

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-K

(Mark One)

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2021

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

(State or other jurisdiction
of incorporation or organization)

91-1835664

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

40 Marcus Drive, Suite 1, Melville, New York

(Address of principal executive offices)

11747

(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

**Common Stock
\$0.0001 par value**

Trading Symbol(s)

BRTX

Name of each exchange on which registered

Nasdaq Capital Market

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

None

(Title of Class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 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

Non-accelerated filer

Accelerated filer

Smaller reporting company

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

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, 2021, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$19,923,800 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 No

As of March 28, 2022, there were 3,626,603 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

INDEX

	Page No.
<u>Forward-Looking Statements</u>	3
<u>PART I</u>	
Item 1. <u>Business.</u>	3
Item 1A. <u>Risk Factors.</u>	35
Item 1B. <u>Unresolved Staff Comments.</u>	35
Item 2. <u>Properties.</u>	35
Item 3. <u>Legal Proceedings.</u>	35
Item 4. <u>Mine Safety Disclosures.</u>	35
<u>PART II</u>	
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</u>	36
Item 6. <u>[Reserved].</u>	37
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations.</u>	37
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk.</u>	74
Item 8. <u>Financial Statements and Supplementary Data.</u>	74
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.</u>	74
Item 9A. <u>Controls and Procedures.</u>	75
Item 9B. <u>Other Information.</u>	77
Item 9C. <u>Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.</u>	77
<u>PART III</u>	
Item 10. <u>Directors, Executive Officers and Corporate Governance.</u>	78
Item 11. <u>Executive Compensation.</u>	83
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</u>	86
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence.</u>	89
Item 14. <u>Principal Accountant Fees and Services.</u>	89
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules.</u>	90
Item 16. <u>Form 10-K Summary.</u>	92
<u>Signatures</u>	93

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*, and *ThermoStem*. 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, or 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, or IND, application to the U.S. Food and Drug Administration, or 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 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.

Between March and July 2021, two United States patents related to our *ThermoStem Program* were issued to us.

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

In June 2021, a Japanese patent related to our *ThermoStem Program* was issued to us.

In August 2021, an Australian patent related to our *ThermoStem Program* was issued to us.

In September 2021, a notice of allowance was issued for an Israeli patent application in our *ThermoStem Program*. The application is expected to issue as an Israeli patent in the near future.

In September 2021, we were awarded a National Institutes of Health Small Business Technology Transfer (STTR) Phase 1 grant for \$256,000 to evaluate the therapeutic effects on our hypoxic cultured bone marrow derived mesenchymal stem cells (*BRTX-100*) after encapsulation with a PEG-peptide hydrogel. The work is being done in collaboration with Washington University of St. Louis.

In October 2021, we effected a 1-for-4,000 reverse split of our common stock. All share and per share amounts in this Annual Report give retroactive effect to such reverse split.

In November 2021, ten separate United States patent applications were filed for our *Disc/Spine Program*.

In November 2021, we completed a \$23,000,000 underwritten public offering of units of securities pursuant to which an aggregate of 2,300,000 shares of our common stock and warrants for the purchase of an aggregate of 2,645,000 shares of our common stock were issued. We intend to use the net proceeds from the offering as follows: (i) undertaking of clinical trials with respect to *BRTX-100* and its related collection and delivery procedure; (ii) pre-clinical research and development with respect to our *ThermoStem Program*; and (iii) for general corporate and working capital purposes. In connection with the public offering, our common stock was listed on the Nasdaq Capital Market.

In November 2021, concurrently with the consummation of the public offering, we issued an aggregate of 313,789 shares of our common stock, 1,543,158 shares of our Series A preferred stock and warrants for the purchase of an aggregate of 1,856,938 shares of our common stock in exchange for convertible promissory notes in the aggregate principal amount of \$10,046,897, together with accrued interest thereon, and warrants for the purchase of an aggregate of 3,677,997 shares of our common stock. Such indebtedness and warrants were exchanged at a price of \$10.00 per unit of securities, consistent with the public offering price of our units of common stock and warrants. The newly issued warrants are exercisable for a period of five years at an exercise price of \$10.00 per share.

In November 2021, Patrick F. Williams and David Rosa were elected directors and Robert E. Kristal was elected as our Chief Financial Officer.

In November 2021, we reduced the number of shares of common stock we are authorized to issue from 300,000,000,000 to 75,000,000 in a manner consistent with our 1-for-4,000 reverse split.

In December 2021, we entered into a Master Service Agreement with Professional Research Consulting Inc. d/b/a PRC Clinical, a contract research organization, or CRO, specializing in clinical trial management, to conduct our Phase 2 clinical trial.

Materials Events During 2022

In January 2022, Robert Paccasassi was elected our Vice President of Quality Assurance/Regulatory Compliance.

In January 2022, a notice of allowance was issued for a Japanese patent application in our *ThermoStem Program*. The application is expected to issue as a Japanese patent in the near future.

In March 2022, a United States patent related to BRTX-100, our lead cell therapy candidate, was issued. We have been granted license rights with regard to the patent. See “Business – Disc/Spine Program – License” below.

(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, or 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 and have commenced such clinical trial through the execution of a CRO agreement with PRC Clinical, the commencement of clinical trial site identification, the purchase of manufacturing equipment and the expansion of our laboratory to include capabilities for clinical production. In March 2022, a United States patent related to *BRTX-100*, was issued. We have been granted license rights with regard to the patent. 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, or BADSC, to generate brown adipose tissue, or BAT. We refer to this as our *ThermoStem Program*. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research conducted by us and others 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 65 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 are concentrating 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, if we are not successful, 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, which would adversely impact our prospects.

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 five United States patents, nine foreign patents, three United States patent applications, and eight foreign patent applications related to research regarding our *ThermoStem Program*, we have obtained licenses for eleven United States patent applications 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 research laboratory facility with Good Manufacturing Practice, or cGMP, capabilities to produce clinical grade products and will seek to further develop cellular-based treatments, products and protocols, stem cell-related intellectual property, or IP, and translational research applications. See “Laboratory” below.

We have not generated any significant revenues to date. In November 2021, we completed a \$23,000,000 public offering of our securities. Such funds are sufficient for us to complete our Phase 2 clinical trial investigating the use of *BRTX-100* in the treatment of chronic lower back pain arising from degenerative disc disease, as further described in this section, as well as to continue our pre-clinical research and development efforts with respect to our *ThermoStem Program* and to satisfy our current working capital needs; however, the implementation of our business plan, as discussed below, will require the receipt of additional financing to fund our research and development efforts, including our contemplated Phase 3 clinical trial with regard to *BRTX-100* and our contemplated clinical trials relating to our *ThermoStem Program*, and otherwise fund our operations. We 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 \$35,000,000 in additional financing to complete our contemplated Phase 3 clinical trial investigating the use of *BRTX-100* (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, and fund general operations. No assurance can be given that the anticipated amount of required funding is 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. If we are unable to obtain adequate funding, we may be required to significantly curtail or discontinue our proposed operations.

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, or 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 2016 market report from Trinity Partners, a global life sciences consulting firm, 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 one 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. The product candidate was developed utilizing in part the license described below under "*License*." As described below under "*BRTX-100*" and "*Production and Delivery*," *BRTX-100* is a hypoxic (low oxygen) stem cell product developed through a culturing process. 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 have commenced our Phase 2 clinical trial through the execution of a CRO agreement with PRC Clinical, the commencement of clinical trial site identification, the purchase of manufacturing equipment and the expansion of our laboratory to include capabilities for clinical production. We believe that, based upon our periodic reports to the FDA as to the commencement of the clinical trial, the existing IND remains effective.

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 (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.

In March 2022, a United States patent related to *BRTX-100*, was issued. We have been granted license rights with respect to the patent.

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.

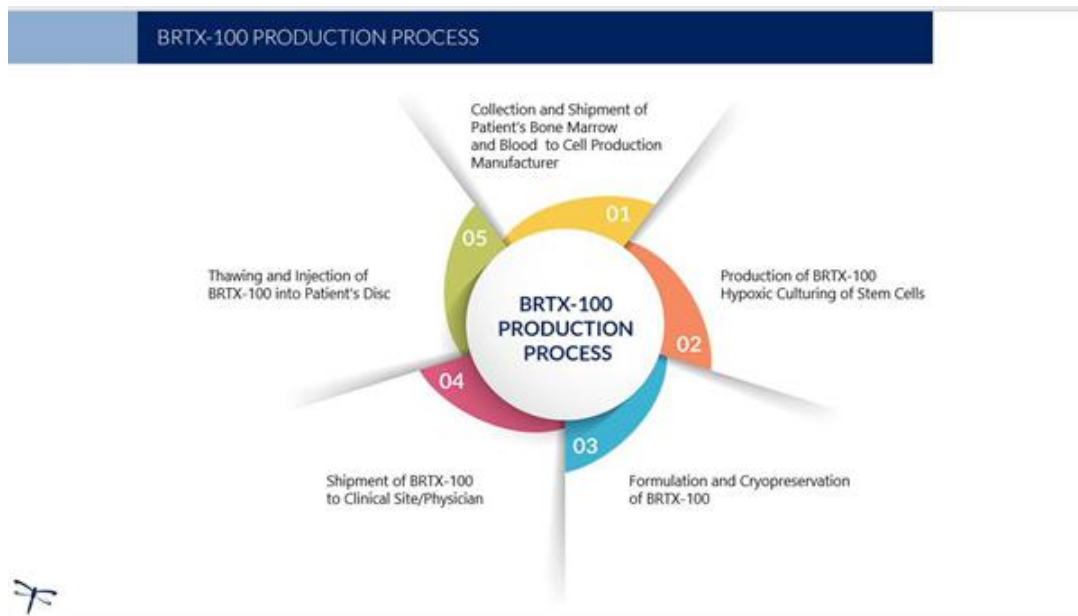
Mesenchymal stem cells used in *BRTX-100* are similar to other MSCs under development by others; however, in order to enhance the survivability of our bone marrow-derived MSCs in the avascular environment of the damaged disc, *BRTX-100* is designed to expand under hypoxic conditions for a period of approximately 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.

In September 2021, we were awarded a National Institutes of Health Small Business Technology Transfer (STTR) Phase 1 grant for \$256,000 to evaluate the therapeutic effects on our hypoxic cultured bone marrow derived mesenchymal stem cells (*BRTX-100*) after encapsulation with a PEG-peptide hydrogel. The work is being done in collaboration with Washington University of St. Louis.

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, or Regenerative, that became effective in April 2012, or the Regenerative License Agreement, we 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 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 provided for the requirement that we complete our Phase 2 clinical trial by a certain date in order to maintain the exclusive nature of the licenses. Such date has passed and accordingly our rights are non-exclusive. We are currently in negotiations with Regenerative with regard to a possible reinstatement of the exclusive nature of the licenses. No assurances can be given in this regard. The lack of exclusivity will not impact our ability to conduct our Phase 2 clinical trial with regard to *BRTX-100*. 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 by Regenerative 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 have commenced our Phase 2 clinical trial through the execution of a CRO agreement with PRC Clinical, the commencement of clinical trial site identification, the purchase of manufacturing equipment and the expansion of our laboratory to include capabilities for clinical production.

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 (we intend to utilize 15 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 - percentage 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

In December 2021, we entered into a Master Service Agreement with Professional Research Consulting Inc. d/b/a PRC Clinical, a contract research organization, or CRO, specializing in clinical trial management, to conduct our Phase 2 clinical trial.

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.

As an alternative to undertaking any necessary clinical trials 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 in lieu of product sales revenue. 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, or 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

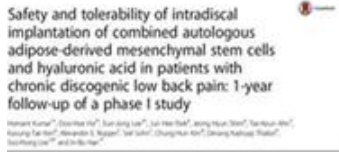
Human data from studies of therapies comparative to *BRTX-100* have shown reduced pain, increased function, and an absence of significant safety issues with a durable response, as shown below:



- **Description:** 33 patients diagnosed with degenerative disc disease received an intradiscal injection of autologous, hypoxic cultured, bone marrow-derived MSCs (15.1 to 51.6 million cells) as part of a US based investigator initiated study. Prospective registry data was obtained at multiple time intervals up to 6 years post-treatment.
- **Results:** Study results on the use of hypoxic cultured autologous MSCs demonstrated no safety issues, substantially reduced pain, increased function, and reduced disc bulge size. Pain change score relative to baseline were significant at 3, 36, 48, 60 and 72 months post-treatment. Single assessment numeric evaluation ratings showed improvement of 60% at 3 years post treatment. Functional rating index post-treatment change scores exceeded the minimally clinically important difference. 85% of the patients (n=20) who underwent post-treatment MRIs had a 25 % reduction in disc bulge size.



- **Description:** 24 patients with chronic back pain were randomized into either treatment group or control group. Treatment group received 25x10⁶ bone marrow-derived MSCs. Clinical outcomes were followed up for 1 year and included evaluation of pain, disability and quality of life.
- **Results:** Feasibility and safety of a 25x10⁶ cell dose was confirmed and clinical efficacy was identified. MSC-treated patients displayed a quick and significant improvement in algo-functional indices versus controls. VAS and ODI were significantly reduced at 3 months after MSC transplantation and the improvement maintained at 6 and 12 months. Degeneration, quantified by Pfirrmann grading, improved in the MSC-treated patients and worsened in the control group.



- **Description:** 10 patients with chronic back pain received a single injection of 20x10⁶ and 40x10⁶ of autologous adipose-derived MSCs. Safety and clinical outcomes were evaluated by assessing VAS, ODI, Short Form-36 (SF-36), and imaging at regular intervals over 1 year.
- **Results:** No serious or adverse events were reported during the 1-year follow up period. VAS, ODI, and SF-36 scores significantly improved in both dosing cohorts compared to base line. In addition three patients of the ten included in the study were determined to have increased water content based on an increased diffusion coefficient on diffusion MRI.

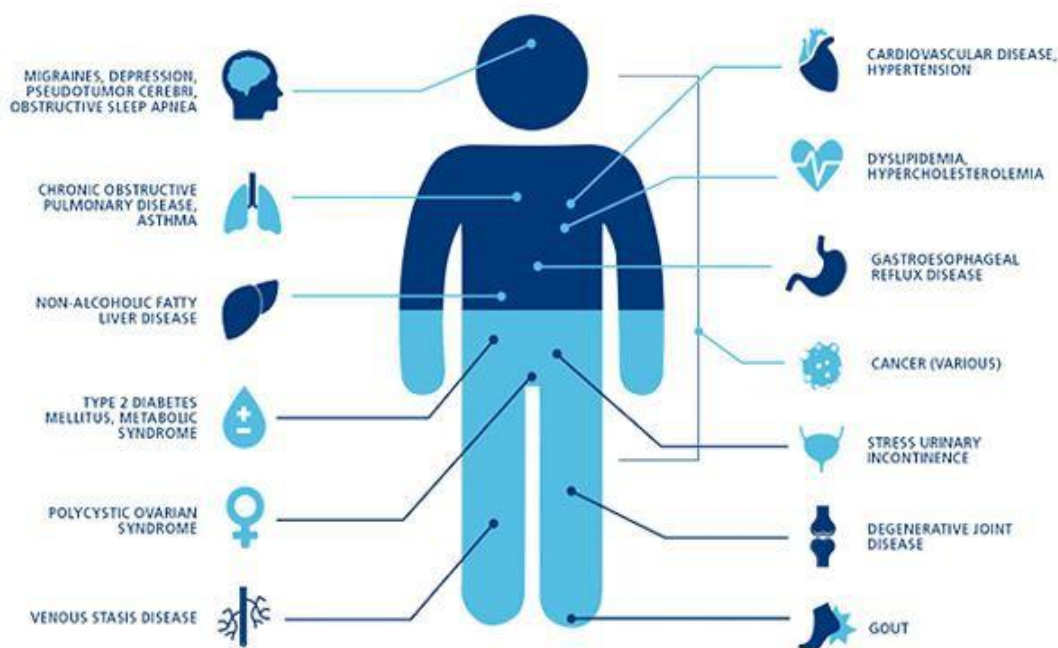
The United States is the world's leading consumer of hydrocodone (99%) and oxycodone (83%) and leads the world in per capital consumption of such drugs (twice as much as second ranked Canada). In 2020, 91,000 persons in the United States died from overdoses.

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, or 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. As discussed in a 2020 article published in the *International Journal of Molecular Sciences*, 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, or the Foundation, and a Research Agreement with the University of Utah, or the Utah Research Agreement. Pursuant to the Assignment Agreement, which provides for royalty payments, we acquired the rights to two provisional patent applications that relate to human brown fat cell lines. No royalty amounts are payable to date. The applications have been converted to a utility application in the United States and several foreign jurisdictions. Pursuant to the Utah Research Agreement, the University of Utah 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. 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. The Research Agreement expired upon completion of the services provided for therein.

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 research collaboration 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 June 2021, a Japanese patent related to our *ThermoStem Program* was issued to us.

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

In August 2021, an Australian patent related to our *ThermoStem Program* was issued to us.

In September 2021, a notice of allowance was issued for an Israeli patent application in our *ThermoStem Program*. The application is expected to issue as an Israeli patent in the near future.

In January 2022, a notice of allowance was issued for a Japanese patent application in our *ThermoStem Program*. The application is expected to issue as a Japanese patent in the near future.

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 in 2022. Following the completion of such studies, if successful, we intend to file an IND with the FDA and initiate a clinical trial. 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, or CND, that is a needle system with a curved inner cannula to allow access to difficult-to-locate regions for the delivery or removal of fluids and other substances. The 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*. 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 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.

In 2021 and 2022, we expanded our laboratory to include capabilities for the clinical production of our pipeline of clinical and investigational cell therapy candidates. Our expanded cGMP facility is anticipated to include process development space, ISO 7 cleanrooms and state-of-the-art equipment. We have expanded our research and development operations to include clinical manufacturing, a necessary step for our Phase 2 clinical trial for *BRTX-100*. The new facility has been designed to provide cGMP manufacturing according to FDA and European Medicines Agency regulations and guidelines to support clinical grade cell production. 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*, twelve 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. In addition, in March 2022, a United States patent related to *BRTX-100*, was issued. The other ten applications remain 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 three pending United States patent applications and five United States patents within three patent families. With regards to the first patent family, 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 four applications have been granted as foreign patents). With regards to the third patent family in the *ThermoStem Program*, patent applications have been filed in four foreign jurisdictions.

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	
<i>Disc/Spine (brtxDisc)</i>	1	U.S. Patent No. 11,278,573 B2 ^b	US	Methods and compositions to facilitate repair of avascular tissue	
	1	17/527,489 ^a	US		
	1	17/527,494 ^a	US		
	1	17/527,498 ^a	US		
	1	17/527,503 ^a	US		
	1	17/527,505 ^a	US		
	1	17/527,510 ^a	US		
	1	17/527,512 ^a	US		
	1	17/527,516 ^a	US		
	1	17/527,523 ^a	US		
	1	17/527,527 ^a	US		
		1	U.S. Patent No. 9,113,950 B2 ^b	US	Therapeutic delivery device
<i>Metabolic (ThermoStem)</i>	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	U.S. Patent No. 11,066,646	US		
	2	17/348,218	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	AU Patent No. 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 ^c	Israel		
	3	JP Patent No. 6887249	Japan		
	3	2021-123173 ^c	Japan		
	3	2022-15511	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			
4	2020265664	Australia			
4	20798130.9	Europe			
4	287557	Israel			
4	2021-564135	Japan			

^a Patent application filed by licensor assignee, Regenexx, LLC

^b Patent issued to licensor assignee, Regenexx, LLC

^c Application has been allowed, but not yet issued as a patent

In March 2014, we entered into a Research and Development Agreement with Rohto Pharmaceutical Co., Ltd., a Japanese pharmaceutical company, or Rohto. Pursuant to the Research and Development Agreement with Rohto, we were engaged to provide research and development services with regard to stem cells. The agreement with Rohto expired upon the completion of the services provided for therein.

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

-  bioRestorative
therapies
- BRTX-100
- THERMOSTEM

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, 2021 and 2020, we incurred \$729,058 and \$876,829, 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. Wayne Olan, Dr. Joy Cavagnaro, Dr. Jason Lipetz, Dr. Harvinder Sandhu, Dr. Christopher Plataras and Dr. Gerard A. Malanga. The Disc Advisory Committee members are Dr. Lipetz (Chairman), Dr. Olan, Dr. Sandhu, Dr. Plataras and Dr. Malanga. See “Management” for a listing of the principal positions for Drs. Marasco, Olan, Cavagnaro, Lipetz, Sandhu, Plataras 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.

The Biologics Price Competition and Innovation Act, or the BPCIA, sets forth an abbreviated pathway for the approval of biosimilar and interchangeable biological products that could be used by future competitors, if any, of our product candidates are approved by the FDA as a biologic. 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, or 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:

		
PRODUCT & DESCRIPTION	BRTX-100 adult stem cell biologic, administered via anticipated 30-minute in-office intradiscal injection	MPC-06-ID: adult stem cell biologic, administered via 30 -minute outpatient intradiscal injection
KEY ATTRIBUTES		
	Hypoxic cultured – in low oxygen environment (5%)	Normoxic cultured – with normal oxygen environment (~20%)
	Autologous – uses patients own stem cells	Allogeneic – uses human derived stem cells (not from patient)
	Autologous Platelet Lysate Carrier	Hyaluronic Acid Carrier
	100% Animal-Free Manufacturing Process	Animal Products Used in Manufacturing Process
STAGE OF DEVELOPMENT	Phase 2 clinical trial approved under active IND 17275	Phase 3 clinical trial

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, or PHS Act, and the Federal Food, Drug, and Cosmetic Act, or FDCA. Stem cells can be regulated under the FDA's Human Cells, Tissues, and Cellular and Tissue-Based Products Regulations, or 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 PHS Act, the FDA issued specific regulations governing the use of HCT/Ps in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations, or CFR, or 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. As of that date, manufacturers of products marketed as HCT/Ps that do not comply with the HCT/P Regulations are 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. The U.S. federal courts have upheld the FDA’s authority to regulate stem cell products under the FDCA that do not comply with the HCT/P Regulations. For example, in June 2021, the U.S. Court of Appeals for the 11th Circuit upheld the FDA’s regulation of stem cells obtained from fat as a “drug” because the cells were not used for a “homologous” use. *United States of America v. US Stem Cell Clinic, LLC*, 998 F.3d 1302 (2021).

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 PHS Act 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, or 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, or 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, or 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 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, or 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, or 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, or 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, or 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. The FDA's recent use of the accelerated approval pathway for an Alzheimer's drug (aducanumab) has been controversial and has attracted Congressional scrutiny. As a result, it is possible that future legislation or regulatory policy changes could make it more difficult to use the accelerated approval pathway.

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, or 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, or 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, or PMA. "New" devices are automatically regulated as Class III devices unless they are shown to be low risk, in which case they may be subject to de novo review to be moved to Class I or Class II. Clinical research of an investigational device is subject to the FDA's Investigational Device Exemption, or 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, or the FTC, has the authority to regulate and police advertising of medical treatments, procedures, and regimens in the United States under the Federal Trade Commission Act, or the FTCA. The FTC has regulatory authority to prevent unfair and deceptive practices and false advertising. Specifically, the FTC requires advertisers and promoters to have a reasonable basis to substantiate and support claims. The FTC has many enforcement powers, one of which is the power to order disgorgement by promoters deemed in violation of the FTCA of any profits made from the promoted business and can order injunctions from further violative promotion. Advertising that we may utilize in connection with our medical tourism operations will be subject to FTC regulatory authority, and we intend to comply with such regulatory régime. Similar laws and requirements are likely to exist in other countries and we intend to comply with such requirements.

Federal Regulation of Clinical Laboratories

Congress passed the Clinical Laboratory Improvement Amendments, or CLIA, in 1988, which provided the Centers for Medicare and Medicaid Services, or CMS, authority over all laboratory testing, except research, that is performed on humans in the United States. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations, or CMSO, has the responsibility for implementing the CLIA program.

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability, and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. Laboratories that handle stem cells and other biologic matter are, therefore, included under the CLIA program. Under the CLIA program, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections, and pay fees. 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.

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, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or 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, or 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, or FCA;
- the federal Anti-Kickback Statute, or 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, or OSHA, regulations and requirements;
- the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to “excess benefit transactions” with tax-exempt organizations;
- the Physician Payments Sunshine Act (in the event that our products are classified as drugs, biologics, devices or medical supplies and are reimbursed by Medicare, Medicaid or the Children’s Health Insurance Program);
- 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 seven employees, all of whom are full-time employees. We believe that our employee relations are good.

ITEM 1A. RISK FACTORS.

Not applicable. See, however, Item 7 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.

None.

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 Nasdaq Capital Market.

Holders

As of March 28, 2022, there were 359 record holders of our shares of common stock.

Dividends

Not applicable.

Recent Sales of Unregistered Securities

During the three months ended December 31, 2021, we issued the following securities in transactions not involving any public offering. For each of the following transactions, we relied upon Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act, as transactions by an issuer not involving any public offering, Section 3(a)(9) of the Securities Act as a security exchanged by an issuer with its existing security holders exclusively where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange, 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, 2020, Quarterly Reports on Form 10-Q for the periods ended March 31, 2021, June 30, 2021 and September 30, 2021 and Current Reports on Form 8-K filed with the Securities and Exchange Commission and press releases made by us), and we were available to answer questions by prospective investors. We reasonably believe that each of the investors is an accredited investor. No proceeds were received from any of the issuances.

Date Issued	Common Stock	Warrants			Purchaser(s)	Consideration ⁽¹⁾
		Shares	Exercise Price	Term (Years)		
10/21/2021	22,917	-	-	-	(2) \$	339,172 ⁽³⁾
11/03/2021	6,490	-	-	-	(2) \$	84,402 ⁽³⁾
11/29/2021	2,500	-	-	-	(2) \$	15,425 ⁽⁴⁾
12/29/2021	2,500	-	-	-	(2) \$	10,050 ⁽⁴⁾

(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 on a cashless net exercise basis pursuant to the exercise of warrants.

(4) Issued in lieu of cash for consulting services rendered.

Issuer Purchases of Equity Securities

The following table sets forth certain information with respect to purchases of common stock made by affiliated purchasers during the quarter ended December 31, 2021:

<u>Period</u>	<u>Total Number of Shares Purchased(1)</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Maximum Number of Shares that May Be Purchased Under the Plans or Programs</u>
10/1/21 – 10/31/21	-	-	-	-
11/1/21 – 11/30/21	19,222	\$ 6.60	-	-
12/1/21 – 12/31/21	799	\$ 5.50	-	-
Total	<u>20,021</u>	<u>\$ 6.56</u>	<u>-</u>	<u>-</u>

(1) Purchases were made by affiliated purchasers in open market transactions.

ITEM 6. [RESERVED]

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, 2021 and 2020 and for the years ended December 31, 2021 and 2020 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*. In March 2022, a United States patent issued in our *Disc/Spine* Program. 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 and have commenced such clinical trial through the execution of a CRO agreement with PRC Clinical, the commencement of clinical trial site identification, the purchase of manufacturing equipment and the expansion of our laboratory to include capabilities for clinical production. 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, March 2021, and July 2021; Australian patents related to the *ThermoStem Program* were issued in April 2017, October 2019 and August 2021; Japanese patents related to the *ThermoStem Program* were issued in December 2017 and June 2021; a notice of allowance also issued in January 2022 for a separate Japanese application in our *ThermoStem Program* and is expected to issue in the near future; Israeli patents related to our *ThermoStem Program* were issued in October 2019 and May 2020; a notice of allowance also issued in September 2021 for a separate Israeli application in our *ThermoStem Program* and is expected to issue in the near future; 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, 2021, our accumulated deficit was \$134,146,129. 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.

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.

In November 2021, we completed a \$23,000,000 underwritten public offering of units of securities pursuant to which an aggregate of 2,300,000 shares of our common stock and warrants for the purchase of an aggregate of 2,645,000 shares of our common stock were issued. We intend to use the net proceeds from the offering as follows: (i) undertaking of clinical trials with respect to *BRTX-100* and its related collection and delivery procedure; (ii) pre-clinical research and development with respect to our *ThermoStem Program*; and (iii) for general corporate and working capital purposes. In connection with the public offering, our common stock was listed on the Nasdaq Capital Market.

In November 2021, concurrently with the consummation of the public offering, we issued an aggregate of 313,789 shares of our common stock, 1,543,158 shares of our Series A preferred stock and warrants for the purchase of an aggregate of 1,856,938 shares of our common stock in exchange for convertible promissory notes in the aggregate principal amount of \$10,046,897, together with accrued interest thereon, and warrants for the purchase of an aggregate of 3,677,997 shares of our common stock. Such indebtedness and warrants were exchanged at a price of \$10.00 per unit of securities, consistent with the public offering price of our units of common stock and warrants. The newly issued warrants are exercisable for a period of five years at an exercise price of \$10.00 per share.

The net proceeds received from our November 2021 public offering are sufficient for us to complete our Phase 2 clinical trial with regard to *BRTX-100*; however, we anticipate that we will require approximately \$35,000,000 in additional funding to complete our contemplated Phase 3 *BRTX-100* clinical trial (assuming the receipt of no revenues). We will also require a substantial amount of additional funding to implement our other programs as discussed in this Annual Report under the caption Item 1 (“Business”), including our metabolic *ThermoStem Program*, and fund general operations. No assurance can be given that the anticipated amount of required funding is 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.

Consolidated Results of Operations

Year Ended December 31, 2021 Compared with Year Ended December 31, 2020

The following table presents selected items in our consolidated statements of operations for the years ended December 31, 2021 and 2020, respectively:

	For The Years Ended December 31,	
	2021	2020
Revenues	\$ 46,000	\$ 77,000
Operating Expenses:		
Marketing and promotion	12,290	28,281
Consulting	74,992	137,250
Research and development	729,058	876,829
General and administrative	25,537,533	1,786,716
Total Operating Expenses	26,353,873	2,829,076
Loss From Operations	(26,307,873)	(2,752,076)
Other (Expense) Income:		
Interest expense	(1,815,366)	(1,640,145)
Loss on extinguishment of notes payable, net	(16,180,056)	(658,152)
Change in fair value of derivative liabilities	-	(2,141,069)
Reorganization items, net	-	(4,081,245)
Total Other Expense	(17,995,422)	(8,520,611)
Net Loss	\$ (44,303,295)	\$ (11,272,687)

Revenues

For the years ended December 31, 2021 and 2020, we generated \$46,000 and \$77,000, 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, 2021, marketing and promotion expenses decreased by \$15,991, or 57%, from \$28,281 to \$12,290 as compared to the year ended December 31, 2020. The decrease is due to our reduced marketing plan during the first half of 2021 due to our emergence from our 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, 2021, consulting expenses decreased by \$62,258, or 45%, from \$137,250 to \$74,992, as compared to the year ended December 31, 2020, due to our reduced usage of consultants during the first half of 2021 due to our emergence from our 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, 2021, research and development expenses decreased by \$147,771, or 17%, from \$876,829 to \$729,058, as compared to the year ended December 31, 2020. The decrease was primarily due to a decrease in stock compensation allocated to our research and development activities of \$95,765.

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, 2021, general and administrative expenses increased by \$23,750,817, or 1,329%, from \$1,786,716 to \$25,537,533, as compared to the year ended December 31, 2020. The increase is primarily due to an increase of approximately \$22,417,254 in stock-based compensation resulting from the issuance of 838,550 stock options and 293,479 RSUs.

We expect that our general and administrative expenses related to operations will continue to 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, 2021, interest expense increased \$175,221, or 11%, as compared to the year ended December 31, 2020. The increase was due to the increase in both interest expense, due to the issuance of an additional \$715,303 in convertible debt, and amortization of debt discount on outstanding notes payable.

Loss on extinguishment of notes payable, net

For the year ended December 31, 2021, we recorded a loss on extinguishment of notes payable, net of \$16,180,056 as compared to a loss on extinguishment of notes payable, net of \$658,152 for the year ended December 31, 2020. The increase is associated with the conversion of \$10,046,897 in outstanding convertible debt principal pursuant to exchange agreements with noteholders in connection with our public offering.

Change in fair value of derivative liabilities

For the year ended December 31, 2021, we did not record a gain (loss) related to the change in fair value of derivative liabilities, as compared to a loss related to the change in fair value of derivative liabilities of \$2,141,069 for the year ended December 31, 2020.

Reorganization items, net

Reorganization items, net consists primarily of costs associated the post-petition Chapter 11 bankruptcy. For the year ended December 31, 2021, we did not record reorganization items, net, as compared to reorganization items, net of \$4,081,245 for the year ended December 31, 2020.

Liquidity and Capital Resources

Liquidity

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

	December 31,	
	2021	2020
Cash	\$ 21,026,727	\$ 3,064,610
Working Capital	\$ 21,104,086	\$ 2,142,229
Notes Payable (Gross)	\$ 250,000	\$ 9,637,102

Availability of Additional Funds

Based upon our accumulated deficit of \$134,146,129 as of December 31, 2021, 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.

On November 9, 2021, we completed a public offering of units, each consisting of one share of common stock and a warrant for the purchase of one share of common stock. Pursuant to the public offering, we issued and sold 2,300,000 units at a public offering price of \$10.00 per unit (resulting in gross proceeds of \$23,000,000) and, pursuant to the exercise of an option granted to the underwriters, warrants for the purchase of 345,000 shares of common stock at a public offering price of \$0.01 per warrant, less underwriting discounts and commissions. The net proceeds of the public offering are sufficient for us to complete our Phase 2 clinical trial investigating the use of *BRTX-100*. Management believes that we have sufficient cash to fund operations for the twelve months from the issuance of the financial statements included in this Annual Report.

Our operating needs include the planned costs to operate our business, including amounts required to fund our clinical trials, 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. 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.

During the years ended December 31, 2021 and 2020, 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, 2021 and 2020 in the amounts of \$3,329,908 and \$1,964,265, respectively. The net cash used in operating activities for the year ended December 31, 2021 was primarily due to cash used to fund a net loss of \$44,303,296, adjusted for non-cash expenses in the aggregate amount of \$40,648,702 and partially offset by \$67,921 of cash generated by changes in the levels of operating assets and liabilities, primarily as a result of decreases in accounts payable and accrued expenses. 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.

Net Cash Used in Investing Activities

Net cash used in investing activities during the year ended December 31, 2021 was \$30,658, due to the purchase of manufacturing equipment. There were no investing activities during the year ended December 31, 2020.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the years ended December 31, 2021 and 2020 was \$21,322,683 and \$5,027,211, respectively. During the year ended December 31, 2021, \$21,072,683 of net proceeds were from equity financings. During the year ended December 31, 2020, \$5,517,211 of net proceeds were from debt financings.

Critical Accounting Policies and Estimates

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. We have not identified any impairment losses.

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. Awards granted to directors are treated on the same basis as awards granted to employees.

Recently Issued Accounting Pronouncements

See Note 3 to our consolidated financial statements for the years ended December 31, 2021 and 2020 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.

We have a limited operating history. Since our inception, we have incurred net losses. As of December 31, 2021, our accumulated deficit was \$134,146,129.

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

Since our inception, we have not generated 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 this Annual Report under Item 1 (“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 and otherwise fund our operations. We anticipate that we will require approximately \$35,000,000 in 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 this Annual Report under Item 1 (“Business”), including our metabolic *ThermoStem Program*, and fund general operations. No assurance can be given that the anticipated amount of required funding is 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.

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 and a master services agreement with PRC Clinical with regard to CRO services discussed in this Annual Report under Item 1 (“Business”), we do not have any material agreements or understandings in place with respect to the implementation of our business strategy. No assurances can be given that we will be able to enter into any necessary agreements with respect to the development of our business. Our inability to enter into any such agreements would have a material adverse effect on our results of operations and financial condition.

We depend on our executive officers and on our ability to attract and retain additional qualified personnel.

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 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. 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 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 our CRO and prospective clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors or approved products post-market for related technology that 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 CRO, other third parties, or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's current Good Clinical Practices, or 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, or CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- delays in our clinical trials caused by the COVID-19 pandemic;
- 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, and potential subjects' concern over the COVID-19 pandemic. 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 we lack 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, concerns over COVID-19, 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 some of our product candidates are subject to regulation as biological drug products, we will need to demonstrate that those products 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, or 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 do not have exclusive license rights with regard to the disc/spine technology. The lack of such exclusive rights could have a material adverse effect upon us.

Pursuant to our license agreement with Regenerative Sciences, LLC, we were required to complete our Phase 2 clinical trial by a certain date in order to maintain our exclusive rights with regard to the disc/spine technology. Such time has passed and accordingly our license rights are currently non-exclusive. We are in negotiations with the licensor with regard to a possible reinstatement of the exclusive nature of our rights. No assurances can be given in this regard. The lack of such exclusive rights will not affect our ability to conduct our Phase 2 clinical trial with regard to *BRTX-100* but could have a material adverse effect upon our business, results of operations and financial condition. See “Item 1 (“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, or 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, or BLA. The FDA has developed considerable experience with the biosimilar and interchangeable biosimilar processes since the enactment of the BPCIA in 2009. Should any of our product candidates be approved via the BLA pathway, we expect that biosimilar applicants will seek approval of biosimilar, and/or interchangeable, versions of our product that could result in lower prices for our 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.

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, or 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, or 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, 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, or 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, or 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, or FTO, search years ago on the licensed technology associated with our *Disc/Spine Program*, modifications made, and/or further developments that may be made, to that technology may not be covered by the initial FTO. No FTO has been undertaken with respect to our *ThermoStem* brown fat initiative.

Litigation, which would result in substantial costs to us and the diversion of effort on our part, may be necessary to enforce or confirm the ownership of any patents issued or licensed to us, or to determine the scope and validity of third-party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, or the Patent Office, or a foreign patent office to determine priority of invention, which could result in substantial costs and diversion of effort, even if the eventual outcome is favorable to us. Any such litigation or interference proceeding, regardless of outcome, could be expensive and time-consuming.

Successful challenges to our patents through oppositions, re-examination proceedings or interference proceedings could result in a loss of patent rights in the relevant jurisdiction. If we are unsuccessful in actions we bring against the patents of other parties, and it is determined that we infringe upon the patents of third parties, we may be subject to litigation, or otherwise prevented from commercializing potential products and/or services in the relevant jurisdiction, or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations or from commercializing certain products and/or services, which could adversely affect our business and results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

In addition, the Supreme Court has recently taken more limiting positions as to what constitutes patentable subject matter. As a result, many patents covering what were previously patentable inventions are now determined to cover inventions which are deemed non-statutory subject matter and are now invalid. As a result of this and subsequent opinions by the Court of Appeals for the Federal Circuit, the Patent Office is now applying more stringent limitations to claims in patent applications and is refusing to grant patents in areas of technology where patents were previously deemed available. Therefore there is a risk that we will be unable to acquire patents to cover our products and if such patents are granted they may subsequently be found to be invalid.

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

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

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, or 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, or 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, or CMS, other divisions the Department of Health and Human Services, or 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, or AKS, the federal civil and criminal False Claims Act, or 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, or 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, or 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. The 2% reduction was paused pursuant to The Coronavirus Aid, Relief, and Economic Security (CARES) Act and subsequent legislation, but will resume on a graduated basis beginning in April 2022. 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. Congress has since 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, regulations, and interpretive determinations 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. In recent years, Congress passed certain legislation to alter aspects of the PPACA. In addition, Congress and select states have continued to propose 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 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. We intend to retain earnings, if any, to finance the development and expansion of our business. Our future dividend policy will be subject to the discretion of our Board of Directors and will be contingent upon future earnings, if any, our financial condition, capital requirements, general business conditions, and other factors. Therefore, we can give no assurance that any dividends of any kind will ever be paid to holders of our common stock.

There is no assurance that an active trading market for our common stock will be sustained.

Our common stock is listed on Nasdaq. However, no assurance can be given that an active market for our common stock 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 development and maintenance of a public trading market depends upon the existence of willing buyers and sellers, the presence of which is not within our control or that of any market maker. Market makers are not required to maintain a continuous two-sided market, are required to honor firm quotations for only a limited number of 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 of an active and liquid market for our securities developing in the foreseeable future. Even if there is a market for our securities, we cannot assure that securityholders 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, or 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 (the “Sarbanes-Oxley Act”), 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.

Material weaknesses in our internal control over financial reporting may cause us to fail to timely and accurately report our financial results or result in a material misstatement of our consolidated financial statements.

We identified control deficiencies in the design and operation of our internal control over financial reporting that constituted a material weakness, as further described in Item 9A of this Annual Report (“Controls and Procedures”). A material weakness 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 consolidated financial statements will not be prevented or detected on a timely basis. Our material weakness related to the following control deficiencies:

- Lack of adherence to formal policies and procedures post-bankruptcy;
- Lack of risk assessment procedures on internal controls to detect financial reporting risks on a timely manner; and
- Lack of sufficient formal procedures and controls to achieve complete and accurate financial reporting and disclosures, including controls over the preparation and review of journal entries and account reconciliations. Additionally, we did not design and maintain controls to ensure appropriate segregation of duties.

The deficiencies described above, if not remedied, could result in a misstatement of one or more account balances or disclosures in our annual or interim consolidated financial statements that would not be prevented or detected, and, accordingly, we determined that these control deficiencies constitute a material weakness.

To address our material weakness, we have added accounting and finance personnel and implemented new financial accounting processes. We intend to continue to take steps to remediate the material weakness described above through implementing enhancements and controls within our accounting systems, hiring additional qualified accounting and finance resources and further evolving our accounting and quarterly and annual close processes. We will not be able to remediate these control deficiencies until these steps have been completed and have been operating effectively for a sufficient period of time. The redesign and implementation of improvements to our accounting and proprietary systems and controls may be costly and time consuming and the cost to remediate may impair our results of operations in the future.

If we fail to remediate our material weakness, identify future material weaknesses in our internal control over financial reporting or fail to meet the demands that have been placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weakness, our reputation, results of operations and financial condition could suffer.

Our stock price may fluctuate significantly and be highly volatile and this may make it difficult for a securityholder to resell our securities at the volume, prices and times the securityholder 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 securityholder to resell our securities at the volume, prices and times the securityholder 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,” “Risks Related to Our Common Stock” and “Risks Associated with Our Nasdaq Listing.”

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 currently have authorization to issue up to 75,000,000 shares of common stock of which, as of March 28, 2022, 3,626,603 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. In addition, there are 1,543,158 shares of Series A preferred stock issued and outstanding. Such shares are convertible under certain circumstances into an equal number of shares of common stock.

Pursuant to our Chapter 11 Plan of Reorganization, an aggregate of 262,432 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.

Pursuant to our November 2021 public offering of securities, we issued warrants for the purchase of an aggregate of 2,645,000 shares of common stock as well as underwriter warrants for the purchase of 235,970 shares of common stock. We have an effective registration statement on Form S-1 under the Securities Act registering the issuance of such shares. The shares issuable pursuant to the registration statement on Form S-1 will be freely tradable in the public market, except for shares held by affiliates. In addition, in connection with the public offering and pursuant to exchange agreements entered into with holders of convertible notes and warrants, we issued an aggregate of 313,789 shares of common stock and warrants for the purchase of an aggregate of 1,856,938 shares of common stock. The shares of common stock issued to such holders are eligible for resale in the open market (subject to Rule 144 volume limitations applicable to affiliates), potentially causing sales in the market to increase and our stock price to decline. We have agreed to register the resale of the shares of common stock issuable upon exercise of such warrants. The issuance of shares of common stock upon exercise of the above warrants would dilute the ownership of our stockholders.

We also have an effective registration statement on Form S-8 under the Securities Act registering 1,175,000 shares of our common stock issuable under our 2021 Stock Incentive Plan, or the 2021 Plan. As of March 28, 2022, options to purchase 838,550 shares of our common stock were outstanding under the 2021 Plan. In addition, as of such date, 220,528 RSUs were outstanding under the 2021 Plan. The shares issuable pursuant to the registration statement 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 (and other affiliates) upon their exercise of options held by them 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 18,456,842 shares of preferred stock without further stockholder approval, containing such rights and preferences as our Board of Directors shall determine. We may also 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 currently 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. Of such 20,000,000 authorized shares, 1,543,158 shares of Series A preferred stock are issued and outstanding. 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 Securities and Exchange Commission, or 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. The market price for shares of our common stock is currently below \$5.00 and we do not satisfy any of the exceptions to the SEC’s definition of penny stock. Accordingly, our common stock is currently 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.

Risks Associated with Our Nasdaq Listing

We cannot assure you that we will be able to continue to comply with the minimum bid price requirement of Nasdaq.

Although the market price of our common stock satisfied the initial listing minimum bid price requirement for Nasdaq, there can be no assurance that the market price of our common stock will remain at the \$1.00 per share level required for continuing compliance with that requirement. There are many factors, such as negative financial or operational results, that could adversely affect the market price of our common stock and jeopardize our ability to maintain Nasdaq's minimum bid price requirement.

The market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.

Although we believe that our Nasdaq listing may help generate greater or broader investor interest, including institutional investors, there can be no assurances in that regard. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

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, or 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 and 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, 2021.

Management has completed such evaluation and 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 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, 2021 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, 2021 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, 2021 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:

- Lack of 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.
- Lack of sufficient formal procedures and controls to achieve complete and accurate financial reporting and disclosures, including controls over the preparation and review of journal entries and account reconciliations.

Management's Plan to Remediate the Material Weaknesses

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 Chief Financial Officer, who is overseeing the financial reporting process and implementation of enhanced controls and governance;
- Engagement of external financial consulting firm to continue to enhance financial reporting, financial operations and internal controls; and
- Documentation of key procedures and controls using a risk-based approach.

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 2021 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Remediation of Material Weakness in Internal Control over Financial Reporting

We had previously reported that, as of December 31, 2020, we had identified the following material weakness in our internal control over financial reporting:

- Inadequate segregation of duties due to limited personnel consistent with control objectives;

During the year ended December 31, 2021, we took corrective action and/or placed in operation controls to address the material weaknesses described above by engaging an outsourced financial consulting firm and hiring a CFO to ensure that segregation of duties is maintained.

Based on the corrective actions described above, it is management's conclusion that the material weakness noted above that existed as of December 31, 2020 has been remediated.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

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.

<u>Name</u>	<u>Age</u>	<u>Positions Held</u>
Lance Alstodt	51	Chief Executive Officer, President and Chairman of the Board
Francisco Silva	47	Vice President of Research and Development, Secretary and Director
Robert E. Kristal	55	Chief Financial Officer
Robert Paccasassi	53	Vice President of Quality Assurance/Regulatory Compliance
Nickolay Kukekov, Ph.D.	48	Director, Compensation Committee Chair
Patrick F. Williams	49	Director, Audit Committee Chair
David Rosa	58	Director, Nominating Committee Chair

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.

Robert E. Kristal

Robert E. Kristal has served as our Chief Financial Officer since November 2021. Mr. Kristal is an experienced Wall Street and Bay Street professional who has served in various management roles within multiple business lines of investment banks. From 2016 to 2020, he was Head of Equity Research at H.C. Wainwright. Mr. Kristal provided investment banking and merchant banking services from 2013 to 2016 at H.C. Wainwright and T.R. Winston. He is a Chartered Financial Analyst. Mr. Kristal received a Bachelor of Arts degree in Economics from Wilfrid Laurier University and a Bachelor of Commerce (Honors) degree in Finance from the University of Windsor.

Robert Paccasassi

Robert Paccasassi has served as our Vice President of Quality Assurance/Regulatory Compliance since December 2021, having previously served in such position from August 2016 to September 2020, and having previously served as our Director of Quality and Compliance from September 2015 to August 2016. Mr. Paccasassi has over 20 years of experience in highly regulated product operations, with specific expertise in GMP (large and small molecule) clinical and commercial quality assurance and regulatory compliance leadership roles. He was the Director of Quality Systems (GMP) at Merck KGaA (Darmstadt, Germany) from 2011 to 2014. In this role, Mr. Paccasassi was responsible for leading the ongoing development and implementation of the Corporate Quality Unit's global GMP policies, processes and directives. He held key quality and compliance management roles at EMD Serono, Biogen Idec, Millennium Pharmaceuticals and Regeneron Pharmaceuticals. Mr. Paccasassi was a Chief Technologist/Site Head overseeing all day to day technical and quality operations of two cGMP biologic production laboratories for Curative Health Services. He was also a Medical Technologist working in the field of immunohematology at Brigham & Women's Hospital, Boston, Massachusetts. Mr. Paccasassi received a Masters in Business Administration (MBA) degree from Johnson & Wales University and a Bachelor of Science degree in Medical Technology/Biology from the University of Rhode Island.

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.

Patrick F. Williams

Patrick F. Williams has served as one of our directors since November 2021. Mr. Williams has more than 20 years of experience across medical device, consumer product goods and technology sectors. Appointed as Chief Financial Officer of STAAR Surgical Company, or STAAR, in July 2020, Mr. Williams is responsible for optimizing the financial performance of STAAR and ensuring the scalability of various functions to support high growth expansion. From 2016 to 2019, he served as the Chief Financial Officer of Sientra, Inc. before transitioning to General Manager for its miraDry® business unit. From 2012 to 2016, Mr. Williams served as Chief Financial Officer of ZELTIQ Aesthetics, Inc., a publicly-traded medical device company that was acquired by Allergan. Previously, he served as Vice President in finance, strategy and investor relations roles from 2007 to 2012 at NuVasive, Inc., a San-Diego based medical device company servicing the spine sector. He has also held finance roles with Callaway Golf and Kyocera Wireless. Mr. Williams received an MBA in Finance and Management from San Diego State University and a Bachelor of Arts in Economics from the University of California, San Diego. We believe that Mr. Williams' executive-level management experience with healthcare-related businesses, including his financial management expertise, give him the qualifications to serve as one of our directors.

David Rosa

David Rosa has served as one of our directors since November 2021. Mr. Rosa has served as the Chief Executive Officer, President and a director of NeuroOne Medical Technologies Corporation, or NeuroOne (Nasdaq: NMTC), since July 2017 and served as Chief Executive Officer and a director of NeuroOne, Inc., formerly its wholly-owned subsidiary, from October 2016 until December 2019, when NeuroOne, Inc. merged with and into NeuroOne. NeuroOne is committed to providing minimally invasive and hi-definition solutions for EEG recording, brain stimulation and ablation solutions for patients suffering from epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders that may improve patient outcomes and reduce procedural costs. From November 2009 to November 2015, Mr. Rosa served as the Chief Executive Officer and President of Sunshine Heart, Inc., n/k/a CHF Solutions, Inc. (Nasdaq: CHFS), a publicly-held early-stage medical device company. From 2008 to November 2009, he served as Chief Executive Officer of Milksmart, Inc., a company that specializes in medical devices for animals. From 2004 to 2008, Mr. Rosa served as the Vice President of Global Marketing for Cardiac Surgery and Cardiology at St. Jude Medical, Inc. He serves as a director on the board of directors of Biotricity Inc (OTCMKTS: BTCY). We believe that Mr. Rosa's senior leadership experience in the medical device industry and his strong technical, strategic, and operational expertise give him the qualifications to serve as one of our directors.

Scientific Advisory Board

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

Name	Principal Positions
Wayne Marasco, M.D., Ph.D. Chairman	Professor, Department of Cancer Immunology & AIDS, Dana-Farber Cancer Institute; Professor of Medicine, Harvard Medical School; Principal Faculty Member, Harvard Stem Cell Institute
Wayne J. Olan, M.D.	Director, Interventional and Endovascular Neurosurgery; Associate Professor, Neurosurgery and Radiology, George Washington University Medical Center; Consulting Physician, Department of Radiology, National Institutes of Health
Joy Cavagnaro, Ph.D., DABT, RAC	President and Founder, Access BIO, L.C.; Fellow, Academy of Toxicological Sciences and the Regulatory Professional Society; Formerly Senior Pharmacologist and Director of Quality Assurance, Food and Drug Administration's Center for Biologics Evaluation and Research
Jason Lipetz, M.D. Chairman, Disc Advisory Committee	Founder, Long Island Spine Rehabilitation Medicine; Chief of Spine Medicine, Northwell Health Spine Center; Clinical Assistant Professor, Department of Physical Medicine and Rehabilitation, Zucker School of Medicine at Hofstra/Northwell
Harvinder Sandhu, M.D.	Orthopedic Spine Surgeon, Hospital for Special Surgery; 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; Formerly Director of The Penn Spine and Rehabilitation Center; 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; Chair, American Academy of Physical Medicine and Rehabilitation Task Force on Regenerative Medicine; Past President, Interventional Orthopedic Foundation

Family Relationships

There are no family relationships among any of our executive officers, directors and Scientific Advisory Board members.

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	2024
Patrick F. Williams	III	2023
David Rosa	II	2022

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 or her earlier resignation or removal.

Audit Committee

The Audit Committee of the Board of Directors is responsible for overseeing our accounting and financial reporting processes and the audits of our financial statements. The members of the Audit Committee are Mr. Williams (Chair), Dr. Kukekov and Mr. Rosa.

Audit Committee Financial Expert

Our Board has determined that Mr. Williams qualifies as an “audit committee financial expert,” as that term is defined in Item 407(d)(5) of Regulation S-K.

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, 2021. 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, 2021, our officers, directors and 10% stockholders complied with all Section 16(a) filing requirements applicable to them, except that Mr. Kristal filed his Form 3 and one Form 4 (reporting one transaction) late.

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, 2021 and 2020 by (i) our principal executive officer, and (ii) our most highly compensated executive officer, other than our principal executive officer, who was serving as an executive officer as of December 31, 2021 and whose total compensation for the 2021 fiscal year, as determined by Regulation S-K, Item 402, exceeded \$100,000 (the individuals falling within categories (i) and (ii) are collectively referred to as the Named Executive Officers):

Name and Principal Position	Year	Salary	Bonus	Stock Awards⁽¹⁾	Option Awards⁽¹⁾	All Other Compensation	Total
Lance Alstodt	2021	\$ 275,000	\$ -	\$ 6,984,812	\$ 14,081,677	\$ -	\$ 21,341,489
Chief Executive Officer ⁽²⁾	2020	\$ 64,317	\$ -	\$ -	\$ -	\$ -	\$ 64,317
Francisco Silva	2021	\$ 259,375	\$ -	\$ 6,984,812	\$ 14,081,677	\$ -	\$ 21,325,864
VP, Research and Development	2020	\$ 207,553	\$ -	\$ -	\$ -	\$ -	\$ 207,553

(1) Amounts reflect the aggregate grant date fair value of grants made in the fiscal year computed in accordance with stock-based accounting rules (FASB ASC Topic 718-Stock Compensation). Assumptions used in the calculations of these amounts are included in Note 8 to our consolidated financial statements included in this Annual Report.

(2) 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.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information on outstanding equity awards as of December 31, 2021 to the Named Executive Officers:

Name	Option Awards					Stock Awards			Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested
	Number of securities underlying unexercised options 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	
Lance Alstodt	201,767	91,712(1)	-	\$ 13.50	3/18/2031	-	\$ -	-	\$ -
Lance Alstodt	21,030	21,029(2)	-	\$ 13.50	11/4/2031	-	\$ -	-	\$ -
Lance Alstodt	-	-	-	\$ -	-	146,740(3)	\$ 636,852	-	\$ -
Francisco Silva	201,767	91,712(1)	-	\$ 13.50	3/18/2031	-	\$ -	-	\$ -
Francisco Silva	21,030	21,029(2)	-	\$ 13.50	11/4/2031	-	\$ -	-	\$ -
Francisco Silva	-	-	-	\$ -	-	146,740(3)	\$ 636,852	-	\$ -
Francisco Silva	1	-	-	\$ 18,800	2/10/2022	-	\$ -	-	\$ -
Francisco Silva	1	1(4)	-	\$ 18,800	5/2/2022	-	\$ -	-	\$ -
Francisco Silva	1	-	-	\$ 18,800	12/7/2022	-	\$ -	-	\$ -
Francisco Silva	1	-	-	\$ 18,800	10/4/2023	-	\$ -	-	\$ -
Francisco Silva	3	-	-	\$ 18,800	2/18/2024	-	\$ -	-	\$ -
Francisco Silva	1	-	-	\$ 18,800	3/12/2024	-	\$ -	-	\$ -
Francisco Silva	9	-	-	\$ 18,800	10/23/2024	-	\$ -	-	\$ -
Francisco Silva	6	-	-	\$ 18,800	9/4/2025	-	\$ -	-	\$ -
Francisco Silva	15	-	-	\$ 14,920	6/10/2026	-	\$ -	-	\$ -
Francisco Silva	20	-	-	\$ 11,200	7/12/2027	-	\$ -	-	\$ -
Francisco Silva	25	-	-	\$ 4,920	10/29/2028	-	\$ -	-	\$ -

(1) Option becomes exercisable in five nearly equal quarterly installments beginning on March 18, 2022.

(2) Option becomes exercisable in eight nearly equal quarterly installments beginning on November 4, 2022.

(3) Restricted stock vests in three nearly equal annual installments beginning on March 18, 2022.

(4) 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.

Employment Agreements

Lance Alstodt

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 currently is entitled to receive an annual salary of \$400,000 (giving effect to a \$150,000 performance salary increase received in November 2021). 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 293,479 shares of our common stock at an exercise price of \$47.60 per share (which exercise price was subsequently reduced to \$13.50 per share and further reduced, subject to stockholder approval, to \$5.08 per share) and (ii) 146,740 restricted stock units, or RSUs. The option vests to the extent of 50% thereof on the date of grant, 12.5% on November 4, 2021 and the balance in six equal quarterly installments commencing on December 18, 2021. 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 time 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 RSUs 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. In March 2022, we and Mr. Alstodt agreed that, in lieu of a \$50,000 increase in his annual salary (as provided for in his employment agreement), we issued to Mr. Alstodt 12,438 RSUs (having a value of \$50,000), which RSUs will vest in twelve equal monthly installments. Such grant was in consideration of Mr. Alstodt deferring his right to receive the \$50,000 increase in his salary for one year. Effective in March 2023, pursuant to his employment agreement, Mr. Alstodt will be entitled to his annual increase of \$50,000 in his salary (plus, in March 2023, the \$50,000 salary increase deferral discussed above).

Francisco Silva

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 currently entitled to receive an annual salary of \$375,000 (giving effect to a \$150,000 performance salary increase received in November 2021). 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 293,479 shares of our common stock at an exercise price of \$47.60 per share (which exercise price was subsequently reduced to \$13.50 per share and further reduced, subject to stockholder approval, to \$5.08 per share) and (ii) 146,740 RSUs. The option vests to the extent of 50% thereof on the date of grant, 12.5% on November 4, 2021 and the balance in six equal quarterly installments commencing on December 18, 2021. 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 time 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. In March 2022, we and Mr. Silva agreed that, in lieu of a \$50,000 increase in his annual salary (as provided for in his employment agreement), we issued to Mr. Silva 12,438 RSUs (having a value of \$50,000), which RSUs will vest in twelve equal monthly installments. Such grant was in consideration of Mr. Silva deferring his right to receive the \$50,000 increase in his salary for one year. Effective in March 2023, pursuant to his employment agreement, Mr. Silva will be entitled to his annual increase of \$50,000 in his salary (plus, in March 2023, the \$50,000 salary increase deferral discussed above).

Director Compensation

The following table sets forth certain information concerning the compensation of our non-employee directors for the fiscal year ended December 31, 2021:

<u>Name</u>	<u>Fees Earned or Paid in Cash</u>	<u>Stock Awards</u>	<u>Option Awards⁽¹⁾</u>	<u>Non-Equity Incentive Plan Compensation</u>	<u>Nonqualified Deferred Compensation Earnings</u>	<u>All Other Compensation</u>	<u>Total</u>
Nickolay Kukekov	\$ -	\$ -	\$ 128,194 ⁽²⁾	\$ -	\$ -	\$ -	\$ 128,194
Patrick F. Williams	\$ -	\$ -	\$ 53,287 ⁽³⁾	\$ -	\$ -	\$ -	\$ 53,287
David Rosa	\$ -	\$ -	\$ 53,287 ⁽⁴⁾	\$ -	\$ -	\$ -	\$ 53,287

(1) Amounts reflect the aggregate grant date fair value of grants made in the fiscal year computed in accordance with stock-based accounting rules (FASB ASC Topic 718-Stock Compensation). Assumptions used in the calculations of these amounts are included in Note 8 to our consolidated financial statements included in this Annual Report.

(2) As of December 31, 2021. Dr. Kukekov held options for the purchase of 25,236 shares of common stock.

(3) As of December 31, 2021, Mr. Williams held options for the purchase of 10,490 shares of common stock.

(4) As of December 31, 2021, Mr. Rosa held options for the purchase of 10,490 shares of common stock.

Dr. Kukekov and Messrs. Williams and Rosa, our non-employee directors, as compensation for their services as a director, are granted stock options by us from time to time.

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

Principal Stockholders

The following table sets forth certain information regarding the beneficial ownership of our common stock, as of March 28, 2022, 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 following table also sets forth certain information regarding the beneficial ownership of our Series A preferred stock as of March 28, 2022.

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 3,626,603 shares of common stock and 1,543,158 shares of Series A preferred stock outstanding as of March 28, 2022.

<u>Name and Address of Beneficial Owner</u>	<u>Number of Shares of Common Stock Beneficially Owned</u>	<u>Approximate Percent of Class</u>	<u>Number of Shares of Series A Preferred Stock Beneficially Owned</u>	<u>Approximate Percent of Class</u>
Directors and Executive Officers				
Lance Alstodt ⁽¹⁾	306,396(2)	7.9%	-	-
Francisco Silva ⁽¹⁾	304,074(3)	7.9%	-	-
Nickolay Kukekov	12,618(4)	*	-	-
Patrick F. Williams	2,623(4)	*	-	-
David Rosa	2,623(4)	*	-	-
All directors and executive officers as a group (7 persons)	632,337(5)	15.3%	-	-
Certain Beneficial Owners				
Dale Broadrick ⁽⁶⁾	508,484(7)	14.0%	-	-
Auctus Fund, LLC ⁽⁸⁾	180,967(9)	4.99%	1,543,158(10)	100%

* Less than 1%

(1) Address is 40 Marcus Drive, Suite One, Melville, New York 11747.

(2) Includes 241,139 shares of common stock issuable upon the exercise of currently exercisable options.

(3) Includes 241,223 shares of common stock issuable upon the exercise of currently exercisable options and 11,829 shares of common stock held by Mr. Silva in a retirement account.

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

(5) Includes 504,229 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

(6) Address is 3003 Brick Church Pike, Nashville, Tennessee

(7) Based upon Amendment No. 6 to Schedule 13D filed with the Securities and Exchange Commission. Includes 1,359 shares common stock issuable upon the exercise of currently exercisable warrants.

(8) Address is 545 Boylston Street, 2nd Floor, Boston, Massachusetts 02116.

(9) Auctus Fund, LLC, or Auctus, holds a warrant for the purchase of up to 1,676,580 shares of our common stock. In addition, Auctus’ shares of Series A preferred stock are convertible into an aggregate of 1,543,158 shares of our common stock. However, such warrant is not exercisable, and such Series A preferred stock is not convertible into shares of our common stock, to the extent Auctus would beneficially own, after such exercise and/or conversion, more than 4.99% of our outstanding shares of common stock. The number of shares of common stock reflected in the table above as being beneficially owned by Auctus equals 4.99% of our outstanding common stock as of March 28, 2022 as we are aware of the number of shares of common stock actually owned by Auctus as of such date.

(10) Pursuant to the Certificate of Designations of Preferred Stock with regard to the Series A preferred stock, Auctus, as the sole holder of the 1,543,158 outstanding shares of Series A preferred stock, is entitled to vote such shares based on the number of shares of common stock into which such shares are convertible (currently 1,543,158); however, pursuant to such Certificate of Designations of Preferred Stock, the voting rights of the holder of the shares of Series A preferred stock is limited to 4.99% of our then outstanding shares of common stock. Accordingly, as of March 28, 2022, based upon there being 3,626,603 shares of common stock outstanding, the holder of the Series A preferred stock was entitled to 180,967 votes.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information as of December 31, 2021 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	839,639 ⁽¹⁾	\$ 13.50	336,450 ⁽²⁾
Total	<u>839,639</u>	<u>\$ 13.50</u>	<u>336,450</u>

(1) Includes options to purchase up to 1,089 shares of common stock under the Company's 2010 Plan.

(2) Includes 293,480 unvested Restricted Stock Units outstanding at December 31, 2021.

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

Director Independence

Board of Directors

Our Board of Directors is comprised of Lance Alstodt (Chair), Francisco Silva, Nickolay Kukekov, Patrick F. Williams and David Rosa. Each of Dr. Kukekov, Mr. Williams and Mr. Rosa is an “independent director” based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

Audit Committee

Mr. Williams (Chair), Dr. Kukekov and Mr. Rosa are the members of our Board’s Audit Committee. Each of Mr. Williams, Dr. Kukekov and Mr. Rosa 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. Our Board of Directors has determined that Mr. Williams qualifies as an “audit committee financial expert,” as that term is defined in Item 407(d)(5) of Regulation S-K.

Nominating Committee

Mr. Rosa (Chair), Dr. Kukekov and Mr. Williams are the members of our Board’s Nominating Committee. Each of Mr. Rosa, Dr. Kukekov and Mr. Williams 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 (Chair), Mr. Williams and Mr. Rosa are the members of our Board’s Compensation Committee. Each of Dr. Kukekov, Mr. Williams and Mr. Rosa 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 served as our independent registered public accountants for the years ended December 31, 2021 and 2020.

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, 2021 and 2020:

	Friedman LLP	
	2021	2020
Audit fees (1)	\$ 95,000	\$ 80,000
Audit-related fees (2)	40,500	-
Tax fees (3)	-	-
All other fees (4)	-	-
	<u>\$ 135,500</u>	<u>\$ 80,000</u>

- (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, 2021 and 2020, and the review of our condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q.
- (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 in connection with the filing of Forms S-1 and S-8 registration 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*](#)
- 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 [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](#)
- 10.2 [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](#)
- 10.3 [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](#)
- 10.4 [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](#)
- 10.5 [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](#)
- 10.6 [BioRestorative Therapies, Inc. 2021 Stock Incentive Plan, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated March 18, 2021, wherein such document is identified as Exhibit 99.1](#)
- 10.7 [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 March 18, 2021, wherein such document is identified as Exhibit 99.2](#)
- 10.8 [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 March 18, 2021, wherein such document is identified as Exhibit 99.3](#)

- 10.9 [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 March 18, 2021, wherein such document is identified as Exhibit 99.4](#)
- 10.10 [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 March 18, 2021, wherein such document is identified as Exhibit 99.5](#)
- 10.11 [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 March 18, 2021, wherein such document is identified as Exhibit 99.6](#)
- 10.12 [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 March 18, 2021, wherein such document is identified as Exhibit 99.7](#)
- 10.13 [Non-Qualified Stock Option Award Agreement, dated as of November 4, 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 November 4, 2021, wherein such document is identified as Exhibit 99.2](#)
- 10.14 [Non-Qualified Stock Option Award Agreement, dated as of November 4, 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 November 4, 2021, wherein such document is identified as Exhibit 99.3](#)
- 10.15 [Non-Qualified Stock Option Award Agreement, dated as of November 4, 2021, between BioRestorative Therapies, Inc. and Nickolay Kukekov*](#)
- 10.16 [Non-Qualified Stock Option Award Agreement, dated as of November 4, 2021, between BioRestorative Therapies, Inc. and Patrick F. Williams*](#)
- 10.17 [Non-Qualified Stock Option Award Agreement, dated as of November 4, 2021, between BioRestorative Therapies, Inc. and David Rosa*](#)
- 10.18 [Amendment No. 1 to Non-Qualified Stock Option Award Agreement, dated as of November 4, 2021, between BioRestorative Therapies, Inc. and Lance Alstodt*](#)
- 10.19 [Amendment No. 1 to Non-Qualified Stock Option Award Agreement, dated as of November 4, 2021, between BioRestorative Therapies, Inc. and Francisco Silva*](#)
- 10.20 [Common Stock Purchase Warrant, dated November 9, 2021, issued by BioRestorative Therapies, Inc. pursuant to public offering*](#)
- 10.21 [Common Stock Purchase Warrant, dated November 9, 2021, issued by BioRestorative Therapies, Inc. to Auctus Fund, LLC*](#)
- 10.22 [Amendment No. 2 to Non-Qualified Stock Option Award Agreement, dated as of December 10, 2021, between BioRestorative Therapies, Inc. and Lance Alstodt*](#)
- 10.23 [Amendment No. 2 to Non-Qualified Stock Option Award Agreement, dated as of December 10, 2021, between BioRestorative Therapies, Inc. and Francisco Silva*](#)
- 10.24 [Amendment No. 1 to Non-Qualified Stock Option Award Agreement, dated as of December 10, 2021, between BioRestorative Therapies, Inc. and Nickolay Kukekov*](#)
- 10.25 [Amendment No. 1 to Non-Qualified Stock Option Award Agreement, dated as of December 10, 2021, between BioRestorative Therapies, Inc. and Patrick F. Williams*](#)
- 10.26 [Amendment No. 1 to Non-Qualified Stock Option Award Agreement, dated as of December 10, 2021, between BioRestorative Therapies, Inc. and David Rosa*](#)

- 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 Inline XBRL Instance Document *
- 101.SCH Inline XBRL Schema Document *
- 101.CAL Inline XBRL Calculation Linkbase Document*
- 101.DEF Inline XBRL Definition Linkbase Document*
- 101.LAB Inline XBRL Label Linkbase Document*
- 101.PRE Inline XBRL Presentation Linkbase Document*
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL 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: March 30, 2022

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.

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ Lance Alstodt</u> Lance Alstodt	Chief Executive Officer, President, Chairman of the Board and Director (Principal Executive Officer)	March 30, 2022
<u>/s/ Francisco Silva</u> Francisco Silva	Vice President, Research and Development and Director	March 30, 2022
<u>/s/ Robert E. Kristal</u> Robert E. Kristal	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2022
<u>/s/ Nickolay Kukekov</u> Nickolay Kukekov	Director	March 30, 2022
<u>/s/ Patrick F. Williams</u> Patrick F. Williams	Director	March 30, 2022
<u>/s/ David Rosa</u> David Rosa	Director	March 30, 2022

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONSOLIDATED FINANCIAL STATEMENTS

TABLE OF CONTENTS

	<u>Page</u>
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM (PCAOB FIRM ID: 711)	F-2
CONSOLIDATED FINANCIAL STATEMENTS:	
Consolidated Balance Sheets as of December 31, 2021 and December 31, 2020	F-4
Consolidated Statements of Operations For the Years Ended December 31, 2021 and December 31, 2020	F-5
Consolidated Statements of Stockholders' Equity (Deficit) For the Years Ended December 31, 2021 and December 31, 2020	F-6
Consolidated Statements of Cash Flows For the Years Ended December 31, 2021 and December 31, 2020	F-7
Notes to Consolidated Financial Statements For the Years Ended December 31, 2021 and December 31, 2020	F-8 - F-32

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, 2021 and 2020, and the related consolidated statements of operations, changes in equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, 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.

Accounting for debt conversions and warrant modifications

Description of the Matter

As described in Note 7 of the consolidated financial statements, the Company entered into various settlement agreements with lenders to exchange convertible note payables and outstanding warrants for shares of the Company's common and preferred stock and warrants ("Settlements"). In connection with the settlements, the Company recognized a loss on extinguishment of debt of approximately \$16,000,000. We have identified the assessment of the accounting of the settlements to be a critical audit matter because of the judgements necessary for management to determine if the settlements resulted in debt extinguishment. The interpretation and application of the relevant accounting literature required significant auditor judgment due to the complexity of the agreement and required auditor judgment when performing audit procedures to audit management's assessment of the accounting treatment for the amendment.

How We Addressed the Matter in Our Audit

We obtained an understanding over managements process for assessing the accounting considerations of the settlements, specifically, management's assessment of the accounting treatment of the arrangement supporting the conclusion that the settlements were accounted for as a debt extinguishment. To evaluate management's accounting conclusion, we performed audit procedures that included, among others, assessing the Company's accounting memorandum and other documentation, including the application of the relevant accounting guidance. We read the relevant documents and agreements and compared the terms to the Company's accounting documentation. We also evaluated the presentation of the transactions in the consolidated financial statements and the related footnote disclosure.

Stock Based Compensation – Equity Transactions

Description of the Matter

As described in Note 8 of the consolidated financial statements, the Company entered into equity agreements which include stock based compensation. These agreements include transactions, including the issuance of stock options and restricted stock awards, that are required to be recorded at their estimated fair values. The Company's determination of the estimated fair values involves the identification of related financial instruments and a clear understanding of the terms of the agreements. Auditing management's estimates of fair value requires a high degree of auditor judgment and an increased extent of effort, including the need to carefully examine to understand the true nature of the related agreements.

How We Addressed the Matter in Our Audit

Our audit procedures related to determination of the estimated fair values of these equity transactions included the following, among others;

- We obtained an understanding of management's process and methodology to develop the estimates.
- We examined signed contracts and amendments.
- We evaluated the reasonableness of the inputs and assumptions used by management in developing the estimates.
- We evaluated the adequacy of the disclosures related to these fair value measurements.

/s/ Friedman LLP

We have served as the Company's auditor since 2020.
Marlton, New Jersey
March 30, 2022

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
ASSETS		
Current Assets:		
Cash	\$ 21,026,727	\$ 3,064,610
Accounts receivable	5,000	17,000
Prepaid expenses	436,181	105,407
Total Current Assets	<u>21,467,908</u>	<u>3,187,017</u>
Property and equipment, net	37,993	21,914
Right of use asset	357,805	473,849
Intangible assets, net	589,740	664,268
Total Assets	<u>\$ 22,453,446</u>	<u>\$ 4,347,048</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	\$ 50,827	\$ 118,851
Accrued expenses and other current liabilities	134,970	767,566
Lease liability, current portion	119,055	158,371
PPP loan payable, current portion	58,970	-
Total Current Liabilities	<u>363,822</u>	<u>1,044,788</u>
Lease liability, net of current portion	301,645	363,519
Notes payable, net of debt discount of \$- and \$5,366,869, respectively	-	4,270,233
PPP loan payable, net of current portion	191,030	-
Total Liabilities	<u>856,497</u>	<u>5,678,540</u>
Commitments and Contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, \$0.01 par value; Authorized, 20,000,000 shares;	-	-
Series A Convertible Preferred stock, \$0.01 par value; 1,543,158 Authorized, 1,543,158 and 0 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	15,432	-
Common stock, \$0.0001 par value; Authorized, 75,000,000 shares; 3,520,391 and 715,544 issued and outstanding at December 31, 2021 and December 31, 2020, respectively	353	72
Additional paid in capital	155,727,292	88,511,269
Accumulated deficit	(134,146,128)	(89,842,833)
Total Stockholders' Equity (Deficit)	<u>21,596,949</u>	<u>(1,331,492)</u>
Total Liabilities and Stockholders' Equity (Deficit)	<u>\$ 22,453,446</u>	<u>\$ 4,347,048</u>

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, 2021	December 31, 2020
Revenues	\$ 46,000	\$ 77,000
Operating expenses:		
Marketing and promotion	12,290	28,281
Consulting	74,992	137,250
Research and development	729,058	876,829
General and administrative	25,537,533	1,786,716
Total operating expenses	<u>26,353,873</u>	<u>2,829,076</u>
Loss from operations	<u>(26,307,873)</u>	<u>(2,752,076)</u>
Other expense:		
Interest expense	(1,815,366)	(1,640,145)
Loss on extinguishment of notes payable, net	(16,180,056)	(658,152)
Change in fair value of derivative liabilities	-	(2,141,069)
Reorganization items, net	-	(4,081,245)
Total other expense	<u>(17,995,422)</u>	<u>(8,520,611)</u>
Net loss	<u>\$ (44,303,295)</u>	<u>\$ (11,272,687)</u>
Net Loss Per Share - Basic and Diluted	<u>\$ (37.30)</u>	<u>\$ (28.56)</u>
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	<u>1,187,741</u>	<u>394,705</u>

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

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance at January 1, 2021	-	\$ -	715,544	\$ 72	\$ 88,511,269	\$ (89,842,833)	\$ (1,331,492)
Shares and warrants issued for cash related to public offering, net	-	-	2,300,000	230	21,072,453	-	21,072,683
Shares issued in connection with the public offering in exchange for notes payable, accrued interest and outstanding warrants	1,543,158	15,432	313,789	31	22,611,982	-	22,627,445
Shares issued in exchange of notes payable and accrued interest	-	-	8,069	1	317,376	-	317,377
Shares issued in cashless exercise of warrants	-	-	177,239	18	(82,146)	-	(82,128)
Shares issued in litigation settlement	-	-	750	-	21,000	-	21,000
Fair market value of beneficial conversion feature and warrants issued with convertible notes payable instruments	-	-	-	-	166,404	-	166,404
Stock-based compensation:							
- restricted share units	-	-	-	-	3,671,503	-	3,671,503
- options	-	-	-	-	19,411,976	-	19,411,976
- common stock	-	-	5,000	1	25,475	-	25,476
Net loss	-	-	-	-	-	(44,303,295)	(44,303,295)
Balance as of December 31, 2021	<u>1,543,158</u>	<u>\$ 15,432</u>	<u>3,520,391</u>	<u>\$ 353</u>	<u>\$ 155,727,292</u>	<u>\$ (134,146,128)</u>	<u>\$ 21,596,949</u>
Balance at January 1, 2020	-	\$ -	19,463	\$ 2	\$ 65,793,998	\$ (78,570,146)	\$ (12,776,146)
Shares and warrants issued for cash	-	-	250	-	10,000	-	10,000
Shares issued in exchange for notes payable and accrued interest	-	-	378,950	39	2,558,893	-	2,558,932
Shares issued in satisfaction of bankruptcy allowable claims	-	-	262,432	26	14,381,233	-	14,381,259
Shares issued in cashless exercise of warrants	-	-	54,449	5	(5)	-	-
Fair market value of beneficial conversion feature and warrants issued with 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	<u>-</u>	<u>\$ -</u>	<u>715,544</u>	<u>\$ 72</u>	<u>\$ 88,511,269</u>	<u>\$ (89,842,833)</u>	<u>\$ (1,331,492)</u>

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, 2021	December 31, 2020
Cash flows from operating activities:		
Net Loss	\$ (44,303,295)	\$ (11,272,687)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount	1,133,539	1,278,105
Accretion of interest expense	-	2,810,973
Depreciation and amortization	89,108	121,384
Stock-based compensation	23,108,955	691,701
Shares issued in settlement of litigation	21,000	
Loss on extinguishment of note payables, net	16,180,056	658,152
Reorganization items, net	-	527,455
Change in fair value of derivative liabilities	-	2,141,069
Professional fees paid for services related to bankruptcy proceedings		476,653
Non-cash lease expense	116,044	30,580
Changes in operating assets and liabilities:		
Accounts receivable	12,000	15,000
Prepaid assets and other current assets	(330,774)	(70,208)
Accounts payable	(68,024)	84,631
Accrued interest, expenses and other current liabilities	812,673	542,927
Lease liability	(101,190)	-
Net cash used in operating activities	(3,329,908)	(1,964,265)
Cash flows from investing activities:		
Purchases of equipment	(30,658)	-
Net cash used in investing activities	(30,658)	-
Cash flows from financing activities:		
Proceeds from sale of units in public offering, net	21,072,683	-
Proceeds from notes payable	-	4,290,310
Proceeds from PPP Loan	250,000	-
Proceeds from DIP Financing	-	1,226,901
Financing costs	-	(500,000)
Sales of common stock and warrants for cash	-	10,000
Net cash provided by financing activities	21,322,683	5,027,211
Net increase in cash and cash equivalents	17,962,117	3,062,946
Cash - beginning of year	3,064,610	1,664
Cash - end of year	\$ 21,026,727	\$ 3,064,610
Supplemental cash flow information:		
Cash paid for:		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
Non-cash investing and financing activities:		
Shares issued in exchange for notes payable and accrued interest	\$ 317,377	\$ 2,558,932
Accrued expense exchanged for convertible notes	\$ 715,303	\$ -
Shares issued in satisfaction of bankruptcy allowable claims	\$ -	\$ 14,381,259
Bifurcated embedded conversion options and warrants recorded as derivative liability and debt discount	\$ 166,404	\$ 2,377,818
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
Convertible debt and accrued interest exchanged for common and preferred shares and warrants in public offering	\$ 10,046,897	\$ -
Accrued DIP expenses exchanged for convertible notes	\$ 698,901	\$ -

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

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
NOTES TO 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.

On October 27, 2021, the Company effected a 1-for-4,000 reverse stock split of its common stock. The Company has retroactively applied the reverse stock split made effective on October 27, 2021 to share and per share amounts on the consolidated financial statements for the years ended December 31, 2021 and 2020. As a result, the Company’s authorized shares of common stock was reduced from 300,000,000,000 to 75,000,000. The Company’s authorized shares of preferred stock were not affected by the reverse stock split.

On November 9, 2021, the Company completed a \$23,000,000 underwritten public offering of units of securities pursuant to which an aggregate of 2,300,000 shares of the Company’s common stock and warrants for the purchase of an aggregate of 2,645,000 shares of the Company’s common stock were issued. The Company intends to use the net proceeds from the offering as follows: (i) undertaking of clinical trials with respect to BRTX-100 and its related collection and delivery procedure; (ii) pre-clinical research and development with respect to the Company’s ThermoStem Program; and (iii) for general corporate and working capital purposes. In connection with the public offering, the Company’s common stock was listed on the Nasdaq Capital Market.

On November 9, 2021, concurrently with the consummation of the public offering, the Company issued an aggregate of 313,780 shares of the Company’s common stock, 1,543,158 shares of the Company’s Series A preferred stock and warrants for the purchase of an aggregate of 1,856,938 shares of the Company’s common stock in exchange for convertible promissory notes in the aggregate principal amount of \$10,046,897, together with accrued interest thereon, and warrants for the purchase of an aggregate of 3,677,997 shares of the Company’s common stock. Such indebtedness and warrants were exchanged at a price of \$10.00 per unit of securities, consistent with the public offering price of the Company’s units of common stock and warrants. As a result of the exchange, the Company recorded a loss on extinguishment of notes payable, net of \$16,180,056 on the statement of operations for the year ended December 31, 2021. The newly issued warrants are exercisable for a period of five years at an exercise price of \$10.00 per share.

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. At December 31, 2021, the Company had an accumulated deficit of \$134,146,128 and working capital surplus of approximately \$21,000,000. For the year ended December 31, 2021, the Company had negative cash flows from operations of \$3,329,908. 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 2022, 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: on November 9, 2021, the Company received net proceeds of approximately \$21,073,000 from its public offering. As a result of the above, and cash on hand of approximately \$19,530,625 as of March 28, 2022, the Company believes it has sufficient cash to fund operations for the twelve months subsequent to the filing date.

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 Case

Chapter 11 Accounting

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 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"). 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	<u>\$ (4,081,245)</u>

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, and deferred tax asset and valuation allowance.

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, 2021 and 2020, the Company had approximately \$20,777,000 and \$2,815,000, 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, 2021 and 2020. See "Revenue" below.

During the year ended December 31, 2021, the Company did not have any debt financings.

During the year ended December 31, 2020, 84% 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.

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, 2021 and 2020, the Company recognized \$46,000 and \$77,000, 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, 2021 and 2020. 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, 2021 or 2020.

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, 2021 and 2020, 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, 2021 and 2020, 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 \$12,290 and \$28,281 for the years ended December 31, 2021 and 2020, 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, 2021 and 2020.

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,	
	2021	2020
Options	839,639	1,215
Warrants	4,739,871	3,750,597
Unvested RSUs	293,479	-
Convertible notes	-	109,077 ⁽¹⁾
Total	5,872,989	3,860,889

(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 13,073,094 shares of common stock reserved for future note conversions as of December 31, 2020.

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.

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

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 - Leases 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 three years as of December 31, 2021.

NOTE 4 – PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
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
Manufacturing equipment	30,712	-
Leasehold improvements	304,661	304,661
	<u>931,620</u>	<u>900,908</u>
Less: accumulated depreciation	(893,627)	(878,994)
Property and equipment, net	<u>\$ 37,993</u>	<u>\$ 21,914</u>

Total depreciation expense for the years ended December 31, 2021 and 2020 was \$14,633 and \$46,488, 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, certain performance milestones (or payouts in lieu of performance milestones) had to be satisfied in order for the Company to maintain its exclusive rights with regard to the disc/spine technology. The Company did not timely satisfy the third of these performance milestones (which needed to be satisfied by February 2022). Accordingly, such rights are currently non-exclusive. The Company and the SCTC are currently negotiating the terms of a possible reinstatement of the exclusive nature of the license. In February 2017, the Company received authorization from the Food and Drug Administration (the “FDA”) to proceed with a Phase 2 clinical trial. In February 2022, the Company announced that the United States Patent and Trademark Office has issued a notice of allowance for a patent application relating to the Company’s BRTX-100 clinical program. This patent was issued in March 2022.

Intangible assets consist of the following:

	Patents and Trademarks	Licenses	Accumulated Amortization	Total
Balance as of January 1, 2020	\$ 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
Amortization expense	-	-	(74,528)	(74,528)
Balance as of December 31, 2021	<u>\$ 3,676</u>	<u>\$ 1,301,500</u>	<u>\$ (715,436)</u>	<u>\$ 589,740</u>
Weighted average remaining amortization period at December 31, 2021 (in years)	<u>-</u>	<u>7.9</u>		

Amortization of intangible assets consists of the following:

	Patents and Trademarks	Licenses	Accumulated Amortization
Balance as of January 1, 2020	\$ 3,312	\$ 562,700	\$ 566,012
Amortization expense	364	74,532	74,896
Balance as of December 31, 2020	3,676	637,232	640,908
Amortization expense	-	74,528	74,528
Balance as of December 31, 2021	<u>\$ 3,676</u>	<u>\$ 711,760</u>	<u>\$ 715,436</u>

NOTE 6 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of:

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
Accrued payroll	\$ 28,370	\$ -
Accrued research and development expenses	29,672	-
Accrued general and administrative expenses	76,928	109,968
Accrued DIP and Plan costs related to DIP Funding and Plan	-	657,598 ⁽¹⁾
Total accrued expenses	\$ 134,970	\$ 767,566

(1) Amount represents DIP and Plan costs associated with the Auctus DIP Funding and the Plan. As of December 31, 2020, these amounts were not 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 was converted into a Secured Convertible Note and subsequently, in connection with the Company's public offering, into shares of preferred and common stock and warrants to purchase common stock.

NOTE 7 – NOTES PAYABLE & CHAPTER 11 REORGANIZATION

A summary of the notes payable activity during the years ended December 31, 2021 and 2020 is presented below:

	<u>Related Party Notes</u>	<u>Convertible Notes</u>	<u>Other Notes</u>	<u>Debt Discount</u>	<u>Total</u>
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
Issuances	-	715,303	250,000	(182,805)	782,498
Exchanges for equity	-	(10,352,405)	-	4,416,135	(5,936,270)
Amortization of debt discount	-	-	-	1,133,539	1,133,539
Outstanding, December 31, 2021	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 250,000</u>	<u>\$ -</u>	<u>\$ 250,000</u>

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 then outstanding notes were rescinded and were subject to the conversion rights outlined above.

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”). The DIP Costs and the additional Plan costs in the aggregate totaled \$650,493, of which \$500,000 and \$150,493 were recorded in debt discount and accrued expenses, respectively, on the consolidated balance sheets. On September 27, 2021, these amounts were converted into secured convertible promissory notes totaling an aggregate principal amount of \$715,542, 83,201 Class A Warrants (as described below) and 41,601 Class B Warrants (as described below). In addition, four other persons and entities (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 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 was secured by the grant of a security interest in substantially all of the Company’s assets; the Secured Convertible Notes had 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 \$2.00 (a total of 1,750,000 Class A Warrants in consideration of the Initial Auctus Funding and a total of approximately 174,250 Class A Warrants in the aggregate in consideration of the Other Funding), such Class A Warrants having an exercise price of \$2.00 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 \$4.00 (a total of 875,000 Class B Warrants in consideration of the Initial Auctus Funding and a total of approximately 87,125 Class B Warrants in the aggregate in consideration of the Other Funding), such Class B Warrants having an exercise price of \$4.00 per share.

- iii. The obligation to Auctus with respect to the DIP Funding was exchanged for the following:
 - a. A Secured Convertible Note in the principal amount of approximately \$1,349,591 (110% of the DIP Funding) with a maturity date of November 16, 2023;
 - b. A Class A Warrant to purchase 613,451 shares of common stock; and
 - c. A Class B Warrant to purchase 306,725 shares of common stock (as to which 181,571 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 167,781 shares of common stock, of which 54,449 and 113,332 were issued during 2020 and 2021, respectively).

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 6,130 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 was treated as an allowed general unsecured claim in such amount and exchanged for 11,113 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 262,432 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 were 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 had 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 was increased to 300,000,000,000 and the par value of the shares of common stock was reduced to \$0.0001 per share. On October 27, 2021, in connection with the Company's 1-for-4,000 reverse split (see Note 1 – Organization and Business Operations), the Company reduced the number of shares of common stock authorized to be issued from 300,000,000,000 to 75,000,000.

See “Conversion, Exchanges and Other” for a discussion of the exchange and conversion of the convertible notes and warrants issued pursuant to the Plan.

The Company recorded \$681,763 and \$368,810 of interest expense related to notes payable and convertible note payable for the years ended December 31, 2021 and 2020, respectively.

Convertible Notes

Issuances

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 3,875 shares of the Company's common stock. See below within Note 9- 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 bore interest at 7% per annum with a maturity date of November 16, 2023. The outstanding principal and interest was 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 was 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 3,806,587 shares of the Company's common stock at exercise prices ranging between \$2.00 and \$4.00 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 being amortized over the term of the respective Secured Convertible Notes.

See “Conversion, Exchanges and Other” for a discussion of the exchange and conversion of the convertible notes and warrants issued pursuant to the Plan.

Conversions, Exchanges and Other

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 378,950 shares of the Company’s common stock at conversion prices ranging from \$0.40 and \$40.00 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.

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 bore 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.

During the year ended December 31, 2021, the Company and certain lenders converted unsecured convertible notes with an aggregate amount of \$317,377 (including \$6,314 of accrued interest) for an aggregate amount of 8,069 shares of the Company’s common stock at a conversion price of \$40.00 per share.

During October 2021, the Company entered into an Exchange Agreement (the “Auctus Agreement”) with Auctus to exchange outstanding convertible promissory notes in the aggregate principal amount of \$8,826,952, \$596,446 in accrued interest, and outstanding warrants for the purchase of an aggregate of 3,441,586 shares of the Company’s common stock for units of common stock and warrants that were issued by the Company in its underwritten public offering (the “Public Offering”), except that, to the extent the issuance of common stock pursuant to the Auctus Agreement would result in Auctus being the beneficial owner of more than 4.99% of the Company’s outstanding common stock, the Company would instead issue to Auctus shares of Series A preferred stock. On November 9, 2021, in connection with the Public Offering, the Company issued to Auctus 133,422 shares of the Company’s common stock, 1,543,158 shares of the Company’s Series A preferred stock, and warrants for the purchase of 1,676,580 shares of the Company’s common stock. In connection with the exchanges, the Company recognized a loss on extinguishment of debt of \$6,293,317 recorded in the consolidated statements of operations.

In addition, during October 2021, the Company entered into Exchange Agreements with the Other Lenders with regard to the exchange by the Other Lenders of outstanding convertible promissory notes in the aggregate principal amount of \$419,945, \$25,115 in accrued interest, and warrants to purchase of an aggregate of 236,411 shares of the Company’s common stock for the units that were to be issued in the Public Offering. On November 9, 2021, in connection with the Public Offering, the Company issued the Other Lenders an aggregate of 94,951 shares of the Company’s common stock and warrants for the purchase of an aggregate of 94,942 shares of common stock.

Effective November 9, 2021, pursuant to the terms of their convertible notes, the Company issued to Desmarais and Tuxis Trust an aggregate of 85,416 shares of common stock, with a fair value of \$10.00 per share, and warrants for the purchase of an aggregate of 85,416 shares of common stock, upon the conversion of an aggregate principal and accrued interest amount of \$800,000 and \$54,159, respectively, upon the Company’s listing on the Nasdaq Capital Market.

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.

Pursuant to the Plan, the obligation to Auctus with respect to the DIP Funding was exchanged for two Secured Convertible Notes (see Note 7 – Notes Payable & Chapter 11 Reorganization) for an aggregate principal amount of \$1,349,591 which bore 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 920,176 shares of Company's common stock with exercise prices ranging between \$2.00 and \$4.00 per share.

On September 27, 2021, pursuant to the Plan, for 110% of the DIP Costs, the Company issued to Auctus secured two convertible promissory notes in the aggregate principal amount of \$183,043, with a maturity date of November 16, 2023. The notes bore interest at 7% per annum which was payable on maturity. Amounts due under the notes were convertible into shares of the Company's common stock at a conversion price equal to the average five daily volume weighted average price on the latest day prior to the conversion date. In connection with the notes, the Company granted to Auctus Class A Warrants to purchase up to 83,201 shares of the Company's common stock at an exercise price of \$2.00 per share. The Class A Warrants were scheduled to expire on November 16, 2025. In addition, in connection with the notes, the Company granted to Auctus Class B Warrants to purchase up to 41,601 shares of the Company's common stock at an exercise price of \$4.00 per share. The Class B Warrants were scheduled to expire on November 16, 2025. The warrants had an aggregate grant date fair value of \$152,300 which was recorded as a debt discount and was being amortized over the term of the notes. In addition, the notes contained a beneficial conversion feature with a relative fair value of \$14,103 which was recorded as a debt discount and was being amortized over the term of the notes. On November 9, 2021, the principal amount of and accrued interest on the notes was exchanged pursuant to the Auctus Agreement. As of December 31, 2021, there was no principal outstanding.

On September 27, 2021, pursuant to the Plan, for 110% of the Plan Costs, the Company issued to Auctus a secured convertible promissory note in the principal amount of \$532,499, with a maturity date of November 16, 2023. The note bore interest at 7% per annum which was payable on maturity. Amounts due under the note were convertible into shares of the Company's common stock at a conversion price equal to the average five daily volume weighted average price on the latest day prior to the conversion date. On November 9, 2021, the principal amount of and accrued interest on the note was exchanged pursuant to the Auctus Agreement. As of December 31, 2021, there was no principal outstanding.

Public Offering Exchange

On November 9, 2021, in connection with the public offering all of the above outstanding convertible notes, associated accrued interest and warrants held by Auctus, as well as outstanding convertible notes in the aggregate principal amount of \$1,219,945, associated accrued interest and warrants for the purchase of an aggregate of 236,411 shares of common stock to other investors, were exchanged for an aggregate amount of 1,856,938 units of common stock and warrants (of the type issued pursuant to the Company's public offering) (except that Auctus received shares of Series A preferred stock in lieu of common stock with regard to a portion of the exchanged amount, as described in Note 8 – Stockholders' Equity (Deficit)), ultimately resulting in the issuance of an aggregate of approximately 1,543,000 shares of Series A preferred stock, approximately 314,000 shares of common stock and approximately 1,857,000 warrants (see Note 8 – Stockholders' Equity (Deficit)).

Other Loans

On March 14, 2021, under the U.S. Small Business Administration's Paycheck Protection Program, the Company entered into a note payable with a financial institution for \$250,000 at an interest rate of 1% per annum and a maturity date of March 14, 2026. Pursuant to the note, principal and interest payments are deferred for ten months. At that time the Company may apply for loan forgiveness. If the Company does not apply for loan forgiveness, or if the loan forgiveness is denied, the Company will be required to make monthly payments of \$5,100 starting on January 14, 2022. As of December 31, 2021, the Company has not applied for loan forgiveness. All remaining unpaid principal and interest is due and payable at the maturity date. At December 31, 2021, \$250,000 was outstanding. The Company applied for loan forgiveness on a timely basis, and subsequent to December 31, 2021, the total amount of \$250,000 was forgiven (see Note 13).

Future minimum payments under the above notes payable following the year ended December 31, 2021 are as follows:

2022	\$	58,970
2023		59,562
2024		60,161
Thereafter		71,307
Total future minimum payments		250,000
Less: discount		-
		250,000
Less: current		(58,970)
	\$	191,030

NOTE 8 - STOCKHOLDERS' EQUITY (DEFICIT)

Authorized Capital and Reverse Split

On November 16, 2020, 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 was increased to 300,000,000,000 and the par value of the shares of its common stock was reduced to \$0.0001 per share.

On November 16, 2021, in connection with the Company's October 27, 2021 1-for-4,000 reverse split (see Note 1 – Organization and Business Operations), the Company reduced the number of shares of common stock authorized to be issued from 300,000,000,000 to 75,000,000.

Series A Preferred

On November 8, 2021, in connection with with the Company's public offering, the Company's Board of Directors adopted a resolution allowing for the authorization of and issuance of 1,543,458 shares of the Company's Preferred Stock, \$.01 par value per share, designated as Series A Preferred Stock ("Series A"). The Series A has a liquidation preference of \$0.001 per share.

Dividends

Series A holders shall be entitled to receive, when and as declared by the Board of Directors, dividends on a pari passu basis with the the holders of the shares of the Company's common stock based upon the number of shares of common stock into which the Series A is then convertible.

Voting Rights

Series A holders shall be entitled to vote on all matters presented to the stockholders of the Company and shall be entitled to such number of votes that equal the number of shares of common stock that each share of Series A held may be converted into; provided, however, that in no event shall a Series A holder be entitled to vote more than 4.99% of the then outstanding shares of common stock.

Conversion

Optional Conversion - Each share of Series A is convertible, at any time, at the option of the Series A holder, into one share of common stock; provided, however, that in no event shall a Series A holder be entitled to convert any shares of Series A to the extent that such conversion would result in beneficial ownership by the Series A holder of more than 4.99% of the outstanding shares of common stock.

Automatic Conversion – In the event that an event occurs which has the effect of reducing a Series A holder's beneficial ownership of shares of common stock to less than 4.5% of the then publicly disclosed outstanding shares of common stock, then within five business days thereafter, the Series A holder shall provide notice to the Company to such effect. Such notice shall have the effect of a notice of conversion such that the Series A holder's post-conversion ownership of common stock will be 4.99% of the then publicly disclosed outstanding shares of common stock.

Series A Preferred Stock Issuance

On November 9, 2021, pursuant to the Auctus Agreement (see Note 7 – Notes Payable & Chapter 11 Reorganization), the Company issued Auctus approximately 1,543,000 shares of Series A preferred stock.

2021 Stock Incentive Plan

On March 18, 2021, the Company's Board of Directors adopted the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the "2021 Plan"). Pursuant to the 2021 Plan, a total of 1,175,000 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.

Compensatory Common Stock Issuance

During the year ended December 31, 2021, the Company issued 5,000 shares of immediately vested common stock value at \$25,476 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, 2020, the Company issued 250 shares of the Company's common stock and a five-year immediately vested warrant for the purchase of 250 shares of the Company's common stock with an exercise price of \$60 per share to a certain investor for gross proceeds of \$10,000. The warrant had an aggregate grant date fair value of \$10,000. The warrant was subject to the Company's sequencing policy and, as a result, was initially recorded as a derivative liability. See Note 9 - 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 3,806,587 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 had exercise prices ranging between \$2.00 and \$4.00 per share. The warrants along with the beneficial conversion feature had an aggregate relative fair value of \$5,075,449 and were recorded as a debt discount.

During the year ended December 31, 2021, the Company issued 750 shares of the Company's common stock in settlement of litigation proceedings with a fair value of \$21,000.

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,	
	2021	2020
Risk free interest rate	0.98%	0.41% - 1.63%
Expected term (years)	4.10 - 5.00	5.00 - 5.00
Expected volatility	314%	202% - 278%
Expected dividends	0.00%	0.00%

The weighted average estimated fair value of the warrants granted during the years ended December 31, 2021 and 2020 was approximately \$11.77 and \$40.00 per share, respectively.

During the year ended December 31, 2020, the Company issued an aggregate of 54,449 shares of the Company's common stock, with fair value range of \$25.20 to \$67.60, as a result of the cashless exercise of 57,919 warrants by Auctus.

On October 21, 2021, the Company issued 22,917 shares of common stock to a warrant holder, as a result of the cashless exercise of 25,000 warrants.

During the year ended December 31, 2021, the Company issued an aggregate of 147,832, shares of the Company's common stock, as a result of the cashless exercise of 170,473 warrants by Auctus.

A summary of the warrant activity during the years ended December 31, 2021 and 2020 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2020	2,095	\$ 5,720		
Granted	3,806,837	2.80		
Exercised	(57,919)	4.00		
Forfeited	(415)	8,560		
Outstanding, December 31, 2020	3,750,598	\$ 4.40		
Issued	4,862,710	9.91		
Exercised	(195,473)	4.00		
Exchanged or forfeited	(3,677,964)	3.39		
Outstanding, December 31, 2021	4,739,871	\$ 11.78	4.9	\$ -
Exercisable, December 31, 2021	4,739,871	\$ 11.78	4.9	\$ -

The following table presents information related to stock warrants at December 31, 2021:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
\$ 10	4,501,937	4.9	4,501,937
\$ 12.50	235,970	4.9	235,970
\$ 60	250	3.0	250
\$ 800	869	2.8	869
\$ 2,240	39	2.5	39
\$ 3,400	264	2.2	264
\$ 4,000	55	2.1	55
\$ 8,000	19	1.8	19
\$ 14,000	18	1.5	18
\$ 16,000	435	1.5	435
\$ 16,600	14	0.8	14
\$ 20,000	1	0.5	1
	<u>4,739,871</u>	4.9	<u>4,739,871</u>

Stock Options

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

	For the Year Ended December 31, 2021
Risk free interest rate	1.25% - 1.48%
Expected term (years)	5.00 - 10.00
Expected volatility	354%
Expected dividends	0.00%

The Company granted options for the purchase of 838,550 shares of common stock during the year ended December 31, 2021.

The weighted average grant date fair value of the stock options granted during the years ended December 31, 2021 and 2020, was approximately \$26,571,050 and \$-, respectively.

A summary of the option activity during the years ended December 31, 2021 and 2020 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2020	1,220	\$ 3,960		
Granted	-	-		
Forfeited	(5)	5,960		
Outstanding, December 31, 2020	1,215	\$ 3,920		
Granted	838,550	13.50		
Expired	(126)	3,000		
Outstanding, December 31, 2021	<u>839,639</u>	<u>\$ 18.73</u>	<u>9.45</u>	<u>\$ -</u>
Exercisable, December 31, 2021	<u>349,237</u>	<u>\$ 26.00</u>	<u>9.45</u>	<u>\$ -</u>

The following table presents information related to stock options at December 31, 2021:

Options Outstanding		Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
\$ 13.50	838,550	9.5	348,156
\$ 1,040	44	7.7	44
\$ 3,000	1,026	5.0	1,018
\$ 22,800	1	2.5	1
\$48,200 - \$52,000	9	2.0	9
\$80,000 - \$120,000	9	0.2	9
	<u>839,639</u>	<u>9.5</u>	<u>349,237</u>

On March 18, 2021, the Company, pursuant to two employment agreements, granted to its Chief Executive Officer, President and Chairman of the Board and its Vice President, Research and Development options to purchase an aggregate of 586,959 shares of the Company's common stock (see Note 10 – Commitments and Contingencies). The options had an exercise price of \$47.60 per share and vest to the extent of 50% on the date of grant, 25% on the one-year anniversary of the grant date and 25% on the two-year anniversary of the grant date. On November 4, 2021, the Company reduced the exercise price of these options from \$47.60 per share to \$13.50 per share and revised the vesting period. On December 10, 2021, the Company further reduced the exercise price of these options from \$13.50 per share to \$5.08 per share, subject to stockholder approval. Per ASC 718 – Compensation – Stock Compensation, the Company accounted for these changes as a modification and the net effect was immaterial to the financial statements as a whole.

On November 4, 2021, the Company granted options to purchase an aggregate of 140,824 shares of its common stock (including options to purchase 10,490 shares each granted to Robert Kristal, its Chief Financial Officer, Patrick Williams, a director of the Company, and David Rosa, a director of the Company) to its officers and directors at an exercise price of \$13.50 per share. Also included within the 140,824 share option grants were grants to each of Mr. Alstodt and Mr. Silva for the purchase of 42,059 shares of common stock and to Dr. Nickolay Kukekov, a director of the Company, for the purchase of 25,236 shares of common stock. The option grants to Mr. Alstodt, Mr. Silva, and Dr. Kukekov have a ten year term and an exercise price of \$13.50 per share. Such options are exercisable to the extent of 50% on the date of grant and 50% quarterly over a period of two years commencing one year from the date of grant. On December 10, 2021, the Company reduced the exercise price of the options from \$13.50 per share to \$5.08 per share, subject to stockholder approval. Per ASC 718 – Compensation – Stock Compensation, the Company accounted for these changes as a modification and the net effect was immaterial to the financial statements as a whole.

On November 4, 2021, the Company granted options to purchase an aggregate of 110,767 shares of the Company's common stock to members of its Scientific Advisory Board and various employees and consultants at an exercise price of \$13.50 per share. On December 10, 2021, the Company reduced the exercise price of the options from \$13.50 per share to \$5.08 per share, subject to stockholder approval. Per ASC 718 – Compensation – Stock Compensation, the Company accounted for these changes as a modification and the net effect was immaterial to the financial statements as a whole.

Restricted Stock Units

Pursuant to the 2021 Plan, the Company may grant restricted stock units ("RSUs") to employees, consultants or non-employee directors ("Eligible Individuals"). The number, terms and conditions of the RSUs that are granted to Eligible Individuals are determined on an individual basis by the 2021 Plan administrator. On the distribution date, the Company shall issue to the Eligible Individual one unrestricted, fully transferable share of the Company's common stock (or the fair market value of one such share in cash) for each vested and nonforfeitable RSU.

On March 18, 2021, the Company, pursuant to two employment agreements, granted an aggregate of 293,479 RSUs to its Chief Executive Officer, President, and Chairman of the Board and its Vice President, Research and Development (see Note 10 – Commitments and Contingencies) with a fair value of \$47.60 per share. The RSUs vest to the extent of one-third on the one-year anniversary of the grant date, one-third on the two-year anniversary of the grant date, and one-third on the three-year anniversary of the grant date. The RSUs had a grant date fair value of \$13,969,624.

A summary of the unvested RSUs as of December 31, 2021 is as follows:

	Number of Shares
Outstanding, January 1, 2021	-
Granted	293,479
Forfeited	-
Vested	-
Outstanding, December 31, 2021	<u>293,479</u>

The following table presents information related to stock compensation expense:

	For the Years Ended December 31,		Unrecognized at December 31,	Weighted Average Remaining Amortization Period
	2021	2020	2021	(Years)
Consulting	\$ 25,476	\$ 110,557	\$ -	-
Research and development	81,479	177,281	-	-
General and administrative	23,002,000	403,863	9,698,130	2.3
	<u>\$ 23,108,955</u>	<u>\$ 691,701</u>	<u>\$ 9,698,130</u>	<u>2.3</u>

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, 2020	\$ 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
Reclassification of derivative liabilities to equity	(4,375,231)
Ending balance as of December 31, 2020	<u>\$ -</u>

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

	For the Year Ended December 31, 2020
Risk free interest rate	0.06% - 2.16%
Expected term (years)	0.12 – 5.00
Expected volatility	101% - 133%

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 & Chapter 11 Reorganization - Convertible Notes for additional details. See Note 8 – Stockholders' Equity (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 & Chapter 11 Reorganization – 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. 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, *Reorganizations*, 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) 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 1,000 to 1 reverse split; however, on October 27, 2021, the Company effected a 4,000 to 1 reverse split of its common stock.

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

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 was entitled to receive initially an annual salary of \$250,000. The Alstodt Employment Agreement also provides for annual salary increases of \$50,000 per year. In addition, based upon certain performance goals having been met, Mr. Alstodt's salary increased by \$150,000 in November 2021. The Alstodt Employment Agreement also provides for the grant to Mr. Alstodt pursuant to the 2021 Plan of (i) a ten-year option for the purchase of 293,479 shares of common stock of the Company and (ii) 146,740 RSUs of the Company (see Note 8 – Stockholders' Equity (Deficit) for additional information). On November 4, 2021, the Company reduced the exercise price of these options from \$47.60 per share to \$13.50 per share and revised the vesting period. On December 10, 2021, the Company reduced the exercise price of these options from \$13.50 per share to \$5.08 per share, subject to stockholder approval. The aggregate grant date fair value of the above-mentioned equity consideration was \$20,852,838, of which, \$11,370,020 has been recorded as stock-based compensation in general and administrative expenses on the statement of operations for the year ended December 31, 2021. In March 2022, we and Mr. Alstodt agreed that, in lieu of a \$50,000 increase in his annual salary (as provided for in his employment agreement), we issued to Mr. Alstodt 12,438 RSUs (having a value of \$50,000), which RSUs will vest in twelve equal monthly installments. Such grant was in consideration of Mr. Alstodt deferring his right to receive the \$50,000 increase in his salary for one year.

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 was entitled to receive initially an annual salary of \$225,000. The Silva Employment Agreement also provides for annual salary increases of \$50,000 per year. In addition, based upon certain performance goals having been met, Mr. Silva’s salary increased by \$150,000 in November 2021. The Silva Employment Agreement also provides for the grant to Mr. Silva pursuant to the 2021 Plan of (i) a ten-year option for the purchase of 293,479 shares of common stock of the Company and (ii) 146,740 RSUs of the Company (see Note 8 – Stockholders’ Equity (Deficit) for additional information). On November 4, 2021, the Company reduced the exercise price of these options from \$47.60 per share to \$13.50 per share and revised the vesting period. On December 10, 2021, the Company reduced the exercise price of these options from \$13.50 per share to \$5.08 per share, subject to stockholder approval. The aggregate grant date fair value of the above-mentioned equity consideration was \$20,852,838, of which, \$11,370,020 has been recorded as stock-based compensation in general and administrative expenses on the statement of operations for the year ended December 31, 2021. In March 2022, we and Mr. Silva agreed that, in lieu of a \$50,000 increase in his annual salary (as provided for in his employment agreement), we issued to Mr. Silva 12,438 RSUs (having a value of \$50,000), which RSUs will vest in twelve equal monthly installments. Such grant was in consideration of Mr. Silva deferring his right to receive the \$50,000 increase in his salary for one year.

On November 4, 2021, the Company appointed Robert Kristal as the Company’s Chief Financial Officer and entered into an employment agreement with him (the “Kristal Employment Agreement”) which provides for a term ending on November 4, 2022. Pursuant to the Kristal Employment Agreement, Mr. Kristal is entitled to receive initially an annual salary of \$175,000. The Kristal Employment Agreement provides for Mr. Kristal to receive a discretionary bonus, upon the approval of the Board of Directors, up to 30% of his base salary. In addition, the Kristal Employment Agreement provides for the grant to Mr. Kristal pursuant to the 2021 Plan of a ten-year option for the purchase of 10,490 shares of common stock of the Company with an exercise price of \$13.50 per share. On December 10, 2021, the Company reduced the exercise price of these options from \$13.50 per share to \$5.08 per share, subject to stockholder approval. The aggregate grant date fair value of the above-mentioned equity consideration was \$53,288, of which, \$2,220 has been recorded as stock-based compensation in general and administrative expenses on the statement of operations for the year ended December 31, 2021.

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. In June 2021, the Company settled a claim with a lender and issued 750 shares of the Company’s common stock.

Research and Development Agreement and Grant

In September 2021, we were awarded a National Institutes of Health Small Business Technology Transfer (STTR) Phase 1 grant for \$256,000 to evaluate the therapeutic effects on our hypoxic cultured bone marrow derived mesenchymal stem cells (*BRTX-100*) after encapsulation with a PEG-peptide hydrogel. The work is being done in collaboration with Washington University of St. Louis.

On December 20, 2021, the Company entered into a Master Clinical Services Agreement (the “Services Agreement”) with Professional Research Consulting, Inc. (“PRC”) pursuant to which PRC will provide trial management services related to Phase 2 of the Company’s clinical trials. The Services Agreement has a 46-month term with an estimated budgeted cost of \$5,844,380. Upon execution on the Services Agreement the Company made an upfront payment of \$328,152 which was recorded as a prepaid expense on the consolidated balance sheet at December 31, 2021, and will be expensed over the life of the Services Agreement.

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, 2021 and 2020, the Company had approximately \$42,000,000 and \$36,600,000, 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, 2021, approximately \$8,000,000 of federal net operating losses will expire from 2030 to 2038 and approximately \$34,000,000 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, 2019 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, 2021, 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, 2021 and 2020 are summarized as follows:

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 11,100,000	\$ 9,700,000
Stock-based compensation	10,500,000	4,070,000
Research & development tax credits	358,000	358,000
Total deferred tax assets	21,958,000	14,128,000
Deferred tax liabilities:		
Intangible assets	(4,000)	(30,000)
Total deferred tax liabilities	(4,000)	(30,000)
Net deferred tax assets	21,954,000	14,098,000
Valuation allowance	\$ (21,954,000)	\$ (14,098,000)
Deferred tax asset, net of valuation allowance	\$ -	\$ -
Change in valuation allowance	\$ (7,856,000)	\$ (2,086,000)

The income tax provision (benefit) as of December 31, 2021 and 2020 consists of the following:

	December 31,	
	2021	2020
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, 2021 and 2020 is as follows:

	<u>2021</u>	<u>2020</u>
Federal statutory blended income tax rates	(21)%	(21)%
State statutory income tax rate, net of federal benefit	(5)	(5)
Permanent differences	8.3	7.6
Change in valuation allowance	17.7	18.4
Effective tax rate	<u>-%</u>	<u>-%</u>

As of the date of this filing, the Company has not filed its 2021 federal and state corporate income tax returns. The Company expects to file these documents as soon as practicable.

NOTE 12 – LEASES

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.

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:

	<u>Year Ended December 31, 2021</u>	<u>Year Ended December 31, 2020</u>
Lease cost		
Operating lease cost (cost resulting from lease payments)	\$ 158,372	\$ 153,748
Net lease cost	<u>\$ 158,372</u>	<u>\$ 153,748</u>
Operating lease – operating cash flows (fixed payments)	\$ 158,372	\$ 153,748
Operating lease – operating cash flows (liability reduction)	\$ 101,190	\$ 85,465
Non-current leases – right of use assets	\$ 357,805	\$ 473,849
Current liabilities – operating lease liabilities	\$ 119,055	\$ 158,371
Non-current liabilities – operating lease liabilities	\$ 301,645	\$ 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, 2021:

<u>Fiscal Year</u>	<u>Operating Leases</u>
2022	\$ 163,132
2023	168,028
2024	173,060
Total future minimum lease payments	504,220
Amount representing interest	(83,520)
Present value of net future minimum lease payments	<u>\$ 420,700</u>

NOTE 13 – SUBSEQUENT EVENTS

On January 25, 2022, the Company’s received notice that the U.S. Small Business Administration was forgiving the Company’s outstanding PPP Loan in the aggregate principal amount of \$250,000 and associated \$2,027 in interest.

On February 28, 2022, the Company issued an aggregate of 8,000 shares of common stock with a fair value of \$5.56 per share, to various consultants for services rendered, in lieu of cash.

On March 18, 2022, an aggregate of 97,828 of RSUs, vested and the underlying shares of common stock were issued to Mr. Alstodt and Mr. Silva.

CERTIFICATE OF INCORPORATION

OF

BIORESTORATIVE THERAPIES, INC.
(as amended through November 16, 2021)

The undersigned, for the purpose of organizing a corporation under the General Corporation Law of the State of Delaware, certifies:

FIRST: The name of the corporation is BioRestorative Therapies, Inc. (hereinafter referred to as the “Corporation”).

SECOND: The address of the registered office of the Corporation in the State of Delaware is 874 Walker Road, Suite C, Dover, Delaware 19904, in the County of Kent. The name of the registered agent of the Corporation at that address is United Corporate Services, Inc.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the Delaware General Corporation Law.

FOURTH: A. The total number of shares of all classes of stock which the Corporation shall have authority to issue is ninety-five million (95,000,000), consisting of seventy-five million (75,000,000) shares of Common Stock, par value \$.0001 per share (the “Common Stock”), and twenty million (20,000,000) shares of Preferred Stock, par value \$.01 per share (the “Preferred Stock”).

B. The board of directors is authorized, subject to any limitations prescribed by law, to provide for the issuance of shares of Preferred Stock in series, and by filing a certificate pursuant to the applicable law of the State of Delaware (such certificate being hereinafter referred to as a “Preferred Stock Designation”), to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences, and rights of the shares of each such series and any qualifications, limitations or restrictions thereof. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of capital stock of the Corporation entitled to vote thereon, without a vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any Preferred Stock Designation.

C. The Common Stock shall be subject to the express terms of any series of Preferred Stock set forth in the Preferred Stock Designation relating thereto. Each holder of Common Stock shall have one vote in respect of each share of Common Stock held by such holder of record on the books of the Corporation for the election of directors and on all other matters on which stockholders of the Corporation are entitled to vote. The holders of shares of Common Stock shall be entitled to receive, when and if declared by the board of directors, out of the assets of the Corporation which are by law available therefor, dividends payable either in cash, in stock or otherwise.

Upon the effectiveness of the Certificate of Amendment to the Certificate of Incorporation to effect a plan of recapitalization of the Common Stock by effecting a 1-for-20 reverse stock split with respect to the issued and outstanding shares of the Common Stock (the "Reverse Stock Split"), without any change in the powers, preferences and rights or qualifications, limitations or restrictions thereof, and without further action of any kind on the part of the Corporation or its stockholders, every twenty (20) shares of Common Stock outstanding or held by the Corporation in its treasury on the date of effectiveness of the Certificate of Amendment shall be changed and reclassified into one (1) share of Common Stock, par value \$0.001 per share, which shares shall be fully paid and nonassessable shares of Common Stock. There shall be no fractional shares issued upon the Reverse Stock Split. Any fractional shares that result from the Reverse Stock Split shall be rounded up to the next whole number. [Effective July 7, 2015]

Upon the effectiveness of the Certificate of Amendment to the Certificate of Incorporation to effect a plan of recapitalization of the Common Stock by effecting a 1-for-4,000 reverse stock split with respect to the issued and outstanding shares of the Common Stock (the "Reverse Stock Split"), without any change in the powers, preferences and rights or qualifications, limitations or restrictions thereof, and without further action of any kind on the part of the Corporation or its stockholders, every four thousand (4,000) shares of Common Stock outstanding or held by the Corporation in its treasury on the date of effectiveness of the Certificate of Amendment shall be changed and reclassified into one (1) share of Common Stock, par value \$0.0001 per share, which shares shall be fully paid and nonassessable shares of Common Stock. There shall be no fractional shares issued upon the Reverse Stock Split. Any fractional shares that result from the Reverse Stock Split shall be rounded up to the next whole number. [Effective October 27, 2021]

D. The Corporation shall not issue nonvoting equity securities. As to any classes of securities possessing voting power, an appropriate distribution of such power shall be made among such classes, including, in the case of any class of equity securities having a preference over another class of equity securities with respect to dividends, adequate provisions for the election of directors representing such preferred class in the event of a default in the payment of such dividends.

FIFTH: The following provisions are inserted for the management of the business and the conduct of the affairs of the Corporation, and for further definition, limitation and regulation of the powers of the Corporation and of its directors and stockholders:

A. The business and affairs of the Corporation shall be managed by or under the direction of the board of directors. In addition to the powers and authority expressly conferred upon them by statute or by this Certificate of Incorporation or the by-laws of the Corporation, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation.

B. The directors of the Corporation need not be elected by written ballot unless the by-laws so provide.

C. Subject to the rights of the holders of any series of Preferred Stock, any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders, unless otherwise authorized by the board of directors in its sole discretion acting pursuant to a resolution adopted by a majority of the Whole Board. For purposes of this Certificate of Incorporation, the term "Whole Board" shall mean the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships.

D. Special meetings of stockholders of the Corporation may be called only by the board of directors acting pursuant to a resolution adopted by a majority of the Whole Board or by the Chairman of the Board.

E. An annual meeting of stockholders, for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly come before the meeting, shall be held at such place, on such date, and at such time as the board of directors shall fix.

SIXTH: A. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the number of directors shall be fixed from time to time exclusively by the board of directors pursuant to a resolution adopted by a majority of the Whole Board. The directors, other than those who may be elected by the holders of any series of Preferred Stock under specified circumstances, shall be divided into three classes, with the term of office of the first class to expire at the Corporation's first annual meeting of stockholders following the date of adoption of this Certificate of Incorporation, the term of office of the second class to expire at the Corporation's second annual meeting of stockholders following the date of adoption of this Certificate of Incorporation and the term of office of the third class to expire at the Corporation's third annual meeting of stockholders following the date of adoption of this Certificate of Incorporation, with each director to hold office until his or her successor shall have been duly elected and qualified. At each annual meeting of stockholders, (i) directors elected to succeed those directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election, with each director to hold office until his or her successor shall have been duly elected and qualified; and (ii) if authorized by a resolution of the board of directors, directors may be elected to fill any vacancy on the board of directors, regardless of how such vacancy shall have been created.

B. A majority of the Whole Board shall constitute a quorum for all purposes at any meeting of the board of directors, and, except as otherwise expressly required by law or by this Certificate of Incorporation, all matters shall be determined by the affirmative vote of a majority of the directors present at any meeting at which a quorum is present.

C. Subject to the rights of the holders of any series of Preferred Stock then outstanding, newly created directorships resulting from any increase in the authorized number of directors or any vacancies in the board of directors resulting from death, resignation, disqualification, removal from office or other cause shall, unless otherwise required by law or by resolution of the board of directors, be filled only by a majority vote of the directors then in office, though less than a quorum (and not by stockholders), and directors so chosen shall serve for a term expiring at the annual meeting of stockholders at which the term of office of the class to which they have been chosen expires, with each director to hold office until his or her successor shall have been duly elected and qualified. No decrease in the authorized number of directors shall shorten the term of any incumbent director.

D. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the by-laws of the Corporation.

E. Subject to the rights of the holders of any series of Preferred Stock then outstanding, any director, or the entire board of directors, may be removed from office at any time, but only for cause and only by the affirmative vote of the holders of at least seventy-five percent (75%) of the voting power of all of the then-outstanding shares of capital stock of the Corporation then entitled to vote at an election of directors, voting together as a single class.

SEVENTH: The board of directors is expressly empowered to adopt, amend or repeal by-laws of the Corporation. Any adoption, amendment or repeal of the by-laws of the Corporation by the board of directors shall require the approval of a majority of the Whole Board. The stockholders shall also have the power to adopt, amend or repeal the by-laws of the Corporation; provided, however, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least seventy-five percent (75%) of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote thereon, voting together as a single class, shall be required to adopt, amend or repeal any provision of the by-laws of the Corporation.

EIGHTH: A director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) under Section 174 of the Delaware General Corporation Law; or (iv) for any transaction from which the director derived an improper personal benefit. If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

Any repeal or modification of the foregoing paragraph shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification.

NINTH: The Corporation reserves the right to amend or repeal any provision contained in this Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; provided, however, that, notwithstanding any other provision of this Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote, but in addition to any vote of the holders of any class or series of stock of this corporation required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least seventy-five percent (75%) of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote thereon, voting together as a single class, shall be required to amend or repeal this Article NINTH, Sections C or D of Article FIFTH, Article SIXTH, Article SEVENTH, or Article EIGHTH.

TENTH: This Certificate of Incorporation is to become effective on January 1, 2015.

ELEVENTH: The name and address of the incorporator is as follows:

Mark Weinreb
40 Marcus Drive
Melville, New York 11747

I, THE UNDERSIGNED, being the incorporator, for the purpose of forming a corporation pursuant to the Delaware General Corporation Law, do make this Certificate of Incorporation, hereby acknowledging, declaring, and certifying that the foregoing Certificate of Incorporation is my act and deed and that the facts herein stated are true, and have accordingly hereunto set my hand this 22nd day of December 2014.

Incorporator

/s/ Mark Weinreb

Mark Weinreb

NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN

This Non-Qualified Stock Option Award Agreement (this “**Agreement**”) is made and entered into as of November 4, 2021 by and between BioRestorative Therapies, Inc., a Delaware corporation (the “**Company**”), and Nickolay Kukekov (the “**Participant**”).

Grant Date: November 4, 2021
Exercise Price per Share: \$13.50
Number of Option Shares: 25,236
Expiration Date: November 4, 2031

1. **Grant of Option.**

1.1. **Grant; Type of Option.** The Company hereby grants to the Participant an option (the “**Option**”) to purchase the number of Shares of Common Stock of the Company equal to the number of Option Shares set forth above. The Option is being granted pursuant to the terms of the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the “**Plan**”). The Option is intended to be a Non-Qualified Stock Option and *not* an Incentive Stock Option within the meaning of Section 422 of the Code.

1.2. **Consideration; Subject to Plan.** The grant of the Option is made in consideration of the services to be rendered by the Participant to the Company and is subject to the terms and conditions of the Plan. Capitalized terms used but not otherwise defined herein have the meanings given to them in the Plan.

2. **Exercise Period; Vesting.**

2.1 **Vesting Schedule.** The Option will become vested and exercisable with respect to 50% of the Option Shares on the Grant Date, with the remainder vesting quarterly in eight equal installments (at a rate of 1/16 per quarter) with the first quarterly installment vesting on the one-year anniversary of the Grant Date and continuing every three months thereafter until fully vested.

Upon the Participant’s Termination of Service for any reason, the unvested portion of the Option will be forfeited and will not be exercisable.

2.2 **Expiration.** The Option will expire on the Expiration Date set forth above, or earlier as provided in this Agreement or the Plan. The Expiration Date shall not be more than ten years from the Grant Date (or, if the Option is being granted to a Greater Than 10% Stockholder, not more than five years from the Grant Date). To the extent the Expiration Date listed above is inconsistent with this paragraph, this paragraph shall control.

3. **Termination of Service.**

3.1 **Termination for Reasons Other Than Cause, Death, Disability.** If the Participant has a Termination of Service for any reason other than Cause, death or Disability, the Participant may exercise the vested portion of the Option, but only within such period of time ending on the earlier of: (a) the date three months following the Participant's Termination of Service, or (b) the Expiration Date.

3.2 **Termination for Cause.** If the Participant has a Termination of Service for Cause, the Option (whether vested or unvested) shall immediately terminate and cease to be exercisable.

3.3 **Termination due to Disability.** If the Participant has a Termination of Service as a result of the Participant's Disability, the Participant may exercise the vested portion of the Option, but only within such period of time ending on the earlier of: (a) the date 12 months following the Participant's Termination of Service or (b) the Expiration Date.

3.4 **Termination due to Death.** If the Participant has a Termination of Service as a result of the Participant's death, the vested portion of the Option may be exercised by the Participant's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by the person designated to exercise the Option upon the Participant's death, but only within the time period ending on the earlier of: (a) the date 12 months following the Participant's Termination of Service, or (b) the Expiration Date.

4. **Manner of Exercise.**

4.1 **Election to Exercise.** To exercise the Option, the Participant (or in the case of exercise after the Participant's death or incapacity, the Participant's executor, administrator, heir or legatee, as the case may be) must deliver to the Company an executed stock option exercise agreement in such form as is approved by the Committee from time to time (the "**Exercise Agreement**"), which shall set forth, inter alia:

- (a) the Participant's election to exercise the Option;
- (b) the number of Shares of Common Stock being purchased;
- (c) any restrictions imposed on the Shares; and
- (d) any representations, warranties and agreements regarding the Participant's investment intent and access to information as may be required by the Company to comply with applicable securities laws.

If someone other than the Participant exercises the Option, then such person must submit documentation reasonably acceptable to the Company verifying that such person has the legal right to exercise the Option.

4.2 **Payment of Exercise Price.** The entire Exercise Price of the Option shall be payable in full at the time of exercise to the extent permitted by applicable statutes and regulations, either:

- (a) in cash or by certified or bank check at the time the Option is exercised;
- (b) by delivery to the Company of other Shares of Common Stock, duly endorsed for transfer to the Company, with a Fair Market Value on the date of delivery equal to the Exercise Price (or portion thereof) due for the number of Shares being acquired, or by means of attestation whereby the Participant identifies for delivery specific Shares that have a Fair Market Value on the date of attestation equal to the Exercise Price (or portion thereof) and receives a number of Shares equal to the difference between the number of Shares thereby purchased and the number of identified attestation Shares (a “**Stock for Stock Exchange**”);
- (c) through a “cashless exercise program” established with a broker;
- (d) by reduction in the number of Shares otherwise deliverable upon exercise of such Option with a Fair Market Value equal to the aggregate Exercise Price at the time of exercise;
- (e) by any combination of the foregoing methods; or
- (f) in any other form of legal consideration that may be acceptable to the Committee.

4.3 **Withholding.** Prior to the issuance of Shares upon the exercise of the Option, the Participant must make arrangements satisfactory to the Company to pay or provide for any applicable federal, state and local withholding obligations of the Company. The Participant may satisfy any federal, state or local tax withholding obligation relating to the exercise of the Option by any of the following means:

- (a) tendering a cash payment;
- (b) authorizing the Company to withhold Shares of Common Stock from the Shares of Common Stock otherwise issuable to the Participant as a result of the exercise of the Option; provided, however, that no Shares of Common Stock are withheld with a value exceeding the maximum amount of tax required to be withheld by law; or
- (c) delivering to the Company previously owned and unencumbered Shares of Common Stock.

The Company has the right to withhold from any compensation paid to the Participant.

4.4 **Issuance of Shares.** Provided that the Exercise Agreement and payment are in form and substance satisfactory to the Company, the Company shall issue the Shares of Common Stock registered in the name of the Participant, the Participant’s authorized assignee, or the Participant’s legal representative which shall be evidenced by stock certificates representing the Shares with the appropriate legends affixed thereto, appropriate entry on the books of the Company or of a duly authorized transfer agent, or other appropriate means as determined by the Company.

5. **No Right to Continued Employment; No Rights as Shareholder.** Neither the Plan nor this Agreement shall confer upon the Participant any right to be retained in any position, as an Employee, Consultant or Director of the Company. Further, nothing in the Plan or this Agreement shall be construed to limit the discretion of the Company to terminate the Participant's employment or service with the Company at any time, with or without Cause. The Participant shall not have any rights as a shareholder with respect to any Shares of Common Stock subject to the Option unless and until certificates representing the Shares have been issued by the Company to the holder of such Shares, or the Shares have otherwise been recorded on the books of the Company or of a duly authorized transfer agent as owned by such holder.

6. **Transferability.** The Option is only transferable by will or the laws of descent and distribution or in accordance with the limited conditions set forth in Section 9.3(b) of the Plan.. No assignment or transfer of the Option, or the rights represented thereby, whether voluntary or involuntary, by operation of law or otherwise (except to a designated beneficiary, upon death, by will or the laws of descent or distribution or pursuant to Section 9.3(b) of the Plan) will vest in the assignee or transferee any interest or right herein whatsoever, but immediately upon such assignment or transfer the Option will terminate and become of no further effect.

7. **Change in Control – Cash-Out.** In the event of a Change in Control, the Committee may, in its discretion and upon at least ten (10) days' advance notice to the Participant, cancel the Option and pay to the Participant the value of the Option based upon the price per Share of Common Stock received or to be received by other shareholders of the Company in the event. Notwithstanding the foregoing, if at the time of a Change in Control the Exercise Price of the Option equals or exceeds the price paid for a Share of Common Stock in connection with the Change in Control, the Committee may cancel the Option without the payment of consideration therefor.

8. **Adjustments.** The Shares of Common Stock subject to the Option may be adjusted or terminated in any manner as contemplated by the Plan.

9. **Tax Liability and Withholding.** Notwithstanding any action the Company takes with respect to any or all income tax, social insurance, payroll tax, or other tax-related withholding ("Tax-Related Items"), the ultimate liability for all Tax-Related Items is and remains the Participant's responsibility and the Company (a) makes no representation or undertakings regarding the treatment of any Tax-Related Items in connection with the grant, vesting, or exercise of the Option or the subsequent sale of any Shares acquired on exercise; and (b) does not commit to structure the Option to reduce or eliminate the Participant's liability for Tax-Related Items.

10. **Compliance with Law.** The exercise of the Option and the issuance and transfer of Shares of Common Stock shall be subject to compliance by the Company and the Participant with all applicable requirements of federal and state securities laws and with all applicable requirements of any stock exchange on which the Company's Shares of Common Stock may be listed. No Shares of Common Stock shall be issued pursuant to this Option unless and until any then applicable requirements of state or federal laws and regulatory agencies have been fully complied with to the satisfaction of the Company and its counsel. The Participant understands that the Company is under no obligation to register the Shares with the Securities and Exchange Commission, any state securities commission or any stock exchange to effect such compliance.

11. **Notices.** Any notice required to be delivered to the Company under this Agreement shall be in writing and addressed to the Secretary of the Company at the Company's principal corporate offices. Any notice required to be delivered to the Participant under this Agreement shall be in writing and addressed to the Participant at the Participant's address as shown in the records of the Company. Either party may designate another address in writing (or by such other method approved by the Company) from time to time.

12. **Governing Law.** This Agreement will be construed and interpreted in accordance with the laws of the State of Delaware without regard to conflict of law principles.

13. **Interpretation.** Any dispute regarding the interpretation of this Agreement shall be submitted by the Participant or the Company to the Committee for review. The resolution of such dispute by the Committee shall be final and binding on the Participant and the Company.

14. **Options Subject to Plan.** This Agreement is subject to the Plan as approved by the Company's shareholders. The terms and provisions of the Plan as it may be amended from time to time are hereby incorporated herein by reference. In the event of a conflict between any term or provision contained herein and a term or provision of the Plan, the applicable terms and provisions of the Plan will govern and prevail. Notwithstanding the foregoing or anything in this Agreement or the Plan to the contrary, if the Plan is not approved by the Company's stockholders within 12 months of the Board's initial adoption of the Plan, this Agreement will be deemed to be outside the Plan and will otherwise remain in full force and effect.

15. **Successors and Assigns.** The Company may assign any of its rights under this Agreement. This Agreement will be binding upon and inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth herein, this Agreement will be binding upon the Participant and the Participant's beneficiaries, executors, administrators and the person(s) to whom this Agreement may be transferred by will or the laws of descent or distribution.

16. **Severability.** The invalidity or unenforceability of any provision of the Plan or this Agreement shall not affect the validity or enforceability of any other provision of the Plan or this Agreement, and each provision of the Plan and this Agreement shall be severable and enforceable to the extent permitted by law.

17. **Discretionary Nature of Plan.** The Plan is discretionary and may be amended, cancelled or terminated by the Company at any time, in its discretion. The grant of the Option in this Agreement does not create any contractual right or other right to receive any Options or other Awards in the future. Future Awards, if any, will be at the sole discretion of the Company. Any amendment, modification, or termination of the Plan shall not constitute a change or impairment of the terms and conditions of the Participant's employment with the Company.

18. **Amendment.** The Committee has the right to amend, alter, suspend, discontinue or cancel the Option, prospectively or retroactively; provided, that, no such amendment shall adversely affect the Participant's material rights under this Agreement without the Participant's consent.

19. **No Impact on Other Benefits.** The value of the Participant's Option is not part of his or her normal or expected compensation for purposes of calculating any severance, retirement, welfare, insurance or similar employee benefit.

20. **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which together will constitute one and the same instrument. Counterpart signature pages to this Agreement transmitted by facsimile transmission, by electronic mail in portable document format (.pdf), or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing an original signature.

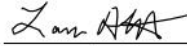
21. **Acceptance.** The Participant hereby acknowledges receipt of a copy of the Plan and this Agreement. The Participant has read and understands the terms and provisions thereof, and accepts the Option subject to all of the terms and conditions of the Plan and this Agreement. The Participant acknowledges that there may be adverse tax consequences upon exercise of the Option or disposition of the underlying Shares and that the Participant should consult a tax advisor prior to such exercise or disposition.

****Signature Page to Follow****

Signature Page to Non-Qualified Stock Option Agreement

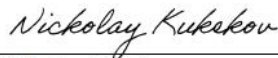
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

BIORESTORATIVE THERAPIES, INC.:



Lance Alstodt
President & CEO

PARTICIPANT:



Nickolay Kukekov

**NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN**

This Non-Qualified Stock Option Award Agreement (this "**Agreement**") is made and entered into as of November 4, 2021 by and between BioRestorative Therapies, Inc., a Delaware corporation (the "**Company**"), and Patrick Williams (the "**Participant**").

Grant Date: November 4, 2021
Exercise Price per Share: \$13.50
Number of Option Shares: 10,490
Expiration Date: November 4, 2031

1. Grant of Option.

1.1. **Grant; Type of Option.** The Company hereby grants to the Participant an option (the "**Option**") to purchase the number of Shares of Common Stock of the Company equal to the number of Option Shares set forth above. The Option is being granted pursuant to the terms of the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the "**Plan**"). The Option is intended to be a Non-Qualified Stock Option and *not* an Incentive Stock Option within the meaning of Section 422 of the Code.

1.2. **Consideration; Subject to Plan.** The grant of the Option is made in consideration of the services to be rendered by the Participant to the Company and is subject to the terms and conditions of the Plan. Capitalized terms used but not otherwise defined herein have the meanings given to them in the Plan.

2. Exercise Period; Vesting.

2.1 **Vesting Schedule.** The Option will become vested and exercisable in eight equal quarterly installments (at a rate of 1/8 per quarter) with the first quarterly installment vesting three months after the Grant Date and continuing every three months thereafter until fully vested on the two-year anniversary of the Grant Date.

Upon the Participant's Termination of Service for any reason, the unvested portion of the Option will be forfeited and will not be exercisable.

2.2 **Expiration.** The Option will expire on the Expiration Date set forth above, or earlier as provided in this Agreement or the Plan. The Expiration Date shall not be more than ten years from the Grant Date (or, if the Option is being granted to a Greater Than 10% Stockholder, not more than five years from the Grant Date). To the extent the Expiration Date listed above is inconsistent with this paragraph, this paragraph shall control.

3. **Termination of Service.**

3.1 **Termination for Reasons Other Than Cause, Death, Disability.** If the Participant has a Termination of Service for any reason other than Cause, death or Disability, the Participant may exercise the vested portion of the Option, but only within such period of time ending on the earlier of: (a) the date three months following the Participant's Termination of Service, or (b) the Expiration Date.

3.2 **Termination for Cause.** If the Participant has a Termination of Service for Cause, the Option (whether vested or unvested) shall immediately terminate and cease to be exercisable.

3.3 **Termination due to Disability.** If the Participant has a Termination of Service as a result of the Participant's Disability, the Participant may exercise the vested portion of the Option, but only within such period of time ending on the earlier of: (a) the date 12 months following the Participant's Termination of Service or (b) the Expiration Date.

3.4 **Termination due to Death.** If the Participant has a Termination of Service as a result of the Participant's death, the vested portion of the Option may be exercised by the Participant's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by the person designated to exercise the Option upon the Participant's death, but only within the time period ending on the earlier of: (a) the date 12 months following the Participant's Termination of Service, or (b) the Expiration Date.

4. **Manner of Exercise.**

4.1 **Election to Exercise.** To exercise the Option, the Participant (or in the case of exercise after the Participant's death or incapacity, the Participant's executor, administrator, heir or legatee, as the case may be) must deliver to the Company an executed stock option exercise agreement in such form as is approved by the Committee from time to time (the "**Exercise Agreement**"), which shall set forth, inter alia:

- (a) the Participant's election to exercise the Option;
- (b) the number of Shares of Common Stock being purchased;
- (c) any restrictions imposed on the Shares; and
- (d) any representations, warranties and agreements regarding the Participant's investment intent and access to information as may be required by the Company to comply with applicable securities laws.

If someone other than the Participant exercises the Option, then such person must submit documentation reasonably acceptable to the Company verifying that such person has the legal right to exercise the Option.

4.2 **Payment of Exercise Price.** The entire Exercise Price of the Option shall be payable in full at the time of exercise to the extent permitted by applicable statutes and regulations, either:

- (a) in cash or by certified or bank check at the time the Option is exercised;
- (b) by delivery to the Company of other Shares of Common Stock, duly endorsed for transfer to the Company, with a Fair Market Value on the date of delivery equal to the Exercise Price (or portion thereof) due for the number of Shares being acquired, or by means of attestation whereby the Participant identifies for delivery specific Shares that have a Fair Market Value on the date of attestation equal to the Exercise Price (or portion thereof) and receives a number of Shares equal to the difference between the number of Shares thereby purchased and the number of identified attestation Shares (a “**Stock for Stock Exchange**”);
- (c) through a “cashless exercise program” established with a broker;
- (d) by reduction in the number of Shares otherwise deliverable upon exercise of such Option with a Fair Market Value equal to the aggregate Exercise Price at the time of exercise;
- (e) by any combination of the foregoing methods; or
- (f) in any other form of legal consideration that may be acceptable to the Committee.

4.3 **Withholding.** Prior to the issuance of Shares upon the exercise of the Option, the Participant must make arrangements satisfactory to the Company to pay or provide for any applicable federal, state and local withholding obligations of the Company. The Participant may satisfy any federal, state or local tax withholding obligation relating to the exercise of the Option by any of the following means:

- (a) tendering a cash payment;
- (b) authorizing the Company to withhold Shares of Common Stock from the Shares of Common Stock otherwise issuable to the Participant as a result of the exercise of the Option; provided, however, that no Shares of Common Stock are withheld with a value exceeding the maximum amount of tax required to be withheld by law; or
- (c) delivering to the Company previously owned and unencumbered Shares of Common Stock.

The Company has the right to withhold from any compensation paid to the Participant.

4.4 **Issuance of Shares.** Provided that the Exercise Agreement and payment are in form and substance satisfactory to the Company, the Company shall issue the Shares of Common Stock registered in the name of the Participant, the Participant’s authorized assignee, or the Participant’s legal representative which shall be evidenced by stock certificates representing the Shares with the appropriate legends affixed thereto, appropriate entry on the books of the Company or of a duly authorized transfer agent, or other appropriate means as determined by the Company.

5. **No Right to Continued Employment; No Rights as Shareholder.** Neither the Plan nor this Agreement shall confer upon the Participant any right to be retained in any position, as an Employee, Consultant or Director of the Company. Further, nothing in the Plan or this Agreement shall be construed to limit the discretion of the Company to terminate the Participant's employment or service with the Company at any time, with or without Cause. The Participant shall not have any rights as a shareholder with respect to any Shares of Common Stock subject to the Option unless and until certificates representing the Shares have been issued by the Company to the holder of such Shares, or the Shares have otherwise been recorded on the books of the Company or of a duly authorized transfer agent as owned by such holder.

6. **Transferability.** The Option is only transferable by will or the laws of descent and distribution or in accordance with the limited conditions set forth in Section 9.3(b) of the Plan.. No assignment or transfer of the Option, or the rights represented thereby, whether voluntary or involuntary, by operation of law or otherwise (except to a designated beneficiary, upon death, by will or the laws of descent or distribution or pursuant to Section 9.3(b) of the Plan) will vest in the assignee or transferee any interest or right herein whatsoever, but immediately upon such assignment or transfer the Option will terminate and become of no further effect.

7. **Change in Control – Cash-Out.** In the event of a Change in Control, the Committee may, in its discretion and upon at least ten (10) days' advance notice to the Participant, cancel the Option and pay to the Participant the value of the Option based upon the price per Share of Common Stock received or to be received by other shareholders of the Company in the event. Notwithstanding the foregoing, if at the time of a Change in Control the Exercise Price of the Option equals or exceeds the price paid for a Share of Common Stock in connection with the Change in Control, the Committee may cancel the Option without the payment of consideration therefor.

8. **Adjustments.** The Shares of Common Stock subject to the Option may be adjusted or terminated in any manner as contemplated by the Plan.

9. **Tax Liability and Withholding.** Notwithstanding any action the Company takes with respect to any or all income tax, social insurance, payroll tax, or other tax-related withholding ("Tax-Related Items"), the ultimate liability for all Tax-Related Items is and remains the Participant's responsibility and the Company (a) makes no representation or undertakings regarding the treatment of any Tax-Related Items in connection with the grant, vesting, or exercise of the Option or the subsequent sale of any Shares acquired on exercise; and (b) does not commit to structure the Option to reduce or eliminate the Participant's liability for Tax-Related Items.

10. **Compliance with Law.** The exercise of the Option and the issuance and transfer of Shares of Common Stock shall be subject to compliance by the Company and the Participant with all applicable requirements of federal and state securities laws and with all applicable requirements of any stock exchange on which the Company's Shares of Common Stock may be listed. No Shares of Common Stock shall be issued pursuant to this Option unless and until any then applicable requirements of state or federal laws and regulatory agencies have been fully complied with to the satisfaction of the Company and its counsel. The Participant understands that the Company is under no obligation to register the Shares with the Securities and Exchange Commission, any state securities commission or any stock exchange to effect such compliance.

11. **Notices.** Any notice required to be delivered to the Company under this Agreement shall be in writing and addressed to the Secretary of the Company at the Company's principal corporate offices. Any notice required to be delivered to the Participant under this Agreement shall be in writing and addressed to the Participant at the Participant's address as shown in the records of the Company. Either party may designate another address in writing (or by such other method approved by the Company) from time to time.

12. **Governing Law.** This Agreement will be construed and interpreted in accordance with the laws of the State of Delaware without regard to conflict of law principles.

13. **Interpretation.** Any dispute regarding the interpretation of this Agreement shall be submitted by the Participant or the Company to the Committee for review. The resolution of such dispute by the Committee shall be final and binding on the Participant and the Company.

14. **Options Subject to Plan.** This Agreement is subject to the Plan as approved by the Company's shareholders. The terms and provisions of the Plan as it may be amended from time to time are hereby incorporated herein by reference. In the event of a conflict between any term or provision contained herein and a term or provision of the Plan, the applicable terms and provisions of the Plan will govern and prevail. Notwithstanding the foregoing or anything in this Agreement or the Plan to the contrary, if the Plan is not approved by the Company's stockholders within 12 months of the Board's initial adoption of the Plan, this Agreement will be deemed to be outside the Plan and will otherwise remain in full force and effect.

15. **Successors and Assigns.** The Company may assign any of its rights under this Agreement. This Agreement will be binding upon and inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth herein, this Agreement will be binding upon the Participant and the Participant's beneficiaries, executors, administrators and the person(s) to whom this Agreement may be transferred by will or the laws of descent or distribution.

16. **Severability.** The invalidity or unenforceability of any provision of the Plan or this Agreement shall not affect the validity or enforceability of any other provision of the Plan or this Agreement, and each provision of the Plan and this Agreement shall be severable and enforceable to the extent permitted by law.

17. **Discretionary Nature of Plan.** The Plan is discretionary and may be amended, cancelled or terminated by the Company at any time, in its discretion. The grant of the Option in this Agreement does not create any contractual right or other right to receive any Options or other Awards in the future. Future Awards, if any, will be at the sole discretion of the Company. Any amendment, modification, or termination of the Plan shall not constitute a change or impairment of the terms and conditions of the Participant's employment with the Company.

18. **Amendment.** The Committee has the right to amend, alter, suspend, discontinue or cancel the Option, prospectively or retroactively; provided, that, no such amendment shall adversely affect the Participant's material rights under this Agreement without the Participant's consent.

19. **No Impact on Other Benefits.** The value of the Participant's Option is not part of his or her normal or expected compensation for purposes of calculating any severance, retirement, welfare, insurance or similar employee benefit.

20. **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which together will constitute one and the same instrument. Counterpart signature pages to this Agreement transmitted by facsimile transmission, by electronic mail in portable document format (.pdf), or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing an original signature.

21. **Acceptance.** The Participant hereby acknowledges receipt of a copy of the Plan and this Agreement. The Participant has read and understands the terms and provisions thereof, and accepts the Option subject to all of the terms and conditions of the Plan and this Agreement. The Participant acknowledges that there may be adverse tax consequences upon exercise of the Option or disposition of the underlying Shares and that the Participant should consult a tax advisor prior to such exercise or disposition.

****Signature Page to Follow****

****Signature Page to Non-Qualified Stock Option Agreement****

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

BIORESTORATIVE THERAPIES, INC.:

Lance Alstodt
President & CEO

PARTICIPANT:

Patrick Williams

NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN

This Non-Qualified Stock Option Award Agreement (this “**Agreement**”) is made and entered into as of November 4, 2021 by and between BioRestorative Therapies, Inc., a Delaware corporation (the “**Company**”), and Dave Rosa (the “**Participant**”).

Grant Date: November 4, 2021
Exercise Price per Share: \$13.50
Number of Option Shares: 10,490
Expiration Date: November 4, 2031

1. **Grant of Option.**

1.1. **Grant; Type of Option.** The Company hereby grants to the Participant an option (the “**Option**”) to purchase the number of Shares of Common Stock of the Company equal to the number of Option Shares set forth above. The Option is being granted pursuant to the terms of the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the “**Plan**”). The Option is intended to be a Non-Qualified Stock Option and *not* an Incentive Stock Option within the meaning of Section 422 of the Code.

1.2. **Consideration; Subject to Plan.** The grant of the Option is made in consideration of the services to be rendered by the Participant to the Company and is subject to the terms and conditions of the Plan. Capitalized terms used but not otherwise defined herein have the meanings given to them in the Plan.

2. **Exercise Period; Vesting.**

2.1 **Vesting Schedule.** The Option will become vested and exercisable in eight equal quarterly installments (at a rate of 1/8 per quarter) with the first quarterly installment vesting three months after the Grant Date and continuing every three months thereafter until fully vested on the two-year anniversary of the Grant Date.

Upon the Participant’s Termination of Service for any reason, the unvested portion of the Option will be forfeited and will not be exercisable.

2.2 **Expiration.** The Option will expire on the Expiration Date set forth above, or earlier as provided in this Agreement or the Plan. The Expiration Date shall not be more than ten years from the Grant Date (or, if the Option is being granted to a Greater Than 10% Stockholder, not more than five years from the Grant Date). To the extent the Expiration Date listed above is inconsistent with this paragraph, this paragraph shall control.

3. **Termination of Service.**

3.1 **Termination for Reasons Other Than Cause, Death, Disability.** If the Participant has a Termination of Service for any reason other than Cause, death or Disability, the Participant may exercise the vested portion of the Option, but only within such period of time ending on the earlier of: (a) the date three months following the Participant's Termination of Service, or (b) the Expiration Date.

3.2 **Termination for Cause.** If the Participant has a Termination of Service for Cause, the Option (whether vested or unvested) shall immediately terminate and cease to be exercisable.

3.3 **Termination due to Disability.** If the Participant has a Termination of Service as a result of the Participant's Disability, the Participant may exercise the vested portion of the Option, but only within such period of time ending on the earlier of: (a) the date 12 months following the Participant's Termination of Service or (b) the Expiration Date.

3.4 **Termination due to Death.** If the Participant has a Termination of Service as a result of the Participant's death, the vested portion of the Option may be exercised by the Participant's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by the person designated to exercise the Option upon the Participant's death, but only within the time period ending on the earlier of: (a) the date 12 months following the Participant's Termination of Service, or (b) the Expiration Date.

4. **Manner of Exercise.**

4.1 **Election to Exercise.** To exercise the Option, the Participant (or in the case of exercise after the Participant's death or incapacity, the Participant's executor, administrator, heir or legatee, as the case may be) must deliver to the Company an executed stock option exercise agreement in such form as is approved by the Committee from time to time (the "**Exercise Agreement**"), which shall set forth, inter alia:

- (a) the Participant's election to exercise the Option;
- (b) the number of Shares of Common Stock being purchased;
- (c) any restrictions imposed on the Shares; and
- (d) any representations, warranties and agreements regarding the Participant's investment intent and access to information as may be required by the Company to comply with applicable securities laws.

If someone other than the Participant exercises the Option, then such person must submit documentation reasonably acceptable to the Company verifying that such person has the legal right to exercise the Option.

4.2 **Payment of Exercise Price.** The entire Exercise Price of the Option shall be payable in full at the time of exercise to the extent permitted by applicable statutes and regulations, either:

- (a) in cash or by certified or bank check at the time the Option is exercised;
- (b) by delivery to the Company of other Shares of Common Stock, duly endorsed for transfer to the Company, with a Fair Market Value on the date of delivery equal to the Exercise Price (or portion thereof) due for the number of Shares being acquired, or by means of attestation whereby the Participant identifies for delivery specific Shares that have a Fair Market Value on the date of attestation equal to the Exercise Price (or portion thereof) and receives a number of Shares equal to the difference between the number of Shares thereby purchased and the number of identified attestation Shares (a “**Stock for Stock Exchange**”);
- (c) through a “cashless exercise program” established with a broker;
- (d) by reduction in the number of Shares otherwise deliverable upon exercise of such Option with a Fair Market Value equal to the aggregate Exercise Price at the time of exercise;
- (e) by any combination of the foregoing methods; or
- (f) in any other form of legal consideration that may be acceptable to the Committee.

4.3 **Withholding.** Prior to the issuance of Shares upon the exercise of the Option, the Participant must make arrangements satisfactory to the Company to pay or provide for any applicable federal, state and local withholding obligations of the Company. The Participant may satisfy any federal, state or local tax withholding obligation relating to the exercise of the Option by any of the following means:

- (a) tendering a cash payment;
- (b) authorizing the Company to withhold Shares of Common Stock from the Shares of Common Stock otherwise issuable to the Participant as a result of the exercise of the Option; provided, however, that no Shares of Common Stock are withheld with a value exceeding the maximum amount of tax required to be withheld by law; or
- (c) delivering to the Company previously owned and unencumbered Shares of Common Stock.

The Company has the right to withhold from any compensation paid to the Participant.

4.4 **Issuance of Shares.** Provided that the Exercise Agreement and payment are in form and substance satisfactory to the Company, the Company shall issue the Shares of Common Stock registered in the name of the Participant, the Participant’s authorized assignee, or the Participant’s legal representative which shall be evidenced by stock certificates representing the Shares with the appropriate legends affixed thereto, appropriate entry on the books of the Company or of a duly authorized transfer agent, or other appropriate means as determined by the Company.

5. **No Right to Continued Employment; No Rights as Shareholder.** Neither the Plan nor this Agreement shall confer upon the Participant any right to be retained in any position, as an Employee, Consultant or Director of the Company. Further, nothing in the Plan or this Agreement shall be construed to limit the discretion of the Company to terminate the Participant's employment or service with the Company at any time, with or without Cause. The Participant shall not have any rights as a shareholder with respect to any Shares of Common Stock subject to the Option unless and until certificates representing the Shares have been issued by the Company to the holder of such Shares, or the Shares have otherwise been recorded on the books of the Company or of a duly authorized transfer agent as owned by such holder.

6. **Transferability.** The Option is only transferable by will or the laws of descent and distribution or in accordance with the limited conditions set forth in Section 9.3(b) of the Plan.. No assignment or transfer of the Option, or the rights represented thereby, whether voluntary or involuntary, by operation of law or otherwise (except to a designated beneficiary, upon death, by will or the laws of descent or distribution or pursuant to Section 9.3(b) of the Plan) will vest in the assignee or transferee any interest or right herein whatsoever, but immediately upon such assignment or transfer the Option will terminate and become of no further effect.

7. **Change in Control – Cash-Out.** In the event of a Change in Control, the Committee may, in its discretion and upon at least ten (10) days' advance notice to the Participant, cancel the Option and pay to the Participant the value of the Option based upon the price per Share of Common Stock received or to be received by other shareholders of the Company in the event. Notwithstanding the foregoing, if at the time of a Change in Control the Exercise Price of the Option equals or exceeds the price paid for a Share of Common Stock in connection with the Change in Control, the Committee may cancel the Option without the payment of consideration therefor.

8. **Adjustments.** The Shares of Common Stock subject to the Option may be adjusted or terminated in any manner as contemplated by the Plan.

9. **Tax Liability and Withholding.** Notwithstanding any action the Company takes with respect to any or all income tax, social insurance, payroll tax, or other tax-related withholding ("Tax-Related Items"), the ultimate liability for all Tax-Related Items is and remains the Participant's responsibility and the Company (a) makes no representation or undertakings regarding the treatment of any Tax-Related Items in connection with the grant, vesting, or exercise of the Option or the subsequent sale of any Shares acquired on exercise; and (b) does not commit to structure the Option to reduce or eliminate the Participant's liability for Tax-Related Items.

10. **Compliance with Law.** The exercise of the Option and the issuance and transfer of Shares of Common Stock shall be subject to compliance by the Company and the Participant with all applicable requirements of federal and state securities laws and with all applicable requirements of any stock exchange on which the Company's Shares of Common Stock may be listed. No Shares of Common Stock shall be issued pursuant to this Option unless and until any then applicable requirements of state or federal laws and regulatory agencies have been fully complied with to the satisfaction of the Company and its counsel. The Participant understands that the Company is under no obligation to register the Shares with the Securities and Exchange Commission, any state securities commission or any stock exchange to effect such compliance.

11. **Notices.** Any notice required to be delivered to the Company under this Agreement shall be in writing and addressed to the Secretary of the Company at the Company's principal corporate offices. Any notice required to be delivered to the Participant under this Agreement shall be in writing and addressed to the Participant at the Participant's address as shown in the records of the Company. Either party may designate another address in writing (or by such other method approved by the Company) from time to time.

12. **Governing Law.** This Agreement will be construed and interpreted in accordance with the laws of the State of Delaware without regard to conflict of law principles.

13. **Interpretation.** Any dispute regarding the interpretation of this Agreement shall be submitted by the Participant or the Company to the Committee for review. The resolution of such dispute by the Committee shall be final and binding on the Participant and the Company.

14. **Options Subject to Plan.** This Agreement is subject to the Plan as approved by the Company's shareholders. The terms and provisions of the Plan as it may be amended from time to time are hereby incorporated herein by reference. In the event of a conflict between any term or provision contained herein and a term or provision of the Plan, the applicable terms and provisions of the Plan will govern and prevail. Notwithstanding the foregoing or anything in this Agreement or the Plan to the contrary, if the Plan is not approved by the Company's stockholders within 12 months of the Board's initial adoption of the Plan, this Agreement will be deemed to be outside the Plan and will otherwise remain in full force and effect.

15. **Successors and Assigns.** The Company may assign any of its rights under this Agreement. This Agreement will be binding upon and inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth herein, this Agreement will be binding upon the Participant and the Participant's beneficiaries, executors, administrators and the person(s) to whom this Agreement may be transferred by will or the laws of descent or distribution.

16. **Severability.** The invalidity or unenforceability of any provision of the Plan or this Agreement shall not affect the validity or enforceability of any other provision of the Plan or this Agreement, and each provision of the Plan and this Agreement shall be severable and enforceable to the extent permitted by law.

17. **Discretionary Nature of Plan.** The Plan is discretionary and may be amended, cancelled or terminated by the Company at any time, in its discretion. The grant of the Option in this Agreement does not create any contractual right or other right to receive any Options or other Awards in the future. Future Awards, if any, will be at the sole discretion of the Company. Any amendment, modification, or termination of the Plan shall not constitute a change or impairment of the terms and conditions of the Participant's employment with the Company.

18. **Amendment.** The Committee has the right to amend, alter, suspend, discontinue or cancel the Option, prospectively or retroactively; provided, that, no such amendment shall adversely affect the Participant's material rights under this Agreement without the Participant's consent.

19. **No Impact on Other Benefits.** The value of the Participant's Option is not part of his or her normal or expected compensation for purposes of calculating any severance, retirement, welfare, insurance or similar employee benefit.

20. **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which together will constitute one and the same instrument. Counterpart signature pages to this Agreement transmitted by facsimile transmission, by electronic mail in portable document format (.pdf), or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing an original signature.

21. **Acceptance.** The Participant hereby acknowledges receipt of a copy of the Plan and this Agreement. The Participant has read and understands the terms and provisions thereof, and accepts the Option subject to all of the terms and conditions of the Plan and this Agreement. The Participant acknowledges that there may be adverse tax consequences upon exercise of the Option or disposition of the underlying Shares and that the Participant should consult a tax advisor prior to such exercise or disposition.

****Signature Page to Follow****

****Signature Page to Non-Qualified Stock Option Agreement****

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

BIORESTORATIVE THERAPIES, INC.:

Lance Alstodt
President & CEO

PARTICIPANT:

Dave Rosa

**AMENDMENT NO. 1 TO
NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN**

This Amendment No. 1 to Non-Qualified Stock Option Award Agreement (this “**Amendment**”) is made and entered into as of December 10, 2021 by and between BioRestorative Therapies, Inc., a Delaware corporation (the “**Company**”), and Lance Alstodt (the “**Participant**”).

RECITALS

- A. The Company granted to the Participant an option to purchase 42,059 shares of the Common Stock of the Company pursuant to the terms of a Non-Qualified Stock Option Award Agreement (the “**Option**”) under the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the “**Plan**”) on November 4, 2021.
- B. The Company wishes to amend the Exercise Price per Share in the Option to reflect the current Fair Market Value.
- C. The Company and the Participant wish to enter into this Amendment, pursuant to Section 18 of the Option, to amend and modify the Option by the terms of this Amendment and preserve the remaining terms of the Option without modification or amendment.
- D. This Amendment is subject to stockholder approval of an amendment to the Plan which grants authority to the Board of Directors of the Company or a committee thereof to reduce the Exercise Price per Share in the Option (“**Stockholder Approval**”).

AMENDMENT

In consideration of the above recitals, which are incorporated herein by reference, and the promises set forth in this Amendment and the Option, and for other good and valuable consideration, the nature and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

- 1. The Exercise Price per Share is hereby deleted and replaced with the following:
Exercise Price per Share: \$5.08
- 2. The foregoing change to the Option is subject to Stockholder Approval.
- 3. Except as otherwise amended by this Amendment, all other provisions of the Option will remain unchanged and in full force and effect.

Signature Page to Follow

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first above written.

BIORESTORATIVE THERAPIES, INC.

By: _____
Francisco Silva
VP of Research and Development

PARTICIPANT

Lance Alstodt

****Signature Page to Amendment No. 1 to Non-Qualified Stock Option Award Agreement****

**AMENDMENT NO. 1 TO
NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN**

This Amendment No. 1 to Non-Qualified Stock Option Award Agreement (this “**Amendment**”) is made and entered into as of December 10, 2021 by and between BioRestorative Therapies, Inc., a Delaware corporation (the “**Company**”), and Francisco Silva (the “**Participant**”).

RECITALS

- A. The Company granted to the Participant an option to purchase 42,059 shares of the Common Stock of the Company pursuant to the terms of a Non-Qualified Stock Option Award Agreement (the “**Option**”) under the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the “**Plan**”) on November 4, 2021.
- B. The Company wishes to amend the Exercise Price per Share in the Option to reflect the current Fair Market Value.
- C. The Company and the Participant wish to enter into this Amendment, pursuant to Section 18 of the Option, to amend and modify the Option by the terms of this Amendment and preserve the remaining terms of the Option without modification or amendment.
- D. This Amendment is subject to stockholder approval of an amendment to the Plan which grants authority to the Board of Directors of the Company or a committee thereof to reduce the Exercise Price per Share in the Option (“**Stockholder Approval**”).

AMENDMENT

In consideration of the above recitals, which are incorporated herein by reference, and the promises set forth in this Amendment and the Option, and for other good and valuable consideration, the nature and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

- 1. The Exercise Price per Share is hereby deleted and replaced with the following:
Exercise Price per Share: \$5.08
- 2. The foregoing change to the Option is subject to Stockholder Approval.
- 3. Except as otherwise amended by this Amendment, all other provisions of the Option will remain unchanged and in full force and effect.

Signature Page to Follow

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first above written.

BIORESTORATIVE THERAPIES, INC.

By: _____
Lance Alstodt
Chief Executive Officer

PARTICIPANT

Francisco Silva

****Signature Page to Amendment No. 1 to Non-Qualified Stock Option Award Agreement****

COMMON STOCK PURCHASE WARRANT

BIORESTORATIVE THERAPIES, INC.

Warrant Shares: 2,645,000
CUSIP: 090655135

Initial Exercise Date: November 9, 2021

THIS COMMON STOCK PURCHASE WARRANT (the “Warrant”) certifies that, for value received, CEDE & CO. or its assigns (the “Holder”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the “Initial Exercise Date”) and on or prior to 5:00 p.m. (New York City time) on November 9, 2026 (the “Termination Date”) but not thereafter, to subscribe for and purchase from BioRestorative Therapies, Inc., a Delaware corporation (the “Company”), up to 2,645,000 shares (as subject to adjustment hereunder, the “Warrant Shares”) of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee (“DTC”) shall initially be the sole registered holder of this Warrant, subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

“Affiliate” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“Bid Price” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is quoted on the OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the OTC Markets Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to “stay at home”, “shelter-in-place”, “non-essential employee” or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Registration Statement” means the Company’s registration statement on Form S-1 (File No. 333-258611).

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Subsidiary” means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Trading Day” means a day on which the Common Stock is traded on a Trading Market.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transfer Agent” means Transshare Corporation, the current transfer agent of the Company, with a mailing address of Bayside Center 1, 17755 North US Highway 19, Suite 140, Clearwater, Florida 33764, and any successor transfer agent of the Company.

“Underwriting Agreement” means the amended and restated underwriting agreement, dated as of November 8, 2021, among the Company and Roth Capital Partners, LLC as representative of the underwriters named therein, as amended, modified or supplemented from time to time in accordance with its terms.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted bid average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not the Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the OTC Markets Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Warrant Agency Agreement” means that certain warrant agency agreement, dated on or about the Initial Exercise Date, by and between the Company and the Warrant Agent.

“Warrant Agent” means the Transfer Agent and any successor warrant agent of the Company.

“Warrants” means this Warrant and other Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

Notwithstanding the foregoing in this Section 2(a), a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be **\$10.00**, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing $[(A-B) (X)]$ by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, on the Termination Date, if on such date there is no effective registration statement registering, or the prospectus contained therein is not available for, the issuance of the Warrant Shares to the Holder, then this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

- i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$5 per Trading Day (increasing to \$10 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered on or prior to 12:00 p.m. (New York City time) on the Initial Exercise Date, which may be delivered at any time after the time of execution of the Underwriting Agreement, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date and the Initial Exercise Date shall be the Warrant Share Delivery Date for purposes hereunder, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by such Warrant Share Delivery Date.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all costs of any legal opinion required by the Company's transfer agent and any Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it is acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or reclassification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder’s option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company’s control, including not approved by the Company’s Board of Directors, Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. “Black Scholes Value” means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the “OV” function on Bloomberg, L.P. (“Bloomberg”) determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the greater of (i) the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (ii) the highest VWAP during the period beginning on the Trading Day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder’s request pursuant to this Section 3(d) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within five Business Days of the Holder’s election (or, if later, on the date of consummation of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

g) Voluntary Adjustment By Company. Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant, subject to the prior written consent of the Holder, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with applicable securities laws, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depository), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then such action may be taken or such right may be exercised on the next succeeding Trading Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at 40 Marcus Drive, Suite One, Melville, New York 11747, Attention: Chief Executive Officer, email address: lalstodt@biorestorative.com, or such other email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. In addition to being entitled to exercise all rights granted by law, including recovery of damages, the Holder will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder or the beneficial owner of this Warrant, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Warrant Agency Agreement. If this Warrant is held in global form through DTC (or any successor depository), this Warrant is issued subject to the Warrant Agency Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agency Agreement, the provisions of this Warrant shall govern and be controlling.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

BIORESTORATIVE THERAPIES, INC.

By: _____
Name: Lance Alstodt
Title: President and Chief Executive Officer

NOTICE OF EXERCISE

TO: BIORESTORATIVE THERAPIES, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number:

Email Address:

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

COMMON STOCK PURCHASE WARRANT
BIORESTORATIVE THERAPIES, INC.

Warrant Shares: 1,676,580

Initial Exercise Date: November 9, 2021

THIS COMMON STOCK PURCHASE WARRANT (the “Warrant”) certifies that, for value received, AUCTUS FUND, LLC or its assigns (the “Holder”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the “Initial Exercise Date”) and on or prior to 5:00 p.m. (New York City time) on November 9, 2026 (the “Termination Date”) but not thereafter, to subscribe for and purchase from BioRestorative Therapies, Inc., a Delaware corporation (the “Company”), up to 1,676,580 shares (as subject to adjustment hereunder, the “Warrant Shares”) of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

“Affiliate” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“Bid Price” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is quoted on the OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the OTC Markets Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to “stay at home”, “shelter-in-place”, “non-essential employee” or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Subsidiary” means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Trading Day” means a day on which the Common Stock is traded on a Trading Market.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transfer Agent” means Transshare Corporation, the current transfer agent of the Company, with a mailing address of Bayside Center 1, 17755 North US Highway 19, Suite 140, Clearwater, Florida 33764, and any successor transfer agent of the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted bid average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not the Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the OTC Markets Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Warrants” means this Warrant.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be **\$10.00**, subject to adjustment hereunder (the "Exercise Price").

c) Registration Rights Agreement. Concurrently herewith, the Company and the Holder are entering into a Registration Rights Agreement of even date with respect to the resale of the Warrant Shares.

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by physical delivery of a certificate or book entry, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$5 per Trading Day (increasing to \$10 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all costs of any legal opinion required by the Company's transfer agent and any Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it is acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or reclassification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company's control, including not approved by the Company's Board of Directors, Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the greater of (i) the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (ii) the highest VWAP during the period beginning on the Trading Day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder's request pursuant to this Section 3(d) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within five Business Days of the Holder's election (or, if later, on the date of consummation of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

g) Voluntary Adjustment By Company. Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant, subject to the prior written consent of the Holder, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with applicable securities laws, this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then such action may be taken or such right may be exercised on the next succeeding Trading Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at 40 Marcus Drive, Suite One, Melville, New York 11747, Attention: Chief Executive Officer, email address: lalstodt@biorestorative.com, or such other email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. In addition to being entitled to exercise all rights granted by law, including recovery of damages, the Holder will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

BIORESTORATIVE THERAPIES, INC.

By: _____
Name: Lance Alstodt
Title: President and Chief Executive Officer

NOTICE OF EXERCISE

TO: BIORESTORATIVE THERAPIES, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall be in lawful money of the United States.

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

**AMENDMENT NO. 2 TO
NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN**

This Amendment No. 2 to Non-Qualified Stock Option Award Agreement (this “**Amendment**”) is made and entered into as of December 10, 2021 (the “**Effective Date**”) by and between BioRestorative Therapies, Inc., a Delaware corporation (the “**Company**”), and Lance Alstodt (the “**Participant**”).

RECITALS

- A. The Company granted to the Participant an option to purchase 1,173,917,974 shares of the Common Stock of the Company pursuant to the terms of a Non-Qualified Stock Option Award Agreement (the “**Option**”) under the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the “**Plan**”) on March 18, 2021 (the “**Grant Date**”).
- B. The Company effected a 1-for-4,000 reverse split of its Common Stock on October 27, 2021 (the “**Reverse Split**”).
- C. On November 4, 2021, the Company and the Participant entered into Amendment No. 1 to Non-Qualified Stock Option Award Agreement to amend the Exercise Price per Share in the Option to reflect the then current Fair Market Value, to indicate that the number of Option Shares (after giving effect to the Reverse Split) is 293,479 and to amend the vesting schedule.
- D. The Company wishes to amend the Exercise Price per Share in the Option to reflect the current Fair Market Value.
- E. The Company and the Participant wish to enter into this Amendment, pursuant to Section 18 of the Option, to amend and modify the Option by the terms of this Amendment and preserve the remaining terms of the Option without modification or amendment.
- F. This Amendment is subject to stockholder approval of an amendment to the Plan which grants authority to the Board of Directors of the Company or a committee thereof to reduce the Exercise Price per Share in the Option (“**Stockholder Approval**”).

AMENDMENT

In consideration of the above recitals, which are incorporated herein by reference, and the promises set forth in this Amendment and the Option, and for other good and valuable consideration, the nature and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

- 1. The Exercise Price per Share is hereby deleted and replaced with the following:
Exercise Price per Share: \$5.08
- 2. The foregoing change to the Option is subject to Stockholder Approval.
- 3. Except as otherwise amended by this Amendment, all other provisions of the Option will remain unchanged and in full force and effect.

Signature Page to Follow

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first above written.

BIORESTORATIVE THERAPIES, INC.

By: _____
Francisco Silva
VP of Research and Development

PARTICIPANT

Lance Alstodt

****Signature Page to Amendment No. 2 to Non-Qualified Stock Option Award Agreement****

**AMENDMENT NO. 2 TO
NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN**

This Amendment No. 2 to Non-Qualified Stock Option Award Agreement (this “**Amendment**”) is made and entered into as of December 10, 2021 (the “**Effective Date**”) by and between BioRestorative Therapies, Inc., a Delaware corporation (the “**Company**”), and Francisco Silva (the “**Participant**”).

RECITALS

- A. The Company granted to the Participant an option to purchase 1,173,917,974 shares of the Common Stock of the Company pursuant to the terms of a Non-Qualified Stock Option Award Agreement (the “**Option**”) under the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the “**Plan**”) on March 18, 2021 (the “**Grant Date**”).
- B. The Company effected a 1-for-4,000 reverse split of its Common Stock on October 27, 2021 (the “**Reverse Split**”).
- C. On November 4, 2021, the Company and the Participant entered into Amendment No. 1 to Non-Qualified Stock Option Award Agreement to amend the Exercise Price per Share in the Option to reflect the then current Fair Market Value, to indicate that the number of Option Shares (after giving effect to the Reverse Split) is 293,479 and to amend the vesting schedule.
- D. The Company wishes to amend the Exercise Price per Share in the Option to reflect the current Fair Market Value.
- E. The Company and the Participant wish to enter into this Amendment, pursuant to Section 18 of the Option, to amend and modify the Option by the terms of this Amendment and preserve the remaining terms of the Option without modification or amendment.
- F. This Amendment is subject to stockholder approval of an amendment to the Plan which grants authority to the Board of Directors of the Company or a committee thereof to reduce the Exercise Price per Share in the Option (“**Stockholder Approval**”).

AMENDMENT

In consideration of the above recitals, which are incorporated herein by reference, and the promises set forth in this Amendment and the Option, and for other good and valuable consideration, the nature and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

- 1. The Exercise Price per Share is hereby deleted and replaced with the following:
Exercise Price per Share: \$5.08
- 2. The foregoing change to the Option is subject to Stockholder Approval.
- 3. Except as otherwise amended by this Amendment, all other provisions of the Option will remain unchanged and in full force and effect.

Signature Page to Follow

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first above written.

BIORESTORATIVE THERAPIES, INC.

By:

Lance Alstodt
Chief Executive Officer

PARTICIPANT

Francisco Silva

****Signature Page to Amendment No. 2 to Non-Qualified Stock Option Award Agreement****

**AMENDMENT NO. 1 TO
NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN**

This Amendment No. 1 to Non-Qualified Stock Option Award Agreement (this “**Amendment**”) is made and entered into as of December 10, 2021 by and between BioRestorative Therapies, Inc., a Delaware corporation (the “**Company**”), and Nickolay Kukekov (the “**Participant**”).

RECITALS

- A. The Company granted to the Participant an option to purchase 25,236 shares of the Common Stock of the Company pursuant to the terms of a Non-Qualified Stock Option Award Agreement (the “**Option**”) under the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the “**Plan**”) on November 4, 2021.
- B. The Company wishes to amend the Exercise Price per Share in the Option to reflect the current Fair Market Value.
- C. The Company and the Participant wish to enter into this Amendment, pursuant to Section 18 of the Option, to amend and modify the Option by the terms of this Amendment and preserve the remaining terms of the Option without modification or amendment.
- D. This Amendment is subject to stockholder approval of an amendment to the Plan which grants authority to the Board of Directors of the Company or a committee thereof to reduce the Exercise Price per Share in the Option (“**Stockholder Approval**”).

AMENDMENT

In consideration of the above recitals, which are incorporated herein by reference, and the promises set forth in this Amendment and the Option, and for other good and valuable consideration, the nature and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

- 1. The Exercise Price per Share is hereby deleted and replaced with the following:
Exercise Price per Share: \$5.08
- 2. The foregoing change to the Option is subject to Stockholder Approval.
- 3. Except as otherwise amended by this Amendment, all other provisions of the Option will remain unchanged and in full force and effect.

Signature Page to Follow

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first above written.

BIORESTORATIVE THERAPIES, INC.

By: _____
Lance Alstodt
Chief Executive Officer

PARTICIPANT

Nickolay Kukekov

****Signature Page to Amendment No. 1 to Non-Qualified Stock Option Award Agreement****

**AMENDMENT NO. 1 TO
NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN**

This Amendment No. 1 to Non-Qualified Stock Option Award Agreement (this “**Amendment**”) is made and entered into as of December 10, 2021 by and between BioRestorative Therapies, Inc., a Delaware corporation (the “**Company**”), and Patrick Williams (the “**Participant**”).

RECITALS

- A. The Company granted to the Participant an option to purchase 10,490 shares of the Common Stock of the Company pursuant to the terms of a Non-Qualified Stock Option Award Agreement (the “**Option**”) under the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the “**Plan**”) on November 4, 2021.
- B. The Company wishes to amend the Exercise Price per Share in the Option to reflect the current Fair Market Value.
- C. The Company and the Participant wish to enter into this Amendment, pursuant to Section 18 of the Option, to amend and modify the Option by the terms of this Amendment and preserve the remaining terms of the Option without modification or amendment.
- D. This Amendment is subject to stockholder approval of an amendment to the Plan which grants authority to the Board of Directors of the Company or a committee thereof to reduce the Exercise Price per Share in the Option (“**Stockholder Approval**”).

AMENDMENT

In consideration of the above recitals, which are incorporated herein by reference, and the promises set forth in this Amendment and the Option, and for other good and valuable consideration, the nature and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

- 1. The Exercise Price per Share is hereby deleted and replaced with the following:
Exercise Price per Share: \$5.08
- 2. The foregoing change to the Option is subject to Stockholder Approval.
- 3. Except as otherwise amended by this Amendment, all other provisions of the Option will remain unchanged and in full force and effect.

Signature Page to Follow

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first above written.

BIORESTORATIVE THERAPIES, INC.

By: _____
Lance Alstodt
Chief Executive Officer

PARTICIPANT

Patrick Williams

****Signature Page to Amendment No. 1 to Non-Qualified Stock Option Award Agreement****

**AMENDMENT NO. 1 TO
NON-QUALIFIED STOCK OPTION AWARD AGREEMENT
UNDER THE
BIORESTORATIVE THERAPIES, INC.
2021 STOCK INCENTIVE PLAN**

This Amendment No. 1 to Non-Qualified Stock Option Award Agreement (this “**Amendment**”) is made and entered into as of December 10, 2021 by and between BioRestorative Therapies, Inc., a Delaware corporation (the “**Company**”), and David Rosa (the “**Participant**”).

RECITALS

- A. The Company granted to the Participant an option to purchase 10,490 shares of the Common Stock of the Company pursuant to the terms of a Non-Qualified Stock Option Award Agreement (the “**Option**”) under the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the “**Plan**”) on November 4, 2021.
- B. The Company wishes to amend the Exercise Price per Share in the Option to reflect the current Fair Market Value.
- C. The Company and the Participant wish to enter into this Amendment, pursuant to Section 18 of the Option, to amend and modify the Option by the terms of this Amendment and preserve the remaining terms of the Option without modification or amendment.
- D. This Amendment is subject to stockholder approval of an amendment to the Plan which grants authority to the Board of Directors of the Company or a committee thereof to reduce the Exercise Price per Share in the Option (“**Stockholder Approval**”).

AMENDMENT

In consideration of the above recitals, which are incorporated herein by reference, and the promises set forth in this Amendment and the Option, and for other good and valuable consideration, the nature and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

- 1. The Exercise Price per Share is hereby deleted and replaced with the following:
Exercise Price per Share: \$5.08
- 2. The foregoing change to the Option is subject to Stockholder Approval.
- 3. Except as otherwise amended by this Amendment, all other provisions of the Option will remain unchanged and in full force and effect.

Signature Page to Follow

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first above written.

BIORESTORATIVE THERAPIES, INC.

By: _____
Lance Alstodt
Chief Executive Officer

PARTICIPANT

David Rosa

****Signature Page to Amendment No. 1 to Non-Qualified Stock Option Award Agreement****

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-255681, 333-196299, 333-203310, 333-210555, 333-214621, 333-228434 and 333-233309) of BioRestorative Therapies, Inc. (the "Company") of our report dated March 30, 2022, relating to the consolidated financial statements, which appear in this Annual Report on Form 10-K of the Company.

/s/ Friedman LLP

Marlton, New Jersey
March 30, 2022

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: March 30, 2022

/s/ Lance Alstodt

Lance Alstodt
Principal Executive Officer

SECTION 302 CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Robert Kristal, 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: March 30, 2022

/s/ Robert Kristal

Robert Kristal
Principal Financial Officer

**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 officers of BioRestorative Therapies, Inc. (the “Company”) hereby certify that the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 (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: March 30, 2022

/s/ Lance Alstodt

Lance Alstodt
Principal Executive Officer

/s/ Robert Kristal

Robert Kristal
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.
