the Company's assets; the Secured Convertible Notes have the following features:

- Maturity date of three years following the Effective Date;

- Interest at the rate of 7% per annum;
- The right of the holder to convert the indebtedness into shares of common stock of the Company at a price equal to the volume weighted average price for the common stock over the five trading days immediately preceding the conversion; and
- Mandatory conversion of all indebtedness at such time as the common stock is listed on the Nasdaq Capital Market or another senior exchange on the same terms as provided to investors in connection with a public offering undertaken in connection with such listing;

b. Warrants (each, a "Class A Warrant") to purchase a number of shares of common stock equal to the amount of the Funding provided divided by $0.0005 (a total of 7,000,000,000 Class A Warrants in consideration of the Initial Auctus Funding and a total of approximately 697,000,000 Class A Warrants in the aggregate in consideration of the Other Funding), such Class A Warrants having an exercise price of $0.0005 per share; and

c. Warrants (each, a "Class B Warrant" and together with the Class A Warrants, the "Plan Warrants") to purchase a number of shares of common stock equal to the Funding provided divided by $0.001 (a total of 3,500,000,000 Class B Warrants in consideration of the Initial Auctus Funding and a total of approximately 348,500,000 Class B Warrants in the aggregate in consideration of the Other Funding), such Class B Warrants having an exercise price of $0.001 per share.

iii. The obligation to Auctus with respect to the DIP Funding has been exchanged for the following:

a. A Secured Convertible Note in the principal amount of approximately $1,349,591 (110% DIP Funding) with a maturity date of November 16, 2023;

b. A Class A Warrant to purchase 2,453,802,480 shares of common stock; and

c. A Class B Warrant to purchase 1,226,901,240 shares of common stock (as to which 544,697,452 shares of common stock have been exercised on a net exercise basis, pursuant to the terms of the Class B Warrant, with respect to the issuance of 512,124,200 shares of common stock, of which 217,796,200 and 294,328,000 were issued during 2020 and 2021, respectively).

In addition, Auctus shall be entitled to receive a Secured Convertible Note in exchange for its allowed DIP Costs and allowed Plan costs in a manner in which the DIP Funding was treated and may be entitled to a Class A Warrant and a Class B Warrant in consideration of such costs.

The claim arising from the secured promissory notes of the Company, dated February 20, 2020 and February 26, 2020, in the original principal amounts of $320,200 and $33,562, respectively, issued to John Desmarais ("Desmarais") (collectively, the "Desmarais Notes"), was treated as an allowed secured claim in the aggregate amount of $490,699 and was exchanged for a Secured Convertible Note in such amount.

iv. The claim arising from the promissory note issued in June 2016 by the Company to Desmarais in the original principal amount of $175,000 was treated as an allowed general unsecured claim in the amount of $245,192 and was satisfied and exchanged for 24,519,200 shares of common stock.

v. The claim arising from the promissory note issued in June 2016 by the Company to Tuxis Trust, an entity related to Desmarais, in the original principal amount of $500,000 was treated as follows:

a. $444,534,43 was treated as an allowed general unsecured claim in such amount and exchanged for 44,453,400 shares of common stock; and

b. $309,301 was treated as an allowed secured claim in such amount and exchanged for a Secured Convertible Note in such amount with a maturity date of November 16, 2023.

vi. Holders of allowed general unsecured claims (other than Auctus and the Other Lenders) received an aggregate of 1,049,726,797 shares of common stock where were valued at the fair market value of the stock at issuance date of $14,381,259 with an associated loss of $3,883,991 recognized in Reorganization Items, net on the accompanying consolidated statement of operations in exchange for approximately $10,497,268 outstanding accounts payable and convertible debt (including accrued interest), with such shares being subject to a leak-out restriction prohibiting each holder from selling, without consent of the Company, more than 33% of its shares during each of the three initial 30 day periods following the Effective Date.

vii. Auctus and the Other Lenders have been issued, in respect of their allowed general unsecured claims ($3,261,819 in the case of Auctus and an aggregate of approximately $382,400 in the case of the Other Lenders), a convertible promissory note of the Company (each, an "Unsecured Convertible Note") in the allowed amount of the claim, which Unsecured Convertible Notes have the following material features:

a. Maturity date of three years from the Effective Date;

b. Interest at the rate of 5% per annum;

c. The right of the holder to convert the indebtedness into shares of common stock at a price equal to the volume weighted average for the common stock over the five trading days immediately preceding the conversion;

d. Mandatory conversion of all outstanding indebtedness at such time as the common stock listed on the Nasdaq Capital Market or another senior exchange on the same terms as provided to investors in connection with a public offering undertaken in connection with such listing; and

e. A leak-out restriction prohibiting each holder from selling, without the consent of the Company, more than 16.6% of the underlying shares received upon conversion during each of the six initial 30 day periods following the Effective Date.

viii. The issuance of (a) the shares of common stock and the Unsecured Convertible Notes to the holders of allowed general unsecured claims and (b) the Secured Convertible Notes and Plan Warrants to Auctus in exchange for the DIP Funding and any common stock into which those Secured Convertible Notes and those Plan Warrants may be converted is exempt from the registration requirements of the Securities Act of 1933, as amended, pursuant to the Bankruptcy Code Section 1145. Such securities shall be freely transferrable subject to Section 1145(b)(i) of the Bankruptcy Code.

Pursuant to the Plan, on the Effective Date, the Company filed a Certificate of Amendment to its Certificate of Incorporation pursuant to which, among other things, the number of shares of common stock authorized to be issued by the Company has been increased to 300,000,000,000 and the par value of the shares of common stock has been reduced to $0.0001 per share.

*Related Party Notes*

As of December 31, 2019, related party notes consisted of notes payable issued to certain directors of the Company, family members of an officer of the Company, and the Tuxis Trust (the "Trust"). A former director and principal stockholder of the Company (the "Director/Principal Stockholder") serves as a trustee of the Trust, which was established for the benefit of his immediate family. As of December 31, 2020, there were no related party notes outstanding.

During the year ended December 31, 2019, the Company issued to family members of officers of the Company and a Scientific Advisory Board member (the "SAB Member") notes payable in the aggregate principal amount of $635,000, which bore interest at the rate of 12% - 15% per annum and provided for original maturity dates between July 2019 and May 2020.

During the year ended December 31, 2019, the holders of certain related party notes in the aggregate principal amount of $505,000 entered into agreements with the Company pursuant to which the parties agreed that the maturity of the promissory notes held by such holders would be extended or further extended from dates from December 2018 and August 2019 to dates between July 2019 and December 2019. In consideration of the extensions, such notes in the aggregate principal amount of $475,000 provided for an exchange of such notes for shares of common stock and warrants, as described below, in connection with a public offering of the Company's securities (a "Public Offering"). The exchange price for the indebtedness was to be equal to the lesser of (i) 75% of the public offering price of the common stock, or units of common stock and warrants, as the case may be, offered pursuant to the Public Offering or (ii) $0.60 per share (subject to adjustment for reverse stock splits and the like) (the "Exchange Price"). The number of shares of common stock issuable pursuant to the warrants to be issued to such holders was to be equal to the number of shares of common stock issuable to them upon conversion of the principal amount of their respective notes. The exchange price of the warrants to be issued to such holders was to be the lesser of (i) 125% of the Exchange Price or (ii) $0.80 per share (subject to adjustment for reverse stock splits and the like). Since the fair value of the new ECO exceeded 10% of the carrying amount of the debt, the note extensions were accounted for as extinguishments, and accordingly the Company recognized an aggregate net loss on extinguishment of $145,066 in connection with the derecognition of the net carrying amount of the extinguished debt of $510,887 (inclusive of $475,000 of principal and $35,887 of accrued interest) and the issuance of the new convertible notes in the same amount, plus the fair value of the new notes' ECOs of an aggregate of $145,066. As a result of the Company's Chapter 11 reorganization, the exchange did not occur.

During the year ended December 31, 2019, the Company and a certain related party lender agreed to further extend the maturity date of a certain related party note with a principal balance of $25,000 from a maturity date in September 2019 to a new maturity date in October 2019, effective September 30, 2019.

During the year ended December 31, 2019, the Company, a then director of the Company, and the Trust agreed that promissory notes held by the director and the Trust in the outstanding principal amounts of $175,000 and $500,000, respectively, would be exchanged for shares of common stock and warrants, as described below, in connection with a Public Offering. The exchange price for the indebtedness was to be equal to 75% of the public offering price of the common stock, or units of common stock and warrants, as the case may be, offered pursuant to the Public Offering (the "Director/Trust Exchange Price"). The number of shares of common stock issuable pursuant to the warrants to be issued to the director and the Trust was to be in the same ratio to the number of shares of common stock issued upon exchange of their indebtedness as the number of shares of common stock subject to any warrants included as part of units offered pursuant to the Public Offering (the "Public Warrants") bore to the number of shares of common stock issued as part of the Public Offering units. The exercise price of the warrants to be issued to the director and the Trust was to be 125% of the Director/Trust Exchange Price and the term of the warrants was to be the same term as the Public Warrants. Concurrently with the exchange, the exercise prices of outstanding warrants held by the director and the Trust for the purchase of an aggregate of 1,377,842 shares of common stock of the Company was to be reduced from between $1.50 and $4.00 per share to $0.75 per share and the expiration dates of such warrants was to be extended from between December 2019 and March 2022 to December 2023. The exchange agreements were submitted for approval by the stockholders of the Company, which was obtained in August 2019. As a result of the Company's Chapter 11 reorganization the exchange did not occur.

As of December 31, 2019, certain related party notes in the aggregate principal amount of $485,000 were convertible into shares of common stock of the Company at a conversion price of $0.60 per share, subject to adjustment, and a five-year warrant for the purchase of a number of shares equal to the number of shares issued upon the conversion of the principal amounts of the notes.

During the years ended December 31, 2020 and 2019, the Company partially repaid certain related party notes in the aggregate principal amount of $- and $70,000, respectively.

During the year ended December 31, 2020, the Company issued to a former board member notes payable in the aggregate principal amount of $353,762, which bore interest at the rate of 12% per annum and provided for an original maturity date of March 10, 2020. On November 16, 2020, pursuant to the Bankruptcy (See Note 7 – Notes Payable – Chapter 11 Reorganization), these notes were exchanged for a Secured Convertible Note in the principal amount of $490,698 which bears interest at the rate of 7% per annum and has a maturity date of November 16, 2023.

During the year ended December 31, 2020, pursuant to the Bankruptcy (See Note 7 – Notes Payable – Chapter 11 Reorganization), the Company's original promissory note issued to the Director/Principal Stockholder in the principal amount of $175,000 was treated as an allowed general unsecured claim in the amount of $245,192 and was satisfied and exchanged for 24,519,178 shares of common stock. During the year ended December 31, 2020, the Director/Principal Stockholder resigned as a director of the Company. As a result, the Director/Principal Stockholder is not a related party at December 31, 2020.

During the year ended December 31, 2020, pursuant to the Bankruptcy (See Note 7 – Notes Payable – Chapter 11 Reorganization), the Company's original promissory note issued to the Trust in the principal amount of $500,000 was treated as follows: (i) $444,534 was treated as an allowed general unsecured claim in such amount and exchanged for 44,453,443 shares of common stock and (ii) $309,301 was treated as an allowed secured claim in such an amount and exchanged for a secured convertible note which bears interest at a rate of 7% per annum with a maturity date of November 16, 2023. During the year ended December 31, 2020, the former board member who serves as the trustee of the Trust resigned as a director. As a result, the Trust is not a related party at December 31, 2020.

*Convertible Notes*

**Issuances**

During the year ended December 31, 2019, the Company issued certain lenders convertible notes payable in the aggregate principal amount of $9,765,325 for aggregate cash proceeds of $9,086,353. The difference of $678,973 was recorded as a debt discount and will be amortized over the terms of the respective notes. The convertible notes bore interest at rates ranging between 8% to 15% per annum payable at maturity with original maturity dates ranging between July 2019 through December 2020. In connection with the issuance of certain convertible notes, the Company issued the lenders an aggregate of 78,873 shares of the Company's common stock and the relative fair value of $61,220 was recorded as debt discount and is being amortized over the terms of the respective notes. In connection with the issuance of certain convertible notes, the Company issued the lenders five-year warrants to purchase an aggregate of 295,000 shares of the Company's common stock at exercise prices ranging from $0.45 per share to $1.00 per share. The aggregate grant date value of the warrants was $104,198, which was recorded as debt discount and is being amortized over the terms of the respective convertible notes. The warrants were subject to the Company's sequencing policy and, as a result, were initially recorded as derivative liabilities. See below within this Note 7 – Notes Payable – Convertible Notes – Conversions, Exchanges and Other and Note 9 – Derivative Liabilities for additional details regarding the ECOs of the convertible notes. During the year ended December 31, 2019, $675,523 in outstanding principal and $73,485 in accrued interest was converted into 46,158,719 shares of the Company's common stock. During the year ended December 31, 2019, the Company made cash payments in the aggregate amount of $2,499,476 towards the outstanding principal on the notes.

During the year ended December 31, 2019, a certain convertible note in the principal amount of $148,014 was issued concurrently with the extinguishment of a certain other note payable in the same principal amount. See below within this Note 7 – Notes Payable – Convertible Notes – Conversions, Exchanges and Other for additional details. During the year ended December 31, 2019, $148,014 of outstanding principal and $1,901 of accrued interest was converted into 513,788 shares of the Company's common stock.

During the year ended December 31, 2020, the Company issued to a certain lender a convertible note payable in the principal amount of $88,000 for aggregate cash proceeds of $85,000. The difference was recorded as a debt discount and will be amortized over the term of the note. The convertible note bore interest at 10% per annum payable at maturity with an original maturity date of January 31, 2021. The outstanding principal and accrued interest was convertible after 180 days at a conversion price of 61% of the lowest daily volume weighted average price over the twenty days prior to the conversion date. The convertible note contained a cross-default provision and was in default at issuance. As a result, the convertible note bore a default interest of 22% per annum. Pursuant to the Bankruptcy (see Note 7 – Notes Payable – Chapter 11 Reorganization), the convertible note, in the aggregate amount of $155,000 (including principal and accrued interest), was exchanged for 15,500,000 shares of the Company's common stock. See below within Note 7- Derivative Liabilities for additional details regarding the ECO of the convertible note.

On November 16, 2020, in connection with the Plan, the Company issued to Auctus and the Other Lenders (See Note 7 – Notes Payable – Chapter 11 Reorganization) Secured Convertible Notes in the aggregate principal amount of $3,848,548 that bear interest at 7% per annum with a maturity date of November 16, 2023. The outstanding principal and interest is convertible at the holders' discretion at any time at a conversion price equal to the average five-day daily volume weighted average price prior to the conversion date. At the date of issuance, this resulted in a beneficial conversion feature in the aggregate of $124,147 and is being amortized over the term of the respective Secured Convertible Notes. In connection with these Secured Convertible Notes, the Company issued five-year warrants to purchase an aggregate of 15,226,346,970 shares of the Company's common stock at exercise prices ranging between $0.0005 and $0.001 per share. The aggregate grant date fair value of the warrants was $152,263,470. As a result, the Company recorded a debt discount related to the fair market value of beneficial conversion feature and warrants issued of $5,075,449 was and is being amortized over the term of the respective Secured Convertible Notes.

**Embedded Conversion Options and Note Provisions**

As of December 31, 2019, outstanding convertible notes in the aggregate principal amount of $6,006,576 were convertible into shares of common stock of the Company as follows: (i) $2,243,750 of aggregate principal amount of convertible notes were convertible at a fixed price ranging from $0.25 to $2.00 per share for the first six months following the respective issue date, and thereafter at a conversion price generally equal to 58% of the fair value of the Company's stock, subject to adjustment, until the respective note had been paid in full, (ii) $2,872,826 of aggregate principal amount of convertible notes were convertible generally at a range of 58% to 65% of the fair value of the Company's stock, subject to adjustment, depending on the note, and (iii) $890,000 of aggregate principal amount of convertible notes were convertible into shares of common stock of the Company at a conversion price ranging from $0.50 to $0.60 per share, subject to adjustment, and five-year warrants to purchase common stock of the Company in the same ratio. The warrants provide for an exercise price ranging from $0.75 to $0.80 per share, subject to adjustment. Convertible notes in the aggregate principal amount of $340,000 provided for a mandatory conversion into common stock of the Company and warrants to purchase common stock of the Company in the same ratio upon the completion of an underwritten public offering by the Company of its securities whereby the conversion price was to be equal to the lower of the respective original conversion terms, or 75% of the offering price for the shares of common stock of the Company, or units of shares of common stock of the Company and warrants, as the case may be, sold pursuant to the public offering. The Company analyzes the ECOs of its convertible notes at issuance to determine whether the ECO should be bifurcated and accounted for as a derivative liability or if the ECO contains a beneficial conversion feature. See below within this Note 7 – Notes Payable – Convertible Notes – Embedded Conversion Options and Note Provisions and Note 9 – Derivative Liabilities for additional details regarding the ECOs of the convertible notes.

As of December 31, 2019, a portion of convertible notes with an aggregate principal balance of $1,271,750, which were not yet convertible, became convertible into shares of the Company's common stock subsequent to December 31, 2019 at a conversion price generally equal to 58% of the fair value of the Company's stock, subject to adjustment, until the respective notes had been paid in full.

As of December 31, 2019, outstanding convertible notes in the aggregate principal amount of $3,537,438 had prepayment premiums, whereby, in the event that the Company elected to prepay certain notes during the one hundred eighty-day period following the issue date, the respective holder was entitled to receive a prepayment premium of up to 135%, depending on the note, on the then outstanding principal balance including accrued interest.

As of December 31, 2019, outstanding convertible notes in the aggregate principal amount of $4,626,874 had most favored nation ("MFN") provisions, whereby, so long as such respective note was outstanding, upon any issuance by the Company of any security with certain identified provisions more favorable to the holder of such security, then at the respective holder's option, those more favorable terms were to become a part of the transaction documents with the holder. As of December 31, 2019, notes with applicable MFN provisions were convertible using MFN conversion prices equal to 58% of the fair market value of the Company's stock, as defined.

During the year ended December 31, 2019, the Company determined that certain ECOs of issued or extended convertible notes were derivative liabilities. The aggregate issuance date value of the bifurcated ECOs was $5,331,147, of which $4,771,974 was recorded as a debt discount and is being amortized over the terms of the respective convertible notes and $414,108 was recognized as part of an extinguishment loss as described below. As of December 31, 2019, outstanding notes totaling $3,289,111 were in default. See Note 9 – Derivative Liabilities for additional details. On the Petition Date, pursuant to ASC 852, *Reorganizations*, the Company wrote-off $4,375,231 in outstanding derivative liabilities related to certain ECOs of issued or extended convertible notes. The write-off is recorded in Reorganization Items, net in the accompanying consolidated statements of operations.

**Conversions, Exchanges and Other**

During the year ended December 31, 2019, the Company and certain lenders exchanged certain convertible notes with bifurcated ECOs with an aggregate net carrying amount of $5,328,918 (including an aggregate of $2,631,595 of principal less debt discount of $634,525, $181,912 of accrued interest and $3,230,780 related to the separated ECOs accounted for as derivative liabilities) for an aggregate of 54,464,158 shares of the Company's common stock at conversion prices ranging from $0.01 to $0.43 per share. The common stock had an aggregate exchange date value of $6,230,102 and, as a result, the Company recorded a loss on extinguishment of notes payable of $508,743. See Note 9 – Derivative Liabilities for additional details.

During the year ended December 31, 2019, the Company repaid an aggregate principal amount of $4,894,604 of convertible notes payable, $267,997 of the respective aggregate accrued interest and an aggregate of $813,730 of prepayment premiums. As a result of the repayments, the Company recorded a loss on extinguishment of notes payable of $1,242,669 and an aggregate of $428,939 of the related debt discounts were extinguished.

During the year ended December 31, 2019, a certain lender to the Company acquired a promissory note (classified in Other Notes) issued by the Company in the outstanding amount of $148,014 (inclusive of accrued interest reclassified to principal of $23,013) from a certain lender to the Company. The Company exchanged the acquired note for a new convertible note in the principal amount of $148,014 which accrued interest at a rate of 12% per annum, payable on the maturity date in March 2020. The ECO of the note was subject to sequencing and the issuance date fair value of $84,798 was accounted for as a derivative liability (see Note 9 – Derivative Liabilities for additional details). Since the fair value of the new ECO exceeded 10% of the principal amount of the new note, the note exchange was accounted for as an extinguishment, and accordingly the Company recognized a net loss on extinguishment of $90,994 in connection with the derecognition of the net carrying amount of $141,818 of the extinguished debt and the issuance of the new convertible notes in the aggregate principal amount $148,014 plus the fair value of the new note's ECO of an aggregate of $84,798.

During the year ended December 31, 2019, the Company and certain lenders agreed to extend or further extend the maturity dates of certain convertible notes payable with an aggregate principal balance of $678,102 from maturity dates ranging from June 2019 to July 2019 to new maturity dates ranging from July 2019 to July 2020. In consideration of the extensions of certain convertible notes with an aggregate principal balance of $650,000, the Company modified the conversion terms of the lenders' notes to provide for a mandatory conversion into common stock of the Company and a five-year warrant to purchase common stock of the Company in the same ratio upon the completion of an underwritten public offering by the Company of its securities, whereby, the conversion price was to be equal to the lower of the respective original conversion terms, or 75% of the offering price for the shares of common stock of the Company, or units of shares of common stock of the Company and warrants, as the case may be, sold pursuant to the public offering. Since the fair value of the new ECO exceeded 10% of the carrying amount of the debt, the note extensions were accounted for as extinguishments, and accordingly the Company recognized an aggregate net loss on extinguishment of $329,310 in connection with the derecognition of the net carrying amount of the extinguished debt of $702,387 (inclusive of $650,000 of principal and $52,387 of accrued interest) and the issuance of the new convertible notes in the same amount, plus the fair value of the new notes' ECOs of an aggregate of $329,310.

During the year ended December 31, 2019, the Company and certain lenders agreed to further extend the maturity dates of certain convertible notes payable with an aggregate principal balance of $150,000 from maturity dates in September 2019 to new maturity dates in October 2019, effective September 30, 2019.

During the year ended December 31, 2020, the Company and certain lenders exchanged convertible notes with bifurcated ECOs with an aggregate net carrying amount of $1,580,587 (including an aggregate of $523,516 of principal less debt discount of $234,301, $126,043 of accrued interest and $1,165,329 related to the separated ECOs accounted for as derivative liabilities) for an aggregate of 1,515,799,750 shares of the Company's common stock at conversion prices ranging from $0.0001 and $0.01 per share. In addition, prior to the Petition Date, certain lenders intended to exchange outstanding debt (inclusive of accrued interest) for shares of the Company's common stock; however, the Company did not have sufficient shares authorized or reserved to effect the exchanges. As of December 31, 2020, these shares have yet to be issued (See Note 10 – Commitments and Contingencies – Conversion of Convertible Notes).

On November 16, 2020, pursuant to the Plan, Auctus and the Other Lenders exchanged various convertible notes with an aggregate principal amount of $2,742,895 for unsecured convertible promissory notes with an aggregate principal amount of $3,644,274 which bear interest at 5% per annum with a maturity date of November 16, 2023. In connection with the exchanges, the Company recognized a loss on extinguishment of debt of $1,488,172 recorded in reorganization items, net in the consolidated statements of operations.

*Other Notes*

**Issuances**

During the year ended December 31, 2019, the Company issued certain lenders notes payable in the aggregate principal amount of $340,000. The notes bore interest at 15% per annum payable at maturity with original maturity dates ranging between November 2019 through November 2020. Pursuant to the Bankruptcy (See Note 7 – Notes Payable – Chapter 11 Reorganization) these notes were exchanged for an aggregate amount of 47,170,000 shares of the Company's common stock.

**Exchange and Other**

During the year ended December 31, 2019, the Company and a certain lender agreed to an extension of the maturity date of a certain note payable with a principal balance of $125,000 from a maturity date in January 2019 to a new maturity date in December 2019. In consideration of the extension, the Company issued the lender 10,000 shares of the Company's common stock. The issuance date fair value of the common stock of $7,052 was recorded as debt discount and was amortized over the remaining term of the note.

During the year ended December 31, 2019, a convertible promissory note in the principal amount of $148,014 was issued concurrently with the extinguishment of a certain other note payable in the same principal amount. See above within Note 7 – Notes Payable – Convertible Notes – Conversions, Exchanges and Other for additional details.

During the year ended December 31, 2019, the Company partially repaid a certain promissory note in the principal amount of $7,500.

*Debtor-in-Possession Financing*

During the year ended December 31, 2020, and subsequent to the Petition Date, in connection with the Chapter 11 Case, the Company received debtor-in-possession loans of $1,189,413 in the aggregate from Auctus.

The proceeds from the DIP Funding were used (a) for working capital and other general purposes of the Company; (b) United States Trustee fees; (c) Bankruptcy Court approved professional fees and other administrative expenses arising in the Chapter 11 Case; and (d) interest, fees, costs and expenses incurred in connection with the DIP Funding, including professional fees.

The maturity date of the DIP Funding was to be the earliest to occur of (a) July 6, 2020; (b) ten days following entry of an order confirming a chapter 11 plan in the Chapter 11 Case; (c) ten days following the entry of an order approving the sale of the Company or the Company's assets; or (d) the occurrence of an event of default under the promissory note evidencing the DIP Funding (the "DIP Note") following any applicable grace or cure periods.

Interest on the outstanding principal amount of the DIP Note was to be payable in arrears on the maturity date at the rate of 8% per annum. Upon the occurrence and during the continuance of an event of default, all obligations under the DIP Note were to bear interest at a rate equal to the then current rate plus an additional 2% per annum.

Pursuant to the Plan, the obligation to Auctus with respect to the DIP Funding has been exchanged for two Secured Convertible Notes (See Note 7 – Notes Payable – Chapter 11 Reorganization) for an aggregate principal amount of $1,349,591 which bear interest at 7% per annum with a maturity date of November 16, 2023. In connection with the Secured Convertible Notes, Auctus received warrants to purchase an aggregate of 3,680,703,720 shares of Company's commons stock with exercise prices ranging between $0.0005 and $0.001 per share.

**NOTE 8 - STOCKHOLDERS' DEFICIT**

*Authorized Capital and 2010 Equity Plan*

In March 2019, the Board of Directors of the Company approved an increase in the number of authorized shares of common stock to 150,000,000, subject to stockholder approval. Additionally, the Board of Directors approved an increase in the number of authorized shares issuable under the Company's 2010 Equity Participation Plan to 20,000,000, subject to stockholder approval. In May 2019, such stockholder approval was obtained.

In March 2019, the Board of Directors determined to submit to the Company's stockholders for their approval amendments to the Certificate of Incorporation of the Company (with the Board of Directors having the authority to select and file one such amendment) to effect a reverse split of the Company's common stock at a ratio of not less than 1-for-2 and not more than 1-for-20, with the Board of Directors having the discretion as to whether or not the reverse stock split was to be effected, and with the exact ratio of any reverse stock split to be set at a whole number within the above range as determined by the Board of Directors in its discretion. Concurrently, the Board of Directors determined to submit to the Company's stockholders for their approval a proposal to authorize the Board of Directors, in the event the reverse stock split proposal was approved by the stockholders, in its discretion, to reduce the number of authorized shares of common stock in proportion to the percentage decrease in the number of outstanding shares of common stock resulting from the reverse split (or a lesser decrease in authorized shares of common stock as determined by the Board of Directors in its discretion). In May 2019, the Company's stockholders approved the foregoing proposals.

On November 13, 2019 the Board of Directors and stockholders approved an increase in the number of authorized shares of common stock to 300,000,000, as well as the grant to the Board of Directors of authority to adopt an amendment to the Certificate of Incorporation of the Company to effect a reverse split of the Company's common stock at a ratio of not less than 1-for-2 and not more than 1-for-100. As of the date of this filing the reverse stock split has not been effected.

On November 16, 2020, and pursuant to the Chapter 11 plan of reorganization the Company filed a Certificate of Amendment to its Certificate of Incorporation pursuant to which, among other things, the number of shares of common stock authorized to be issued by the Company has been increased to 300,000,000,000 and the par value of the shares of its common stock has been reduced to $0.0001 per share. The effect of the change in par value has been reflected in the statement of changes in stockholders' equity for the years ended December 31, 2020 and 2019.

*Compensatory Common Stock Issuance*

During the year ended December 31, 2019, the Company issued 75,000 shares of immediately vested shares of common stock value at $30,000 to a consultant for services rendered.

*Warrant and Option Valuation*

The Company has computed the fair value of warrants and options granted using the Black-Scholes option pricing model. The expected term used for warrants and options issued to non-employees is the contractual life and the expected term used for options issued to employees and directors is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the "simplified" method to develop an estimate of the expected term of "plain vanilla" employee option grants. The Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

*Common Stock and Warrant Offerings*

During the year ended December 31, 2019, the Company issued an aggregate of 5,663,301 shares of common stock of the Company, five-year immediately vested warrants to purchase an aggregate of 4,611,746 shares of common stock of the Company at exercise prices ranging from $0.20 per share to $1.00 per share and one-year immediately vested warrants to purchase an aggregate of 1,051,555 shares of common stock of the Company at an exercise price of $0.70 per share to certain investors for aggregate gross proceeds of $1,658,500. The warrants had an aggregate grant date fair value of $1,240,165. The warrants were subject to the Company's sequencing policy and, as a result, were initially recorded as derivative liabilities. See Note 9 – Derivative Liabilities for additional details.

During the year ended December 31, 2019, the Company issued five-year immediately vested warrants to purchase an aggregate of 395,000 shares of the Company's common stock in association with the issuance of certain convertible debt. The warrants have exercise prices ranging from $0.35 per share to $1.00 per share. The warrants had an aggregate grant date fair value of $116,200. The warrants were subject to the Company's sequencing policy and, as a result, were initially recorded as derivative liabilities. See Note 9 – Derivative Liabilities for additional details.

During the year ended December 31, 2019, the Company and a warrant holder agreed to reduce the exercise prices of an aggregate of 2,111,111 outstanding warrants previously issued with original exercise prices of $0.70 and $0.85 per share to an exercise price of $0.15 per share and extend expiration dates of such outstanding warrants from dates between February 2020 and May 2020 to new expiration dates between February 2024 and May 2024. See Note 9 – Derivative Liabilities for additional details. As a result, the Company recorded a decrease in the derivative liability of $233,333 for the 3,333,333 warrants remaining under the Company's sequencing policy.

During the year ended December 31, 2020, the Company issued 1,000,000 shares of the Company's common stock and a five-year immediately vested warrant for the purchase of 1,000,000 shares of the Company's common stock with an exercise price of $0.015 per share to a certain investor for gross proceeds of $10,000. The warrants had an aggregate grant date fair value of $10,000. The warrants were subject to the Company's sequencing policy and, as a result, were initially recorded as derivative liabilities. See Note 7 - Derivative Liabilities for additional details.

During the year ended December 31, 2020, the Company issued five-year immediately vested warrants to purchase an aggregate of 15,226,346,970 shares of the Company's common stock in association with the issuance of certain secured convertible debt pursuant to the Plan (See Note 7 – Convertible Notes – Issuances). The warrants have exercise prices ranging between $0.0005 and $0.001 per share. The warrants along with the beneficial conversion feature had an aggregate relative fair value of $5,075,449 and was recorded as a debt discount.

The above mentioned warrants contain anti-dilution protection, whereas, if the Company, at any time while the warrants are outstanding, shall, among other events, sell or grant any option to purchase, or sell or grant any right to reprice, or otherwise dispose of or issue any common stock or securities entitling any person or entity to acquire shares of common stock at an effective price per share less than the existing exercise price then the exercise price of the warrants shall be reduced at the option of the warrant holder to such lower price and the number of shares issuable upon exercise of the warrants shall be correspondingly increased.

*Warrant Compensation*

The Company recorded stock–based compensation expense of $- and $56,000 for the years ended December 31, 2020 and 2019, respectively, related to stock warrants issued as compensation, which is reflected as consulting expense in the consolidated statements of operations.

*Warrant Activity Summary*

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

| | For the Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Risk free interest rate | 0.41% - 1.63% | 1.38% - 2.62% |
| Expected term (years) | 5.00 - 5.00 | 1.00 - 5.00 |
| Expected volatility | 202% - 278% | 140% - 167% |
| Expected dividends | 0.00% | 0.00% |

The weighted average estimated fair value of the warrants granted during the years ended December 31, 2020 and 2019 was approximately $0.01 and $0.23 per share, respectively.

During the year ended December 31, 2020 and subsequent to the Effective Date, the Company issued an aggregate of 217,796,200 shares of the Company's common stock, with fair value range of $0.0063 to $0.0169, as a result of the cashless exercise of 231,677,703 warrants to Auctus.

A summary of the warrant activity during the years ended December 31, 2020 and 2019 is presented below:

| | **Number of Warrants** | **Weighted Average Exercise Price** | **Weighted Average Remaining Life In Years** | **Aggregate Intrinsic Value** |
|---|---|---|---|---|
| Outstanding, January 1, 2019 | 3,483,403 | $ 3.63 | | |
| Granted | 6,162,301 | 0.44 | | |
| Exercised | - | - | | |
| Forfeited | (1,266,527) | 5.41 | | |
| Outstanding, December 31, 2019 | 8,379,177 | $ 1.43 | | |
| Issued | 15,227,346,970 | 0.0007 | | |
| Exercised | (231,677,703) | 0.001 | | |
| Expired | (1,660,241) | 2.14 | | |
| Outstanding, December 31, 2020 | 15,002,388,203 | $ 0.0011 | 2.9 | $ 95,965,883 |
| | | | | |
| Exercisable, December 31, 2020 | 15,002,388,203 | $ 0.0011 | 2.9 | $ 95,965,883 |

The following table presents information related to stock warrants at December 31, 2020:

| Warrants Outstanding | | Warrants Exercisable | |
|---|---|---|---|
| Exercise Price | Outstanding Number of Warrants | Weighted Average Remaining Life In Years | Exercisable Number of Warrants |
| $ 0.00 - $0.015 | 14,995,669,267 | 2.9 | 14,995,669,267 |
| $ 0.20 - $0.99 | 5,106,746 | 3.5 | 5,106,746 |
| $ 2.00 - $2.99 | 75,000 | 2.8 | 75,000 |
| $ 3.00 - $3.99 | 70,000 | 2.5 | 70,000 |
| $ 4.00 - $4.99 | 1,293,023 | 1.0 | 1,293,023 |
| $ 5.00 - $5.99 | 174,167 | 0.5 | 174,167 |
| | 15,002,388,203 | 2.9 | 15,002,388,203 |

*Stock Options*

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

| | For the Years Ended December 31, |
|---|---|
| | 2019 |
| Risk free interest rate | 1.47% - 2.72% |
| Expected term (years) | 10.00 |
| Expected volatility | 133% - 140% |
| Expected dividends | 0.00% |

The weighted average estimated fair value of the stock options granted during the years ended December 31, 2020 and 2019, was approximately $- and $0.36 per share, respectively.

During the year ended December 31, 2019, the Company issued the Chairman of the Disc Committee of its Scientific Advisory Board (the “Disc Committee Chairman”) a ten-year option to purchase up to 70,000 shares of the Company’s common stock at an exercise price of $1.00 per share. The options vest ratably over three years on the issuance date anniversaries. The grant date value of the option of $44,247 will be recognized over the expected vesting period as consulting expense in the consolidated statements of operations.

During the year ended December 31, 2019, the Board of Directors reduced the exercise price of outstanding stock options for the purchase of an aggregate of 4,631,700 shares of common stock of the Company (with exercise prices ranging between $1.00 and $4.70 per share) to $0.75 per share, which was the closing price for the Company’s common stock on the day prior to determination, as reported by the OTCQB market. The exercise price reduction related to options held by, among others, the Company’s officers, directors, advisors and employees. The incremental value of the modified options compared to the original options, both valued as of the respective modification date, of $452,637 is being recognized over the vesting term of the options, which will be reflected as consulting, research and development, and general and administrative expenses in the amounts of $187,861, $56,856 and $207,920, respectively, in the consolidated statements of operations.

During the year ended December 31, 2019, the Company issued the Disc Committee Chairman an immediately vested ten-year option to purchase up to 175,000 shares of the Company’s common stock at an exercise price of $0.26 per share. The grant date value of the option of $43,141 was immediately recognized as consulting expense in the consolidated statements of operations.

A summary of the option activity during the years ended December 31, 2020 and 2019 is presented below:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Life In Years | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding, January 1, 2019 | 4,703,785 | $ 3.21 | | |
| Granted | 245,000 | 0.36 | | |
| Forfeited | (69,168) | 2.79 | | |
| Outstanding, December 31, 2019 | 4,879,617 | $ 0.99 | | |
| Issued | - | - | | |
| Expired | (20,000) | 1.49 | | |
| Outstanding, December 31, 2020 | 4,859,617 | $ 0.98 | 6.2 | $ - |
| | | | | |
| Exercisable, December 31, 2020 | 4,694,955 | $ 0.99 | 6.1 | $ - |

The following table presents information related to stock options at December 31, 2020:

| Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|
| Exercise Price | Outstanding Number of Options | Weighted Average Remaining Life In Years | | Exercisable Number of Options |
| $0.26 - $0.74 | 175,000 | 8.7 | | 175,000 |
| $0.75 - $0.99 | 4,607,117 | 6.1 | | 4,442,455 |
| $1.00 - $5.99 | 5,000 | 3.5 | | 5,000 |
| $6.00 - $19.99 | 37,500 | 3.0 | | 37,500 |
| $20.00 - $30.00 | 35,000 | 1.2 | | 35,000 |
| | 4,859,617 | 6.1 | | 4,694,955 |

The following table presents information related to stock option expense:

| | For the Years Ended December 31, | | Unrecognized at December 31, | Weighted Average Remaining Amortization Period |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | (Years) |
| Consulting | $ 110,557 | $ 539,690 | $ - | - |
| Research and development | 177,281 | 417,838 | 81,482 | 0.8 |
| General and administrative | 403,863 | 670,995 | 15,073 | 0.8 |
| | $ 691,701 | $ 1,628,523 | $ 96,555 | 0.8 |

**NOTE 9 – DERIVATIVE LIABILITIES**

The following table sets forth a summary of the changes in the fair value of Level 3 derivative liabilities that are measured at fair value on a recurring basis:

| | |
|---|---|
| Beginning balance as of January 1, 2019 | $ 1,094,607 |
| Issuance of derivative liabilities | 6,650,667 |
| Extinguishment of derivative liabilities in connection with convertible note repayments and exchanges | (3,230,779) |
| Change in fair value of derivative liabilities | (788,970) |
| Reclassification of derivative liabilities to equity | (2,809,566) |
| Beginning balance as of December 31, 2019 | $ 915,959 |
| Issuance of derivative liabilities | 2,483,532 |
| Extinguishment of derivative liabilities in connection with convertible note repayments and exchanges | (1,165,329) |
| Change in fair value of derivative liabilities | 2,141,069 |
| Write-off of derivative liabilities pursuant to ASC 852 | (4,375,231) |
| Ending balance as of December 31, 2020 | $ - |

In applying the Multinomial Lattice and Black-Scholes option pricing models to derivatives issued and outstanding during the years ended December 31, 2020 and 2019, the Company used the following assumptions:

| | For the Years Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Risk free interest rate | 0.06% - 2.16% | 1.54% - 2.16% |
| Expected term (years) | 0.12 – 5.00 | 0.08 – 5.00 |
| Expected volatility | 101% - 133% | 91% - 133% |

During the year ended December 31, 2019, the Company recorded new derivative liabilities in the aggregate amounts of $5,331,147 and $1,400,365 related to the ECOs of certain convertible notes payable and warrants subject to sequencing, respectively. See Note 7 – Notes Payable – Convertible Notes for additional details. See Note 10 – Commitments and Contingencies and Note 8 – Stockholders' Deficit for warrants issued and deemed to be derivative liabilities.

During the year ended December 31, 2019, the Company extinguished an aggregate of $3,230,780 of derivative liabilities in connection with repayments and exchanges of certain convertible notes payable into shares of the Company's common stock. See Note 7 – Notes Payable – Convertible Notes for additional details.

During the year ended December 31, 2019, the Company reclassified an aggregate of $2,809,566 of derivative liabilities to equity as a result of a change in the sequencing status.

On December 31, 2019, the Company recomputed the fair value of ECOs recorded as derivative liabilities to be $962,042. The Company recorded a gain on the change in fair value of these derivative liabilities of $118,600 for the year ended December 31, 2019.

On December 31, 2019, the Company recomputed the fair value of the derivative liabilities related to outstanding warrants to be $34,762. These warrants are either redeemable for cash equal to the Black-Scholes value, as defined, at the election of the warrant holder upon a fundamental transaction pursuant to the warrant terms or were issued subsequent to the commencement of sequencing. The Company recorded a gain on the change in fair value of these derivative liabilities of $670,370 for the year ended December 31, 2019.

During the year ended December 31, 2020, the Company recorded new derivative liabilities in the aggregate amount of $2,473,532 and $10,000 related to the ECOs of certain convertible notes payable and warrants subject to sequencing, respectively. See Note 7 – Notes Payable – Convertible Notes for additional details. See Note 8 – Stockholders' Deficit for warrants issued and deemed to be derivative liabilities.

During the year ended December 31, 2020, the Company extinguished an aggregate of $1,165,329 of derivative liabilities in connection with the exchanges of certain convertible notes payable into shares of the Company's common stock. See Note 7 – Notes Payable – Conversions, Exchanges and Other for additional details.

During the year ended December 31, 2020 and prior to the Petition Date, the Company recomputed the fair value of ECOs and warrants recorded as derivative liabilities to be $4,375,231 and $-, respectively. The Company recorded a loss on the change in fair value of these derivative liabilities of $2,141,069.

During the year ended December 31, 2020 and subsequent to the Petition Date, pursuant to ASC 852, *Reorganziations*, the Company wrote-off $4,375,231 of derivative liabilities related to the convertible notes included in the Chapter 11 Reorganization allowable claims. The Company recorded the write-off in Reorganization Items, net on the consolidated statement of operations as of December 31, 2020.

**NOTE 10 – COMMITMENTS AND CONTINGENCIES**

*Litigation, Claims and Assessments*

**Coventry Enterprises, LLC**

On February 11, 2020, pursuant to an Order to Show Cause of the United States District Court of the Eastern District of New York (the "Court"), in the matter of Coventry Enterprises, LLC vs. BioRestorative Therapies, Inc., pending the hearing of the plaintiff's application for a preliminary injunction, the Court issued a temporary restraining order enjoining the Company from issuing any additional shares of stock except for purposes of fulfilling the plaintiff's share reserve requests or conversion requests until such reserve requests were fulfilled and enjoining the Company from reserving authorized shares for any other party until the plaintiff's reserve requests were fulfilled. Pursuant to a hearing held on February 13, 2020, the temporary restraining order with regard to the Company issuing shares of common stock was not continued.

On March 11, 2020, the Court ordered that the Company (i) convene and hold a special meeting, by no later than March 18, 2020, of the Board of Directors of the Company (the "Board"), for approval of certain changes to the shares of the Company, as set forth below; (ii) approve a reverse split and/or a stock consolidation, solely of the Company's outstanding shares, at a ratio of 1,000 to 1, (iii) approve of the continuation of the Company's then total authorized shares of common stock at 2,000,000,000 shares; and (iv) to call a special meeting of stockholders of the Company, within ten days of the special meeting of the Board and by not later than March 25, 2020, to approve the foregoing. On March 18, 2020, the Board considered the matter, and, based upon the Court order, determined to approve the foregoing items, including the 1,000 to 1 reverse split, subject to the Company having available funds to effectuate such items. As discussed above in Note 7 – Notes Payable – Chapter 11 Reorganization on March 20, 2020, the Company filed a petition commencing its Chapter 11 Case. As of the date of this report, the Company has not effected the reverse split.

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

*Appointment or Departure of Directors and Certain Officers*

The Company and Mark Weinreb, its former Chief Executive Officer ("Former CEO"), were parties to an employment agreement that, as amended, was to expire on December 31, 2019. Pursuant to the employment agreement, as amended, in the event that (a) the Former CEO's employment was terminated by the Company without cause, or (b) the Former CEO terminated his employment for "good reason" (each as defined in the employment agreement), or (c) the term of the Former CEO's employment agreement was not extended beyond December 31, 2019 and within three months of such expiration date, his employment was terminated by the Company without "cause" or the Former CEO terminated his employment for any reason, the Former CEO was to be entitled to receive severance in an amount equal to his then annual base salary and certain benefits, plus $100,000 (in lieu of bonus). Further, in the event that the Former CEO's employment was terminated by the Company without cause, or the Former CEO terminated his employment for "good reason", following a "change in control" (as defined in the employment agreement), the Former CEO would be entitled to receive severance in an amount equal to one and one-half times his then annual base salary and certain benefits, plus $300,000 (in lieu of bonus). Additionally, as part of the amended employment agreement, the Former CEO was entitled to new performance-based cash bonuses payable for the years ending December 31, 2018 and 2019, such that an aggregate of up to 50% of the Former CEO's then annual base salary per annum could be earned for such year pursuant to the satisfaction of such goals. On March 16, 2020, the Company and the Former CEO, entered into an agreement pursuant to which, among other matters, the term of his employment agreement with the Company was extended to the earlier of (i) September 30, 2020 or (ii) the effective date of a plan of liquidation of the Company. The Former CEO resigned his employment with the Company on November 16, 2020, the effective date of the Chapter 11 reorganization. Based upon such termination of employment, the Former CEO was entitled to receive his severance of $400,000 and certain benefits plus $100,000, and the option accelerations as discussed above. The severance amount was generally considered an unsecured claim in the Company's Chapter 11 Case and the Former CEO received shares of the Company's common stock in exchange for such claim in a manner consistent with other unsecured creditors.

*Conversion of Convertible Notes*

During the year ended December 31, 2020, certain lenders requested to exchange a portion of their outstanding convertible note principal and accrued interest for shares of the Company's common stock. As of the Petition Date these shares had yet to be issued to the lenders; however, the shares of the Company's common stock issued for unsecured claims as part of the Plan to the certain lenders represented the aggregate unsecured claims less the principal and accrued interest that was represented in the uneffected exchanges. The Company believes that there may be a potential contingency related to the non-issued shares that would be settled in shares of the Company's common stock and not monetary compensation.

**NOTE 11 – INCOME TAXES**

The Company identified its federal and New York tax returns as its "major" tax jurisdictions. The period its income tax returns are subject to examination for these jurisdictions is 2017 through 2020. The Company believes its income tax filing positions and deductions will be sustained on audit, and it does not anticipate any adjustments that would result in a material change to its financial position. Therefore, no liabilities for uncertain tax positions have been recorded.

At December 31, 2020 and 2019, the Company had approximately $36,600,000 and $29,900,000, respectively, of federal and state net operating losses that may be available to offset future taxable income. As a result of the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), certain future carryforwards do not expire. At December 31, 2020 approximately $8,000,000 of federal net operating losses will expire from 2029 to 2037 and approximately $28,600,000 have no expiration. In accordance with Section 382 of the Internal Revenue Code, the usage of the Company's net operating loss carryforwards are subject to annual limitations due to several greater than 50% ownership changes. The Section 382 limitations resulted in approximately $28,200,000 of federal NOLs not being realizable as of December 31, 2018 and the cumulative reversal of approximately $9,600,000 of net operating loss deferred tax assets.

The Company has not performed a formal analysis for the year ended December 31, 2020, but it believes its ability to use such net operating losses and tax credit carryforwards in the future is subject to annual limitations due to change of control provisions under Sections 382 and 383 of the Internal Revenue Code, which will significantly impact its ability to realize these deferred tax assets.

The Company's net deferred tax assets, liabilities and valuation allowance as of December 31, 2020 and 2019 are summarized as follows:

| | December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 9,700,000 | $ 7,800,000 |
| Stock-based compensation | 4,070,000 | 3,880,000 |
| Research & development tax credits | 358,000 | 358,000 |
| Total deferred tax assets | 14,128,000 | 12,038,000 |
| | | |
| Deferred tax liabilities: | | |
| Intangible assets | (30,000) | (26,000) |
| Total deferred tax liabilities | (30,000) | (26,000) |
| | | |
| Net deferred tax assets | 14,098,000 | 12,012,000 |
| | | |
| Valuation allowance | $ (14,098,000) | $ (12,012,000) |
| | | |
| Deferred tax asset, net of valuation allowance | $ - | $ - |
| | | |
| Change in valuation allowance | $ (2,086,000) | $ (3,834,000) |

The income tax provision (benefit) as of December 31, 2020 and 2019 consists of the following:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Federal: | | |
| Current | $ - | $ - |
| Deferred | - | - |
| State and local: | | |
| Current | - | - |
| Deferred | - | - |
| Total income tax provision (benefit) | $ - | $ - |

A reconciliation of the statutory federal income tax benefit to actual tax benefit for the years ended December 31, 2020 and 2019 is as follows:

| | 2020 | 2019 |
|---|---|---|
| Federal statutory blended income tax rates | (21)% | (21)% |
| State statutory income tax rate, net of federal benefit | (5) | (5) |
| Permanent differences | 7.6 | 0.1 |
| True-ups and other | - | (0.3) |
| Change in valuation allowance | 18.4 | 26.2 |
| Effective tax rate | -% | -% |

As of the date of this filing, the Company has not filed its 2020 or 2019 federal and state corporate income tax returns. The Company expects to file these documents as soon as practicable.

**NOTE 12 – LEASES**

With the adoption of ASC 842, operating lease agreements are required to be recognized on the balance sheet as ROU assets and corresponding lease liabilities.

The Company is a party to a lease for 6,800 square feet of space located in Melville, New York (the “Melville Lease”) with respect to its corporate and laboratory operations. The Melville Lease was scheduled to expire in March 2020 (subject to extension at the option of the Company for a period of five years) and provided for an annual base rental during the initial term ranging between $132,600 and $149,260. In June 2019, the Company exercised its option to extend the Melville Lease and entered into a lease amendment with the lessor whereby the five-year extension term commenced on January 1, 2020 with annual base rent ranging between $153,748 and $173,060.

On August 1, 2019, the Company recognized ROU assets and lease liabilities of $638,246. The Company elected to not recognize ROU assets and lease liabilities arising from short-term office leases (leases with initial terms of twelve months or less, which are deemed immaterial) on the balance sheets. On June 1, 2019, the Company exercised its right to extend its existing lease of office space for an additional five years.

When measuring lease liabilities for leases that were classified as operating leases, the Company discounted lease payments using its estimated incremental borrowing rate at August 1, 2019. The weighted average incremental borrowing rate applied was 12%.

The following table presents net lease cost and other supplemental lease information:

| | Year Ended December 31, 2020 |
|---|---|
| Lease cost | |
| Operating lease cost (cost resulting from lease payments) | $ 153,748 |
| Short term lease cost | - |
| Sublease income | - |
| Net lease cost | $ 153,748 |
| | |
| Operating lease – operating cash flows (fixed payments) | $ 153,748 |
| Operating lease – operating cash flows (liability reduction) | $ 85,465 |
| Non-current leases – right of use assets | $ 473,849 |
| Current liabilities – operating lease liabilities | $ 158,371 |
| Non-current liabilities – operating lease liabilities | $ 363,519 |

Future minimum payments under non-cancelable leases for operating leases for the remaining terms of the leases following the year ended December 31, 2020:

| Fiscal Year | Operating Leases |
|---|---|
| 2021 | $ 158,371 |
| 2022 | 163,132 |
| 2023 | 168,028 |
| 2024 | 173,060 |
| Total future minimum lease payments | 662,591 |
| Amount representing interest | (140,701) |
| Present value of net future minimum lease payments | $ 521,890 |

**NOTE 13 – SUBSEQUENT EVENTS**

*Exercise of Warrants*

During March 2021, the Company issued an aggregate of 294,328,000 shares of common stock to Auctus, with a fair value of $0.01 per share, as a result of the exercise of warrants associated with the Plan.

*Conversion of Notes Payable*

On January 26, 2021, the Company issued 11,123,856 shares of common stock, with a fair value of $0.012 per share, as a result of the conversion of a convertible note in the principal amount of $118,397 and $1,151 in accrued interest.

On March 11, 2021, the Company issued 8,285,719 shares of common stock with a fair value of $0.015 per share, as a result of the conversion of a convertible note in the principal amount of $92,666 and $1,460 in accrued interest.

*Appointment or Departure of Directors and Certain Officers*

On March 18, 2021, Nickolay Kukekov was elected a director of the Company.

On March 18, 2021, the Company's Board of Directors adopted the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the "Plan"). Pursuant to the Plan, a total of 4,700,000,000 shares of common stock are authorized to be issued pursuant to the grant of stock options, restricted stock units, restricted stock, stock appreciation rights and other incentive awards.

On March 18, 2021, the Company and Lance Alstodt, its President, Chief Executive Officer and Chairman of the Board, entered into an employment agreement (the "Alstodt Employment Agreement") which provides for a term ending on March 18, 2026. Pursuant to the Alstodt Employment Agreement, Mr. Alstodt is entitled to receive initially an annual salary of $250,000. Mr. Alstodt's annual salary will increase by $50,000 per year. In addition, in the event certain performance goals are met, Mr. Alstodt's salary will increase by $150,000. The Alstodt Employment Agreement also provides for the grant to Mr. Alstodt pursuant to the Plan of (i) a ten year option for the purchase of 1,173,917,974 shares of common stock of the Company and (ii) 586,958,987 restricted stock units of the Company ("RSUs").

On March 18, 2021, the Company and Francisco Silva, its Vice President, Research and Development, entered into an employment agreement (the "Silva Employment Agreement") which provides for a term ending on March 18, 2026. Pursuant to the Silva Employment Agreement, Mr. Silva is entitled to receive initially an annual salary of $225,000. Mr. Silva's annual salary will increase by $50,000 per year. In addition, in the event certain performance goals are met, Mr. Silva's salary will increase by $150,000. The Silva Employment Agreement also provides for the grant to Mr. Silva pursuant to the Plan of (i) a ten year option for the purchase of 1,173,917,974 shares of common stock of the Company and (ii) 586,958,987 RSUs.

**Exhibit 23**

**INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT**

We consent to the incorporation by reference in the Registration Statements of BioRestorative Therapies, Inc. (the "Company") on Form S-8 (File Nos. 333-196299, 333-203310, 333-210555, 333-214621, 333-228434 and 333-233309) of our report dated April 29, 2021 with respect to our audit of the consolidated financial statements of BioRestorative Therapies, Inc. and Subsidiary as of December 31, 2020 and 2019 and for the years then ended, which report is included in this Annual Report on Form 10-K of BioRestorative Therapies, Inc. for the year ended December 31, 2020.

*/s/ Friedman LLP*
Friedman LLP
Marlton, New Jersey
April 29, 2021

**Exhibit 31.1**

**SECTION 302 CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**

I, Lance Alstodt, certify that:

1. I have reviewed this Annual Report on Form 10-K of BioRestorative Therapies, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 29, 2021

*/s/ Lance Alstodt*

Lance Alstodt
Principal Executive Officer

**Exhibit 31.2**

**SECTION 302 CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER**

I, Lance Alstodt, certify that:

1. I have reviewed this Annual Report on Form 10-K of BioRestorative Therapies, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 29, 2021

*/s/ Lance Alstodt*

Lance Alstodt
Principal Financial Officer

**Exhibit 32**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**

**AND PRINCIPAL FINANCIAL OFFICER**

**PURSUANT TO**

**18 U.S.C. SECTION 1350,**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. § 1350, the undersigned officer of BioRestorative Therapies, Inc. (the "Company") hereby certifies that the Company's Annual Report on Form 10-K for the year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 29, 2021

*/s/ Lance Alstodt*

Lance Alstodt
Principal Executive Officer and
Principal Financial Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. § 1350 and is not being filed as part of the Report or as a separate disclosure document.