

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

FORM 10-K/A
Amendment No. 1

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023

☐ **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)

Nevada
(State or other jurisdiction
of incorporation or organization)

30-1341024
(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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock \$0.0001 par value	BRTX	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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023, the aggregate market value of the registrant’s common stock held by non-affiliates of the registrant was \$13,663,719 based on the closing sale price as reported on the Nasdaq Capital 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, 2024, there were 6,769,919 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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EXPLANATORY NOTE

Restatement of Previously Issued Consolidated Financial Statements

On May 23, 2024, BioRestorative Therapies, Inc. (the “Company”), in consultation with its Audit Committee, concluded that its previously issued (i) consolidated financial statements as of and for the two years ended December 31, 2023 included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023 (the “Annual Periods”) and (ii) unaudited interim condensed consolidated financial statements as of and for the quarters ended March 31, 2022 through September 30, 2023 included in the Company’s quarterly reports on Form 10-Q for the periods ended March 31, 2023, June 30, 2023 and September 30, 2023 (the “Interim Periods”, and, together with the Annual Periods, the “Affected Periods”) should be restated because of a misapplication in the guidance around the accounting for certain warrants, as discussed below, and should no longer be relied upon.

The warrants at issue are the following:

(i) the warrants to purchase an aggregate of 2,645,000 shares of the Company’s common stock, issued in November 2021 pursuant to an underwritten public offering, which warrants provide for an exercise price of \$10.00 per share (the “Public Warrants”);

(ii) the warrants to purchase an aggregate of 1,856,938 shares of the Company’s common stock, issued in November 2021 pursuant to a private offering, which warrants provide for an exercise price of \$10.00 per share (the “Private Warrants”); and

(iii) the warrants to purchase an aggregate of 235,970 shares of the Company’s common stock, issued in November 2021 to the underwriter of the public offering, which warrants provide for an exercise price of \$12.50 per share (together with the Public Warrants and the Private Warrants, the “Warrants”).

Historically, the Warrants were included as a component of stockholders’ equity on the balance sheet. It has now been determined, in accordance with Accounting Standards Codification 815, that the Warrants should be included as a component of liabilities on the balance sheets and the statements of operations should include the effect of subsequent changes in the estimated fair value of the Warrants (the “Restatement”). This Amendment No. 1 to the Annual Report on Form 10-K includes restated consolidated financial statements for the Affected Periods.

Refer to Note 2 – Summary of Significant Accounting Policies – Restatement of Previously Issued Consolidated Financial Statements and Note 3 – Restatement of Previously Issued Unaudited Interim Condensed Consolidated Financial Statements in the accompanying consolidated financial statements included in Part II, Item 8 for additional information.

Internal Control Considerations

In connection with the Restatement, management has re-evaluated its disclosure controls and procedures and internal control over financial reporting as of December 31, 2023. As a result of that assessment, management has concluded that an additional material weakness existed as of December 31, 2023 related to the lack of design and implementation of effective controls over the accounting for warrants issued in connection with equity financings. For a discussion of management’s consideration of disclosure controls and procedures, internal controls over financial reporting, and the material weaknesses identified, see Part II, Item 9A.

Items Restated in this Form 10-K/A

The following items have been restated, as appropriate, to correct the errors noted above:

- Part I, Item 1A. Risk Factors
- Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operation
- Part II, Item 8. Financial Statements and Supplementary Data
- Part II, Item 9A. Controls and Procedures.

Except as described above, no other changes have been made to the original filing of the Company’s Annual Report on Form 10-K for the year ended December 31, 2023 (the “Original Filing”). The Original Filing continues to speak as of the date of the Original Filing, and we have not updated the disclosures contained therein to reflect any events which occurred after the filing of the Original Filing. Accordingly, this Amendment No. 1 should be read in conjunction with our filings with the SEC after the date of the Original Filing.

The Company has not filed, and does not intend to file, amendments to the Quarterly Reports on Form 10-Q for any of the quarters for the years ended December 31, 2022 and 2023. Accordingly, investors should rely only on the financial information and other disclosures regarding the restated periods in this Form 10-K/A or in future filings with the SEC (as applicable), and not on any previously issued or filed reports, earnings releases or similar communications relating to these periods.

In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), new certifications by the Company’s principal executive officer and principal financial officer are filed herewith as exhibits to this Amendment No. 1 pursuant to Rule 13a-14(a) of the Exchange Act and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

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 1A of this Annual Report (“Risk Factors”).

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

Intellectual Property

This Annual Report includes references to our federally registered trademarks, *BioRestorative Therapies* and *Dragonfly* design, *BRTX-100*, *ThermoStem* and *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.

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. Effective December 31, 2022, we reincorporated in Nevada.

We develop therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult 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 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* 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.

We have obtained an exclusive 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. Patents related to the *ThermoStem Program* have been issued in the United States and other jurisdictions.

Further, we are seeking to develop a biologics-based cosmetic products business. Pursuant to such business, we would manufacture and sell cosmetics and hair growth products designed for cosmetic and aesthetic uses.

Material Events During 2023

In April 2023, we entered into a Capital On Demand™ Sales Agreement, or the Sales Agreement, with JonesTrading Institutional Services LLC, or the Agent, pursuant to which we may offer and sell, from time to time, through or to the Agent, shares of our common stock having an aggregate offering price of up to \$6,109,000. To date, we have sold approximately \$622,000 of our shares pursuant to the Sales Agreement.

In April 2023, we announced that we had completed enrollment for the safety run-in component of our Phase 2 clinical study of *BRTX-100*.

In May 2023, we announced that we had signed a clinical trial agreement with Northwell Health, New York State's largest health care provider and private employer, pursuant to which Northwell Health is participating in our Phase 2 clinical study of *BRTX-100*.

In May 2023, we announced that we had received a license from the New York State Department of Health to act as a tissue bank for the processing of mesenchymal stem cells from autologous donors.

In June 2023, we announced that the final subject in our *BRTX-100* Phase 2 clinical trial safety cohort had been dosed.

In June 2023, we announced that the independent Data Safety Monitoring Board, which is overseeing our Phase 2 clinical trial, unanimously recommended the continuation of our study in accordance with the version of the protocol with no changes.

In June 2023, a Japanese patent related to our *ThermoStem Program* was issued to us.

In June 2023, a United States patent related to our *ThermoStem Program* was issued to us.

In July 2023, a European patent related to our *ThermoStem Program* was issued to us.

In July 2023, we sold 685,033 shares of our common stock in a registered direct public offering. We received gross proceeds of approximately \$2,100,000 from the offering.

In September 2023, we entered into a supply agreement with a supplier of biologic-based cosmetics. Pursuant to the supply agreement, using our cGMP ISO-7 certified clean room, we manufactured tissue-based biologics for cosmetic and aesthetic applications. In December 2023, we terminated the supply agreement.

In December 2023, a United States patent related to our *ThermoStem Program* was issued to us.

Material Events During 2024

In February 2024, we issued 2,000,000 shares of our common stock pursuant to the exercise of warrants. In connection with the issuance, we issued warrants for the purchase of 2,513,686 shares of our common stock and are obligated to issue an additional 1,351,580 shares of our common stock, which additional shares have been fully paid for but have not yet been issued due to a maximum beneficial ownership limitation for one of the warrant holders. We received gross proceeds of approximately \$8,100,000 from the warrant exercise.

(b) Business

General

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

- ***Disc/Spine Program (brtxDisc)***. Our lead cell therapy candidate, *BRTX-100*, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells, or MSCs, collected from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complimentary therapeutic to a surgical procedure. The *BRTX-100* production process utilizes proprietary technology and involves collecting a patient's bone marrow, isolating and culturing stem cells from the bone marrow and cryopreserving the cells. In an outpatient procedure, *BRTX-100* is to be injected by a physician into the patient's damaged disc. The treatment is intended for patients whose pain has not been alleviated by non-surgical procedures and who potentially face the prospect of surgery. We have received authorization from the FDA to commence a Phase 2 clinical trial using *BRTX-100* to treat chronic lower back pain arising from degenerative disc disease. We have commenced such clinical trial through the execution of a CRO agreement with PRC Clinical, the execution of clinical trial site agreements, patient enrollment, the commencement of patient procedures, 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 our *Disc/Spine Program* was issued. We have been granted exclusive 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 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. Patents related to the *ThermoStem Program* have been issued in the United States and other jurisdictions. 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 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.”

We are also seeking to develop a biologics-based cosmetic products business. Pursuant to such business, we would manufacture and sell cosmetics and hair growth products designed for cosmetic and aesthetic uses.

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 seven United States patents, thirteen foreign patents, one United States patent application, and four foreign patent applications related to research regarding our *ThermoStem Program*. We have also obtained licenses for four United States patent applications related to our *Disc/Spine Program*, one United States patent related to our *Disc/Spine Program*, and a license for one United States patent related to a curved needle device.

We have established a research laboratory facility with current Good Manufacturing Practice, or cGMP, capabilities to produce clinical grade products and we 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. In 2023, we raised approximately \$2,680,000 in additional gross proceeds through public offerings of our securities. In February 2024, we also received approximately \$8,100,000 in gross proceeds pursuant to the exercise of warrants. Such aggregate 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 will require significant additional financing to complete our contemplated Phase 3 clinical trial investigating the use of *BRTX-100*. 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 amount of funding that we anticipate may be required for such purposes 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 an exclusive license (see “*Exclusive 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 exclusive license described below under "*Exclusive 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.

In February 2017, pursuant to an IND application, we received authorization from the FDA 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 commenced our Phase 2 clinical trial through the execution of a CRO agreement with PRC Clinical, the execution of clinical trial site agreements, patient enrollment, the commencement of patient procedures, 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 exclusive license rights with respect to the patent. See "*Exclusive License*" below.

BRTX-100

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

Mesenchymal stem cells used in *BRTX-100* are similar to other MSCs under development by others; however, in order to enhance the survivability of our bone marrow-derived MSCs in the avascular environment of the damaged disc, *BRTX-100* is designed to expand under hypoxic conditions for a period of approximately three weeks. This process is intended to result in an approximate 40 million cell count population with enhanced viability and therapeutic potential following injection locally into injured spinal discs. Publications and scientific literature have indicated that MSCs preconditioned in hypoxic environment show enhanced skeletal muscle regeneration properties and improved impacts upon circulation and vascular formation compared to MSCs cultured under normoxic (normal oxygen) conditions.

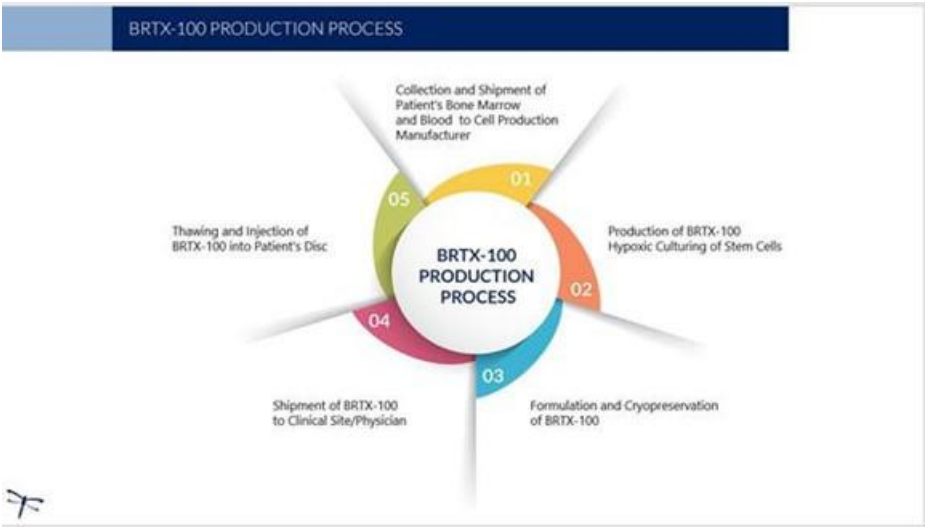
In August 2018, the *Journal of Translational Medicine* published the results of our study evaluating the benefits of long-term hypoxic culturing of human bone marrow-derived MSCs.

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.

Since June 2022, we have entered into clinical trial agreements with 16 sites to conduct our Phase 2 clinical trial targeting chronic lumbar disc disease.

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:



Exclusive License

Pursuant to our license agreement with Regenerative Sciences, LLC, or Regenerative, that became effective in April 2012, or the Regenerative License Agreement, we have obtained, among other things, a worldwide (excluding Asia and Argentina), exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain method for culturing cells for use in our developmental program involving disc and spine conditions, including protruding or painful discs and the treatment of avascular zones. The investigational technology that has been licensed is an advanced stem cell culture and injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the leg and foot. Pursuant to the Regenerative License Agreement, we have also obtained a worldwide, exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain investigational curved needle device for the administration of specific cells and/or cell products to the disc and/or spine (and other parts of the body). It will be necessary to advance the design of this investigational device to facilitate the delivery of substances, including living cells, to specific locations within the body and minimize the potential for damage to nearby structures.

The 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

Pursuant to an IND application we submitted to the FDA, we have obtained 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 commenced our Phase 2 clinical trial through the execution of a CRO agreement with PRC Clinical, the execution of clinical trial agreements with 16 sites, patient enrollment, the commencement of patient procedures, 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.

In April 2023, we announced that we had completed enrollment for the safety run-in component of our Phase 2 clinical study of *BRTX-100*.

In May 2023, we announced that we had signed a clinical trial agreement with Northwell Health, New York State's largest health care provider and private employer, pursuant to which Northwell Health is participating in our Phase 2 clinical study of *BRTX-100*.

In June 2023, we announced that the final subject in our *BRTX-100* Phase 2 clinical trial safety cohort had been dosed.

In June 2023, we announced that the independent Data Safety Monitoring Board, which is overseeing our Phase 2 clinical trial, unanimously recommended the continuation of our study in accordance with the version of the protocol with no changes.

The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee that the clinical trial(s) will be 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.

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:

<p>Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy</p> <p><i>Journal of Translational Medicine</i></p>	<ul style="list-style-type: none"> 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.
<p>Intervertebral Disc Repair by Allogeneic Mesenchymal Bone Marrow Cells: A Randomized Controlled Trial</p> <p><i>Spine</i></p>	<ul style="list-style-type: none"> Description: 24 patients with chronic back pain were randomized into either treatment group or control group. Treatment group received 25×10^6 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 25×10^6 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.
<p>Safety and tolerability of intradiscal implantation of combined autologous adipose-derived mesenchymal stem cells and hyaluronic acid in patients with chronic discogenic low back pain: 1-year follow-up of a phase I study</p> <p><i>Spine</i></p>	<ul style="list-style-type: none"> Description: 10 patients with chronic back pain received a single injection of 20×10^6 and 40×10^6 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.

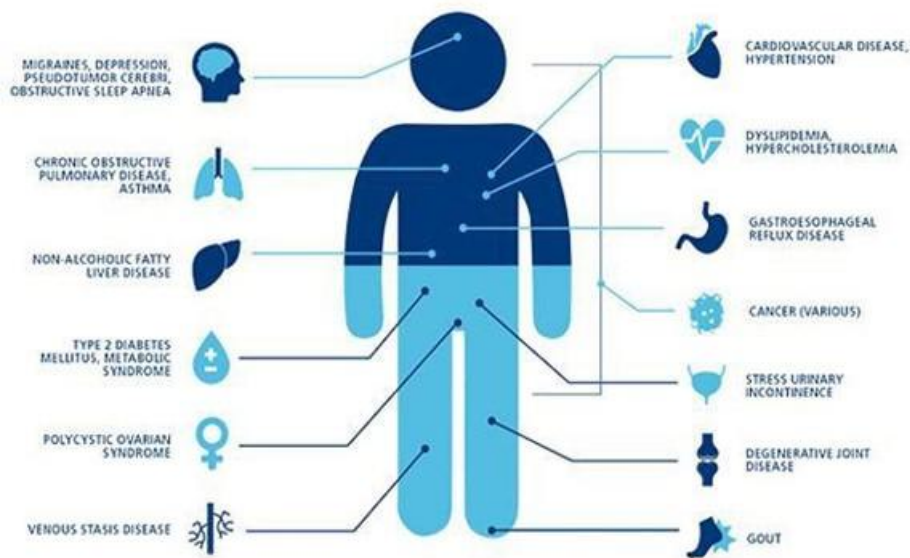
The United States is the world’s leading consumer of hydrocodone (99%) and oxycodone (83%) and leads the world in per capital consumption of such drugs (twice as much as second ranked Canada). In 2020, 91,000 persons in the United States died from overdoses.

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 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 February 2022, a Japanese patent related to our *ThermoStem Program* was issued to us.

In March 2022, an Israeli patent related to our *ThermoStem Program* was issued to us.

In December 2022, we announced that we were awarded a Small Business Innovation Research (SBIR) Phase 1 grant from Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health to enable the development and the evaluation of our *ThermoStem Program* for the treatment of polycystic ovary syndrome (PCOS). The work is to be done in collaboration with Dr. Sheng Wu, Associate Professor, Center for Metabolic Disease Research at Temple University.

In June 2023, a Japanese patent related to our *ThermoStem Program* was issued to us.

In June 2023, a United States patent related to our *ThermoStem Program* was issued to us.

In July 2023, 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 December 2023, a United States patent related to our *ThermoStem Program* was issued to us.

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 2024. 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-Exclusive 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 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 for general research purposes.

We have expanded our laboratory to include capabilities for the clinical production of our pipeline of clinical and investigational cell therapy candidates. Our expanded cGMP facility includes 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. In May 2023, we announced that we had received a license from the New York State Department of Health to act as a tissue bank for the processing of mesenchymal stem cells from autologous donors.

As we develop our business and our stem cell product candidates, and we 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*, thirteen patent applications have been filed with regard to technology that is the subject of the Regenerative License Agreement (see “Disc/Spine Program-Exclusive License” above). Regenerative has been issued a patent from one of these applications with regard to its curved needle therapeutic delivery device. This patent expires in March 2031. In addition, in March 2022, a United States patent related to *BRTX-100* was issued. This patent expires in December 2029. Of the other eleven applications that were filed, four applications remain pending. The patents that are the subject of the Regenerative License Agreement have been assigned to Regenxx, LLC which we have been advised is an affiliate of Regenerative.

In our *ThermoStem Program*, we have one pending United States patent application and seven United States patents within three patent families. Four of the patents expire in June 2032 and three of the patents expire in April 2034. With regard to the first patent family in the *ThermoStem Program*, patent applications have been filed in five foreign jurisdictions (of which four applications have been granted as foreign patents and one application has lapsed). The patents expire in June 2032. With regard 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). The patents expire in April 2034. With regard to the third patent family in the *ThermoStem Program*, patent applications have been filed in four foreign jurisdictions.

Our patent applications and those of Regenxx, LLC are currently in prosecution (i.e., we and Regenxx, LLC are seeking issued patents).

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:

- The logo for BioRestorative Therapies features the word "biorestorative" in a serif font, with "therapies" in a smaller, lowercase sans-serif font below it. To the right of the text is a stylized graphic of a dragonfly.
- BRTX-100
- THERMOSTEM
- 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, 2023 and 2022, we incurred \$4,034,591 and \$3,513,352, 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. Jason Lipetz, Dr. Wayne Olan, Dr. Joy Cavagnaro, Dr. Harvinder Sandhu and Dr. Christopher Plataras. The Disc Advisory Committee members are Dr. Lipetz (Chairman), Dr. Olan, Dr. Sandhu and Dr. Plataras. See Item 10 of this Annual Report ("Directors, Executive Officers and Corporate Governance – Scientific Advisory Board") for a listing of the principal positions for Drs. Marasco, Lipetz, Olan, Cavagnaro, Sandhu and Plataras.

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 include Novo Nordisk, Sanofi, Merck, Eli Lilly, Roche, Pfizer, Regeneron and Altimmune. The recent extensive use of both FDA-approved and compounded versions of glucagon-like peptide-1 (GLP-1) receptor agonist drug products, such as Wegovy and Ozempic (semaglutide) for the treatment of obesity has significantly increased the competition in the obesity market.

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 that 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 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, it is possible that a biosimilar product could be approved as “interchangeable” with our product and therefore substitutable for our product by a healthcare professional under applicable state laws.

We may also face increased competition from stem cell therapies performed by treatment centers that do not require FDA premarket approval. In August 2022, a federal District Court in the case of *United States v. California Stem Cell Treatment Center, Inc.* held that certain autologous adipose stem cell treatments were not “biological products” and therefore did not require FDA approval. The FDA has appealed the decision but, should it be upheld, we could face competition from stem cell clinics that would not be required to undergo the costly and time-consuming FDA approval process.

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

	<div>biorestorative therapies</div>	<div>mesoblast</div>
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 a 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

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 PHSA, 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 PHSA, the FDA issued specific regulations governing the use of HCT/Ps in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations, or CFR, 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, the FDA stated it would 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. Historically, 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 FDA’s interpretations of the HCT/P Regulations. However, in August 2022, a federal District Court in the case of *United States v. California Stem Cell Treatment Center, Inc.* held that certain autologous adipose stem cell treatments that the FDA alleged were biological products were instead within the HCT/P definition and therefore did not require FDA approval. The FDA has appealed the decision but, should it be upheld, it could expand the types of stem cell products that are regulated solely under the HCT/P Regulations.

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

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

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

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

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

Drug and Biological Product Regulation

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

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

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practice, 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. 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, to the FDA 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.

We have determined that, under the FDA's current interpretation of the applicable law, our *BRTX-100* product candidate will be regulated as a biological product under the PHSA. Therefore, we will need to expend significant resources to ensure regulatory compliance. There is no assurance as to whether or when we will receive FDA approval of the *BRTX-100* product candidate. The process of designing, conducting, compiling and submitting the non-clinical and clinical studies required for 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. As a result of the FDA's controversial use of the accelerated approval pathway for an Alzheimer's drug (aducanumab), Congress revised the accelerated approval process as a part of the Food and Drug Omnibus Reform Act of 2022 to provide the FDA with additional authorities to enforce the post-approval study requirements and to withdraw approvals when those requirements are not met.

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, the FDA is authorized 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.

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

The federal Clinical Laboratory Improvement Amendments, or CLIA, provides 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.

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

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations 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 11 employees, all of whom are full-time employees. We believe that our employee relations are good.

ITEM 1A. RISK FACTORS.

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.

Preceding the full risk factors is a list of certain of the risk factors that follow. Reference is made to the complete risk factors for a full description of the risks involved.

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 will need to obtain a significant amount of financing to complete our clinical trials and implement our business plan.
- We will need to enter into agreements in order to implement our business strategy.
- We depend on our executive officers and on our ability to attract and retain additional qualified personnel.

Risks Relating to Change in Accounting Treatment of Our Securities and Restatement of Our Previously Issued Financial Statements in Connection Therewith

- Our warrants are accounted for as a liability and the change in the fair value of our warrants or any other similar derivative liabilities could have a material effect on our financial results.
- Our failure to prepare and timely file our Quarterly Report on Form 10-Q for the period ended March 31, 2024 with the SEC limits our access to the public markets to raise debt or equity capital.
- We identified certain misstatements to our previously issued financial statements and have restated the financial statements described below, which has exposed us to a number of additional risks and uncertainties.

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 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.
- The development of our cell therapy product candidates is subject to uncertainty because autologous cell therapy is inherently variable.
- 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.
- 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.
- 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 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.
- We presently lack manufacturing capabilities to produce our product candidates at commercial scale quantities and do not have an alternate manufacturing supply at this time, which could negatively impact our ability to meet any future demand for the products.
- The commercial potential and profitability of our products are unknown and subject to significant risk and uncertainty.
- We may have difficulties in sourcing brown adipose (fat) tissue.
- 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.
- We are vulnerable to competition and technological change, and also to physicians' inertia.
- 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 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.
- Our cell therapy product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.
- 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 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.
- Our inability to obtain reimbursement for our products and services from private and governmental insurers could negatively impact demand for our products and services.

Risks Related to Our Intellectual Property

- We may not be able to protect our proprietary rights.
- Changes to United States patent law may have a material adverse effect on our intellectual property rights.
- 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.

Risks Related to Government Regulation

- Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory oversight.
- 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.
- 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.
- 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.
- Health care companies have been the subjects of federal and state investigations, and we could become subject to investigations in the future.
- 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.
- 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.

Risks Related to Our Common Stock

- We pay no dividends.
- 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.”
- 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.
- 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.
- 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.

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.
- 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.

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, 2023, our accumulated deficit was \$146,699,334.

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 will require significant additional funding to complete our clinical trials using *BRTX-100*. 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 amount of funding that we anticipate may be required for such purposes 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 agreements relating to the conduct of our Phase 2 clinical trial, 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 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 believe that these possible negative effects have lessened as more of the population has become 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 Relating to Change in Accounting Treatment of Our Securities and Restatement of Our Previously Issued Financial Statements in Connection Therewith

Our Warrants are accounted for as a liability and the change in the fair value of our Warrants or any other similar derivative liabilities could have a material effect on our financial results.

During the preparation of our financial statements for the quarter ended March 31, 2024, our management reevaluated certain warrants issued in 2021 under Accounting Standards Codification (“ASC”) Subtopic 815-40, Contracts in Entity’s Own Equity. ASC Section 815-40-15 addresses equity versus liability treatment and classification of equity-linked financial instruments, including warrants, and states that a warrant may be classified as a component of equity only if, among other things, the warrant is indexed to the issuer’s common stock. Based on its reevaluation, in consultation with our Audit Committee, and after discussion with our independent registered public accounting firm, management concluded that, for certain of our Warrants, we do not control the occurrence of events, such as a tender offer or exchange, that may trigger cash settlement of the Warrants and not result in a change of control of the Company. As a result, such Warrants do not meet the criteria for equity treatment and the Warrants must be recorded as a derivative liability. Additionally, certain other Warrants contain adjustments to the settlement amount based on a variable that is not an input to the fair value of a “fixed-for-fixed” option as defined under ASC 815-40 and, accordingly, such Warrants are not considered indexed to our own stock and are not eligible for an exception from derivative accounting. As a result, we should have classified the Warrants as derivative liabilities in our previously issued financial statements as of and for the years ended December 31, 2023 and 2022 and as of and for the quarters ended March 31, 2022 through September 30, 2023. Under this accounting treatment, we are required to measure the fair value of our Warrants at the end of each reporting period and recognize changes in the fair value from the prior period in our operating results for the current period. As a result of the recurring fair value measurement of our Warrants and any subsequent changes in fair value from a prior period, our results of operations in our financial statements may fluctuate quarterly based on factors which are outside of our control. Due to this recurring fair value measurement, we expect that we will recognize non-cash gains or losses on our Warrants each reporting period and that the amount of such gains or losses could be material.

Our failure to prepare and timely file our Quarterly Report on Form 10-Q for the period ended March 31, 2024 with the SEC limits our access to the public markets to raise debt or equity capital.

We have not yet filed our Quarterly Report on Form 10-Q for the period ended March 31, 2024 with the SEC; therefore, we have not remained current in our reporting requirements with the SEC. We are not currently eligible, without receiving a waiver from the SEC, to use a short-form registration statement on Form S-3, or to use “shelf” registration statements to conduct offerings, until approximately one year from the date we regained and maintain status as a current filer. If we wish to pursue an offering now, we would be required to conduct the offering on an exempt basis or file a registration statement on Form S-1. Using a Form S-1 registration statement for a public offering could take significantly longer than using a registration statement on Form S-3 and increase our transaction costs, and could, to the extent we are not able to conduct offerings using alternative methods, adversely impact our ability to raise capital or complete acquisitions of other companies in a timely manner.

We identified certain misstatements to our previously issued financial statements and have restated the financial statements described below, which has exposed us to a number of additional risks and uncertainties.

As discussed in the Explanatory Note and Notes 2 and 3 of our consolidated financial statements, we have restated our previously issued audited financial statements as of and for the years ended December 31, 2022 and 2023 and our interim financial statements as of and for the quarterly periods ended March 31, 2022 through September 30, 2023.

As a result of the misstatements discussed and the Restatement, we have become subject to a number of additional risks and uncertainties and unanticipated costs for accounting, legal and other fees and expenses, including risks of lawsuit relating to securities offered by us in public and private offerings as well as claims by purchasers of our shares of common stock in the public market. Any actions, lawsuits or other legal proceedings related to the misstatements or the Restatement could result in liabilities, reputational harm and defense and other costs, regardless of the outcome of the lawsuit or proceeding.

We cannot ensure that litigation or other claims by stockholders will not be brought in the future arising out of the Restatement. We may also be subject to further examinations, investigations, proceedings and orders by regulatory authorities as a result of the Restatement. Any such further actions could be expensive and damaging to our business, results of operations and financial condition.

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 just recently commenced a Phase 2 clinical trial using BRTX-100 to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs.

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

- suspensions, delays or changes in the design, initiation, enrollment, implementation or completion of required clinical trials; adverse changes in our financial position or significant and unexpected increases in the cost of our clinical development program; changes or uncertainties in, or additions to, the regulatory approval process that require us to alter our current development strategy; clinical trial results that are negative, inconclusive or less than desired as to safety and/or efficacy, which could result in the need for additional clinical studies or the termination of the product’s development; delays in our ability to manufacture the product in quantities or in a form that is suitable for any required clinical trials;
- intellectual property constraints that prevent us from making, using, or commercializing any of our cell therapy product candidates;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of these product candidates may be insufficient or inadequate; the inability to generate sufficient pre-clinical, toxicology, or other in vivo or in vitro data, to support the initiation of clinical studies;
- delays in reaching agreement on acceptable terms with prospective 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 or other health emergencies;
- 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 not accepting clinical data from trials that are conducted at clinical sites in countries where the standard of care is potentially different from the United States; and
- failure to raise sufficient funds to complete our clinical trials.

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

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

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

We anticipate that we will not be able to commercialize our *BRTX-100* product candidate for at least five years.

We may experience delays and other difficulties in enrolling a sufficient number of patients in our clinical trials which could delay or prevent the receipt of necessary regulatory approvals.

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

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

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

We have just recently commenced the clinical trials necessary to obtain FDA approval to market our product candidate, *BRTX-100*. 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, 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 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 at this time, which could negatively impact our ability to meet any future demand for the products.

We have utilized our laboratory to provide the cell processing services necessary for clinical production of *BRTX-100* for our Phase 2 disc clinical trial. We believe that we have sufficient laboratory capacity to provide such services with regard to the balance of the Phase 2 trial; however, we would need to significantly expand our manufacturing capabilities to provide such cell processing services 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 may seek to utilize a third-party manufacturer for *BRTX-100* or any of our other product candidates; however, we do not have any arrangements in place with a third-party manufacturer. 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*.

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.

We may also face increased competition from stem cell therapies performed by treatment centers that do not require FDA premarket approval. In August 2022, a federal District Court in the case of *United States v. California Stem Cell Treatment Center, Inc.* held that certain autologous adipose stem cell treatments were not “biological products” and therefore did not require FDA approval. The FDA has appealed the decision but, should it be upheld, we could face competition from stem cell clinics that would not be required to undergo the costly and time-consuming FDA approval process.

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, as well as the Inflation Reduction Act, passed in August 2022, and other health reforms include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs and biologics 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. For example, 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, advisors, 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, policies, or court decisions may cause delays in the approval or rejection of an application, make it easier for our competitors to gain regulatory approval to enter the marketplace, or allow competitors to enter the market without having to obtain FDA approval. 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 and Medicaid programs. 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. 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.

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 in April 2013 and, following passage of the Bipartisan Budget Act of 2018, will remain in effect through 2030 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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.

In August 2022, President Biden signed the Inflation Reduction Act, or the IRA, which provides for (i) the government to set or negotiate prices for select high-cost Medicare Part D (beginning in 2026) and Medicare Part B drugs (beginning in 2028) that are more than nine years (for small-molecule drugs) or 13 years (for biological products) from their FDA approval, (ii) manufacturers to pay a rebate for Medicare Part B and Part D drugs when prices increase faster than inflation beginning in 2022 for Medicare Part D and 2023 for Medicare Part B drugs, and (iii) Medicare Part D redesign which replaces the current coverage gap provisions and establishes a \$2,000 cap for out-of-pocket limits costs for Medicare beneficiaries beginning in 2025, with manufacturers being responsible for 10% of costs up to the \$2,000 cap and 20% after that cap is reached. Implementation of the IRA is expected to be carried out through upcoming actions by regulatory authorities, the outcome of which is uncertain.

Healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and decreased reimbursement. 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, the IRA, and/or additional legislation or regulation enacted in the future may impact our business. If the PPACA, the IRA, 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, or 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 have caused and 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 material weaknesses, 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 weaknesses related to the following control deficiencies:

- Lack of adherence to formal policies and procedures;
- Lack of risk assessment procedures on internal controls to detect financial reporting risks on a timely manner;
- Lack of sufficient formal management testing over documented formal procedures and controls, and time to evaluate continuous effectiveness of controls to achieve complete and accurate financial reporting and disclosures, including documented controls over the preparation and review of journal entries and account reconciliations; and
- Lack of design and implementation of effective controls over the accounting for warrants issued in connection with equity financings.

The deficiencies described above have resulted and, 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 constituted material weaknesses.

To address our material weaknesses, we have engaged an external financial consulting firm to assist us with implementing enhancements and controls within our accounting systems, 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 and Management has concluded, through testing, that the controls are operating effectively. 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 20, 2024, 6,769,919 shares were issued and outstanding. In addition, as discussed in Item 1 (“Business – Business Development – Material Events During 2024”), we are obligated to issue an additional 1,351,580 shares of common stock. 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 1,398,158 shares of Series B preferred stock issued and outstanding. Such shares are convertible under certain circumstances into an equal number of shares of common stock.

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 (of which warrants for the purchase of an aggregate of 1,675,000 shares of common stock have been exercised) as well as underwriter warrants for the purchase of 235,970 shares of common stock. We have an effective registration statement on Form S-3 under the Securities Act registering the issuance of such shares. The shares issuable pursuant to the registration statement on Form S-3 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 (of which warrants for the purchase of an aggregate of 1,676,580 shares of common stock have been exercised). 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 registered 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.

In addition, in February 2024, in connection with the warrant exercises discussed in Item 1 (“Business – Business Development – Material Events During 2024”), we issued warrants for the purchase of an aggregate of 2,513,686 shares of common stock. We have agreed to file a registration statement with the SEC to register the resale of the shares of common stock underlying such warrants.

We also have effective registration statements on Form S-8 under the Securities Act registering an aggregate of 3,850,000 shares of our common stock issuable under our 2021 Stock Incentive Plan, or the 2021 Plan (of which 319,797 shares have been issued). As of March 20, 2024, options to purchase 3,401,608 shares of our common stock were outstanding under the 2021 Plan. The shares issued and issuable pursuant to the registration statements on Form S-8 will be freely tradable in the public market, except for shares held by affiliates. We may include a resale prospectus in a 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.

Further, we have an effective shelf registration statement on Form S-3 under the Securities Act registering \$75,000,000 of our equity and debt securities. Pursuant to the requirements of Form S-3, we currently may sell pursuant to such Form S-3, during any 12 month period, securities having an aggregate market value of no more than one-third of the aggregate market value of the shares of our common stock held by non-affiliates.

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 incorporated in Nevada. Anti-takeover provisions in Nevada law and our articles 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, 1,398,158 shares of Series B 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.

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 has helped generate greater and 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 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 1C. CYBERSECURITY.

We recognize the critical importance of cybersecurity in safeguarding sensitive information, maintaining operational resilience, and protecting stakeholders' interests.

We are in the process of establishing a cybersecurity policy designed to establish a comprehensive framework for identifying, assessing, mitigating, and responding to cybersecurity risks across the organization and implement protocols to evaluate, recognize, and address significant risks, including those posed by cybersecurity threats. This strategy will encompass the utilization of standard traffic monitoring tools, educating personnel to identify and report abnormal activities, and partnering with reputable service providers capable of upholding security standards equivalent to or exceeding our own.

These measures are to be integrated into our broader operational risk management framework aimed at minimizing exposure to unnecessary risks across our operations. For cybersecurity, we collaborate with consultants and third-party service providers to implement industry-standard strategies aimed at identifying and mitigating potential threats or vulnerabilities within our systems. Additionally, the policy strategy will have a comprehensive cybersecurity crisis response plan to manage high severity security incidents, ensuring efficient coordination across the organization.

Cybersecurity threats have not significantly impacted our operations, and we do not anticipate such risks materially affecting our business, strategy, financial condition, or results of operations. However, given the escalating sophistication of cybersecurity threats, our preventive measures may not always suffice. Despite well-designed controls, we acknowledge the inability to foresee all security breaches, including those stemming from third-party misuse of AI technologies, and the potential challenges in implementing timely preventive measures. See Item 1A (“Risk Factors - 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.”) for further insights into cybersecurity attack-related risks that we may face.

Our Chief Financial Officer will oversee our information security programs, including cybersecurity initiatives, and our cybersecurity incident response process. The Audit Committee of the Board oversees cybersecurity risk management activities, supported by our management, the Board of Directors, and external consultants. We assess and prioritize risks based on potential impact, implement technical controls, and monitor third-party vendors’ security practices.

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 a current annual base rental of \$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, 2024, there were 352 record holders of our shares of common stock.

Dividends

Not applicable.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

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. as of December 31, 2023 and 2022 and for the years ended December 31, 2023 and 2022 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 Item 1A of this Annual Report ("Risk Factors") for a discussion of some of the uncertainties, risks and assumptions associated with these statements. This "Management's Discussion and Analysis of Financial Condition and Results of Operations" has been amended and restated to give effect to the restatement of our consolidated financial statements, as more fully described in Note 2 to our financial statements entitled "Restatement of Previously Issued Consolidated Financial Statements". For further detail regarding the Restatement, see "Explanatory Note" and "Item 9A. Controls and Procedures."

Overview

We develop therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult 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 have received authorization from the FDA 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 commenced such clinical trial through the execution of a CRO agreement with PRC Clinical, the execution of clinical trial site agreements, patient enrollment, the commencement of patient procedures, the purchase of manufacturing equipment and the expansion of our laboratory to include capabilities for clinical production. We have obtained an exclusive 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, July 2021, June 2023 and December 2023; 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, June 2021, February 2022 and June 2023; Israeli patents related to our *ThermoStem Program* were issued in October 2019, May 2020 and March 2022; and European patents related to the *ThermoStem Program* were issued in April 2020, January 2021 and July 2023.

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 Phase 2 clinical trial with regard to *BRTX-100*.

We are seeking to develop a biologics-based cosmetic products business. Pursuant to such business, we would manufacture and sell cosmetics and hair growth products designed for cosmetic and aesthetic uses.

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, 2023, our accumulated deficit was \$146,699,334. 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.

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 are using 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) 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 September 2022, the 1,543,158 shares of Series A preferred stock were exchanged for an equal number of shares of Series B preferred stock. As of March 28, 2024, there were 1,398,158 shares of Series B preferred stock issued and outstanding.

In April 2023, we entered into a Capital on Demand Sales Agreement with JonesTrading Institutional Services LLC, or the Sales Agent, under which we currently have the ability to issue and sell shares of our common stock, from time to time, through the Sales Agent, up to an aggregate offering price of approximately \$6,109,000 in what is commonly referred to as an “at-the-market”, or ATM, program. During the year ended December 31, 2023, we sold 132,827 shares of our common stock under the ATM program with the Sales Agent at a weighted-average gross price of approximately \$4.68 per share and raised approximately \$622,000 of gross proceeds. The total commissions and related legal fees were approximately \$127,000, and we received net proceeds of approximately \$495,000. As of December 31, 2023, we had remaining capacity to sell up to an additional \$5,487,000 of common stock under the ATM program.

In July 2023, we sold an aggregate of 685,033 shares of our common stock in a registered direct public offering. We received net proceeds of approximately \$1,854,000 from the offering.

The net proceeds received from our November 2021 public offering, the ATM program and the registered direct offering are sufficient for us to complete our Phase 2 clinical trial with regard to *BRTX-100*; however, we will require significant 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 amount of funding that we anticipate may be required for such purposes 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, 2023 Compared with Year Ended December 31, 2022

The following table presents selected items in our consolidated statements of operations for the years ended December 31, 2023 and 2022, respectively:

	For the Years Ended December 31,	
	2023 (As Restated)	2022 (As Restated)
Revenues, net	\$ 145,800	\$ 119,800
Operating Expenses:		
Research and development	4,034,591	3,513,352
General and administrative	11,331,983	15,580,473
Total Operating Expenses	15,366,574	19,093,825
Loss From Operations	(15,220,774)	(18,974,025)
Other Income:		
Interest income	(552,293)	(11,650)
Gain on PPP loan forgiveness	-	(250,000)
Grant income	(83,333)	(110,518)
Other income	(169,664)	(107,088)
Change in fair value of derivative liabilities	(3,997,780)	(5,272,473)
Total Other Income	(4,803,070)	(5,751,729)
Net Loss	\$ (10,417,704)	\$ (13,222,296)

Revenues

For the years ended December 31, 2023 and 2022, we generated \$145,800 and \$119,800, respectively, of royalty revenue in connection with our sublicense agreement.

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, 2023, research and development expenses increased by \$521,239, or 15%, to \$4,034,591 compared to \$3,513,352 for the year ended December 31, 2022. The increase was primarily driven by increased compensation of \$857,294 due to salary increases and bonuses, increased lab supplies expenses of \$193,298, increased repair and maintenance expenses of \$30,521, increased license agreements and fees expenses of \$25,155 and increased consulting fees of \$112,581, offset by a decrease in lab site fees of \$53,029, and a decrease in PRC service expenses of \$644,245 as the result of non-recurring start-up and execution expenses incurred during the year ended December 31, 2022.

We expect that our research and development expenses will continue to increase with the continuation of the aforementioned initiatives.

General and administrative

General and administrative expenses consist primarily of salaries, bonuses, payroll taxes 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, 2023, general and administrative expenses decreased by \$4,248,490, or 27% to \$11,331,983 from \$15,580,473 for the year ended December 31, 2022. The decrease was primarily driven by a \$4,753,377 decrease in stock-based compensation, decreased franchise tax expense of \$130,850, decreased amortization expense of \$104,630, decreased travel expense of \$84,122, and decreased insurance expense of \$53,858, all offset by an increase in compensation of \$775,678 due to salary increases and bonuses, increased investor relations expense of \$80,957, increased professional fees of \$44,056, and an increase in office supplies expense of \$10,616.

We expect that our general and administrative expenses related to operations will increase as we expand our staff, develop our infrastructure and incur additional costs to support the growth of our business.

Interest income

For the year ended December 31, 2023, interest income increased \$540,643, or 4641%, to \$552,293 from \$11,650 for the year ended December 31, 2022. The increase was due to the interest and dividend income of the investments held in marketable securities.

Gain on PPP loan forgiveness

Under the terms of the U.S. Small Business Administration's Paycheck Protection Program, or PPP, our \$250,000 PPP loan was forgiven during the year ended December 31, 2022.

Grant income

Grant income of \$83,333 during the year ended December 31, 2023 consisted of funding received under a National Institutes of Health Small Business Technology Transfer (STTR) Phase 1 grant, offset by related expenses. Grant income of \$110,518 during the year ended December 31, 2022 consisted of funding received under a \$256,000 National Institutes of Health Small Business Technology Transfer (STTR) Phase 1 grant, which we were awarded in September 2021.

Other income

For the year ended December 31, 2023, other income of \$169,664 primarily related to an Employee Retention Tax Credit, gains from settlements of certain accrued expenses and realized and unrealized gain on investments. For the year ended December 31, 2022, other income of \$107,088 primarily related to gains from settlements of certain accrued expenses and unrealized gain on investments.

Change in fair value of derivative liabilities

For the years ended December 31, 2023 and 2022, we recognized a gain on the change in fair value of derivative liabilities of \$3,997,780 and \$5,272,473, respectively, related to the reduction in the fair value of the warrants that are accounted for as derivative liabilities and, accordingly, are remeasured at each financial reporting date.

Liquidity and Capital Resources

Liquidity

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

	December 31,	
	2023	2022
Cash and cash equivalents	\$ 884,377	\$ 1,713,772
Investments held in marketable securities	\$ 10,181,618	\$ 13,035,636
Working capital (<i>As Restated</i>)	\$ 8,783,181	\$ 9,146,455

Availability of Additional Funds

Based upon our accumulated deficit of \$146,699,334 as of December 31, 2023, along with our forecast for continued operating losses and our need for financing to fund our contemplated clinical trials, as of such date, we require additional equity and/or debt financing to continue our operations. However, based on cash on hand and investments as of December 31, 2023 and the receipt of approximately \$8,100,000 in gross proceeds in February 2024 pursuant to the warrant exercises discussed below, 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.

“At-the-Market” Offering

In April 2023, we entered into a Capital on Demand Sales Agreement with JonesTrading Institutional Services LLC, or the Sales Agent, under which we currently have the ability to issue and sell shares of our common stock, from time to time, through the Sales Agent, up to an aggregate offering price of approximately \$6,109,000 in what is commonly referred to as an “at-the-market”, or ATM, program. During the year ended December 31, 2023, we sold 132,827 shares of our common stock under the ATM program with the Sales Agent at a weighted-average gross price of approximately \$4.68 per share and raised approximately \$622,000 of gross proceeds. The total commissions and related legal fees were approximately \$127,000, and we received net proceeds of approximately \$495,000. As of December 31, 2023, we had remaining capacity to sell up to an additional approximately \$5,487,000 of common stock under the ATM program.

Registered Direct Offering

In July 2023, we sold an aggregate of 685,033 shares of our common stock in a registered direct public offering. We received net proceeds of approximately \$1,831,000 from the offering.

Warrant Exercises

In February 2024, we received gross proceeds of approximately \$8,100,000 pursuant to the exercise of outstanding warrants. See Item 1 (“Business – Business Development – Material Events During 2024”) for additional information.

Cash Flows

During the years ended December 31, 2023 and 2022, our sources and uses of cash were as follows:

	Year Ended December 31,	
	2023	2022
	(As Restated)	(As Restated)
Net cash used in operating activities	\$ (6,430,211)	\$ (5,913,100)
Net cash provided by (used in) investing activities	3,252,043	(13,399,855)
Net cash provided by financing activities	2,348,773	-
Net decrease in cash	<u>\$ (829,395)</u>	<u>\$ (19,312,955)</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was \$6,430,211 for the year ended December 31, 2023, primarily due to cash used to fund the net loss of \$10,417,704 which gives effect to net non-cash expenses of \$3,472,167, partially offset by \$515,326 of cash provided by changes in our operating assets and liabilities. Net cash used in operating activities was \$5,913,100 for the year ended December 31, 2022, primarily due to cash used to fund the net loss of \$13,222,296 which gives effect to net non-cash expenses of \$7,295,052, partially offset by \$14,144 of cash provided by changes in operating assets and liabilities.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities increased by \$16,651,898 for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to the initial use of cash in the amount of \$16,000,000 for the purchase of investments held in marketable securities made in 2022 for which there was no corresponding activity in 2023.

Net Cash Provided by Financing Activities

Net cash provided by financing activities increased by \$2,348,773 for the year ended December 31, 2023 compared to the year ended December 31, 2022 due to the net proceeds from the ATM and registered direct public offerings of our common stock.

Effects of Inflation

We do not believe that inflation had a material impact on our business, revenues or operating results during the periods presented.

Critical Accounting Estimates

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP, which require our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or the use of different estimates that we reasonably could have used in the current period would have a material impact on our financial condition or results of operations. There are items within our financial statements that require estimation but are not deemed critical, as defined above.

For a detailed discussion of our significant accounting policies and related judgments, see Note 2 of the Notes to Consolidated Financial Statements in “Item 8. Financial Statements and Supplementary Data” of this Annual Report.

Recently Issued Accounting Pronouncements

See Note 2 to our consolidated financial statements for the years ended December 31, 2023 and 2022 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.

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 Amendment No. 1 to 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, 2023.

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, 2023 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, 2023 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, 2023 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;
- Lack of risk assessment procedures on internal controls to detect financial reporting risks in a timely manner;
- Lack of sufficient formal management testing over documented formal procedures and controls, and time to evaluate continuous effectiveness of controls to achieve complete and accurate financial reporting and disclosures, including documented controls over the preparation and review of journal entries and account reconciliations; and
- Lack of design and implementation of effective controls over the accounting for warrants issued in connection with equity financings.

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 weaknesses are remediated, such that these controls are designed, implemented, and are operating effectively for a sufficient period of time. The remediation actions include:

- Management personnel, including our Chief Financial Officer, are overseeing the financial reporting process and implementation of enhanced controls and governance;
- Engagement of external financial consulting firm with expertise in accounting for significant and complex non-routine transactions to continue to enhance financial reporting, financial operations and internal controls; and
- Documentation of key procedures and controls using a risk-based approach.

Management is committed to maintaining a strong internal controls environment and implementing measures designed to help ensure that control deficiencies contributing to the material weakness are remediated as soon as possible. We have documented key procedures and controls using a risk-based approach and have, therefore, made progress toward remediation. We continue to implement our remediation plan, which includes continued engagement of an external financial consulting firm to enhance financial reporting and operations as well as design and implementation of controls. We will consider the material weakness remediated after the applicable controls operate for a sufficient period of time, and Management has concluded, through testing, that the controls are operating effectively.

We 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 2023 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

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.

Name	Age	Positions Held
Lance Alstodt	53	Chief Executive Officer, President and Chairman of the Board
Francisco Silva	49	Vice President of Research and Development, Secretary and Director
Robert E. Kristal	57	Chief Financial Officer
Robert Paccasassi	55	Vice President of Quality Assurance/Regulatory Compliance
Nickolay Kukekov, Ph.D.	50	Director, Compensation Committee Chair
Patrick F. Williams	51	Director, Audit Committee Chair
David Rosa	60	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 and Chair of our Board's Compensation Committee since November 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 and Chair of our Board's Audit Committee 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 and Chair of our Board's Nominating Committee 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. (Nasdaq:BTCY) and Healthcare Triangle, Inc. (Nasdaq:HCTI). Mr. Rosa is Chairman of Neuro Event Labs, a privately-held company in Finland, and an Advisory Board member of SYNAPS Dx, a privately-held company in Bethesda, Maryland. 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
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
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
Harvinder Sandhu, M.D.	Orthopedic Spine Surgeon, Hospital for Special Surgery; Formerly Chief of Spinal Surgery Service, UCLA Medical Center
Christopher Plataras, 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

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	2026
Francisco Silva	II	2025
Nickolay Kukekov	I	2024
Patrick F. Williams	III	2026
David Rosa	II	2025

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, 2023. 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, 2023, our officers, directors and 10% stockholders complied with all Section 16(a) filing requirements applicable to them, except that each of Mr. Alstodt and Mr. Silva filed one Form 4 late (each reporting one transaction) and Dale Broadrick, a 10% stockholder, filed three Forms 4 late (reporting an aggregate of eight transactions).

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, 2023 and 2022 by (i) our principal executive officer, and (ii) our two most highly compensated executive officers, other than our principal executive officer, who were serving as an executive officer as of December 31, 2023 and whose total compensation for the 2023 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	2023	\$ 479,167	\$ 475,000 ⁽²⁾	\$ -	\$ 300,000	\$ -	\$ 1,254,167
Chief Executive Officer	2022	\$ 400,000	\$ -(2)	\$ 52,364	\$ -	\$ -	\$ 452,364
Francisco Silva	2023	\$ 454,167	\$ 437,500 ⁽³⁾	\$ -	\$ 300,000	\$ -	\$ 1,191,667
VP, Research and Development	2022	\$ 375,000	\$ -(3)	\$ 52,364	\$ -	\$ -	\$ 427,364
Robert Kristal	2023	\$ 240,624	\$ 127,500 ⁽⁴⁾	\$ -	\$ 250,000	\$ -	\$ 618,124
Chief Financial Officer	2022	\$ 175,000	\$ -(4)	\$ -	\$ -	\$ -	\$ 175,000

(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) The 2023 Bonus amount represents (a) a discretionary bonus is the amount of \$250,000 in consideration of 2023 services which was paid in 2024 and (b) a discretionary bonus in the amount of \$225,000 in consideration of 2022 services which was paid in 2023.

(3) The 2023 Bonus amount represents (a) a discretionary bonus in the amount of \$225,000 in consideration of 2023 services which was paid in 2024 and (b) a discretionary bonus in the amount of \$212,500 in consideration of 2022 services which was paid in 2023.

(4) The 2023 Bonus amount represents (a) a discretionary bonus in the amount of \$75,000 in consideration of 2023 services which was paid in 2024 and (b) a discretionary bonus in the amount of \$52,500 in consideration of 2022 services which was paid in 2023.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information on outstanding equity awards as of December 31, 2023 to the Named Executive Officers:

Name	Option Awards					Stock Awards			
	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options	Option exercise price	Option expiration date	Number of shares or units of stock that have not vested	Market value of shares of units that have not vested	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested
Lance Alstodt	293,479	-	-	\$ 5.08	3/18/2031	-	\$ -	-	\$ -
Lance Alstodt	34,174	7,885(1)	-	\$ 5.08	11/4/2031	-	\$ -	-	\$ -
Lance Alstodt	53,381	53,381(2)	-	\$ 2.91	2/17/2033	-	\$ -	-	\$ -
Lance Alstodt	-	-	-	\$ -	-	48,913(3)	\$ 85,104	-	\$ -
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	-	\$ -	-	\$ -
Francisco Silva	293,479	-	-	\$ 5.08	3/18/2031	-	\$ -	-	\$ -
Francisco Silva	34,174	7,885(1)	-	\$ 5.08	11/4/2031	-	\$ -	-	\$ -
Francisco Silva	53,381	53,381(2)	-	\$ 2.91	2/17/2033	-	\$ -	-	\$ -
Francisco Silva	-	-	-	\$ -	-	48,913(3)	\$ 85,104	-	\$ -
Robert Kristal	10,490	-	-	\$ 5.08	11/4/2031	-	\$ -	-	\$ -
Robert Kristal	44,484	44,484(2)	-	\$ 2.91	2/17/2033	-	\$ -	-	\$ -

(1) Option becomes exercisable in three nearly equal quarterly installments beginning on February 4, 2024.

(2) Option becomes exercisable in eight nearly equal quarterly installments beginning on February 17, 2024.

(3) Restricted stock vests on March 18, 2024.

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 \$550,000 (giving effect to a \$150,000 performance salary increase received in November 2021 and \$50,000 annual increases in salary pursuant to his employment agreement). 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 to \$5.08 per share) and (ii) 146,740 restricted stock units, or RSUs. The option vested 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 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 or in the event of a change in control (as defined in the 2021 Plan). 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 vested 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, 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 \$525,000 (giving effect to a \$150,000 performance salary increase received in November 2021 and \$50,000 annual increases in salary pursuant to his employment agreement). 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 to \$5.08 per share) and (ii) 146,740 RSUs. The option vested 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 remain exercisable until its expiration date notwithstanding such termination of employment with us. In addition, the RSUs granted to Mr. Silva will vest in the event of the termination of his employment without cause or in the event of a change in control (as defined in the 2021 Plan). 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 vested 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.

Director Compensation

The following table sets forth certain information concerning the compensation of our non-employee directors for the fiscal year ended December 31, 2023:

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Nickolay Kukekov	\$ 30,000	\$ -	\$ 90,000 ⁽¹⁾	\$ -	\$ -	\$ -	\$ 120,000
Patrick F. Williams	\$ 30,000	\$ -	\$ 90,000 ⁽²⁾	\$ -	\$ -	\$ -	\$ 120,000
David Rosa	\$ 30,000	\$ -	\$ 90,000 ⁽³⁾	\$ -	\$ -	\$ -	\$ 120,000

(1) As of December 31, 2023, Dr. Kukekov held options for the purchase of 57,264 shares of common stock.

(2) As of December 31, 2023, Mr. Williams held options for the purchase of 42,518 shares of common stock.

(3) As of December 31, 2023, Mr. Rosa held options for the purchase of 42,518 shares of common stock.

Dr. Kukekov and Messrs. Williams and Rosa, our non-employee directors, as compensation for their services as a director, are entitled to receive per annum \$30,000 in cash and \$90,000 in option grants.

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 20, 2024, 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 B preferred stock as of March 20, 2024.

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 6,769,919 shares of common stock (exclusive of the shares of common stock issuable to Auctus Fund, LLC, or Auctus, as discussed in footnote (10) to the following table) and 1,398,158 shares of Series B preferred stock outstanding as of March 20, 2024.

Name and Address of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Approximate Percent of Class	Number of Shares of Series B Preferred Stock Beneficially Owned	Approximate Percent of Class
Directors and Executive Officers				
Lance Alstodt ⁽¹⁾	790,805 ⁽²⁾	10.7%	-	-
Francisco Silva ⁽¹⁾	756,666 ⁽³⁾	10.3%	-	-
Robert Kristal ⁽¹⁾	205,668 ⁽⁴⁾	3.0%	-	-
Nickolay Kukekov	95,510 ⁽⁵⁾	1.4%	-	-
Patrick F. Williams	82,341 ⁽⁵⁾	1.2%	-	-
David Rosa	82,341 ⁽⁵⁾	1.2%	-	-
All directors and executive officers as a group (7 persons)	2,186,862 ⁽⁶⁾	25.4%	-	-
Certain Beneficial Owners				
Dale Broadrick ⁽⁷⁾	926,126 ⁽⁸⁾	13.7%	-	-
Auctus Fund, LLC ⁽⁹⁾				
Auctus Fund Management LLC ⁽⁹⁾				
Alfred Sollami ⁽⁹⁾				
Louis Posner ⁽⁹⁾	679,753 ⁽¹⁰⁾	9.99%	1,398,158 ⁽¹¹⁾	100%

* Less than 1%

(1) Address is c/o BioRestorative Therapies, Inc., 40 Marcus Drive, Suite One, Melville, New York 11747.

(2) Includes 618,933 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

(3) Includes 597,079 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days and 12,136 shares of common stock held by Mr. Silva in a retirement account.

(4) Includes 197,674 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

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

(6) Includes 1,847,409 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

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

(8) Based upon Amendment No. 9 to Schedule 13D and Forms 4 filed with the SEC. Includes 1,109 shares common stock issuable upon the exercise of currently exercisable warrants and 477,972 shares of common stock held by Fleetco Inc. of which Mr. Broadrick is a 93% stockholder.

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

- (10) Based upon Amendment No. 2 to Schedule 13G filed with the SEC and other filings made by us with the SEC, Auctus holds a warrant for the purchase of up to 1,257,435 shares of our common stock. In addition, Auctus' shares of Series B preferred stock are convertible into an aggregate of 1,398,158 shares of our common stock. In connection with the transaction in which the warrants were issued to Auctus, we issued to Auctus certain shares of our common stock and have agreed to issue to Auctus, upon receipt of notice from Auctus, subject to the limitation discussed below, 1,351,580 shares of our common stock, or the Additional Shares. However, such warrant is not exercisable for the purchase of our common stock, such Series B preferred stock is not convertible into shares of our common stock and the Additional Shares are not issuable to the extent Auctus would beneficially own, after such exercise, conversion or issuance, more than 9.99% of our outstanding shares of common stock. Auctus has advised that, as of March 20, 2024, it owned 645,320 shares of common stock, which represented 9.5% of the then 6,769,919 outstanding shares of common stock, and that the Additional Shares are issuable to it, upon notice from it, to the extent that such issuances would not result in Auctus beneficially owning after such issuances more than 9.99% of our outstanding shares of common stock. Based upon the foregoing, as of March 20, 2024, 34,433 Additional Shares are issuable to Auctus (to comply with the 9.99% beneficial ownership limitation), the remaining Additional Shares are not issuable, Auctus' warrant is not currently exercisable for the purchase of shares of common stock and its Series B preferred stock is not currently convertible into shares of common stock. The number of shares of common stock beneficially owned by Auctus includes the 34,433 Additional Shares currently issuable to it. Without the 9.99% limitation discussed above, Auctus would have beneficial ownership of 4,652,493 shares of common stock.
- (11) Pursuant to the Certificate of Designations of Preferred Stock with regard to the Series B preferred stock, Auctus, as the sole holder of the 1,398,158 outstanding shares of Series B preferred stock, is entitled to vote such shares based on the number of shares of common stock into which such shares are convertible (currently 1,398,158); however, pursuant to such Certificate of Designations of Preferred Stock, as indicated in footnote (10), such Series B preferred stock is not convertible into shares of common stock to the extent Auctus would beneficially own, after such conversion, more than 9.99% of our then outstanding shares of common stock. Since Auctus has advised that, as of March 20, 2024, it owned 645,320 shares of common stock, which represented 9.5% of the outstanding shares of common stock, and, as indicated in footnote (10) above, 34,433 Additional Shares are issuable to it, Auctus' Series B preferred stock is not currently convertible into shares of common stock. Accordingly, as of March 20, 2024, Auctus, as the sole holder of the Series B preferred stock, is not entitled to any votes for such shares.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information as of December 31, 2023 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	1,466,892	\$ 4.11	2,063,311 ⁽¹⁾
Total	<u>1,466,892</u>	<u>\$ 4.11</u>	<u>2,063,311</u>

(1) Includes 97,824 unvested restricted stock units outstanding at December 31, 2023.

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.

Marcum LLP served as our independent registered public accountants for the years ended December 31, 2023 and 2022.

The following is a summary of the fees billed or expected to be billed to us by Marcum LLP, our independent registered public accountants, for professional services rendered with respect to the fiscal years ended December 31, 2023 and 2022 and by Friedman LLP, our former independent registered public accountants, for professional services rendered with respect to the fiscal year ended December 31, 2022:

	2023	2022	
	Marcum LLP	Marcum LLP	Friedman LLP
Audit Fees (1)	\$ 101,500	\$ 65,000	\$ 30,000
Audit-Related Fees (2)	37,000	2,500	4,000
Tax Fees (3)	-	-	-
All Other Fees (4)	-	-	-
	<u>\$ 138,500</u>	<u>\$ 67,500</u>	<u>\$ 34,000</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, 2023 and 2022, 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, S-3 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.

- 3.1 [Amended and Restated Articles of Incorporation, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated December 29, 2022, wherein such document is identified as Exhibit 3.3](#)
- 3.2 [Certificate of Designations of Series B Preferred Stock, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated December 29, 2022, wherein such document is identified as Exhibit 3.4](#)
- 3.3 [Bylaws, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated December 29, 2022, wherein such document is identified as Exhibit 3.5](#)
- 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 [Letter agreement, dated November 21, 2022, by and among BioRestorative Therapies, Inc., Regenerative Sciences, LLC and Regenexx, LLC with regard to License Agreement, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, wherein such document is identified as Exhibit 10.4](#)
- 10.5 [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](#)
- 10.6 [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](#)
- 10.7 [BioRestorative Therapies, Inc. 2021 Stock Incentive Plan, as amended*](#)
- 10.8 [Executive 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](#)
- 10.9 [Executive 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](#)

- 10.10 [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](#)
- 10.11 [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](#)
- 10.12 [Executive Employment Agreement, dated as of November 4, 2021, between BioRestorative Therapies, Inc. and Robert Kristal*](#)
- 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, 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, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.15](#)
- 10.16 [Non-Qualified Stock Option Award Agreement, dated as of November 4, 2021, between BioRestorative Therapies, Inc. and Patrick F. Williams, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.16](#)
- 10.17 [Non-Qualified Stock Option Award Agreement, dated as of November 4, 2021, between BioRestorative Therapies, Inc. and David Rosa, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.17](#)
- 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, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.18](#)
- 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, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.19](#)
- 10.20 [Common Stock Purchase Warrant, dated November 9, 2021, issued by BioRestorative Therapies, Inc. pursuant to public offering, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.20](#)
- 10.21 [Common Stock Purchase Warrant, dated November 9, 2021, issued by BioRestorative Therapies, Inc. to Auctus Fund, LLC, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.21](#)
- 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, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.22](#)

- 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, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.23](#)
- 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, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.24](#)
- 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, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.25](#)
- 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, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021, wherein such document is identified as Exhibit 10.26](#)
- 10.27 [Executive Employment Agreement, dated as of December 29, 2021, between BioRestorative Therapies, Inc. and Robert Paccasassi*](#)
- 10.28 [Incentive Stock Option Award Agreement, dated as of February 17, 2023, between BioRestorative Therapies, Inc. and Lance Alstodt, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, wherein such document is identified as Exhibit 10.28](#)
- 10.29 [Incentive Stock Option Award Agreement, dated as of February 17, 2023, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, wherein such document is identified as Exhibit 10.29](#)
- 10.30 [Incentive Stock Option Award Agreement, dated as of February 17, 2023, between BioRestorative Therapies, Inc. and Robert Kristal, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, wherein such document is identified as Exhibit 10.30](#)
- 10.31 [Incentive Stock Option Award Agreement, dated as of February 17, 2023, between BioRestorative Therapies, Inc. and Robert Paccasassi, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, wherein such document is identified as Exhibit 10.31](#)
- 10.32 [Non-Qualified Stock Option Award Agreement, dated as of February 17, 2023, between BioRestorative Therapies, Inc. and Nickolay Kukekov, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, wherein such document is identified as Exhibit 10.32](#)
- 10.33 [Non-Qualified Stock Option Award Agreement, dated as of February 17, 2023, between BioRestorative Therapies, Inc. and Patrick F. Williams, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, wherein such document is identified as Exhibit 10.33](#)
- 10.34 [Non-Qualified Stock Option Award Agreement, dated as of February 17, 2023, between BioRestorative Therapies, Inc. and David Rosa, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, wherein such document is identified as Exhibit 10.34](#)

10.35	<u>Capital on Demand™ Sales Agreement, dated as of April 14, 2023, by and between BioRestorative Therapies, Inc. and JonesTrading Institutional Services LLC, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated April 14, 2023, wherein such document is identified as Exhibit 1.1</u>
10.36	<u>Incentive Stock Option Award Agreement, dated as of February 13, 2024, between BioRestorative Therapies, Inc. and Lance Alstodt*</u>
10.37	<u>Incentive Stock Option Award Agreement, dated as of February 13, 2024, between BioRestorative Therapies, Inc. and Francisco Silva*</u>
10.38	<u>Incentive Stock Option Award Agreement, dated as of February 13, 2024, between BioRestorative Therapies, Inc. and Robert Kristal*</u>
10.39	<u>Incentive Stock Option Award Agreement, dated as of February 13, 2024, between BioRestorative Therapies, Inc. and Robert Paccasassi*</u>
10.40	<u>Non-Qualified Stock Option Award Agreement, dated as of February 13, 2024, between BioRestorative Therapies, Inc. and Nickolay Kukekov*</u>
10.41	<u>Non-Qualified Stock Option Award Agreement, dated as of February 13, 2024, between BioRestorative Therapies, Inc. and Patrick F. Williams*</u>
10.42	<u>Non-Qualified Stock Option Award Agreement, dated as of February 13, 2024, between BioRestorative Therapies, Inc. and David Rosa*</u>
14	<u>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</u>
21	<u>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</u>
23	<u>Independent Registered Public Accounting Firm's Consent*</u>
31.1	<u>Principal Executive Officer Certification*</u>
31.2	<u>Principal Financial Officer Certification*</u>
32	<u>Section 1350 Certification**</u>
97	<u>Clawback Policy*</u>
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 Amendment No. 1 to the report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIORESTORATIVE THERAPIES, INC.

Dated: June 11, 2024

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this Amendment No. 1 to the 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)	June 11, 2024
<u>/s/ Francisco Silva</u> Francisco Silva	Vice President, Research and Development and Director	June 11, 2024
<u>/s/ Robert E. Kristal</u> Robert E. Kristal	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	June 11, 2024
<u>/s/ Nickolay Kukekov</u> Nickolay Kukekov	Director	June 11, 2024
<u>/s/ Patrick F. Williams</u> Patrick F. Williams	Director	June 11, 2024
<u>/s/ David Rosa</u> David Rosa	Director	June 11, 2024

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BIORESTORATIVE THERAPIES, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BioRestorative Therapies, Inc. (the “Company”) as of December 31, 2023 and 2022, the related consolidated statements of operations, changes in stockholders’ equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Restatement of 2023 and 2022 Financial Statements

As discussed in Note 2 to the financial statements, the accompanying financial statements as of December 31, 2023 and 2022 and for each of the years then ended, have been restated to correct a misstatement relating to the Company’s accounting for warrants.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company’s auditor since 2020.

Marlton, New Jersey

March 29, 2024, except for Note 2, Note 8, Note 9 and Note 11, as to which the date is June 11, 2024

BIORESTORATIVE THERAPIES, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2023	2022
	(As Restated)	(As Restated)
Assets		
Current Assets:		
Cash and cash equivalents	\$ 884,377	\$ 1,713,772
Investments held in marketable securities	10,181,618	13,035,636
Accounts receivable	19,300	16,000
Prepaid expenses and other current assets	305,231	363,082
Total current assets	11,390,526	15,128,490
Property and equipment, net	356,055	261,003
Right-of-use assets	151,447	241,760
Intangible assets, net	713,692	803,438
Total Assets	<u>\$ 12,611,720</u>	<u>\$ 16,434,691</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	189,389	170,902
Accrued expenses and other current liabilities	711,686	130,072
Lease liability, current portion	162,317	139,328
Derivative liabilities	1,543,953	5,541,733
Total Current Liabilities	2,607,345	5,982,035
Lease liability, net of current portion	-	162,317
Total Liabilities	<u>2,607,345</u>	<u>6,144,352</u>
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value; 20,000,000 shares authorized; Series B Convertible Preferred Stock; 1,543,158 shares designated, 1,398,158 and 1,518,158 shares issued and outstanding at December 31, 2023 and 2022, respectively	13,982	15,182
Common stock, \$0.0001 par value; 75,000,000 shares authorized; 4,706,917 and 3,677,775 shares issued and outstanding at December 31, 2023 and 2022, respectively	471	369
Additional paid-in capital	156,689,256	146,556,418
Accumulated deficit	(146,699,334)	(136,281,630)
Total Stockholders' Equity	10,004,375	10,290,339
Total Liabilities and Stockholders' Equity	<u>\$ 12,611,720</u>	<u>\$ 16,434,691</u>

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

BIORESTORATIVE THERAPIES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2023	2022
	(As Restated)	(As Restated)
Revenues, net	\$ 145,800	\$ 119,800
Operating Expenses:		
Research and development	4,034,591	3,513,352
General and administrative	11,331,983	15,580,473
Total Operating Expenses	15,366,574	19,093,825
Loss From Operations	(15,220,774)	(18,974,025)
Other Income:		
Interest income	(552,293)	(11,650)
Gain on PPP loan forgiveness	-	(250,000)
Grant income	(83,333)	(110,518)
Other income	(169,664)	(107,088)
Change in fair value of derivative liabilities	(3,997,780)	(5,272,473)
Total Other Income	(4,803,070)	(5,751,729)
Net Loss	\$ (10,417,704)	\$ (13,222,296)
Net Loss Per Share - Basic and Diluted	\$ (2.47)	\$ (3.65)
Weighted Average Common Shares Outstanding -		
Basic and Diluted	4,218,347	3,617,858

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

BIORESTORATIVE THERAPIES, INC.

**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022**

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance - January 1, 2022 (as previously reported)	1,543,158	\$ 15,432	-	\$ -	3,520,391	\$ 353	\$ 155,727,292	\$ (134,146,128)	\$ 21,596,949
Effect of restatement	-	-	-	-	-	-	(21,901,000)	11,086,794	(10,814,206)
Balance - January 1, 2022 (as restated)	1,543,158	15,432	-	-	3,520,391	353	133,826,292	(123,059,334)	10,782,743
Issuance of Series B Convertible Preferred Stock in exchange for Series A Convertible Preferred Stock	(1,543,158)	(15,432)	1,543,158	15,432	-	-	-	-	-
Warrants issued in connection with license exclusivity agreement	-	-	-	-	-	-	117,030	-	117,030
Conversion of Series B Convertible Preferred Stock into common stock	-	-	(25,000)	(250)	25,000	3	247	-	-
Stock-based compensation:									
Restricted share units	-	-	-	-	116,486	11	4,735,097	-	4,735,108
Options	-	-	-	-	-	-	7,741,864	-	7,741,864
Common stock	-	-	-	-	15,898	2	135,888	-	135,890
Net loss (as restated)	-	-	-	-	-	-	-	(13,222,296)	(13,222,296)
Balance - December 31, 2022 (as restated)	-	-	1,518,158	15,182	3,677,775	369	146,556,418	(136,281,630)	10,290,339
Stock-based compensation:									
Restricted share units	-	-	-	-	89,840	9	4,633,655	-	4,633,664
Options	-	-	-	-	-	-	3,141,803	-	3,141,803
Common stock	-	-	-	-	1,442	-	7,500	-	7,500
Conversion of Series B Convertible Preferred Stock into common stock	-	-	(120,000)	(1,200)	120,000	12	1,188	-	-
Issuance and sale of common stock, net of issuance costs	-	-	-	-	817,860	81	2,348,692	-	2,348,773
Net loss (as restated)	-	-	-	-	-	-	-	(10,417,704)	(10,417,704)
Balance - December 31, 2023 (as restated)	-	\$ -	1,398,158	\$ 13,982	4,706,917	\$ 471	\$ 156,689,256	\$ (146,699,334)	\$ 10,004,375

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

BIORESTORATIVE THERAPIES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2023 (As Restated)	2022 (As Restated)
Cash Flows From Operating Activities:		
Net loss	\$ (10,417,704)	\$ (13,222,296)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	165,735	120,545
Dividend and interest income	(569,068)	(76,004)
Stock-based compensation	7,782,967	12,612,862
Gain on PPP loan forgiveness	-	(250,000)
Non-cash lease expense	90,313	160,122
Change in fair value of derivative liabilities	(3,997,780)	(5,272,473)
Changes in operating assets and liabilities:		
Accounts receivable	(3,300)	(11,000)
Prepaid expenses and other current assets	57,851	73,099
Accounts payable	18,487	120,075
Accrued expenses and other current liabilities	581,616	(4,898)
Lease liability	(139,328)	(163,132)
Net Cash Used In Operating Activities	<u>(6,430,211)</u>	<u>(5,913,100)</u>
Cash Flows From Investing Activities:		
Sale of marketable securities	20,964,373	9,492,304
Purchase of marketable securities	(17,541,287)	(22,451,936)
Purchase of intangible assets	-	(175,000)
Purchases of equipment	(171,043)	(265,223)
Net Cash Provided By (Used In) Investing Activities	<u>3,252,043</u>	<u>(13,399,855)</u>
Cash Flows From Financing Activities:		
Net proceeds from issuance of common stock in ATM transactions	494,783	-
Net proceeds from issuance of common stock in registered direct offering	1,853,990	-
Net Cash Provided By Financing Activities	<u>2,348,773</u>	<u>-</u>
Net Decrease In Cash and Cash Equivalents	(829,395)	(19,312,955)
Cash and Cash Equivalents - Beginning of the Year	<u>1,713,772</u>	<u>21,026,727</u>
Cash and Cash Equivalents - End of the Year	<u>\$ 884,377</u>	<u>\$ 1,713,772</u>
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
Non-cash investing and financing activities:		
Warrants issued as consideration for intangible assets	\$ -	\$ 117,030
Return and cancellation of shares in lieu of payroll tax withholding	\$ 39,308	\$ -

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

BIORESTORATIVE THERAPIES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - ORGANIZATION, LIQUIDITY 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 December 23, 2022, the Company reincorporated from Delaware to Nevada by filing Articles of Incorporation with the state of Nevada. The reincorporation was structured as a statutory merger.

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 satisfying liabilities in the normal course of business. For the year ended December 31, 2023, the Company had a net loss of \$10.4 million and negative cash flows from operations of \$6.4 million. The Company anticipates that it will continue to incur net losses and negative cash flows from operations as it executes its development plans for 2024 and beyond, as well as other potential strategic and business development initiatives. The Company has previously funded, and plans to continue funding, these losses primarily through current cash on hand, investments in marketable securities and additional infusions of cash from equity and debt financing. Subsequent to December 31, 2023, the Company raised gross proceeds of approximately \$8.1 million in connection with a warrant exercise program, which is further discussed in Note 12 – Subsequent Events.

Based on cash on hand as of the date these financial statements were issued, which includes \$8.1 million of gross proceeds from the warrant exercise program, the Company believes it has sufficient cash on hand in order to fund operations for at least the twelve months after the issuance date of these financial statements.

Current funds noted above 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 needed 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.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”), which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the consolidated financial statements do not necessarily purport to represent realizable or settlement values. The accompanying consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

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. The information contained in the website or connected thereto is not intended to be incorporated by reference into the accompanying financial statements or these footnotes. 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 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying 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

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Stem Pearls. All intercompany accounts and transactions have been eliminated in consolidation.

Restatement of Previously Issued Consolidated Financial Statements

On May 23, 2024, the Company, in consultation with its Audit Committee, concluded that its previously issued (i) consolidated financial statements as of and for the two years ended December 31, 2023 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 (the "Annual Periods") and (ii) unaudited interim condensed consolidated financial statements as of and for the quarters ended March 31, 2022 through September 30, 2023 included in the Company's quarterly reports on Form 10-Q for the periods ended March 31, 2023, June 30, 2023 and September 30, 2023 (the "Interim Periods", and, together with the Annual Periods, the "Affected Periods") should be restated because of a misapplication in the guidance around the accounting for certain warrants, as discussed below, and should no longer be relied upon.

The warrants at issue are the following:

- (i) the warrants to purchase an aggregate of 2,645,000 shares of the Company's common stock, issued in November 2021 pursuant to an underwritten public offering, which warrants provide for an exercise price of \$10.00 per share (the "Public Warrants");
- (ii) the warrants to purchase an aggregate of 1,856,938 shares of the Company's common stock, issued in November 2021 pursuant to a private offering, which warrants provide for an exercise price of \$10.00 per share (the "Private Warrants"); and
- (iii) the warrants to purchase an aggregate of 235,970 shares of the Company's common stock, issued in November 2021 to the underwriter of the public offering, which warrants provide for an exercise price of \$12.50 per share (together with the Public Warrants and the Private Warrants, the "Warrants").

Historically, the Warrants were included as a component of stockholders' equity. It has now been determined, in accordance with Accounting Standards Codification ("ASC") 815, that the Warrants should be included at fair value as a component of liabilities on the balance sheets, and the statements of operations should include the subsequent non-cash changes in estimated fair value of the Warrants (the "Restatement"). See Note 11 – Fair Value Measurement for details of the estimated fair value of the Warrants.

The Company evaluated the materiality of these misstatements and determined the effect of correcting these misstatements was material to the Affected Periods. As a result of the material misstatements, the Company has restated its consolidated financial statements for the Affected Periods in accordance with ASC 250, Accounting Changes and Error Corrections (the "Restated Financial Statements").

A reconciliation from the amounts previously reported for the Affected Periods to the restated amounts in the Restated Financial Statements is provided for the impacted financial statement line items below for: (i) the consolidated balance sheets as of December 31, 2023 and 2022; (ii) the consolidated statements of operations for the years ended December 31, 2023 and 2022; (iii) the consolidated statements of changes in stockholders' equity for the years ended December 31, 2023 and 2022; and (iv) the consolidated statements of cash flows for the years ended December 31, 2023 and 2022. The amounts labeled "Restatement Adjustments" represent the effects of the Restatement.

The following tables present the effects of the Restatement on the Company's consolidated balance sheets as of December 31, 2023 and 2022:

December 31, 2023			
	As Previously Stated	Restatement Adjustments	As Restated
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Derivative liabilities	\$ -	\$ 1,543,953	\$ 1,543,953
Total current liabilities	\$ 1,063,392	\$ 1,543,953	\$ 2,607,345
Total liabilities	\$ 1,063,392	\$ 1,543,953	\$ 2,607,345
Stockholders' equity			
Additional paid-in capital	\$ 178,590,256	\$ (21,901,000)	\$ 156,689,256
Accumulated deficit	\$ (167,056,381)	\$ 20,357,047	\$ (146,699,334)
Total stockholders' equity	\$ 11,548,328	\$ (1,543,953)	\$ 10,004,375
Total liabilities and stockholders' equity	\$ 12,611,720	\$ -	\$ 12,611,720

December 31, 2022			
	As Previously Stated	Restatement Adjustments	As Restated
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Derivative liabilities	\$ -	\$ 5,541,733	\$ 5,541,733
Total current liabilities	\$ 440,302	\$ 5,541,733	\$ 5,982,035
Total liabilities	\$ 602,619	\$ 5,541,733	\$ 6,144,352
Stockholders' equity			
Additional paid-in capital	\$ 168,457,418	\$ (21,901,000)	\$ 146,556,418
Accumulated deficit	\$ (152,640,897)	\$ 16,359,267	\$ (136,281,630)
Total stockholders' equity	\$ 15,832,072	\$ (5,541,733)	\$ 10,290,339
Total liabilities and stockholders' equity	\$ 16,434,691	\$ -	\$ 16,434,691

The following tables present the effects of the Restatement on the Company's consolidated statements of operations for the years ended December 31, 2023 and 2022:

For the Year Ended December 31, 2023			
	As Previously Stated	Restatement Adjustments	As Restated
Change in fair value of derivative liabilities	\$ -	\$ (3,997,780)	\$ (3,997,780)
Total other income	\$ (805,290)	\$ (3,997,780)	\$ (4,803,070)
Net (loss) income	\$ (14,415,484)	\$ 3,997,780	\$ (10,417,704)
Earnings (loss) per share - basic and diluted	\$ (3.42)	\$ 0.95	\$ (2.47)

For the Year Ended December 31, 2022			
	As Previously Stated	Restatement Adjustments	As Restated
Change in fair value of derivative liabilities	\$ -	\$ (5,272,473)	\$ (5,272,473)
Total other income	\$ (479,256)	\$ (5,272,473)	\$ (5,751,729)
Net (loss) income	\$ (18,494,769)	\$ 5,272,473	\$ (13,222,296)

Loss per share:			
Earnings (loss) per share - basic and diluted	\$ (5.11)	\$ 1.46	\$ (3.65)

The following tables present the effects of the Restatement on the Company's consolidated statements of changes in stockholders' equity for the years ended December 31, 2023 and 2022:

Balance - December 31, 2023 (as previously reported)	\$	178,590,256	\$	(167,056,381)	\$	11,548,328
Adjustment due to cumulative error correction		(21,901,000)		16,359,267		(5,541,733)
Change in fair value of derivative liability		-		3,997,780		3,997,780
Balance - December 31, 2023 (as restated)	\$	<u>156,689,256</u>	\$	<u>(146,699,334)</u>	\$	<u>10,004,375</u>
Balance - December 31, 2022 (as previously reported)	\$	168,457,418	\$	(152,640,897)	\$	15,832,072
Adjustment due to cumulative error correction		(21,901,000)		11,086,794		(10,814,206)
Change in fair value of derivative liability		-		5,272,473		5,272,473
Balance - December 31, 2022 (as restated)	\$	<u>146,556,418</u>	\$	<u>(136,281,630)</u>	\$	<u>10,290,339</u>

The following tables present the effects of the Restatement on the Company's consolidated statements of cash flows for the years ended December 31, 2023 and 2022:

	December 31, 2023		
	As Previously Stated	Restatement Adjustments	As Restated
Cash Flows From Operating Activities:			
Net (loss) income	\$ (14,415,484)	\$ 3,997,780	\$ (10,417,704)
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Change in fair value of derivative liability	\$ -	\$ (3,997,780)	\$ (3,997,780)
Net Cash Used In Operating Activities	\$ (6,430,211)	\$ -	\$ (6,430,211)
	December 31, 2022		
	As Previously Stated	Restatement Adjustments	As Restated
Cash Flows From Operating Activities:			
Net (loss) income	\$ (18,494,769)	\$ 5,272,473	\$ (13,222,296)
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Change in fair value of derivative liability	\$ -	\$ (5,272,473)	\$ (5,272,473)
Net Cash Used In Operating Activities	\$ (5,913,100)	\$ -	\$ (5,913,100)

The remainder of the notes to the Company's consolidated financial statements have been updated and restated, as applicable, to reflect the impact of the Restatement described above.

See Note 3 - Restatement of Previously Issued Unaudited Interim Condensed Consolidated Financial Statements for details of the effect of the Restatement on the Interim Periods.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, together with amounts disclosed in the related notes to the 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.

Reclassifications

Certain prior period balance sheet, statement of operations and statement of cash flows amounts have been reclassified to conform to the Company's fiscal 2023 presentation. These reclassifications have no impact on the Company's previously reported net loss.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist of a cash account in a financial institution. The Company maintains deposits in its cash account in excess of the Federal Depository Insurance Coverage limit of \$250,000. As of December 31, 2023, the Company had not experienced losses on this account.

The royalties related to the Company's sublicense comprised 100% of the Company's revenue during the years ended December 31, 2023 and 2022. See "Revenue Recognition" below.

Revenue Recognition

The Company accounts for revenue in accordance with Accounting Standards Codification (“ASC”) 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. In November 2022, the Company’s license rights under the agreement became exclusive. 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. 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, 2023 and 2022, the Company recognized \$145,800 and \$119,800, respectively, of revenue related to the Company’s sublicenses.

Practical Expedients

As part of ASC 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 606 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.

Cash and Cash Equivalents

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, 2023 or 2022.

Accounts Receivable

Accounts receivable are carried at their contractual amounts, less a provision for current expected credit losses. The reserve represents the Company's best estimate of expected credit losses it may experience in the Company's receivable portfolio. Management estimates the allowance for credit losses based on an ongoing review of existing economic conditions, the financial conditions of the customers, historical trends in credit losses, and the amount and age of past due accounts. The Company writes off accounts receivable against the provision for current expected credit losses when a balance is determined to be uncollectible. The Company did not record a provision for current expected credit losses as of December 31, 2023 or 2022.

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.

Intangible Assets

The Company records its intangible assets at cost in accordance with 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.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including definite-lived intangible assets and right-of-use assets from operating leases, 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, 2023 and 2022, we determined that there was no impairment charge for our long-lived assets.

Derivative Financial Instruments

The Company evaluates all of its agreements to determine if such instruments have derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments, the Company uses a weighted-average Black-Scholes option pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period.

Fair Value of Financial Instruments

Fair value is defined as the amount that would be received for selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and is measured using inputs in one of the following three categories:

Level 1 measurements are based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access. Valuation of these items does not entail a significant amount of judgment.

Level 2 measurements are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active or market data other than quoted prices that are observable for the assets or liabilities.

Level 3 measurements are based on unobservable data that are supported by little or no market activity and are significant to the fair value of the assets or liabilities.

The Company considers cash and cash equivalents, investments held in marketable securities, accounts receivable, accounts payable and derivative liabilities to meet the definition of financial instruments. As of December 31, 2023 and 2022, the carrying amount of cash and cash equivalents, investments held in marketable securities, accounts receivable, and accounts payable approximate their fair value due to the relatively short period of time between their origination and their expected realization or payment. The Warrants are measured at fair value (see Note 11 – Fair Value Measurement for additional details).

During the years ended December 31, 2023 and 2022, the Company recognized aggregate dividend and interest income of \$569,068 and \$76,004 respectively, on its marketable securities, which was included within other income on its consolidated statements of operations.

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 period. The dilutive effect, if any, of stock options and warrants are calculated using the treasury stock method. All outstanding convertible preferred stock is 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 preferred stock have been excluded from the Company's computation of diluted net loss per common share for the periods presented.

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:

	For the Years Ended December 31,	
	2023	2022
Stock options	1,466,892	864,639
Warrants	4,791,019	4,791,082
Unvested RSUs	97,827	201,870
Convertible Preferred Stock	1,398,158	1,518,158
	<u>7,753,896</u>	<u>7,375,749</u>

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and then is recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period, on a straight-line basis. The Company computes the fair value of equity-classified warrants and options granted using the Black-Scholes option pricing model. Option forfeitures are recorded as incurred as a reduction of amounts previously expensed.

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 asset 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.

Leases

The Company determines whether an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use (“ROU”) assets and operating lease liabilities in our consolidated balance sheets.

ROU assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company’s leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments at commencement date. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that it will exercise the option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses*, which requires entities to estimate all expected credit losses for financial assets measured at amortized cost basis, including trade receivables, held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The Company adopted this guidance on January 1, 2023. The adoption of this accounting standard did not have a material impact on the Company’s consolidated financial statements.

NOTE 3 - RESTATEMENT OF PREVIOUSLY ISSUED UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

The following tables present the effects of the Restatement described in Note 2 - Summary of Significant Accounting Policies – Restatement of Previously Issued Consolidated Financial Statements on the Company’s unaudited interim condensed consolidated financial statements for the periods indicated.

The following tables present the effects of the Restatement on the Company’s unaudited interim condensed consolidated balance sheets as of the dates indicated:

	March 31, 2022			
	As Previously Stated	Restatement Adjustments	As Restated	
	(unaudited)		(unaudited)	
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Derivative liabilities	\$ -	\$ 14,205,418	\$ 14,205,418	
Total current liabilities	\$ 493,829	\$ 14,205,418	\$ 14,699,247	
Total liabilities	\$ 762,186	\$ 14,205,418	\$ 14,967,604	
Stockholders' equity				
Additional paid-in capital	\$ 159,103,184	\$ (21,901,000)	\$ 137,202,184	
Accumulated deficit	\$ (138,962,278)	\$ 7,695,582	\$ (131,266,696)	
Total stockholders' equity	\$ 20,156,702	\$ (14,205,418)	\$ 5,951,284	
Total liabilities and stockholders' equity	\$ 20,918,888	\$ -	\$ 20,918,888	

					June 30, 2022		
					As Previously Stated	Restatement Adjustments	As Restated
					(unaudited)		(unaudited)
LIABILITIES AND STOCKHOLDERS' EQUITY							
Current liabilities							
Derivative liabilities	\$	-	\$	6,430,025	\$		6,430,025
Total current liabilities	\$	621,781	\$	6,430,025	\$		7,051,806
Total liabilities	\$	855,841	\$	6,430,025	\$		7,285,866
Stockholders' equity							
Additional paid-in capital	\$	162,207,334	\$	(21,901,000)	\$		140,306,334
Accumulated deficit	\$	(143,637,519)	\$	15,470,975	\$		(128,166,544)
Total stockholders' equity	\$	18,585,612	\$	(6,430,025)	\$		12,155,587
Total liabilities and stockholders' equity	\$	19,441,453	\$	-	\$		19,441,453

					September 30, 2022		
					As Previously Stated	Restatement Adjustments	As Restated
					(unaudited)		(unaudited)
LIABILITIES AND STOCKHOLDERS' EQUITY							
Current liabilities							
Derivative liabilities	\$	-	\$	7,220,748	\$		7,220,748
Total current liabilities	\$	717,179	\$	7,220,748	\$		7,937,927
Total liabilities	\$	915,903	\$	7,220,748	\$		8,136,651
Stockholders' equity							
Additional paid-in capital	\$	165,281,862	\$	(21,901,000)	\$		143,380,862
Accumulated deficit	\$	(148,293,344)	\$	14,680,252	\$		(133,613,092)
Total stockholders' equity	\$	17,004,315	\$	(7,220,748)	\$		9,783,567
Total liabilities and stockholders' equity	\$	17,920,218	\$	-	\$		17,920,218

					March 31, 2023		
					As Previously Stated	Restatement Adjustments	As Restated
					(unaudited)		(unaudited)
LIABILITIES AND STOCKHOLDERS' EQUITY							
Current liabilities							
Derivative liabilities	\$	-	\$	7,030,083	\$		7,030,083
Total current liabilities	\$	470,391	\$	7,030,083	\$		7,500,474
Total liabilities	\$	593,927	\$	7,030,083	\$		7,624,010
Stockholders' equity							
Additional paid-in capital	\$	171,796,596	\$	(21,901,000)	\$		149,895,596
Accumulated deficit	\$	(158,325,119)	\$	14,870,917	\$		(143,454,202)
Total stockholders' equity	\$	13,487,037	\$	(7,030,083)	\$		6,456,954
Total liabilities and stockholders' equity	\$	14,080,964	\$	-	\$		14,080,964

June 30, 2023				
	As Previously Stated	Restatement Adjustments	As Restated	
	(unaudited)		(unaudited)	
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Derivative liabilities	\$ -	\$ 9,758,930	\$ 9,758,930	
Total current liabilities	\$ 812,853	\$ 9,758,930	\$ 10,571,783	
Total liabilities	\$ 896,433	\$ 9,758,930	\$ 10,655,363	
Stockholders' equity				
Additional paid-in capital	\$ 173,695,154	\$ (21,901,000)	\$ 151,794,154	
Accumulated deficit	\$ (161,305,671)	\$ 12,142,070	\$ (149,163,601)	
Total stockholders' equity	\$ 12,403,864	\$ (9,758,930)	\$ 2,644,934	
Total liabilities and stockholders' equity	\$ 13,300,297	\$ -	\$ 13,300,297	

September 30, 2023				
	As Previously Stated	Restatement Adjustments	As Restated	
	(unaudited)		(unaudited)	
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Derivative liabilities	\$ -	\$ 2,065,177	\$ 2,065,177	
Total current liabilities	\$ 932,619	\$ 2,065,177	\$ 2,997,796	
Total liabilities	\$ 975,033	\$ 2,065,177	\$ 3,040,210	
Stockholders' equity				
Additional paid-in capital	\$ 177,042,781	\$ (21,901,000)	\$ 155,141,781	
Accumulated deficit	\$ (164,231,163)	\$ 19,835,823	\$ (144,395,340)	
Total stockholders' equity	\$ 12,826,068	\$ (2,065,177)	\$ 10,760,891	
Total liabilities and stockholders' equity	\$ 13,801,101	\$ -	\$ 13,801,101	

The following tables present the effect of the Restatement on the Company's unaudited interim condensed consolidated statements of operations for the periods indicated:

For the Three Months Ended March 31, 2022				
	As Previously Stated	Restatement Adjustments	As Restated	
	(unaudited)		(unaudited)	
Change in fair value of derivative liabilities	\$ -	\$ 3,391,212	\$ 3,391,212	
Total other (income) expense	\$ (237,643)	\$ 3,391,212	\$ 3,153,569	
Net loss	\$ (4,816,150)	\$ (3,391,212)	\$ (8,207,362)	
Earnings (loss) per share - basic and diluted	\$ (1.37)	\$ (0.96)	\$ (2.33)	

For the Three Months Ended June 30, 2022			For the Six Months Ended June 30, 2022		
As Previously Stated	Restatement Adjustments	As Restated	As Previously Stated	Restatement Adjustments	As Restated
(unaudited)		(unaudited)	(unaudited)		(unaudited)
Change in fair value of derivative liabilities	\$ -	\$ (7,775,393)	\$ (7,775,393)	\$ -	\$ (4,384,181)
Total other (income) expense	\$ 46,613	\$ (7,775,393)	\$ (7,728,780)	\$ (191,030)	\$ (4,384,181)
Net (loss) income	\$ (4,675,241)	\$ 7,775,393	\$ 3,100,152	\$ (9,491,391)	\$ (5,107,210)
Earnings (loss) per share - basic:	\$ (1.28)	\$ 2.14	\$ 0.85	\$ (2.65)	\$ 1.22
Weighted average common shares outstanding - diluted	3,638,383	5,818,645	9,457,028	3,581,110	-
Earnings (loss) per share - diluted	\$ (1.28)	\$ 0.82	\$ 0.33	\$ (2.65)	\$ 1.22

For the Three Months Ended September 30, 2022			For the Nine Months Ended September 30, 2022		
As Previously Stated	Restatement Adjustments	As Restated	As Previously Stated	Restatement Adjustments	As Restated
(unaudited)		(unaudited)	(unaudited)		(unaudited)
Change in fair value of derivative liabilities	\$ -	\$ 790,723	\$ 790,723	\$ -	\$ (3,593,458)
Total other expense (income)	\$ 46,125	\$ 790,723	\$ 836,848	\$ (144,905)	\$ (3,593,458)
Net (loss) income	\$ (4,655,825)	\$ (790,723)	\$ (5,446,548)	\$ (14,147,216)	\$ (3,593,458)
Earnings (loss) per share - basic and diluted	\$ (1.28)	\$ (0.22)	\$ (1.50)	\$ (3.93)	\$ 1.00

For the Three Months Ended March 31, 2023				
	As Previously Stated (unaudited)	Restatement Adjustments	As Restated (unaudited)	
Change in fair value of derivative liabilities	\$ -	\$ 1,488,350	\$ 1,488,350	
Total other income	\$ (94,876)	\$ 1,488,350	\$ 1,393,474	
Net (loss) income	\$ (5,684,222)	\$ (1,488,350)	\$ (7,172,572)	
Earnings (loss) per share - basic and diluted	\$ (1.53)	\$ (0.40)	\$ (1.93)	

	For the Three Months Ended June 30, 2023			For the Six Months Ended June 30, 2023		
	As Previously Stated (unaudited)	Restatement Adjustments	As Restated (unaudited)	As Previously Stated (unaudited)	Restatement Adjustments	As Restated (unaudited)
Change in fair value of derivative liabilities	\$ -	\$ 2,728,847	\$ 2,728,847	\$ -	\$ 4,217,197	\$ 4,217,197
Total other income	\$ (135,999)	\$ 2,728,847	\$ 2,592,848	\$ (230,875)	\$ 4,217,197	\$ 3,986,322
Net (loss) income	\$ (2,980,552)	\$ (2,728,847)	\$ (5,709,399)	\$ (8,664,774)	\$ (4,217,197)	\$ (12,881,971)
Earnings (loss) per share - basic and diluted	\$ (0.77)	\$ (0.70)	\$ (1.47)	\$ (2.28)	\$ (1.11)	\$ (3.39)

	For the Three Months Ended September 30, 2023			For the Nine Months Ended September 30, 2023		
	As Previously Stated (unaudited)	Restatement Adjustments	As Restated (unaudited)	As Previously Stated (unaudited)	Restatement Adjustments	As Restated (unaudited)
Change in fair value of derivative liabilities	\$ -	\$ (7,693,753)	\$ (7,693,753)	\$ -	\$ (3,476,556)	\$ (3,476,556)
Total other income	\$ (178,951)	\$ (7,693,753)	\$ (7,872,704)	\$ (409,826)	\$ (3,476,556)	\$ (3,886,382)
Net (loss) income	\$ (2,925,492)	\$ 7,693,753	\$ 4,768,261	\$ (11,590,266)	\$ 3,476,556	\$ (8,113,710)
Earnings (loss) per share - basic:	\$ (0.64)	\$ 1.68	\$ 1.04	\$ (2.85)	\$ 0.85	\$ (2.00)
Weighted average common shares outstanding - diluted	4,570,843	7,753,923	12,324,766	4,061,975	-	4,061,975
Earnings (loss) per share - diluted	\$ (0.64)	\$ 1.03	\$ 0.39	\$ (2.85)	\$ 0.85	\$ (2.00)

The following tables present the effect of the Restatement on the Company's unaudited interim condensed consolidated statements of changes in stockholders' equity for the periods indicated:

	Additional Paid-In Capital	Accumulated Deficit	Total
Balance - March 31, 2022 (as previously reported)	\$ 159,103,184	\$ (138,962,278)	\$ 20,156,702
Adjustment due to cumulative error correction	(21,901,000)	11,086,794	(10,814,206)
Change in fair value of derivative liability	-	(3,391,212)	(3,391,212)
Balance - March 31, 2022 (as restated)	\$ 137,202,184	\$ (131,266,696)	\$ 5,951,284
Balance - June 30, 2022 (as previously reported)	\$ 162,207,334	\$ (143,637,519)	\$ 18,585,612
Adjustment due to cumulative error correction	(21,901,000)	11,086,794	(10,814,206)
Change in fair value of derivative liability	-	4,384,181	4,384,181
Balance - June 30, 2022 (as restated)	\$ 140,306,334	\$ (128,166,544)	\$ 12,155,587
Balance - September 30, 2022 (as previously reported)	\$ 165,281,862	\$ (148,293,344)	\$ 17,004,315
Adjustment due to cumulative error correction	(21,901,000)	11,086,794	(10,814,206)
Change in fair value of derivative liability	-	3,593,458	3,593,458
Balance - September 30, 2022 (as restated)	\$ 143,380,862	\$ (133,613,092)	\$ 9,783,567

	Additional Paid-In Capital	Accumulated Deficit	Total
Balance - March 31, 2023 (as previously reported)	\$ 171,796,596	\$ (158,325,119)	\$ 13,487,037
Adjustment due to cumulative error correction	(21,901,000)	16,359,267	\$ (5,541,733)
Change in fair value of derivative liability	<u>-</u>	<u>(1,488,350)</u>	<u>(1,488,350)</u>
Balance - March 31, 2023 (as restated)	<u>\$ 149,895,596</u>	<u>\$ (143,454,202)</u>	<u>\$ 6,456,954</u>
Balance - June 30, 2023 (as previously reported)	\$ 173,695,154	\$ (161,305,671)	\$ 12,403,864
Adjustment due to cumulative error correction	(21,901,000)	16,359,267	\$ (5,541,733)
Change in fair value of derivative liability	<u>-</u>	<u>(4,217,197)</u>	<u>(4,217,197)</u>
Balance - June 30, 2023 (as restated)	<u>\$ 151,794,154</u>	<u>\$ (149,163,601)</u>	<u>\$ 2,644,934</u>
Balance - September 30, 2023 (as previously reported)	\$ 177,042,781	\$ (164,231,163)	\$ 12,826,068
Adjustment due to cumulative error correction	(21,901,000)	16,359,267	\$ (5,541,733)
Change in fair value of derivative liability	<u>-</u>	<u>3,476,556</u>	<u>3,476,556</u>
Balance - September 30, 2023 (as restated)	<u>\$ 155,141,781</u>	<u>\$ (144,395,340)</u>	<u>\$ 10,760,891</u>

The following tables present the effect of the Restatement on the Company's unaudited interim condensed consolidated statements of cash flows for the periods indicated:

	March 31, 2022		
	As Previously Stated	Restatement Adjustments	As Restated (unaudited)
Cash Flows From Operating Activities:			
Net (loss) income	\$ (4,816,150)	\$ (3,391,212)	\$ (8,207,362)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Change in fair value of derivative liability	\$ -	\$ 3,391,212	\$ 3,391,212
Net Cash Used In Operating Activities	\$ (1,594,634)	\$ -	\$ (1,594,634)

	June 30, 2022		
	As Previously Stated (unaudited)	Restatement Adjustments	As Restated (unaudited)
Cash Flows From Operating Activities:			
Net (loss) income	\$ (9,491,391)	\$ 4,384,181	\$ (5,107,210)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Change in fair value of derivative liability	\$ -	\$ (4,384,181)	\$ (4,384,181)
Net Cash Used In Operating Activities	\$ (2,845,756)	\$ -	\$ (2,845,756)

September 30, 2022			
	As Previously Stated	Restatement Adjustments	As Restated
	(unaudited)		(unaudited)
Cash Flows From Operating Activities:			
Net (loss) income	\$ (14,147,216)	\$ 3,593,458	\$ (10,553,758)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Change in fair value of derivative liability	\$ -	\$ (3,593,458)	\$ (3,593,458)
Net Cash Used In Operating Activities	\$ (4,297,412)	\$ -	\$ (4,297,412)

March 31, 2023			
	As Previously Stated	Restatement Adjustments	As Restated
	(unaudited)		(unaudited)
Cash Flows From Operating Activities:			
Net (loss) income	\$ (5,684,222)	\$ (1,488,350)	\$ (7,172,572)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Change in fair value of derivative liability	\$ -	\$ 1,488,350	\$ 1,488,350
Net Cash Used In Operating Activities	\$ (2,348,740)	\$ -	\$ (2,348,740)

June 30, 2023			
	As Previously Stated	Restatement Adjustments	As Restated
	(unaudited)		(unaudited)
Cash Flows From Operating Activities:			
Net (loss) income	\$ (8,664,774)	\$ (4,217,197)	\$ (12,881,971)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Change in fair value of derivative liability	\$ -	\$ 4,217,197	\$ 4,217,197
Net Cash Used In Operating Activities	\$ (3,479,065)	\$ -	\$ (3,479,065)

September 30, 2023			
	As Previously Stated	Restatement Adjustments	As Restated
	(unaudited)		(unaudited)
Cash Flows From Operating Activities:			
Net (loss) income	\$ (11,590,266)	\$ 3,476,556	\$ (8,113,710)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Change in fair value of derivative liability	\$ -	\$ (3,476,556)	\$ (3,476,556)
Net Cash Used In Operating Activities	\$ (4,656,785)	\$ -	\$ (4,656,785)

NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	December 31,	
	2023	2022
Medical equipment	\$ 352,133	\$ 352,133
Furniture and fixtures	123,486	123,486
Computer software and equipment	136,205	117,544
Office equipment	18,779	18,779
Manufacturing equipment	395,232	242,852
Leasehold improvements	342,048	342,048
	1,367,883	1,196,842
Less: accumulated depreciation	(1,011,828)	(935,839)
Property and equipment, net	\$ 356,055	\$ 261,003

Total depreciation expense for the years ended December 31, 2023 and 2022 was \$75,989 and \$42,212, respectively. Depreciation expense is reflected in general and administrative expenses and research and development expenses in the consolidated statements 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 (excluding Asia and Argentina), exclusive, royalty-bearing license from the SCTC to utilize or sublicense a certain method for culturing cells and 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). 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 became non-exclusive. However, the Company and the SCTC entered into an amended agreement under which the Company paid \$175,000 and issued 51,370 warrants, with a fair value of \$117,030, in exchange for renewed exclusivity. The consideration transferred to the SCTC in exchange for exclusivity was capitalized to intangible assets on the Company’s consolidated balance sheet as of December 31, 2022.

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 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, 2022	\$ 3,676	\$ 1,301,500	\$ (715,436)	\$ 589,740
Consideration transferred for license exclusivity	-	292,030	-	292,030
Amortization expense	-	-	(78,332)	(78,332)
Balance as of December 31, 2022	3,676	1,593,530	(793,768)	803,438
Amortization expense	-	-	(89,746)	(89,746)
Balance as of December 31, 2023	\$ 3,676	\$ 1,593,530	\$ (883,514)	\$ 713,692
Weighted average remaining amortization period at December 31, 2023 (in years)	-	10.9		

Amortization of intangible assets consists of the following:

	Patents and Trademarks	Licenses	Accumulated Amortization
Balance as of January 1, 2022	\$ 3,676	\$ 711,760	\$ 715,436
Amortization expense	-	78,332	78,332
Balance as of December 31, 2022	3,676	790,092	793,768
Amortization expense	-	89,746	89,746
Balance as of December 31, 2023	\$ 3,676	\$ 879,838	\$ 883,514

Amortization expense for the next five years is as follows:

For the Years Ending December 31,	Total
2024	\$ 89,746
2025	89,746
2026	89,746
2027	89,746
2028	89,746
	<u>\$ 448,730</u>

NOTE 6 - ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of:

	December 31,	
	2023	2022
Accrued bonuses	\$ 638,000	\$ 26,250
Accrued general and administrative expenses	73,686	103,822
Total accrued expenses and other current liabilities	<u>\$ 711,686</u>	<u>\$ 130,072</u>

NOTE 7 - NOTES PAYABLE

A summary of the notes payable activity during the years ended December 31, 2023 and 2022 is presented below:

Outstanding, January 1, 2022	\$ 250,000
Issuance	-
Forgiveness	<u>(250,000)</u>
Outstanding, December 31, 2022	-
Issuance	-
Forgiveness	-
Outstanding, December 31, 2023	<u>\$ -</u>

NOTE 8 - STOCKHOLDERS' EQUITY*Series A Preferred Stock*

On November 8, 2021, in connection with the Company's public offering, the Company's Board of Directors adopted a resolution allowing for the designation and issuance of 1,543,158 shares of the Company's Preferred Stock, \$.01 par value per share, designated as Series A Preferred Stock ("Series A"). The Series A had a liquidation preference of \$0.001 per share. On September 8, 2022, the Company issued 1,543,158 shares of Series B Preferred Stock ("Series B") to Auctus Fund, LLC ("Auctus") in exchange for an equal number of shares of the Company's outstanding Series A. Simultaneously, the stock certificate representing the Series A shares was being returned to the Company for cancellation. On such date and upon such exchange, the Company's Board of Directors cancelled the Series A.

Series B Preferred Stock

Effective September 8, 2022, the Company issued 1,543,158 shares of Series B to Auctus in exchange for an equal number of shares of the Company's outstanding Series A. The terms of the Series B are substantially identical to those of the Series A, except that, among other things, the limitation on beneficial ownership of common stock of the Company upon a conversion of the Series B into Common Stock, and the limitation on the number of votes attributable to the Series B, is 9.99% of the then outstanding Common Stock of the Company instead of 4.99% as provided for the Series A. The Company is required, at all times, to reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of Common Stock upon the full conversion of the Series B. The Series B is not subject to redemption by the Company or any Series B holder. The exchange of Series A for Series B had no impact on the Company's financial statements as of December 31, 2022.

Dividends

Series B holders shall be entitled to receive, when and as declared by the Board of Directors, dividends on a pari passu basis with the holders of the shares of Common Stock based upon the number of shares of Common Stock into which the Series B is then convertible.

Voting Rights

Series B holders shall be entitled to vote on all matters presented to the stockholders of the Company for a vote at a meeting of stockholders of the Company or a written consent in lieu of a meeting of stockholders of the Company, and shall be entitled to such number of votes for each share of Series B entitled to vote at such meetings or pursuant to such consent, voting together with the holders of shares of Common Stock and other shares of preferred stock who are entitled to vote, and not as a separate class, except as required by law. The number of votes to which the Series B holders shall be entitled to vote for each share of Series B shall equal the number of shares of Common Stock into which such Series B is then convertible; provided, however, that in no event shall a Series B holder be entitled to vote more than 9.99% of the then outstanding shares of Common Stock.

Conversion

Optional Conversion - Each share of Series B shall be convertible, at any time and from time to time, at the option of the Series B holder, into one share of Common Stock; provided, however, that in no event shall a Series B holder be entitled to convert any shares of Series B to the extent that such conversion would result in beneficial ownership by such Series B holder of more than 9.99% of the outstanding shares of common stock.

Automatic Conversion - From time to time, in the event that an event occurs which has the effect of reducing a Series B holder's beneficial ownership of shares of Common Stock to less than 9.5% of the then publicly disclosed outstanding shares of Common Stock, then, within five business days, the Series B holder is required to provide notice to the Company to such effect, which notice shall state the number of shares of Common Stock beneficially owned by the Series B holder and shall provide reasonable detail with regard thereto, including the number of derivative securities compromising a portion of such beneficial share amount. Such notice shall have the effect of a notice of conversion with respect to the conversion of such number of shares of Series B as would increase the Series B holder's beneficial ownership of Common Stock to 9.99% of the then publicly disclosed outstanding shares of Common Stock.

On October 25, 2022, Auctus converted 25,000 shares of Series B into 25,000 shares of Common Stock. The number of shares of Series B remaining outstanding after this conversion was 1,518,158.

On April 4, 2023, Auctus converted 120,000 shares of Series B into 120,000 shares of Common Stock. As of December 31, 2023, the number of shares of Series B remaining outstanding after giving effect to such conversion was 1,398,158.

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"). The 2021 Plan was approved by the Company's stockholders on August 17, 2021. Pursuant to the 2021 Plan, a total of 1,175,000 shares of common stock were initially authorized to be issued pursuant to the grant of stock options, restricted stock units, restricted stock, stock appreciation rights and other incentive awards. On December 10, 2021, the Company's Board of Directors approved an amendment to increase the number of shares of Common Stock authorized to be issued from 1,175,000 to 2,500,000. Such amendment was approved by the Company's stockholders on November 3, 2022. On July 13, 2023, the Company's Board of Directors approved an amendment to the 2021 Plan to increase the number of shares of Common Stock authorized to be issued from 2,500,000 to 3,850,000. Such amendment was approved by the Company's stockholders on September 13, 2023.

Compensatory Common Stock Issuance

During the year ended December 31, 2022, the Company issued 15,898 shares of immediately vested common stock with an aggregate value of \$135,888 to third parties for services rendered. During the year ended December 31, 2023, the Company issued 1,442 shares of immediately vested common stock with a value of \$7,500 to a consultant for services rendered.

Sales of Common Stock

In April 2023, the Company entered into a Capital on Demand Sales Agreement with JonesTrading Institutional Services LLC (the "Sales Agent") under which the Company currently has the ability to issue and sell shares of its Common Stock, from time to time, through the Sales Agent, up to an aggregate offering price of approximately \$6,109,000 in what is commonly referred to as an "at-the-market" ("ATM") program. During the year ended December 31, 2023, the Company sold 132,827 shares of its Common Stock at a weighted average price of \$4.68 per share and raised \$494,782 in net proceeds under the ATM program. As of December 31, 2023, the Company had remaining capacity to sell up to an additional \$5,487,000 of common stock under the ATM program.

On July 13, 2023, the Company sold an aggregate of 685,033 shares of Common Stock to several institutional buyers and accredited investors in a registered direct offering at an offering price of \$3.03 per share. The offering closed on July 13, 2023 with net proceeds of \$1,853,990. The Company intends to use the net proceeds from the offering in connection with its clinical trials with respect to its lead cell therapy candidate, BRTX-100, pre-clinical research and development with respect to its metabolic ThermoStem Program and for general corporate purposes and working capital.

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.

See Note 11 – Fair Value Measurement – for details regarding the fair value estimates of the Warrants that are classified as derivative liabilities.

Warrant Activity Summary

A summary of the warrant activity during the year ended December 31, 2023 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years
Outstanding, January 1, 2023	4,791,082	\$ 10.71	
Granted	-		
Exercised	-		
Expired	(63)	10,397	
Outstanding, December 31, 2023	<u>4,791,019</u>	<u>\$ 10.57</u>	<u>2.9</u>
Exercisable, December 31, 2023	<u>4,791,019</u>	<u>\$ 10.57</u>	<u>2.9</u>

In applying the Black-Scholes option pricing model to warrants granted during 2022, the Company used the following assumptions:

	For the Year Ended December 31, 2022
Risk free interest rate	4.40%
Expected term (years)	5.00
Expected volatility	313.55%
Expected dividends	0.00%

The weighted average estimated fair value of the warrants granted during the year ended December 31, 2022 was \$2.28 per warrant. The Company did not issue any warrants during the year ended December 31, 2023.

The following table presents information related to stock warrants at December 31, 2023:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
\$ 2.92	51,370	3.9	51,370
\$ 10.00	4,501,938	2.9	4,501,938
\$ 12.00	235,970	2.9	235,970
\$ 60.00	250	1.0	250
\$ 800.00	869	0.8	869
\$ 2,240.00	39	0.5	39
\$ 2,800.00	264	0.3	264
\$ 3,400.00	264	0.3	264
\$ 4,000.00	55	0.1	55
	<u>4,791,019</u>		<u>4,791,019</u>

Stock Options

A summary of the option activity during the year ended December 31, 2023 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, January 1, 2023	864,639	\$ 5.08		
Granted	629,017	2.91		
Exercised	-			
Forfeited	(26,764)	4.87		
Outstanding, December 31, 2023	<u>1,466,892</u>	<u>\$ 4.11</u>	<u>7.4</u>	<u>\$ -</u>
Exercisable, December 31, 2023	<u>1,201,526</u>	<u>\$ 4.33</u>	<u>7.1</u>	<u>\$ -</u>

The weighted average grant date fair value of the stock options granted during the years ended December 31, 2023 and 2022 was approximately \$3.00 and \$4.88, respectively.

The following table presents information related to stock options at December 31, 2023:

Options Outstanding		Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
\$ 2.91	654,017	7.5	412,604
\$ 5.08	812,875	6.9	788,922
	<u>1,466,892</u>		<u>1,201,526</u>

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

	For the Years Ended December 31,	
	2023	2022
Risk free interest rate	4.22%	2.42%
Expected term (years)	3.50	3.50
Expected volatility	175.00%	285.91%
Expected dividends	0.00%	0.00%

Restricted Share Units

Pursuant to the 2021 Plan, the Company may grant restricted stock units (“RSUs”) to employees, consultants or non-employee directors (“Eligible Recipients”). The number, terms and conditions of the RSUs that are granted to Eligible Recipients are determined on an individual basis by the 2021 Plan administrator. On the distribution date, the Company shall issue to the Eligible Recipient 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.

A summary of the unvested RSUs as of December 31, 2023 is as follows:

	Number of Shares
Non-vested at January 1, 2023	201,870
Granted	-
Vested	(104,043)
Forfeited	-
Non-vested at December 31, 2023	97,827

Stock-Based Compensation Expense

The following table presents information related to stock-based compensation expense:

	For the Years Ended December 31,		Unrecognized at December 31, 2023	Weighted Average Remaining Amortization Period (Years)
	2023	2022		
General and administrative	\$ 7,782,967	\$ 12,612,862	\$ 1,557,071	0.83
Total	\$ 7,782,967	\$ 12,612,862	\$ 1,557,071	0.83

NOTE 9 - INCOME TAXES

The Company identified its federal and New York tax returns as its “major” tax jurisdictions. The Company is no longer subject to income tax income examinations by these tax authorities for taxable years ended December 31, 2018, and prior. The Company reviewed the prior New York state income tax filings and concluded that the prior year return will be amended to change the apportionment from zero to 100%. 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, 2023, the Company had approximately \$63,500,000 and \$13,600,000, 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, 2023, approximately \$7,800,000 of federal net operating losses will expire from 2030 to 2038 and approximately \$55,700,000 have no expiration but are subject to a utilization limit equal to 80% of current taxable income.

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, 2023, and 2022 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, 2023, 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.

Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2023. For the period ended December 31, 2023, the Company has recorded a full valuation allowance recorded against the gross deferred tax asset balance as management believes that it is more likely than not that the results of operations will not generate sufficient taxable income to realize any of the deferred tax assets.

As of the date of this filing, the Company has not filed its 2023 federal and state corporate income tax returns. The Company expects to file these documents as soon as practicable.

The Company's net deferred tax assets, liabilities and valuation allowance as of December 31, 2023 and 2022 are summarized as follows:

	December 31,	
	2023	2022
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 14,311,000	\$ 13,200,000
Stock-based compensation	15,788,000	13,810,000
Research and development costs	1,676,000	655,000
Research and development credits	330,000	330,000
Right-of-use assets	25,000	-
Other	4,000	-
Total Deferred Tax Assets	32,134,000	27,995,000
Deferred Tax Liabilities:		
Depreciation	(122,000)	(106,000)
Intangible assets	(47,000)	(113,000)
Lease liability	(39,000)	-
Other	(86,000)	-
Total Deferred Tax Liabilities	(294,000)	(219,000)
Net Deferred Tax Asset	31,840,000	27,776,000
Less: valuation allowance	(31,840,000)	(27,776,000)
Deferred Tax Asset, Net of Valuation Allowance	\$ -	\$ -
Change in valuation allowance	\$ (4,064,000)	\$ (5,822,000)

The income tax provision (benefit) as of December 31, 2023 and 2022 consists of the following:

	December 31,	
	2023	2022
	(As Restated)	(As Restated)
Federal:		
Current	\$ -	\$ -
Deferred	(3,090,000)	(4,351,000)
State & Local:		
Current	-	-
Deferred	(974,000)	(1,471,000)
	(4,064,000)	(5,822,000)
Change in valuation allowance	4,064,000	5,822,000
Income tax provision (benefit)	\$ -	\$ -

A reconciliation of the statutory federal income tax benefit to actual tax benefit for the years ended December 31, 2023 and 2022 is as follows:

	December 31,	
	2023	2022
	(As Restated)	(As Restated)
Federal statutory rate	21.0%	21.0%
State rate, net of federal benefit	1.7%	7.8%
Permanent differences	7.2%	7.8%
Tax return to provision adjustment	-0.2%	7.3%
Change in valuation allowance	-29.7%	-44.0%
	0.0%	0.0%

NOTE 10 – 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:

	For the Years Ended December 31,	
	2023	2022
Lease Costs		
Operating lease cost (cost resulting from lease payments)	\$ 168,028	\$ 163,132
Net lease costs	\$ 168,028	\$ 163,132
Operating lease - operating cash flows (fixed payments)	\$ 168,028	\$ 163,132
Operating lease - operating cash flows (liability reduction)	\$ 139,328	\$ 119,055
Non-current leases - right of use assets	\$ 151,447	\$ 241,760
Current liabilities - operating lease liabilities	\$ 162,317	\$ 139,328
Non-current liabilities - operating lease liabilities	\$ -	\$ 162,317

Future minimum payments under non-cancelable leases for operating leases for the remaining terms of the leases following the year ended December 31, 2023:

Fiscal Year	Operating Leases
2024	\$ 173,060
Total future minimum lease payments	173,060
Amount representing interest	(10,743)
Present value of net future minimum lease payments	\$ 162,317

NOTE 11 – FAIR VALUE MEASUREMENT

The Company accounts for the Warrants as liabilities in accordance with the guidance contained in ASC 815-40, Derivatives and Hedging — Contracts in Entity's Own Equity. In the case of certain of the Warrants, the Company does not control the occurrence of events, such as a tender offer or exchange, that may trigger cash settlement of the Warrants and not result in a change of control of the Company. As a result, such Warrants do not meet the criteria for equity treatment and the Warrants must be recorded as a derivative liability. Additionally, certain other Warrants contain adjustments to the settlement amount based on a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under ASC 815-40 and, accordingly, such Warrants are not considered indexed to the Company's own stock and are not eligible for an exception from derivative accounting.

During the years ended December 31, 2023 and 2022, the Company estimated the aggregate fair value of the Warrants to purchase an aggregate of 4,737,908 shares of common stock classified as derivative liabilities using the Black-Scholes option pricing model (Level 3 inputs) using the following assumptions:

	For the Years Ended December 31,	
	2023	2022
Risk free interest rate	4.04%	4.12%
Expected term (years)	2.86	3.86
Expected volatility	87%	94%
Expected dividends	0.00%	0.00%

The following table sets forth a summary of the changes in the fair value of Level 3 liabilities that are measured at fair value on a recurring basis during the years ended December 31, 2022 and 2023:

	As Restated
Balance, January 1, 2022	\$ 10,814,206
Change in fair value of derivative liability	(5,272,473)
Outstanding, December 31, 2022	5,541,733
Change in fair value of derivative liability	(3,997,780)
Outstanding, December 31, 2023	\$ 1,543,953

Assets and liabilities measured at fair value on a recurring basis are as follows:

	Fair value measurements at reporting date using:				
	Quoted prices in active markets for identical liabilities (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total Fair Value	
Assets:					
Marketable securities as of December 31, 2023	\$ 10,181,618	\$ -	\$ -	\$ 10,181,618	
Marketable securities as of December 31, 2022	\$ 13,035,636	\$ -	\$ -	\$ 13,035,636	
Liabilities:					
Derivative liabilities as of December 31, 2023 (As Restated)	\$ -	\$ -	\$ 1,543,953	\$ 1,543,953	
Derivative liabilities as of December 31, 2022 (As Restated)	\$ -	\$ -	\$ 5,541,733	\$ 5,541,733	

NOTE 12 - SUBSEQUENT EVENTS

Warrant Exercise and Issuance

On February 6, 2024, the Company entered into agreements with certain holders of its existing warrants exercisable for an aggregate of 3,351,580 shares of its Common Stock (collectively, the “Existing Warrants”), to exercise their warrants at a reduced exercise price of \$2.33 per share, in exchange for new warrants (the “New Warrants”) as described below. The aggregate gross proceeds from the exercise of the Existing Warrants and the payment of the New Warrants, as described below, was approximately \$8.1 million, before deducting financial advisory fees. The reduction of the exercise price of the Existing Warrants and the issuance of the New Warrants was structured as an at-market transaction under Nasdaq rules. Of the 3,351,580 shares of Common Stock issuable upon the exercise of the Existing Warrants, to date, the Company has issued an aggregate of 2,000,000 shares of Common Stock. The remaining 1,351,580 shares of Common Stock, which are issuable to Auctus, are being held in abeyance due to Auctus’ maximum beneficial ownership limitation. Such shares have been fully paid for and are issuable upon notice from Auctus to the Company.

In consideration for the immediate exercise of the Existing Warrants for cash and the payment of \$0.125 per share underlying the New Warrants, the exercising holders received the New Warrants to purchase shares of Common Stock in a private placement pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The New Warrants will be exercisable for a period of five years into an aggregate of up to 2,513,686 shares of Common Stock at an exercise price of \$2.43 per share. The securities offered in the private placement have not been registered under the Securities Act or applicable state securities laws. Accordingly, the securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and such applicable state securities laws. As part of the transaction, the Company agreed to file a resale registration statement with the SEC to register the resale of the shares of Common Stock underlying the New Warrants issued in the private placement.

In connection with the transaction described above, the Company entered into a financial advisory services agreement, dated February 5, 2024, with Roth Capital Partners, LLC (“Roth”), pursuant to which the Company has paid Roth a cash fee of approximately \$528,000 for its services, in addition to reimbursement for certain expenses.

Option Grants

Subsequent to December 31, 2023, the Company granted options to purchase an aggregate 1,934,716 shares of the Company’s common stock at an exercise price of \$1.45 per share to employees, the Company’s board of directors and a member of the Company’s scientific advisory board. The options had an aggregate grant date fair value of \$2,140,000 and vest as follows: (i) options to purchase an aggregate 513,663 shares of common stock vest monthly over one year, and (ii) options to purchase an aggregate of 1,421,053 shares of common stock vest 50% immediately with the remainder vesting quarterly over two years commencing one year from the date of grant. The Company will recognize the grant date fair value of the options proportionate to the vesting period.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of BioRestorative Therapies, Inc. on Forms S-3 (Nos. 333-269631, 333-265052 and 333-258611) and S-8 (Nos. 333-255681, 333-196299, 333-203310, 333-210555, 333-214621, 333-228434, 333-233309, 333-270909 and 333-275571) of our report dated March 29, 2024, except for Note 2, Note 8, Note 9, and Note 11, as to which the date is June 11, 2024, with respect to our audits of the consolidated financial statements of BioRestorative Therapies, Inc. as of December 31, 2023 and 2022 and for the years ended December 31, 2023 and 2022, which report is included in this Amendment No.1 to the Annual Report on Form 10-K/A of BioRestorative Therapies, Inc. for the year ended December 31, 2023.

/s/ Marcum LLP

Marcum LLP
Marlton, New Jersey
June 11, 2024

SECTION 302 CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Lance Alstodt, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 10-K/A 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: June 11, 2024

/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 Amendment No. 1 to the Annual Report on Form 10-K/A 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: June 11, 2024

/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 Amendment No. 1 to the Annual Report on Form 10-K/A for the year ended December 31, 2023 (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: June 11, 2024

/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.
