As filed with the Securities and Exchange Commission on August 6, 2021

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BIORESTORATIVE THERAPIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	8099	91-1835664
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

40 Marcus Drive, Suite One
Melville, New York 11747
(631) 760-8100
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Lance Alstodt, President and Chief Executive Officer
BioRestorative Therapies, Inc.
40 Marcus Drive, Suite One
Melville, New York 11747
(631) 760-8100
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

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 (check one):

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. [ ]

Calculation of Registration Fee

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee
Units consisting of shares of Common Stock, par value $0.0001 per share, and Warrants to purchase shares of Common Stock, par value $0.0001 per share (2)	$ 20,000,000.00	$ 2,182.00
Common Stock included as part of the Units	Included with Units above	$ -

Warrants to purchase shares of Common Stock included as part of the Units (3)	Included with Units above	$ -
Representative Warrants to purchase Common Stock (3)	$ -	$ -
Shares of Common Stock issuable upon exercise of the Warrants (4)(5)	$	$
Shares of Common Stock issuable upon exercise of Representative Warrants (5)(6)	$	$
TOTAL REGISTRATION FEE	$ 20,000,000.00	$ 2,182.00

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.
(2) Includes Units which may be issued upon exercise of a 45-day option granted to the underwriters to cover over-allotments, if any.
(3) In accordance with Rule 457(g) under the Securities Act, because the shares of the registrant's common stock underlying the Warrants and Representative Warrants are registered hereby, no separate registration fee is required with respect to the warrants registered hereby.
(4) There will be issued warrants to purchase share[s] of common stock for every share[s] of common stock offered. The warrants are exercisable at a per share price of % of the common stock public offering price.
(5) Includes shares of common stock which may be issued upon exercise of additional warrants which may be issued upon exercise of 45-day option granted to the underwriters to cover over-allotment, if any.
(6) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The warrants are exercisable at a per share exercise price equal to 120% of the public offering price. As estimated solely for the purpose of recalculating the registration fee pursuant to Rule 457(g) under the Securities Act, the proposed maximum aggregate offering price of the Representative Warrants is $, which is equal to 120% of $ (% of $).

In the event of a stock split, stock dividend, or similar transaction involving the common stock, the number of shares registered shall automatically be increased to cover the additional shares of common stock issuable pursuant to Rule 416 under the Securities Act.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED AUGUST 6, 2021

Units

Each Unit Consisting of

One Share of Common Stock (par value $0.0001)

and

One Warrant to Purchase Share of Common Stock

This is a firm commitment public offering of units of securities (each, a "Unit"), each Unit consisting of one share of common stock, $0.0001 par value per share, and one warrant to purchase share of common stock of BioRestorative Therapies, Inc., a Delaware corporation. Each warrant is immediately exercisable for share of common stock at an exercise price of $ per share (or % of the price of each Unit sold in this offering) and will expire years from the date of issuance.

Our common stock is presently traded on the OTC Market under the symbol "BRTX." We have applied to have our common stock and the warrants offered pursuant to this prospectus listed on The Nasdaq Capital Market under the symbols "BRTX" and "BRTXW," respectively, which listing is a condition to this offering. No assurance can be given that our application will be approved. On August 5, 2021, the last reported sales price for our common stock as quoted on the OTC Market was $0.0045 per share.

The share and per share information in this prospectus do not reflect a contemplated reverse split of our outstanding common stock at a ratio contemplated to be not less than 1-for-20 and not more than 1-for-4000 to occur concurrently with or before this offering.

IN REVIEWING THIS PROSPECTUS, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DESCRIBED IN THE SECTION TITLED "RISK FACTORS" BEGINNING ON PAGE 12 OF THIS PROSPECTUS. INVESTORS SHOULD ONLY CONSIDER AN INVESTMENT IN THESE SECURITIES IF THEY CAN AFFORD THE LOSS OF THEIR ENTIRE INVESTMENT.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

	Per Unit	Total
Public offering price	$	$
Underwriting discounts (1)	$	$
Proceeds to us before offering expenses (2)	$	$

(1) Does not reflect additional compensation to the Representative in the form of warrants to purchase up to shares of common stock (or warrants to purchase up to shares of common stock assuming the underwriters' over-allotment option is fully exercised) at an exercise price equal to 120% of the public offering price. We have also agreed to reimburse the underwriters for certain expenses. With respect to certain investors introduced to the underwriters by us, (a) the underwriting discount will be 3.5% instead of 7.0% and (b) the number of shares issuable pursuant to the warrant to be issued to the Representative shall be 2.5% of the number of shares issued pursuant to the offering instead of 5.0% (in each case, including shares of common stock issuable upon the exercise of the warrants being issued pursuant to this prospectus). The above table assumes the full 7.0% underwriting discount with respect to all offering proceeds. See "Underwriting" on page 116 of this prospectus for a description of these arrangements.

(2) We estimate the total expenses of this offering will be approximately $. Assumes no exercise of the over-allotment option we have granted to the underwriters as described below.

We have granted the underwriters a 45-day option to purchase up to additional Units at the initial public offering price less applicable underwriting discounts. See "Underwriting" on page 116 of this prospectus for a description of these arrangements.

The underwriters expect to deliver our shares and warrants to purchasers in this offering on or about , 2021, subject to satisfaction of customary closing conditions.

Roth Capital Partners

The date of this prospectus is , 2021.

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You should rely only on information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with additional information or information different from that contained in this prospectus. Neither the delivery of this prospectus nor the sale of our securities means that the information contained in this prospectus is correct after the date of this prospectus. This prospectus is not an offer to sell or the solicitation of an offer to buy our securities in any circumstances under which the offer or solicitation is unlawful or in any state or other jurisdiction where the offer is not permitted.

The information in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

No person is authorized in connection with this prospectus to give any information or to make any representations about us, the securities offered hereby or any matter discussed in this prospectus, other than the information and representations contained in this prospectus. If any other information or representation is given or made, such information or representation may not be relied upon as having been authorized by us.

Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

This prospectus includes references to our federally registered trademarks, *BioRestorative Therapies and Dragonfly design*, *BRTX-100, ThermoStem and Stem Pearls*. We also own an allowed trademark application for *BRTX*. The Dragonfly Logo is also registered with the U.S. Copyright Office. This prospectus 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 prospectus 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus contain "forward-looking statements." Forward-looking statements are made based on our management's expectations and beliefs concerning future events impacting our company and are subject to uncertainties and factors relating to our operations and economic environment, all of which are difficult to predict and many of which are beyond our control. You can identify these statements from our use of the words "estimate," "project," "believe," "intend," "anticipate," "expect," "target," "plan," "may" and similar expressions. These forward-looking statements may include, among other things:

- statements relating to projected growth and management's long-term performance goals;
- statements relating to the anticipated effects on results of operations or our financial condition from expected developments or events;
- statements relating to our business and growth strategies; and
- any other statements which are not historical facts.

Forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause our actual results, performance or achievements, or industry results, to differ materially from our expectations of future results, performance or achievements expressed or implied by these forward-looking statements. These forward-looking statements may not be realized due to a variety of factors, including without limitation:

- our current and anticipated cash needs and our need for additional financing;
- federal, state and foreign regulatory requirements;
- our ability to conduct clinical trials with respect to our products and services;
- our ability to develop and commercialize our products and services;
- our ability to enter into agreements to implement our business strategy;
- the acceptance of our products and services by patients and the medical community;
- our ability to secure necessary media and reagents, as well as devices, materials and systems, for our clinical trials and commercial production;
- our manufacturing capabilities to produce our products;
- our ability to obtain brown adipose (fat) tissue in connection with our *ThermoStem Program*;
- our ability to maintain exclusive rights with respect to our licensed disc/spine technology;
- our ability to protect our intellectual property;
- our ability to obtain and maintain an adequate level of product liability insurance;
- our ability to obtain third party reimbursement for our products and services from private and governmental insurers;
- the effects of competition in our market areas;
- our reliance on certain key personnel;
- further sales or other dilution of our equity, which may adversely affect the market price of our common stock; and
- other factors and risks described under "Risk Factors" beginning on page 12 of this prospectus.

You should not place undue reliance on any forward-looking statement. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

PROSPECTUS SUMMARY

This summary is not complete and does not contain all of the information you should consider before investing in the securities offered by this prospectus. Before making an investment decision, you should read the entire prospectus, and any prospectus supplement, carefully, including the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the notes to the financial statements included elsewhere in this prospectus.

Prior to purchasing our securities in this offering, we strongly urge each potential investor to obtain legal and tax advice as to the potential tax and other effects to the investor as a result of purchasing such securities.

Unless the context of this prospectus indicates otherwise, the terms "BioRestorative," "the Company," "we," "us" or "our" refer to BioRestorative Therapies, Inc. and its consolidated subsidiaries, and the number of shares of common stock to be outstanding after this offering excludes shares issuable upon any exercise of the warrants offered by this prospectus and the warrants to be issued to the representative of the underwriters of this offering, referred to as the Representative Warrants.

The share and per share information in this prospectus do not reflect a contemplated reverse split of the outstanding common stock at a ratio contemplated to be not less than 1-for-20 and not more than 1-for-4000 to occur concurrently with or before this offering.

What We Do

We are a life sciences company focused on the development of regenerative medicine products and therapies using cell and tissue protocols, primarily involving adult (non-embryonic) stem cells. Our two core developmental programs, as described below, relate to the treatment of disc/spine disease and metabolic disorders:

- ***Disc/Spine Program (brtxDisc).*** Our lead cell therapy candidate, BRTX-100, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells, or MSCs, collected from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complimentary therapeutic to a surgical procedure. The BRTX-100 production process involves collecting bone marrow and whole blood from a patient, isolating and culturing (in a proprietary method) stem cells from the bone marrow and cryopreserving the cells in an autologous carrier. In an outpatient procedure, BRTX-100 is to be injected by a physician into the patient's painful disc. The treatment is intended for patients whose pain has not been alleviated by non-surgical procedures or conservative therapies and who potentially face the prospect of highly invasive surgical procedures. We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of BRTX-100 in the treatment of chronic lower back pain arising from degenerative disc disease. We have received such authorization from the FDA. We intend to commence such clinical trial during 2022 (assuming the receipt of necessary funding). See "Business-Disc/Spine Program".

- ***Metabolic Program (ThermoStem)***. We are developing a cell-based therapy candidate to target obesity and metabolic disorders using brown adipose (fat) derived stem cells, or BADSC, to generate brown adipose tissue, or BAT. We refer to this as our ThermoStem Program. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research conducted by us and others indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning, as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. See "Business-Metabolic Brown Adipose (Fat) Program".

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

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

Significant Accomplishments

We have made progress toward our goal of offering therapeutic products and medical therapies, using cell and tissue protocols, in the treatment of disc/spine disease and metabolic disorders. Our accomplishments include the following:

Disc/Spine Program

● We have obtained a worldwide (except Asia and Argentina) exclusive license to utilize or sublicense a method for the hypoxic (low oxygen) culturing of cells for use in treating, among other things, disc and spine conditions, including protruding and bulging discs.

● We have developed our lead cell therapy product candidate, *BRTX-100*.

● Institutional review board, or IRB, approved human studies were undertaken with regard to our licensed culturing technology with success rates and no known adverse results.

● We have assembled a management team with significant expertise in the biotechnology field.

● We have an eight member Scientific Advisory Board, including a Professor of Medicine at the Harvard Medical School and the Dana-Faber Cancer Institute, the Director of Interventional and Endovascular Neurosurgery at George Washington University Medical Center, the President of First Medicine, Inc., the former Director of Quality Assurance for the FDA's Center for Biologics Evaluation and Research, the founder of Long Island Spine Rehabilitation Center and Chief of Spine Medicine at Northwell Health Spine Center, an orthopedic spine surgeon at Hospital for Special Surgery, the Clinical Director of Musculoskeletal Spine and Sports Rehabilitation Medicine at MossRehab, and the founder of New Jersey Sports Medicine, LLC. See "Management – Scientific Advisors – Scientific Advisory Board."

● We have engaged highly experienced FDA consultants in connection with our contemplated clinical trials.

● We have established a laboratory in Melville, New York that we use for research purposes and the possible development of cellular-based treatment protocols.

● In February 2017, we obtained 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.

● In March 2018, we engaged Defined Health, a business development and strategy consulting firm, to conduct an independent review of *BRTX-100*. The review collected informed, independent opinions among key opinion leaders, or KOLs (i.e., orthopedic surgeons specializing in back and spine surgery with experience in stem cell therapy), regarding the future therapeutic potential of *BRTX-100*. As noted in the Defined Health report, the KOLs reacted positively to the value proposition of *BRTX-100* and were optimistic that the clinical data presented is likely to be mirrored in future clinical investigations.

Metabolic Program (ThermoStem)

● We established a relationship with Pfizer with regard to a joint study of the development and validation of a human brown adipose (fat) cell model. The services contemplated by our agreement with Pfizer have been provided.

● 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.

● We have established an extensive and unique human brown adipose library.

● We have undertaken pre-clinical animal studies with regard to brown adipose tissue pursuant to which metabolic impact (weight loss; reduced glucose levels) has been observed in mice.

● We have begun to evaluate encapsulation technology for potential use as a cell delivery system for our metabolic program.

● We entered into a research collaboration agreement with the University of Pennsylvania with regard to the understanding of brown adipose (fat) biology and its role in metabolic disorders. The services contemplated by the research collaboration agreement have been provided.

● We entered into a services agreement with the University of Utah pursuant to which the university was to provide research services with regard to our *ThermoStem Program*. The services contemplated by the agreement with University of Utah have been provided.

● United States patents related to the *ThermoStem Program* were issued in September 2015, January 2019, March 2020, March 2021 and July 2021, Australian patents related to the *ThermoStem Program* were issued in April 2017 and October 2019, Japanese patents related to the *ThermoStem Program* were issued in December 2017 and May 2021, Israeli patents related to the *ThermoStem Program* were issued in October 2019 and May 2020 and European patents related to the *ThermoStem Program* were issued in April 2020 and January 2021.

Key Risks and Uncertainties

We are subject to numerous risks and uncertainties, including the following:

● We have a limited operating history; we have incurred substantial losses since inception; we expect to continue to incur losses for the near term.

● Even if we sell all of the securities offered by this prospectus, following the offering, we will need to obtain a significant amount of additional financing to complete our clinical trials with regard to our *Disc/Spine Program* and to implement our other programs, including our metabolic brown fat initiative.

● 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; we anticipate that such commercialization will not take place for at least five years; 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 in enrolling patients in our clinical trials which could delay or prevent the receipt of necessary regulatory approvals; we may not complete them at all.

● 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.

● We presently lack manufacturing capabilities to produce our product candidates at commercial scale quantities and do not have an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the products.

● Pursuant to the license agreement under which we have obtained an exclusive license with regard to our disc/spine technology, we are required to complete our Phase 2 clinical trial by a certain date (which we believe to be February 2022) in order to maintain the exclusive nature of the license; the loss of such exclusive rights would have a material adverse effect upon us.

● We may be unable to obtain and maintain patent protection in the United States and other countries with regard to our product candidates.

● 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.

● Ethical and other concerns surrounding the use of stem cell therapy may negatively impact the public perception of our stem cell products and/or services, thereby suppressing demand for our products and/or services and possibly leading to an even more stringent regulatory environment.

● 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 and risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.

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

● We may not be able to protect our proprietary rights.

● We operate in a highly-regulated environment and may be unable to comply with applicable federal, state, local, and international requirements; failure to comply with applicable government regulation may result in a loss of licensure, registration, and approval or other government enforcement actions.

For a more detailed description of the material risks and uncertainties we face, please see “Risk Factors” beginning on page 12 of this prospectus.

Near-Term Goals

Beginning in the fourth quarter of 2021 and through the end of 2022, we have the following goals:

- Fourth quarter of 2021
    - Enter into a contract with a CRO

- Initiate pre-clinical animal study for our metabolic program
- Issuance of new patents relating to our metabolic program
- Obtain product manufacturing clearance
- Establish clinical sites for our BRTX-100 clinical trial

- 2022

  - Commence our Phase 2 clinical trial investigating the use of BRTX-100 in the treatment of chronic lower back pain arising from degenerative disc disease
  - Have the first patient treated in the clinical trial
  - Have data published from the pre-clinical animal study for our metabolic program
  - Have a pre-IND meeting with the FDA with respect to our metabolic program
  - File a drug master file with the FDA with respect to our metabolic program
  - Clear a safety review of BRTX-100 by an independent data safety monitoring committee

Listing on the Nasdaq Capital Market

We have applied to list our common stock and warrants on The Nasdaq Capital Market, or Nasdaq, under the symbols "BRTX" and "BRTXW," respectively. If our listing application is approved, we expect to list our common stock and warrants on Nasdaq upon consummation of this offering, at which point our common stock will cease to be traded on the OTC Market, or OTC. No assurance can be given that our listing application will be approved. This offering will occur only if Nasdaq approves the listing of our common stock and warrants on Nasdaq. Nasdaq listing requirements include, among other things, a stock price threshold. As a result, prior to effectiveness, we will need to take the necessary steps to meet Nasdaq listing requirements, including but not limited to a reverse split of our common stock. If Nasdaq does not approve the listing of our common stock and warrants, we will not proceed with this offering.

Chapter 11 Reorganization; Exchange of Outstanding Debt and Warrants

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

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

Pursuant to the Plan of Reorganization, among other things, we issued to Auctus and others convertible promissory notes in the aggregate principal amount of $10,357,960 (of which $10,046,897 aggregate principal amount remains outstanding) and warrants for the purchase of an aggregate of 15,725,555,070 shares of our common stock (of which warrants for the purchase of 14,999,272,390 shares of our common stock at a weighted average exercise price of $0.001 per share remain outstanding).

We have had discussions with the holders of outstanding convertible promissory notes in the aggregate principal amount of $9,246,897 and warrants for the purchase of an aggregate of 14,999,272,390 shares of common stock with respect to the exchange of the aggregate principal amount of the convertible promissory notes, together with accrued interest thereon, and the warrants for the Units being offered by this prospectus upon the same terms as being offered to investors in this offering. No assurances can be given that exchange agreements will be entered into with the holders of the convertible promissory notes and warrants, whether upon reasonable terms or otherwise. In the event that agreements are not entered into with regard to the exchange of the outstanding convertible promissory notes into Units, pursuant to the provisions of the notes, the amounts payable pursuant to the notes will automatically convert into the Units offered by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering). In addition to the foregoing, pursuant to the provisions of certain other convertible promissory notes in the aggregate principal amount of $800,000, the amounts payable pursuant to such notes will automatically convert into the Units offered by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering).

Stockholders Meeting

We have scheduled our annual meeting of stockholders to be held on August 17, 2021. At the annual meeting, we are seeking stockholder approval of, among other things, the reincorporation of our company from Delaware to Nevada. In addition, at the meeting, in the event the reincorporation is not approved, we are seeking stockholder approval of a reverse split of our common stock at a ratio of not less than 1-for-20 and not more than 1-for-4000 with our Board of Directors to have authority to determine whether to effect a reverse split as well as the reverse split ratio. Further, in the event the reverse split proposal is approved, we are seeking stockholder approval of an amendment to our certificate of incorporation pursuant to which the number of shares of common stock authorized to be issued by us can be reduced in a manner proportionate to the reverse split or to a lesser or greater degree.

Corporate Information

Our headquarters are located at 40 Marcus Drive, Suite One, Melville, New York 11747. Our telephone number is (631) 760-8100. We maintain certain information on our website at www.biorestorative.com. The information on our website is not (and should not be considered) part of this prospectus and is not incorporated into this prospectus by reference.

Summary of the Offering

Securities Offered:	Units, each Unit consisting of one share of our common stock and one warrant to purchase share of our common stock. Each warrant will have an exercise price of $ per share (% of the public offering price of each Unit), will be exercisable immediately and will expire years from the date of issuance.
Common Stock Outstanding prior to the Offering:	3,350,844,445 shares
Number of Shares:	
Number of Warrants:	
Warrant Exercise Price:	$ per share (% of the public offering price of each Unit)
Common Stock to be Outstanding after the Offering:	shares, excluding the possible sale of over-allotment Units, if any. The number of shares of our common stock to be outstanding after the completion of this offering is based on 3,350,844,445 shares of our common stock outstanding as of July 31, 2021, and excludes the following: ● 4,355,167 shares of common stock (net of cancellations) issuable upon the exercise of outstanding options granted under our 2010 Equity Participation Plan, or the 2010 Plan, as of July 31, 2021, with a weighted average exercise price per share of $0.98; ● 3,521,753,922 shares of common stock issuable upon the exercise of outstanding options and the vesting of outstanding restricted stock units, or RSUs, granted under our 2021 Stock Incentive Plan, or the 2021 Plan, as of July 31, 2021, which options have an exercise price of $0.0119 per share; ● 1,178,246,078 shares of common stock that are available for future issuance under the 2021 Plan as of July 31, 2021; ● 15,005,596,326 shares of common stock issuable upon the exercise of outstanding warrants as of July 31, 2021, with a weighted average exercise price per share of $0.001 (including warrants for the purchase of an aggregate of 14,999,272,390 shares of common stock, as to which discussions have occurred with the holders with regard to the exchange of such warrants for the Units being offered by this prospectus upon the same terms as being offered to investors in this offering);

- an indeterminate number of shares of common stock issuable upon the conversion of outstanding convertible promissory notes in the aggregate principal amount of $10,046,897 as of July 31, 2021, which notes provide for conversion prices based upon the market value of our common stock at the time of conversion (as to which notes in the aggregate principal amount of $9,246,897 discussions have occurred with regard to their exchange for the Units being offered by this prospectus upon the same terms as being offered to investors in this offering and as to which notes in the aggregate principal amount or $10,046,897, the notes provide for automatic conversion into the Units offered by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering));
- shares of common stock issuable upon the exercise of the warrants issued pursuant to this offering;
- shares of common stock issuable upon the exercise of the warrants to be issued to the Representative, as discussed under "Underwriting" on page 116; and
- a contemplated reverse split of our common stock at a ratio contemplated to be not less than 1-for-20 and not more than 1-for-4000 to be effective concurrently with or before this offering.

Underwriters' Over-Allotment Option: The underwriting agreement provides that we will grant to the underwriters an option, exercisable within 45 days after the date of this prospectus, to acquire up to an additional 15% of the total number of Units sold by us pursuant to this offering, solely for the purpose of covering over-allotments, if any.

Use of Proceeds: We estimate that we will receive net proceeds of approximately $ from our sale of Units in this offering, after deducting underwriting discounts and estimated offering expenses payable by us. We intend to use the net proceeds of this offering as follows: undertaking of clinical trials with respect to *BRTX-100* and its related collection and delivery procedure; pre-clinical research and development with respect to our *ThermoStem Program*; and for general corporate and working capital purposes; however, the use of the net proceeds is subject to change at the complete and absolute discretion of our management. For a more complete description of our anticipated use of proceeds from this offering, see "Use of Proceeds."

Assumed Offering Price:	$ per Unit.
Trading Symbol:	Our common stock is presently quoted on the OTC under the symbol "BRTX." We have applied to have our common stock and the warrants offered pursuant to this prospectus listed on Nasdaq under the symbols "BRTX" and "BRTXW," respectively. If our listing application is not approved, we will not complete this offering.
Risk Factors:	Investing in our securities involves substantial risks. You should carefully review and consider the "Risk Factors" section of this prospectus beginning on page 12 and the other information in this prospectus for a discussion of the factors you should consider before you decide to invest in this offering.
Lock-Up:	We and our directors and officers have agreed with the underwriters not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our common stock or securities convertible into common stock for a period of six months after the date of this prospectus. See "Underwriting" on page 116.

Summary Financial Data

The following table sets forth summary consolidated financial data of BioRestorative Therapies, Inc. The financial data as of March 31, 2021 and for the three months ended March 31, 2021 and 2020 have been derived from our unaudited condensed consolidated financial statements included in this prospectus under "Index to Financial Statements". The financial data as of December 31, 2020 and 2019 and for the years then ended have been derived from our audited consolidated financial statements included in this prospectus under "Index to Financial Statements." The summary consolidated financial results in the table below are not necessarily indicative of our expected future operating results. The following summary historical financial information should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the historical financial statements and notes thereto appearing in this prospectus under "Index to Financial Statements."

	For the Three Months Ended March 31,		For The Years Ended December 31,	
	2021	2020	2020	2019
	(unaudited)			
Revenues	$ 18,000	$ 26,000	$ 77,000	$ 130,000
Operating Expenses:				
Marketing and promotion	2,600	22,008	28,281	321,280
Consulting	8,389	34,012	137,250	1,912,683
Research and development	165,254	186,328	876,829	1,722,338
General and administrative	14,896,413	602,641	1,786,716	4,605,704
Total Operating Expenses	15,072,656	844,989	2,829,076	8,562,005
Loss From Operations	(15,054,656)	(818,989)	(2,752,076)	(8,432,005)
Other (Expense) Income:				
Interest expense	181,514	285,926	(362,041)	(1,467,952)
Amortization of debt discount	417,160	1,066,526	(1,278,104)	(3,671,087)
Loss on extinguishment of notes payable, net	-	658,152	(658,152)	(1,895,116)
Change in fair value of derivative liabilities	-	2,141,069	(2,141,069)	788,970
Reorganization items, net	-	2,580,110	(4,081,245)	-
Other income			-	29,300
Total Other Expense	598,674	6,731,783	(8,520,611)	(6,215,885)
Net Loss	$ (15,653,330)	$ (7,550,772)	$ (11,272,687)	$ (14,647,890)

	March 31, 2021	December 31, 2020	December 31, 2019
	(unaudited)		
Balance Sheet Data:			
Cash	$ 2,500,909	$ 3,064,610	$ 1,664
Working capital (deficiency)	$ 1,302,697	$ 2,142,229	$ (13,651,716)
Total assets	$ 3,701,180	$ 4,347,048	$ 1,466,323
Total liabilities	$ 6,395,562	$ 5,678,540	$ 14,242,469
Total stockholders' deficit	$ (2,694,382)	$ (1,331,492)	$ (12,776,146)

RISK FACTORS

In addition to the other information included in this prospectus, the following factors should be carefully considered before making a decision to invest in our securities. Any of the following risks, either alone or taken together, could materially and adversely affect our business, financial condition, liquidity, results of operations and prospects. If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, we could be materially and adversely affected. There may be additional risks that we do not presently know or that we currently believe are immaterial that could also materially and adversely affect our business, financial condition, liquidity, results of operations and prospects. In any such case, the market price of our common stock could decline substantially and you could lose all or a part of your investment.

Risks Related to Our Business Generally

We have a limited operating history; we have incurred substantial losses since inception; we expect to continue to incur losses for the near term; as of March 31, 2021, we had a stockholders' deficiency.

We have a limited operating history. Since our inception, we have incurred net losses. As of March 31, 2021, we had a working capital of $1,302,697 and a stockholders' deficit of $2,694,382.

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

Since our inception, we have not generated 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 prospectus under the caption "Business," will require the receipt of sufficient equity and/or debt financing to purchase necessary equipment, technology and materials, fund our clinical trials and other research and development efforts and otherwise fund our operations. We anticipate that we will require approximately $12,000,000 in financing to complete a Phase 2 clinical trial using *BRTX-100.* We anticipate that we will require approximately $45,000,000 in further additional funding to complete our clinical trials using *BRTX-100* (assuming the receipt of no revenues). We will also require a substantial amount of additional funding to implement our other programs described in this prospectus under the caption "Business," including our metabolic *ThermoStem Program,* and fund general operations. The net proceeds of this offering will not be sufficient to satisfy the foregoing needs. No assurance can be given that the anticipated amounts of required funding are correct or that we will be able to accomplish our goals within the timeframes projected. In addition, no assurance can be given that we will be able to obtain any required financing on commercially reasonable terms or otherwise. In the event we do not obtain the financing required for the above purposes, we may have to curtail our development, marketing and promotional activities, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately we could be forced to discontinue our operations and liquidate.

We may need to obtain additional financing to satisfy debt obligations. An event of default pursuant to our outstanding debt obligations could trigger an acceleration of the due date of such obligations, including our secured debt.

As described in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Availability of Additional Funds", as of March 31, 2021, our outstanding debt of $9,426,039, together with interest at rates ranging between 5% and 7% per annum, was due on November 16, 2023. As of March 31, 2021, the outstanding debt amount of $9,426,039 did not include $657,598 of estimated debtor-in-possession, or DIP, and Plan of Reorganization costs associated with the DIP funding and the Plan of Reorganization (which amount has now been determined to total approximately $715,542), or the Auctus Costs. As of March 31, 2021, $500,000 and $157,598 of the estimated Auctus Costs are recorded in debt discount and accrued expenses, respectively, on the consolidated balance sheets included in this prospectus. The DIP lender is required, pursuant to the Plan of Reorganization, to lend us an additional $2,100,000, as needed. Although our outstanding debt is repayable on November 16, 2023 (unless sooner converted into equity), an event of default pursuant to the secured and unsecured promissory notes evidencing such indebtedness could trigger an acceleration of the due dates of all of the notes. We do not have the financial resources to satisfy such debt obligations. Since the repayment of a substantial portion of our outstanding debt is secured by a security interest in all of our assets, in the event of a default, and foreclosure upon our assets, we could be forced to cease operations and liquidate. We have had discussions with the holders of our outstanding debt in the aggregate principal amount of $9,246,897 to exchange such debt and associated warrants into the Units being offered by this prospectus; however, no assurances can be given that we will enter into exchange agreements with such holders, whether on reasonable terms or otherwise. In the event that agreements are not entered into with regard to the exchange of the outstanding convertible promissory notes into Units, pursuant to the provisions of the notes, the amounts payable pursuant to the notes will automatically convert into the Units offered by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering). In addition to the foregoing, pursuant to the provisions of certain other convertible promissory notes in the aggregate principal amount of $800,000, the amounts payable pursuant to such notes will automatically convert into the Units offered by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering).

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 discussed in this prospectus under the caption "Business," we do not have any material agreements or understandings in place with respect to the implementation of our business strategy. No assurances can be given that we will be able to enter into any necessary agreements with respect to the development of our business. Our inability to enter into any such agreements would have a material adverse effect on our results of operations and financial condition.

We depend on our executive officers and on our ability to attract and retain additional qualified personnel; we do not currently have a Chief Financial Officer.

Our performance is substantially dependent on the performance of Lance Alstodt, our Chief Executive Officer. We rely upon him for strategic business decisions and guidance. We are also dependent on the performance of Francisco Silva, our Vice President of Research and Development. Each of Messrs. Alstodt and Silva is subject to an employment agreement with us. We do not have any key-man insurance policies on the lives of either of our executive officers. We do not currently have a Chief Financial Officer. Pending the hiring of a Chief Financial Officer, we are utilizing financial consultants with regard to the preparation of our financial statements. We believe that our future success in developing marketable products and services and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel, including a Chief Financial Officer. Competition for such personnel is intense, and there can be no assurance that we will be able to attract and retain such personnel. The loss of the services of Mr. Alstodt and/or Mr. Silva or the inability to attract and retain additional personnel, including a Chief Financial Officer, and develop expertise as needed would have a substantial negative effect on our results of operations and financial condition.

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

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

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

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

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

Risks Related to Our Cell Therapy Product Development Efforts

Our future success is significantly dependent on the timely and successful development and commercialization of BRTX-100, our lead product candidate for the treatment of chronic lumbar disc disease; if we encounter delays or difficulties in the development of this product candidate, as well as any other product candidates, our business prospects would be significantly harmed.

We are dependent upon the successful development, approval and commercialization of our product candidates. Before we are able to seek regulatory approval of our product candidates, we must conduct and complete extensive clinical trials to demonstrate their safety and efficacy in humans. Our lead product candidate, *BRTX-100*, is in early stages of development and we have not yet commenced a Phase 2 clinical trial using *BRTX-100* to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs.

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

- suspensions, delays or changes in the design, initiation, enrollment, implementation or completion of required clinical trials; adverse changes in our financial position or significant and unexpected increases in the cost of our clinical development program; changes or uncertainties in, or additions to, the regulatory approval process that require us to alter our current development strategy; clinical trial results that are negative, inconclusive or less than desired as to safety and/or efficacy, which could result in the need for additional clinical studies or the termination of the product's development; delays in our ability to manufacture the product in quantities or in a form that is suitable for any required clinical trials;
- intellectual property constraints that prevent us from making, using, or commercializing any of our cell therapy product candidates;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of these product candidates may be insufficient or inadequate; the inability to generate sufficient pre-clinical, toxicology, or other in vivo or in vitro data, to support the initiation of clinical studies;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board 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 CROs, other third parties, or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's current Good Clinical Practices, or 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 manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing;
- the FDA may not accept clinical data from trials that are conducted at clinical sites in countries where the standard of care is potentially different from the United States; and
- failure to raise sufficient funds to complete our clinical trials.

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

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

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

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

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

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

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

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

We have not commenced the clinical trials necessary to obtain FDA approval to market our product candidate, *BRTX-100*, or any of our other product candidates in development. Since 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 planned clinical trials, and that we may need or use in commercial production, are provided by unaffiliated third parties. Any lack of continued availability of these media, reagents, devices, materials and systems for any reason would have a material adverse effect on our ability to complete these studies and could adversely impact our ability to achieve commercial manufacture of our planned therapeutic products. Although other available sources for these media, reagents, devices, materials and systems may exist in the marketplace, we have not evaluated their cost, effectiveness, or intellectual property foundation and therefore cannot guarantee the suitability or availability of such other potential sources.

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

The successful development of cellular based products is highly uncertain. Product candidates that appear promising in preclinical and early research and development may be delayed or fail to reach later stages of development. Decisions regarding the further development of product candidates must be made with limited and incomplete data, which makes it difficult to ensure or even accurately predict whether the allocation of limited resources and the expenditure of additional capital on specific product candidates will result in desired outcomes. Pre-clinical and clinical data can be interpreted in different ways, and negative or inconclusive results or adverse events during a clinical trial could delay, limit or prevent the development of a product candidate. Positive preclinical data may not continue or occur for future subjects in our clinical studies and may not be repeated or observed in ongoing or future studies involving our product candidates. Furthermore, our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical studies. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include decrease or elimination of pain, adequate duration of response, a delay in the progression of the disease, an improvement in function and/or decrease in disability.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

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

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

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

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

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

We presently lack manufacturing capabilities to produce our product candidates at commercial scale quantities and do not have an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the products.

Currently, we expect our laboratory (or a contract laboratory) to provide the cell processing services necessary for clinical production of *BRTX-100* for our disc clinical trial. To date, we have not produced any products at our laboratory. We expect that we would need to significantly expand our manufacturing capabilities to meet potential commercial demand for *BRTX-100* and any other of our product candidates, if approved, as well as any of our other product candidates that might attain regulatory approval. Such expansion would require additional regulatory approvals. Even if we increase our manufacturing capabilities, it is possible that we may still lack sufficient capacity to meet demand. Ultimately, if we are unable to supply our products to meet commercial demand, whether because of processing constraints or other disruptions, delays or difficulties that we experience, sales of the products and their long-term commercial prospects could be significantly damaged.

We do not presently have a third-party manufacturer for *BRTX-100* or any of our other product candidates. If our facilities at which these product candidates would be manufactured or our equipment were significantly damaged or destroyed, or if there were other disruptions, delays or difficulties affecting manufacturing capacity, our planned and future clinical studies and commercial production for these product candidates would likely be significantly disrupted and delayed. It would be both time consuming and expensive to replace this capacity with third parties, particularly since any new facility would need to comply with the regulatory requirements.

Ultimately, if we are unable to supply our cell therapy product candidates to meet commercial demand (assuming commercial approval is obtained), whether because of processing constraints or other disruptions, delays or difficulties that we experience, our production costs could dramatically increase and sales of the product and its long-term commercial prospects could be significantly damaged.

The commercial potential and profitability of our products are unknown and subject to significant risk and uncertainty.

Even if we successfully develop and obtain regulatory approval for our cell therapy product candidates, the market may not understand or accept the products, which could adversely affect both the timing and level of future sales. Ultimately, the degree of market acceptance of our product candidates (or any of our future product candidates) will depend on a number of factors, including:

- the clinical effectiveness, safety and convenience of the product particularly in relation to alternative treatments;
- our ability to distinguish our products (which involve adult cells) from any ethical and political controversies associated with stem cell products derived from human embryonic or fetal tissue; and
- the cost of the product, the reimbursement policies of government and third-party payors and our ability to obtain sufficient third-party coverage or reimbursement.

Even if we are successful in achieving sales of our product candidates, it is not clear to what extent, if any, the products will be profitable. The costs of goods associated with production of cell therapy products are significant. In addition, some changes in manufacturing processes or procedures generally require FDA or foreign regulatory authority review and approval prior to implementation. We may need to conduct additional pre-clinical studies and clinical trials to support approval of any such changes. Furthermore, this review process could be costly and time-consuming and could delay or prevent the commercialization of product candidates.

We may have difficulties in sourcing brown adipose (fat) tissue.

We use brown adipose (fat) tissue to identify and characterize brown adipose derived stem cells for use in our pre-clinical *ThermoStem Program.* There is no certainty that we will be able to continue to collect brown adipose samples through any relationships that we have, have had or may establish with potential sources of brown adipose tissue. The inability to procure brown fat tissue would have a material adverse effect upon our ability to advance our *ThermoStem Program.*

We are required to complete a certain milestone to maintain our exclusive license rights with regard to the disc/spine technology. The loss of such exclusive rights would have a material adverse effect upon us.

Pursuant to our license agreement with Regenerative Sciences, LLC, we must complete our Phase 2 clinical trial by a certain date (which we believe to be February 2022) in order to maintain our exclusive rights with regard to the disc/spine technology. We will not be able to achieve such milestone. Any loss of such exclusive rights would have a material adverse effect upon our business, results of operations and financial condition. See "Business-Disc/Spine Program – License."

If safety problems are encountered by us or others developing new stem cell-based therapies, our stem cell initiatives could be materially and adversely affected.

The use of stem cells for therapeutic indications is still in the very early stages of development. If an adverse event occurs during clinical trials related to one of our proposed products and/or services or those of others, the FDA and other regulatory authorities may halt clinical trials or require additional studies. The occurrence of any of these events would delay, and increase the cost of, our development efforts and may render the commercialization of our proposed products and/or services impractical or impossible.

We are vulnerable to competition and technological change, and also to physicians' inertia.

We will compete with many domestic and foreign companies in developing our technology and products, including biotechnology, medical device and pharmaceutical companies. Many current and potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources. There is no assurance that our competitors will not succeed in developing alternative products and/or services that are more effective, easier to use, or more economical than those which we may develop, or that would render our products and/or services obsolete and non-competitive. In general, we may not be able to prevent others from developing and marketing competitive products and/or services similar to ours or which perform similar functions or which are marketed before ours.

Competitors may have greater experience in developing products, therapies or devices, conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercialization. It is possible that competitors may obtain patent protection, approval or clearance from the FDA or achieve commercialization earlier than we can, any of which could have a substantial negative effect on our business.

We will compete against cell-based therapies derived from alternate sources, such as bone marrow, adipose tissue, umbilical cord blood and potentially embryos. Doctors historically are slow to adopt new technologies like ours, whatever the merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires very significant marketing expenditures or definitive product performance and/or pricing superiority.

We expect that physicians' inertia and skepticism will also be a significant barrier as we attempt to gain market penetration with our future products and services. We may need to finance lengthy time-consuming clinical studies (so as to provide convincing evidence of the medical benefit) in order to overcome this inertia and skepticism.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute the shares of our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. To date, such efforts have not been successful.

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

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

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

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

Our business plan has been focused historically on capturing a piece of the burgeoning field of cell therapy. We have limited experience in the areas of cell therapy product development and marketing, and in the related regulatory issues and processes. Although we have recruited a team that has experience with designing and conducting clinical trials and have hired FDA consultants, as a company, we have limited experience in conducting clinical trials and no experience in conducting clinical trials through to regulatory approval of any product candidate. In part because of this lack of experience, we cannot be certain that planned clinical trials will begin or be completed on time, if at all. We cannot assure that we will successfully achieve our clinical development goals or fulfill our plans to capture a piece of the cell therapy market.

Our cell therapy business is based on novel technologies that are inherently expensive, risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.

The clinical development, commercialization and marketing of cell and tissue-based therapies are at an early-stage, substantially research-oriented, and financially speculative. To date, very few companies have been successful in their efforts to develop and commercialize a cell therapy product. In general, cell-based or tissue-based products may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their approval or commercial use. In addition, *BRTX-100* is a cell-based candidate that is produced by using a patient's own stem cells derived from bone marrow. Regulatory approval of novel product candidates such as *BRTX-100*, which is manufactured using novel manufacturing processes, can be more complex and expensive and take longer than other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to the FDA's lack of experience with them. To our knowledge, the FDA has not yet approved a disc related stem cell therapy product. This lack of experience may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, which would increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. Furthermore, the number of people who may use cell or tissue-based therapies is difficult to forecast with accuracy. Our future success is dependent on the establishment of a large global market for cell- and tissue-based therapies and our ability to capture a share of this market with our product candidates.

Our cell therapy product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The enactment of the Biologics Price Competition and Innovation Act of 2009, 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. Although the FDA has approved several biosimilar products, complex provisions of the law are still being implemented by the FDA and interpreted by the federal courts. As a result, the ultimate impact, implementation, and meaning of the BPCIA are still subject to some uncertainty and FDA actions and court decisions concerning the law could have a material adverse effect on the future commercial prospects for our biological products.

We believe that, if any of our product candidates are approved as a biological product under a BLA, it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA could approve biosimilar applicants for other reference products that no longer have such exclusivity, thus potentially creating the opportunity for greater competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

The FDA's regulation of therapies derived from stem cell products and technologies is evolving and may continue to evolve. In December 2016, the 21st Century Cures Act, 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, or that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances, or that we will be able to successfully commercialize our products and services in various foreign markets. Delays in receipt of approvals or clearances to market our products and services in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

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

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

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

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

Risks Related to Our Intellectual Property

We may not be able to protect our proprietary rights.

Our commercial success will depend in large part upon our ability to protect our proprietary rights. There is no assurance, for example, that any additional patents will be issued based on our or our licensor's pending applications or, if issued, that such patents will not become the subject of a re-examination, will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products and services incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products and services, duplicate any of our products and services, or design around any patents we obtain.

Our commercial success will also depend upon our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our products, services or processes, obtain licenses, or cease certain activities. If we are required in the future to obtain any licenses from third parties for some of our products and/or services, there can be no guarantee that we would be able to do so on commercially favorable terms, if at all. United States and foreign patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using. Although we conducted a freedom to operate, or FTO, search years ago on the licensed technology associated with our *Disc/Spine Program*, modifications made, and/or further developments that may be made, to that technology may not be covered by the initial FTO. No FTO has been undertaken with respect to our *ThermoStem* brown fat initiative.

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

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

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

In addition to patents, we rely on unpatented trade secrets and proprietary technological expertise. Some of our intended future cell-related therapeutic products and/or services may fit into this category. We also rely, in part, on confidentiality agreements with our partners, employees, advisors, vendors, and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or that we will have adequate remedies for any breach, or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

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

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

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

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

- issue a warning or untitled letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;

- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise demand or require the withdrawal or recall of the product from the market;
- refuse to permit the import or export of products;
- request and publicize a voluntary recall of the product; or
- refuse to allow us to enter into supply contracts, including government contracts.

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

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

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

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

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

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

In addition to the FCPA, we will also need to comply with the foreign government laws and regulations of each individual country in which any therapy centers that we may establish are located and products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. Due to the fact that there are new and emerging stem cell and cell therapy regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not always precisely understood today for each country, creating greater uncertainty for the international regulatory process. Furthermore, there can be no guarantee that laws and regulations will not be implemented, amended and/or reinterpreted in a way that will negatively affect our business. Likewise, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all such healthcare laws and regulations. Failure to comply with such healthcare laws and regulations, as well as the costs associated with such compliance or with enforcement of such healthcare laws and regulations, may have a material adverse effect on our operations or may require restructuring of our operations or impair our ability to operate profitably.

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

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

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

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

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

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

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

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

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

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

- third-party clinical investigators do not perform the clinical trials on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices required by the FDA and other regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;

- inspections of clinical trial sites by the FDA or other regulatory authorities reveal violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit use of some or all of the data in support of marketing applications; or

- the FDA or one or more institutional review boards suspends or terminates the trial at an investigational site, or precludes enrollment of additional subjects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to this Offering and Our Common Stock and Warrants

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; there is no market for our warrants and there is no assurance that an active trading market for our warrants will develop.

We have applied for the listing of our common stock and the warrants being offered pursuant to this prospectus on Nasdaq. However, no assurance can be given that such application will be approved, or, if approved, that an active market for our common stock will be sustained or that any active market for our warrants will develop or, if developed, 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, as well as a variety of related rules implemented by the SEC, have required changes in corporate governance practices and generally increased the disclosure requirements of public companies. As a reporting company, we incur significant legal, accounting and other expenses in connection with our public disclosure and other obligations. Based upon SEC regulations currently in effect, we are required to establish, evaluate and report on our internal control over financial reporting. We believe that compliance with the myriad of rules and regulations applicable to reporting companies and related compliance issues will continue to require a significant amount of time and attention from our management.

Our stock and warrant prices 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 and warrants 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 and warrant prices 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 this Offering and Our Common Stock and Warrants" and "Risks Associated with Our Contemplated Reverse Stock Split and 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 300,000,000,000 shares of common stock of which, as of July 31, 2021, 3,350,844,445 shares were issued and outstanding. We are not restricted from issuing additional shares of our common stock in the future, including securities convertible into, or exchangeable or exercisable for, shares of our common stock.

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

We have effective registration statements on Form S-8 under the Securities Act registering an aggregate of 19,955,000 shares of our common stock issuable under our 2010 Equity Participation Plan, or the 2010 Plan. As of July 31, 2021, options to purchase 4,355,167 shares of our common stock were outstanding under the 2010 Plan. In addition, as of such date, 45,000 shares of common stock were issued as stock grants pursuant to the 2010 Plan. The 2010 Plan terminated on November 17, 2020 and accordingly no further grants may be made under the 2010 Plan.

We also have an effective registration statement on Form S-8 under the Securities Act registering 4,700,000,000 shares of our common stock issuable under our 2021 Stock Incentive Plan, or the 2021 Plan. As of July 31, 2021, options to purchase 2,347,835,948 shares of our common stock were outstanding under the 2021 Plan. In addition, as of such date, 1,173,917,974 RSUs were outstanding under the 2021 Plan. All of such options and RSUs are held by our senior management team, Lance Alstodt and Francisco Silva.

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

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

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

There may be significant future issuances or resales of our common stock pursuant to a contemplated exchange of outstanding convertible promissory notes and warrants for Units; this may materially and adversely dilute stockholders' ownership interest and affect the market price of our securities.

Pursuant to the Plan of Reorganization, we issued warrants for the purchase of an aggregate of 15,725,555,070 shares of our common stock (of which 14,999,272,390 are currently outstanding). In addition, pursuant to the Plan of Reorganization, we issued convertible notes in the aggregate principal amount of $10,357,960 (of which $10,046,897 in aggregate principal amount is currently outstanding). Such notes are convertible into shares of our common stock at prices related to the market price of our common stock at the time of conversion. We have had discussions with the holders of such warrants and with the holders of notes in the aggregate principal amount of $9,246,897 to exchange the warrants and notes into Units on the same terms as being offered to investors by this prospectus. Pursuant to the provisions of the notes in the aggregate principal amount of $10,046,897, if exchange agreements are not entered into, the notes would automatically convert into the Units offered by this prospectus on the same terms as being offered to investors by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering). The recipients of such Units would be entitled to dispose of their securities subject to the requirements of applicable securities laws and subject to any lock-up agreements which such warrantholders and noteholders agree to execute. Upon the expiration of any such lock-up agreements, the shares of common stock issued to such warrantholders and noteholders would become 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 and warrant prices to decline. Additional sales of a substantial number of our shares of our common stock in the public market, or the perception that sales could occur, could have a material adverse effect on the price of our securities. In addition, the issuance of Units to such warrantholders and noteholders would dilute the ownership of our stockholders.

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

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

Investors in this offering will experience immediate and substantial dilution in net tangible book value.

The public offering price will be substantially higher than the net tangible book value per share of our outstanding shares of common stock. As a result, investors in this offering will incur immediate dilution of $ per share, based on the assumed public offering price of $ per Unit. Investors in this offering will pay a price per share that substantially exceeds the book value of our assets after subtracting our liabilities. See "Dilution" for a more complete description of how the value of your investment will be diluted upon the completion of this offering.

If, following this offering, our common stock becomes classified again as a "penny stock," the restrictions of the penny stock regulations of the Securities and Exchange Commission, or SEC, may result in less liquidity for our common stock.

The SEC has adopted regulations which define a "penny stock" to be any equity security that has a market price (as therein defined) of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. Unless exempt, the rules require the delivery, prior to any transaction involving a penny stock by a retail customer, of a disclosure schedule prepared by the SEC relating to the penny stock market. Disclosure is also required to be made about commissions payable to both the broker/dealer and the registered representative and current quotations for the securities. Finally, monthly statements are required to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. If, following this offering, the market price for shares of our common stock falls below $5.00, and we do not satisfy any of the exceptions to the SEC's definition of penny stock, our common stock will be classified as a penny stock. If such should occur, as a result of the penny stock restrictions, brokers or potential investors may be reluctant to trade in our securities, which may result in less liquidity for our securities.

Warrants are speculative in nature.

The warrants offered pursuant to this prospectus do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of $ (% of the public offering price of the Units in this offering), prior to years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

We may invest or spend the proceeds from this offering in ways with which you may not agree.

We intend to use the net proceeds of this offering for the following purposes: (i) the undertaking of clinical trials with respect to *BRTX-100*, our lead product candidate, 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. However, we will retain broad discretion over the use of the proceeds from this offering and may use them for purposes other than those contemplated at the time of this offering. You may not agree with the ways we decide to use these proceeds. See "Use of Proceeds."

Risks Associated with Our Contemplated Reverse Stock Split and Nasdaq Listing

A reverse stock split could cause our stock price to decline relative to its value before the split.

We plan to effect a reverse split of our outstanding common stock concurrently with or before this offering in order to achieve a sufficient increase in our stock price to at least $4.00 per share to enable us to qualify for listing on Nasdaq. There is no assurance that the reverse stock split will be successful in raising our stock price sufficiently to enable us to list on Nasdaq, that we will be accepted by Nasdaq in any event, or that the reverse split will not cause an actual decline in the value of our outstanding common stock.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock, we cannot assure you that we will be able to continue to comply with the minimum bid price requirement of Nasdaq.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock to be in compliance with the minimum bid price requirement of Nasdaq, there can be no assurance that the market price of our common stock following the reverse stock split will remain at the $1.00 per share level required for continuing compliance with that requirement. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines following the effectuation of the reverse stock split, the percentage decline may be greater than would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and jeopardize our ability to meet or maintain Nasdaq's minimum bid price requirement.

Even if the reverse stock split increases the market price of our common stock, there can be no assurance that we will be able to comply with other continued listing standards of Nasdaq.

Even if the market price of our common stock increases sufficiently so that we comply with the minimum bid price requirement, we cannot assure you that we will be able to comply with the other standards, including the corporate governance requirements that we must satisfy in order to maintain a listing of our common stock and/or warrants on Nasdaq. Our failure to meet these requirements may result in our common stock and/or warrants sold in this offering being delisted from Nasdaq, irrespective of our compliance with the minimum bid price requirement.

The reverse stock split may decrease the liquidity of the shares of our common stock.

The liquidity of the shares of our common stock may be affected adversely by the contemplated reverse stock split given the reduced number of shares that will be outstanding following the reverse stock split, especially if the market price of our common stock does not increase correspondingly as a result of the reverse stock split. In addition, the reverse stock split may increase the number of stockholders who own odd lots (i.e., fewer than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following the reverse stock split, the resulting 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 a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. 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.

In order to have our securities listed on Nasdaq, among other requirements, we will need to add independent qualified persons to our Board.

One of the requirements for a Nasdaq listing is that a majority of the members of our Board of Directors be independent and that we have an Audit Committee that has at least three members, all of whom must be independent directors. In addition, at least one member of the Audit Committee must have experience that results in such individual's financial sophistication. There are also listing requirements as to independent directors serving on the Board's Compensation Committee and Nominating Committee. Currently, we have a three member Board of Directors of which only one member is independent. In the event we are unable to attract a sufficient number of independent qualified persons to serve on our Board of Directors, Audit Committee, Compensation Committee and Nominating Committee, we may be unable to have our common stock and warrants listed on Nasdaq, in which case we will not proceed with this offering.

We are seeking stockholder approval of a reincorporation of our company to Nevada; in such event, our Board will have the power and authority to effectuate a reverse split of our common stock without further stockholder approval.

At our annual meeting of stockholders scheduled to be held on August 17, 2021, we are seeking stockholder approval of a reincorporation of our company to Nevada. In the event such reincorporation is approved and we become a Nevada corporation, our Board of Directors will have the power and authority to effectuate a reverse split of our common stock, as well as to determine the reverse split ratio, without the need for stockholder approval.

In connection with the reverse stock split, we may have additional authorized shares of common stock available for issuance; the issuance of such additional shares would dilute the percentage ownership of existing stockholders.

At the annual meeting of stockholders, in the event the reincorporation to Nevada is not approved, we are seeking stockholder approval of a reverse stock split at a ratio of not less than 1-for-20 and not more than 1-for-4000. In addition, in the event the reverse stock split proposal is approved, we are seeking stockholder approval to reduce the number of shares of common stock we will be authorized to issue in proportion to the percentage decrease in the number of outstanding shares of common stock resulting from the reverse stock split or to a lesser or greater extent as determined by our Board of Directors. In the event that our Board of Directors determines to reduce the number of authorized shares of common stock to a lesser extent than the percentage decrease resulting from the reverse stock split, we will, in effect, have additional shares of common stock available for issuance. Any such issuance of shares would result in a dilution of the percentage ownership of existing stockholders.

USE OF PROCEEDS

We estimate that the net proceeds from this offering, after deducting underwriting discounts and offering expenses payable by us, will be approximately $. If the underwriters' over-allotment option is exercised in full, we estimate that our net proceeds will be approximately $.

We intend to use the net proceeds of this offering for the following purposes:

- approximately $ undertaking of clinical trials with respect to *BRTX-100* and its related collection and delivery procedure;
- approximately $ pre-clinical research and development with respect to our *ThermoStem Program; and*
- approximately $ general corporate and working capital purposes.

The amounts and timing of our actual expenditures will depend upon numerous factors, including the status of our research and development efforts. We, therefore, cannot predict the relative allocation of net proceeds that we receive in this offering and may allocate it differently than indicated above. As a result, management will have broad discretion over the use of the net proceeds from this offering.

CAPITALIZATION

The following table sets forth our consolidated capitalization as of March 31, 2021 (i) on an actual basis, and (ii) as adjusted to give effect to the offering at the assumed public offering price of $ per Unit, for total net proceeds of approximately $ (assuming no exercise of the underwriters' over-allotment option).

This information should be read together with our consolidated financial statements and other financial information set forth in our financial statements and related notes included elsewhere in this prospectus.

	At March 31, 2021	
	Actual	**As Adjusted**
Cash	$ 2,500,909	$
Long-Term Liabilities	$ 5,133,272	$
Stockholders' (Deficit) Equity		
Preferred stock, $0.01 par value; 20,000,000 shares authorized, -0- shares issued and outstanding before the offering, and on an as adjusted basis	$ -	$
Common stock, $0.0001 par value; 300,000,000,000 shares authorized; 3,175,911,955 shares issued and outstanding before the offering;		
shares issued and outstanding on an as adjusted basis	317,593	
Additional paid-in capital	102,484,188	
Accumulated deficit	(105,496,163)	
Total stockholders' (deficit) equity	(2,438,890)	
Total capitalization	$ 2,409,516	$

DILUTION

If you invest in the Units offered by this prospectus, you will suffer immediate and substantial dilution in the net tangible book value per share of common stock.

As of March 31, 2021, we had a net tangible book deficit of $(3,340,018), or $(0.001) per share. The net tangible book value (deficit) per share of common stock is determined by subtracting total liabilities from the total book value of the tangible assets and dividing the difference by the number of shares of common stock deemed to be outstanding as of March 31, 2021. After giving effect to the sale of Units offered by us in this offering at an assumed offering price of $ per Unit, which is the last reported sales price of our common stock on the OTC Market on , 2021 and the application of the estimated net proceeds from this offering, our as adjusted net tangible book value as of March 31, 2021 would have been $ or $ per share. This represents an immediate increase in net tangible book value to existing stockholders of $ per share and an immediate dilution to new investors of $ per share. The following table illustrates this per share dilution to new investors purchasing Units in this offering.

Assumed offering price per Unit		$
Net tangible book deficit per share as of March 31, 2021	$ (0.001)	
Increase attributable to new investors in this offering	$	
As adjusted, net tangible book value per share as of March 31, 2021 after the offering		$
Dilution per share to new investors		$

If the underwriters exercise in full their over-allotment option to purchase additional Units in this offering, the pro forma net tangible book value per share after the offering would be $ per share, the increase in net tangible book value per share to existing stockholders would be $ per share and the dilution to new investors purchasing Units in this offering would be $ per share.

The following table sets forth, on an unaudited as adjusted basis, as of March 31, 2021, the difference between the total consideration paid and the average price per share of common stock paid by existing stockholders and by the new investors purchasing Units in this offering at an assumed offering price of $ per Unit, which is the last reported sales price of our common stock on the OTC Market on , 2021 before deducting underwriting discounts and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
			(in thousands)		
Existing stockholders			$		$
New investors			$		$
Totals		100%	$	100%	$

The above discussion and table is based on 3,175,911,955 shares of common stock outstanding as of March 31, 2021, does not reflect the potential sale of up to additional shares of our common stock which may be purchased in this offering at the discretion of the underwriters pursuant to their over-allotment option, and excludes:

- 2,352,195,565 shares of common stock issuable upon the exercise of stock options that were outstanding as of March 31, 2021 at a weighted-average exercise price of $0.0139 per share;
- 14,689,060,954 shares of common stock issuable upon the exercise of warrants to purchase common stock that were outstanding as of March 31, 2021 at a weighted average exercise price of $0.001 per share (inclusive of the warrants contemplated to be exchanged for Units as described in "Prospectus Summary – Chapter 11 Reorganization; Exchange of Outstanding Debt and Warrants");
- 1,178,246,078 shares available for future issuance as of March 31, 2021 under the 2021 Plan;
- 1,173,917,974 shares of common stock issuable upon the vesting of restricted stock units that were outstanding as of March 31, 2021;
- an indeterminate number of shares of common stock issuable upon the exchange of the convertible promissory notes in the aggregate principal amount of $9,426,039 that were outstanding as of March 31, 2021 and are contemplated to be exchanged for Units, as described in "Prospectus Summary – Chapter 11 Reorganization; Exchange of Outstanding Debt and Warrants";
- shares of common stock issuable upon the exercise of the warrants issued pursuant to this offering; and
- shares of common stock issuable upon the exercise of the warrants to be issued to the Representative as discussed under "Underwriting" on page 116.

To the extent that outstanding options and warrants are exercised, investors will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

The following table sets forth selected consolidated financial data of BioRestorative Therapies, Inc. The financial data as of March 31, 2021 and for the three months ended March 31, 2021 and 2020 have been derived from our unaudited condensed consolidated financial statements included in this prospectus under "Index to Financial Statements". The financial data as of December 31, 2020 and 2019 and for the years then ended have been derived from our audited consolidated financial statements included in this prospectus under "Index to Financial Statements." The summary consolidated financial results in the table below are not necessarily indicative of our expected future operating results. The following summary historical financial information should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the historical financial statements and notes thereto appearing in this prospectus under "Index to Financial Statements."

	For the Three Months Ended March 31,		For The Years Ended December 31,	
	2021	2020	2020	2019
	(unaudited)			
Revenues	$ 18,000	$ 26,000	$ 77,000	$ 130,000
Operating Expenses:				
Marketing and promotion	2,600	22,008	28,281	321,280
Consulting	8,389	34,012	137,250	1,912,683
Research and development	165,254	186,328	876,829	1,722,338
General and administrative	14,896,413	602,641	1,786,716	4,605,704
Total Operating Expenses	15,072,656	844,989	2,829,076	8,562,005
Loss From Operations	(15,054,656)	(818,989)	(2,752,076)	(8,432,005)
Other (Expense) Income:				
Interest expense	181,514	285,926	(362,041)	(1,467,952)
Amortization of debt discount	417,160	1,066,526	(1,278,104)	(3,671,087)
Loss on extinguishment of notes payable, net	-	658,152	(658,152)	(1,895,116)
Change in fair value of derivative liabilities	-	2,141,069	(2,141,069)	788,970
Reorganization items, net	-	2,580,110	(4,081,245)	-
Other income			-	29,300
Total Other Expense	598,674	6,731,783	(8,520,611)	(6,215,885)
Net Loss	$ (15,653,330)	$ (7,550,772)	$ (11,272,687)	$ (14,647,890)

		December 31,	
	March 31, 2021	2020	2019
	(unaudited)		
Balance Sheet Data:			
Cash	$ 2,500,909	$ 3,064,610	$ 1,664
Working capital (deficiency)	$ 1,302,697	$ 2,142,229	$ (13,651,716)
Total assets	$ 3,701,180	$ 4,347,048	$ 1,466,323
Total liabilities	$ 6,395,562	$ 5,678,540	$ 14,242,469
Total stockholders' deficit	$ (2,694,382)	$ (1,331,492)	$ (12,776,146)

DETERMINATION OF OFFERING PRICE

The offering price for the Units offered by this prospectus and the exercise price for the warrants forming of a portion of the Units have been negotiated between the underwriters and us. In determining such offering price and exercise price, the following factors were considered:

- prevailing market conditions;
- our historical performance and capital structure;
- estimates of our business potential and earnings prospects;
- an overall assessment of our management; and
- the consideration of these factors in relation to the market valuation of companies in related businesses.

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

As of July 29, 2021, there were 365 record holders of our shares of common stock.

DIVIDEND POLICY

Holders of our shares of common stock are entitled to dividends when, as and if declared by our Board of Directors out of legally available funds.

We have not declared or paid any dividends in the past to the holders of our common stock and do not currently anticipate declaring or paying any dividends in the foreseeable future. We intend to retain earnings, if any, to finance the development and expansion of our business. Future dividend policy will be subject to the discretion of our Board of Directors and will be contingent upon future earnings, if any, our financial condition, capital requirements, general business conditions, and other factors. Therefore, we can give no assurance that any dividends of any kind will ever be paid to holders of our common stock.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the consolidated results of operations and financial condition of BioRestorative Therapies, Inc. and its subsidiary as of March 31, 2021 and for the three months ended March 31, 2021 and 2020 and as of December 31, 2020 and 2019 and for the years ended December 31, 2020 and 2019 should be read in conjunction with our financial statements and the notes to those financial statements that are included elsewhere in this prospectus. 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 prospectus contains forward-looking statements as that term is defined in the federal securities laws. The events described in forward-looking statements contained in this prospectus 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 "Risk Factors" beginning on page 12 of this prospectus for a discussion of some of the uncertainties and risks associated with these statements.

Overview

We develop therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult (non-embryonic) stem cells. We are currently pursuing our Disc/Spine Program with our initial investigational therapeutic product being called BRTX-100. We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of BRTX-100, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We have received such authorization from the FDA. We intend to commence such clinical trial during 2022 (assuming the receipt of necessary funding). We have obtained a license to use technology for investigational adult stem cell treatment of disc and spine conditions, including protruding and bulging lumbar discs. The technology is an advanced stem cell injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the leg and foot. We are also developing our ThermoStem Program. This pre-clinical program involves the use of brown adipose (fat) in connection with the cell-based treatment of type 2 diabetes and obesity as well as hypertension, other metabolic disorders and cardiac deficiencies. United States patents related to the ThermoStem Program were issued in September 2015, January 2019, March 2020, March 2021, and July 2021; Australian patents related to the ThermoStem Program were issued in April 2017 and October 2019; Japanese patents related to the ThermoStem Program were issued in December 2017 and May 2021; Israeli patents related to the ThermoStem Program were issued in October 2019 and May 2020; and European patents related to the ThermoStem Program were issued in April 2020 and January 2021.

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

Our offices are located in Melville, New York where we have established a laboratory facility in order to increase our capabilities for the further development of possible cellular-based treatments, products and protocols, stem cell-related intellectual property and translational research applications.

As of March 31, 2021, our accumulated deficit was $105,496,163 and our stockholders' deficit was $2,694,382. We have historically only generated a modest amount of revenue, and our losses have principally been operating expenses incurred in research and development, marketing and promotional activities in order to commercialize our products and services, plus costs associated with meeting the requirements of being a public company. We expect to continue to incur substantial costs for these activities over at least the next year.

Based upon our forecast for continued operating losses, as of March 31, 2021, we required equity and/or debt financing to continue our operations. As of March 31, 2021, our outstanding debt of $9,426,039, together with interest at rates ranging between 5% and 7% per annum, was due on November 16, 2023. As of March 31, 2021, the outstanding debt amount of $9,426,039 did not include $657,598 of estimated DIP and Plan of Reorganization costs associated with the DIP funding and the Plan of Reorganization, or the Auctus Costs. As of March 31, 2021, the Auctus Costs were not finalized and, of which, $500,000 and $157,598 are recorded in debt discount and accrued expenses, respectively, on the consolidated balance sheets included in this prospectus. The Auctus Costs have now been determined to be $715,542.

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

We anticipate that we will require approximately $12,000,000 in financing to complete a Phase 2 clinical trial with regard to our *Disc/Spine Program*. We anticipate that we will require approximately $45,000,000 in further additional funding to complete such clinical trials (assuming the receipt of no revenues). We will also require a substantial amount of additional funding to implement our other programs as discussed in this prospectus under the caption "Business," including our metabolic *ThermoStem Program*, and fund general operations. No assurance can be given that the anticipated amounts of required funding are correct or that we will be able to accomplish our goals within the timeframes projected. In addition, no assurance can be given that we will be able to obtain any required financing on commercially reasonable terms or otherwise.

We are currently seeking several different financing alternatives to support our future operations. The Plan of Reorganization provides that, at such time as we became current in our periodic SEC filings (which we did upon the filing in April 2021 of our Annual Report on Form 10-K for the year ended December 31, 2020), subject to certain customary conditions, Auctus, which provided debtor-in-possession, or DIP, financing to us during the reorganization process, is to provide a loan to us of $2,100,000, as needed. In addition, Auctus and others provided debt financing in the aggregate principal amount of $3,848,548 at the effective date of our Plan of Reorganization. If we are unable to obtain such financing on a timely basis or other required financing as needed, we may have to curtail our development, marketing and promotional activities, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately we could be forced to discontinue our operations and liquidate. See "Liquidity and Capital Resources" below.

In connection with this offering, we have had discussions with the holders of convertible notes in the aggregate principal amount of $9,246,897 and warrants for the purchase of an aggregate of 14,999,272,390 shares of common stock pursuant to which such holders would exchange such notes and warrants for Units on the same terms as being offered to investors by this prospectus. No assurances can be given that such noteholders and warrantholders will enter into exchange agreements, whether upon reasonable terms or otherwise. In the event that agreements are not entered into with regard to the exchange of the outstanding convertible promissory notes into Units, pursuant to the provisions of the notes, the amounts payable pursuant to the notes will automatically convert into the Units offered by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering). In addition to the foregoing, pursuant to the provisions of certain other convertible promissory notes in the aggregate principal amount of $800,000, the amounts payable pursuant to such notes will automatically convert into the Units offered by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering).

Consolidated Results of Operations

Three Months Ended March 31, 2021 Compared with Three Months Ended March 31, 2020

The following table presents selected items in our unaudited condensed consolidated statements of operations for the three months ended March 31, 2021 and 2020, respectively:

	For The Three Months Ended March 31,	
	2021	**2020**
Revenues	$ 18,000	$ 26,000
Operating Expenses:		
Marketing and promotion	2,600	22,008
Consulting	8,389	34,012
Research and development	165,254	186,328
General and administrative	14,896,413	602,641
Total Operating Expenses	15,072,656	844,989
Loss From Operations	(15,054,656)	(818,989)
Other Expense:		
Interest expense	181,514	285,926
Amortization of debt discount	417,160	1,066,526
Loss on extinguishment of notes payable, net	-	658,152
Change in fair value of derivative liabilities	-	2,141,069
Reorganization items, net	-	2,580,110
Total Other Expense	598,674	6,731,783
Net Loss	$ (15,653,330)	$ (7,550,772)

Revenues

For the three months ended March 31, 2021 and 2020, we generated $18,000 and $26,000, respectively, of royalty revenue in connection with our sublicense agreement.

Marketing and Promotion

Marketing and promotion expenses include advertising and promotion, marketing and seminars, meals, entertainment and travel expenses. For the three months ended March 31, 2021, marketing and promotion expenses decreased by $19,408, or 88%, from $22,008 to $2,600 as compared to the three months ended March 31, 2020. The decrease is primarily due to our reduced marketing plan as we continue to emerge from our Chapter 11 reorganization.

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

Consulting

Consulting expenses consist of consulting fees and stock-based compensation to consultants. For the three months ended March 31, 2021, consulting expenses decreased by $25,623, or 75%, from $34,012 to $8,389, as compared to the three months ended March 31, 2020. The decrease is primarily due to our reduced usage of consultants as we continue to emerge from our Chapter 11 reorganization.

Research and Development

Research and development expenses include cash and non-cash compensation of (a) our Vice President of Research and Development; (b) our Scientific Advisory Board members; and (c) laboratory staff and costs related to our brown fat and disc/spine initiatives. Research and development expenses are expensed as they are incurred. For the three months ended March 31, 2021, research and development expenses decreased by $21,075, or 11%, from $186,328 to $165,254, as compared to the three months ended March 31, 2020. The decrease is primarily due to the decrease of approximately $35,000 in stock compensation allocated to our research and development activities.

We expect that our research and development expenses will increase with the recommencement of our research and development initiatives during the year ending December 31, 2021.

General and Administrative

General and administrative expenses consist primarily of salaries, bonuses, payroll taxes, severance costs and stock-based compensation to employees (excluding any cash or non-cash compensation of our Vice President of Research and Development and our laboratory staff), as well as corporate expenses such as legal and professional fees, investor relations and occupancy related expenses. For the three months ended March 31, 2021, general and administrative expenses increased by $14,293,772, or 2,372%, from $602,641 to $14,896,413, as compared to the three months ended March 31, 2020. The increase is primarily due to an increase of approximately $14,077,000 in stock-based compensation resulting from the issuances of 2,347,835,948 stock options and 1,173,917,974 RSUs.

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

Interest expense

For the three months ended March 31, 2021, interest expense decreased $104,412, or 37%, as compared to the three months ended March 31, 2020. The decrease was due to the decrease in outstanding notes payable as a result of our restructuring under our Chapter 11 reorganization.

Amortization of debt discount

For the three months ended March 31, 2021, amortization of debt discount decreased $649,366, or 61%, as compared to the three months ended March 31, 2020. The decrease was due to the decrease in outstanding notes payable as a result of our restructuring under our Chapter 11 reorganization.

Loss on extinguishment of notes payable, net

For the three months ended March 31, 2021, we did not record a loss on extinguishment of notes payable, as compared to a loss on extinguishment of notes payable of $658,152 for the three months ended March 31, 2020.

Change in fair value of derivative liabilities

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

Reorganization items, net

Reorganization items, net consists primarily of costs associated the post-petition Chapter 11 bankruptcy. For the three months ended March 31, 2021, we did not record reorganization items, net as compared to reorganization costs, net of $2,580,110 for the three months ended March 31, 2020.

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

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

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

Revenues

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

Marketing and promotion

Marketing and promotion expenses include advertising and promotion, marketing and seminars, meals, entertainment and travel expenses. For the year ended December 31, 2020, marketing and promotion expenses decreased by $292,999, or 91%, from $321,280 to $28,281 as compared to the year ended December 31, 2019, due to our reduced spending on marketing prior to and during our Chapter 11 reorganization.

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

Consulting

Consulting expenses consist of consulting fees and stock-based compensation to consultants. For the year ended December 31, 2020, consulting expenses decreased by $1,775,433, or 93%, from $1,912,683 to $137,250, as compared to the year ended December 31, 2019, due to our reduced usage of consultants prior to and during our Chapter 11 reorganization.

Research and development

Research and development expenses include cash and non-cash compensation of (a) our Vice President of Research and Development; (b) our Scientific Advisory Board members; and (c) laboratory staff and costs related to our brown fat and disc/spine initiatives. Research and development expenses are expensed as they are incurred. For the year ended December 31, 2020, research and development expenses decreased by $845,509, or 49%, from $1,722,338 to $876,829, as compared to the year ended December 31, 2019. The decrease was primarily a result of our reduced spending on research and development prior to and during our Chapter 11 reorganization.

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

General and administrative

General and administrative expenses consist primarily of salaries, bonuses, payroll taxes, severance costs and stock-based compensation to employees (excluding any cash or non-cash compensation of our Vice President of Research and Development and our laboratory staff), as well as corporate expenses such as legal and professional fees, investor relations and occupancy related expenses. For the year ended December 31, 2020, general and administrative expenses decreased by $2,818,988, or 61%, from $4,605,704 to $1,786,716, as compared to the year ended December 31, 2019. The decrease is primarily due to our reduced incurrence of general and administrative expenses prior to and during our Chapter 11 reorganization.

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

Interest expense

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

Amortization of debt discount

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

Loss on extinguishment of notes payable, net

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

Change in fair value of derivative liabilities

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

Reorganization items, net

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

Liquidity and Capital Resources

Liquidity

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

		December 31,	
	March 31, 2021	**2020**	**2019**
	(unaudited)		
Cash	$ 2,500,909	$ 3,064,610	$ 1,664
Working Capital (Deficiency)	$ 1,302,698	$ 2,142,229	$ (13,651,716)
Notes Payable (Gross)	$ 9,426,039	$ 9,637,102	$ 8,393,327

Availability of Additional Funds

Based upon our accumulated deficit and stockholders' deficit of $105,496,163 and $2,694,382, respectively, as of March 31, 2021, along with our forecast for continued operating losses and our need for financing to fund our contemplated clinical trials, as of such date, we required additional equity and/or debt financing to continue our operations.

As of March 31, 2021, our outstanding debt of $9,426,039, together with interest at rates ranging between 5% and 7% per annum, was due on November 16, 2023, except for our Paycheck Protection Program, or PPP, loan. As of March 31, 2021, the outstanding debt amount of $9,426,039 did not include $657,598 of estimated Auctus Costs associated with the DIP Funding and the Plan of Reorganization. As of March 31, 2021, the Auctus Costs were not finalized. Of the Auctus Costs, $500,000 and $157,598 are recorded in debt discount and accrued expenses, respectively, on the unaudited condensed consolidated balance sheets included elsewhere in this prospectus. The Auctus Costs have now been determined to be $715,542.

Our operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products and services, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings.

We may be unable to raise sufficient additional capital when we need it or raise capital on favorable terms. We have granted a security interest in all of our assets to certain lenders, including Auctus, in connection with our Chapter 11 Plan of Reorganization. This may impede our ability to raise additional debt financing; however, the holders of the secured debt have agreed to exchange their notes for Units pursuant to this prospectus. In addition, future financing may require us to pledge certain assets and enter into covenants that could restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to significantly curtail or discontinue operations or obtain funds by entering into financing agreements on unattractive terms.

Our unaudited condensed consolidated financial statements included elsewhere in this prospectus have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP, which contemplate our continuation as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The financial statements do not include any adjustment that might result from the outcome of this uncertainty.

The following events have mitigated the above factors with regards to our ability to continue as a going concern: (i) as part of our Chapter 11 reorganization approximately $14,700,000 in outstanding debt and other liabilities were exchanged for (a) shares of common stock, (b) new convertible notes with three year terms or (c) new convertible notes with three year terms and warrants to purchase shares of common stock; (ii) we secured DIP financing during our Chapter 11 reorganization in the aggregate amount of $1,189,413, and $3,848,548 in debt financing as part of our Chapter 11 reorganization to sustain operations; and (iii) pursuant to the Plan of Reorganization, Auctus is required to loan to us, as needed, an additional $2,100,000. As a result of the above, we have sufficient cash to fund operations for the twelve months subsequent to the date of this prospectus. In addition, we will need to obtain further funding of at least $12,000,000 to complete a Phase 2 clinical study of the use of BRTX-100.

During the three months ended March 31, 2021 and 2020 and the years ended December 31, 2020 and 2019, our sources and uses of cash were as follows:

Net Cash Used in Operating Activities

Net cash used in operating activities was $813,702 for the three months ended March 31, 2021, primarily due to the net loss of $15,653,330 which was partially offset by non-cash expenses of $14,519,965 related to amortization of debt discount and stock-based compensation and $319,663 of cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in accounts payable and accrued interest, expenses and other current liabilities, partially offset by a decrease in prepaid assets and other current assets. Net cash used in operating activities was $448,646 for the three months ended March 31, 2020, primarily due to the net loss of $7,550,772, which was partially offset by non-cash expenses of $6,950,957 related to amortization of debt discount, accretion of interest expense, stock-based compensation, change in fair value of derivative liabilities, and loss on extinguishment of notes payable and $151,169 of cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in accounts payable and decreases in prepaid expenses and other current assets.

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

Net Cash Used in Investing Activities

There were no investing activities during the three months ended March 31, 2021 or 2020. During the years ended December 31, 2020 and 2019, cash used in investing activities was $- and $35,631, respectively.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2021 was $250,000, which was due to $250,000 of net proceeds from a loan received under the U.S. Small Business Administration's Paycheck Protection Program. Net cash provided by financing activities for the three months ended March 31, 2020 was $451,762, which was primarily due to $441,762 of net proceeds from debt financings and $10,000 of proceeds from equity financings.

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

Critical Accounting Policies and Estimates

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at dates of the financial statements and the reported amounts of revenue and expenses during the periods. Our significant estimates and assumptions include the recoverability and useful lives of long-lived assets, the fair value of our common stock, stock-based compensation, warrants issued in connection with notes payable, derivative liabilities and the valuation allowance related to our deferred tax assets. Certain of our estimates, including the carrying amount of the intangible assets, could be affected by external conditions, including those unique to us and general economic conditions. It is reasonably possible that these external factors could have an effect on our estimates and could cause actual results to differ from those estimates.

Intangible Assets

Intangible assets are comprised of trademarks and licenses with original estimated useful lives of 10 and 17 years, respectively. Once placed into service, we amortize the cost of the intangible assets over their estimated useful lives on a straight-line basis.

Impairment of Long-lived Assets

We review for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. While our near term liquidity is tight, historically we have been successful in raising capital as needed (although there can be no assurance that we will continue to be successful in raising capital as needed). We continue to progress our scientific agenda. We have not identified any impairment losses.

Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in our financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts, or temporary differences, at enacted tax rates in effect for the years in which the temporary differences are expected to reverse.

We adopted the provisions of Accounting Standards Codification, or ASC, Topic 740-10, which prescribes a recognition threshold and measurement process for financial statements recognition and measurement of a tax position taken or expected to be taken in a tax return.

Stock-Based Compensation

We measure the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. Since the shares underlying our 2010 Plan were registered on May 27, 2014, we estimate the fair value of the awards granted under the Plan based on the market value of our freely tradable common stock as reported on the OTC. The fair value of our restricted equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares. Awards granted to directors are treated on the same basis as awards granted to employees.

Derivative Financial Instruments

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

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

Recently Issued Accounting Pronouncements

See Note 3 to our consolidated financial statements for the years ended December 31, 2020 and 2019 included elsewhere in this prospectus.

Off-Balance Sheet Arrangements

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

Factors That May Affect Future Results and Financial Condition

The information contained under the caption "Risk Factors" beginning on page 12 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.

BUSINESS

General

We are a life sciences company focused on the development of regenerative medicine products and therapies using cell and tissue protocols, primarily involving adult (non-embryonic) stem cells. Our two core developmental programs, as described below, relate to the treatment of disc/spine disease and metabolic disorders:

- ***Disc/Spine Program (brtxDisc).*** Our lead cell therapy candidate, *BRTX-100*, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells, or MSCs, collected from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complimentary therapeutic to a surgical procedure. The *BRTX-100* production process involves collecting bone marrow and whole blood from a patient, isolating and culturing (in a proprietary method) stem cells from the bone marrow and cryopreserving the cells in an autologous carrier. In an outpatient procedure, *BRTX-100* is to be injected by a physician into the patient's painful disc. The treatment is intended for patients whose pain has not been alleviated by non-surgical procedures or conservative therapies and who potentially face the prospect of highly invasive surgical procedures. We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100* in the treatment of chronic lower back pain arising from degenerative disc disease. We have received such authorization from the FDA. We intend to commence such clinical trial during 2022 (assuming the receipt of necessary funding). See "Disc/Spine Program" below.

- ***Metabolic Program (ThermoStem)***. We are developing a cell-based therapy candidate to target obesity and metabolic disorders using brown adipose (fat) derived stem cells, or BADSC, to generate brown adipose tissue, or BAT. We refer to this as our *ThermoStem Program*. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research conducted by us and others indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning, as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. See "Metabolic Brown Adipose (Fat) Program" below.

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

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

Overview

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

Regenerative cell therapy relies on replacing diseased, damaged or dysfunctional cells with healthy, functioning ones or repairing damaged or diseased tissue. A great range of cells can serve in cell therapy, including cells found in peripheral and umbilical cord blood, bone marrow and adipose (fat) tissue. Physicians have been using adult stem cells from bone marrow to treat various blood cancers for more than 60 years (the first successful bone marrow transplant was performed in 1956). Recently, physicians have begun to use stem cells to treat various other diseases. We intend to develop cell and tissue products and regenerative therapy protocols, primarily involving adult stem cells, to allow patients to undergo cellular-based treatments.

We intend to concentrate initially on therapeutic areas in which risk to the patient is low, recovery is relatively easy, results can be demonstrated through sufficient clinical data, and patients and physicians will be comfortable with the procedure. We believe that there will be readily identifiable groups of patients who will benefit from these procedures. We also believe that these procedures will be significantly less expensive than the most common surgical procedure alternatives and will compare favorably, over the long-term, to conservative treatment costs which may persist for years.

Accordingly, we have focused our initial developmental efforts on cellular-based therapeutic products and clinical development programs in selective areas of medicine for which the treatment protocol is minimally invasive. Such areas include the treatment of the disc and spine and metabolic-related disorders. Upon regulatory approval, we will seek to obtain third party reimbursement for our products and procedures; however; if we are 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 obtained five United States patents and eight foreign patents related to research regarding our *ThermoStem Program*, we have obtained licenses for one patent application related to our *Disc/Spine Program* and we have obtained a license for one United States patent related to a curved needle device.

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

We have not generated any significant revenues to date. The implementation of our business plan, as discussed below, will require the receipt of sufficient equity and/or debt financing to purchase necessary equipment, technology and materials, fund our research and development efforts, including our contemplated clinical trials, and otherwise fund our operations. We intend to seek such financing from current stockholders and debtholders as well as from other investors. We also intend to seek to raise capital through investment bankers and from biotech funds, strategic partners and other financial institutions. We anticipate that we will require approximately $12,000,000 in financing to complete a Phase 2 clinical trial investigating the use of *BRTX-100* in the treatment of chronic lower back pain arising from degenerative disc disease and that we will require approximately $45,000,000 in further additional funding to complete such clinical trials, as further described in this section (assuming the receipt of no revenues from operations). We will also require a substantial amount of additional funding to implement our other programs described in this section, and fund general operations. No assurance can be given that the anticipated amounts of required funding are correct or that we will be able to accomplish our goals within the timeframes projected. In addition, no assurance can be given that we will be able to obtain any required financing on commercially reasonable terms or otherwise. If we are unable to obtain adequate funding, we may be required to significantly curtail or discontinue our proposed operations.

Disc/Spine Program

General

Among the initiatives that we are currently pursuing is our *Disc/Spine Program*, with our initial product candidate being called *BRTX-100*. We have obtained a license (see "License" below) that permits us to use technology for adult stem cell treatment of disc and spine conditions. The technology is an advanced stem cell culture and injection procedure into the intervertebral disc, or IVD, that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the leg and foot.

Lower back pain is the most common, most disabling, and most costly musculoskeletal ailment faced worldwide. According to a 2016 market report from Trinity Partners, a global life sciences consulting firm, of the 250 million American adults, nearly 25 million have chronic lower back pain of which approximately 12 million have been diagnosed with and treated for disc degeneration and approximately 5.6 million have pain caused by a protruding or injured disc. We believe that between 500,000 and 1 million invasive surgical procedures are performed each year to try to alleviate the pain associated with these lower back conditions and that such procedures cost approximately $40 billion. Clinical studies have documented that the source of the pain is most frequently damage to the IVD. This can occur when forces, whether a single load or repetitive microtrauma, exceed the IVD's inherent capacity to resist those loads. Aging, obesity, smoking, lifestyle, and certain genetic factors may predispose one to an IVD injury. Current surgical approaches to back pain are extremely invasive (often altering the spine's biomechanics unfavorably and predisposing it to further disc degeneration) and are associated with unacceptably low success rates (with a second operation occurring 10% to 20% of the time). In addition, current surgical approaches are costly with spinal fusion surgery costing approximately $110,000, discectomy costing approximately $20,000 to $50,000 and disc replacement surgery costing approximately $80,000 to $150,000. Even conservative treatments can be costly, with oral medications costing between $1,000 and $2,000 per year, injection treatments costing approximately $8,000 per year and physical therapy costing approximately $20,000 annually. We anticipate that the cost of a single treatment using BRTX-100 will compare favorably to conservative treatments which may continue for years and will be less expensive than the most common surgical procedures.

While once thought to be benign, the natural history of lower back pain is often one of chronic recurrent episodes of pain leading to progressive disability. This is believed to be a direct result of the IVD's poor healing capacity after injury. The IVD is the largest avascular (having few or no blood vessels) structure in the body and is low in cellularity. Therefore, its inherent capacity to heal after injury is poor. The clinical rationale of *BRTX-100* is to deliver a high concentration of the patient's own cultured MSCs into the site of pathology to promote healing and relieve pain.

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

We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We received such authorization from the FDA in February 2017. We intend to commence such clinical trial during 2022 (assuming the receipt of necessary funding). Such clinical trial has not been commenced to date due to the lack of necessary funding. We believe that, based upon our periodic reports to the FDA as to the contemplated commencement of the clinical trial, the existing FDA authorization remains in place.

In addition to developing *BRTX-100*, we may also seek to sublicense the technology to a strategic third party, who may assist in gaining FDA approval for a lumbar disc indication, or third parties for use in connection with cellular-based developmental programs with regard to disc and spine related conditions.

We have established a laboratory, which includes a clean room facility, to perform the production of cell products (possibly including *BRTX-100*) for use in our clinical trials, for third party cell products or for general research purposes. We may also use this laboratory to develop our pipeline of future products and expand our stem cell-related IP. See "Laboratory" and "Technology; Research and Development" below.

BRTX-100

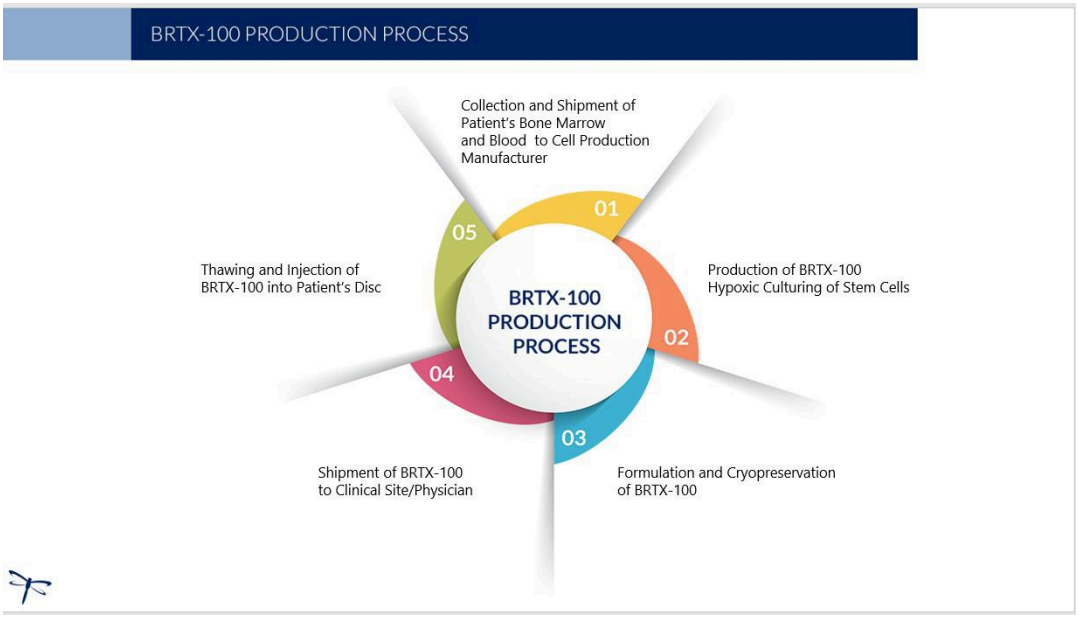
Our lead product candidate*, BRTX-100,* is an autologous hypoxic (low oxygen) cultured mesenchymal stem cell product derived from a patient's own bone marrow and formulated with a proprietary biomaterial carrier (platelet lysate) to increase potency, viability and survivability. We have designed the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

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

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

Production and Delivery

The production of our product candidate, *BRTX-100,* begins with the physician collecting bone marrow from the patient under local anesthesia. Peripheral blood is also collected from the patient. The physician will then send the patient's bone marrow and blood samples to our laboratory (or a contract laboratory) for culturing and formulation. The hypoxic culturing process is intended to result in the selection of a cell population that is suitable for an improved possibility of survival in the internal disc environment. We anticipate that the cell culturing process and product formulation will take approximately three weeks, with an additional two weeks required for quality control testing required to meet product release criteria. We will then send the therapeutic cryopreserved stem cells (*BRTX-100*) in a sterile vial back to the physician's offices where it will undergo a controlled thaw prior to the procedure. The price structure for the procedure and our services has not been determined and no assurances can be given as to the effect that such price structure will have on the marketability of such procedure and services. The following illustrates the process:



License

Pursuant to our license agreement with Regenerative Sciences, LLC, 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 Regenerative License Agreement currently provides for the requirement that we complete our Phase 2 clinical trial by a certain date (which we believe to be February 2022) in order to maintain the exclusive nature of the licenses. The Regenerative License Agreement also provides for a royalty-bearing sublicense of certain aspects of the technology to Regenerative for use for certain purposes, including in the United States and the Cayman Islands. Further, the Regenerative License Agreement requires that Regenerative furnish certain training, assistance and consultation services with regard to the licensed technology. The patents that are the subject of the Regenerative License Agreement have been assigned to Regenexx, LLC which we have been advised by Regenerative is an affiliate of Regenerative.

Animal Study

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

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

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

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

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

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

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

Clinical Trial

We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We have received such authorization from the FDA. We intend to commence such clinical trial during 2022 (assuming the receipt of necessary funding).

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

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

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

The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee that the clinical trial(s) will be commenced or completed or that the product will ultimately receive approval or clearance.

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

Defined Health Report

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

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

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

Similar Therapies

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


Journal of Translational Medicine

RESEARCH Open Access

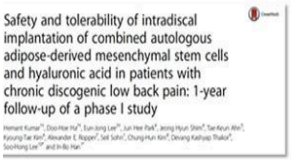
Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy

- **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.


Original Clinical Science—General

Intervertebral Disc Repair by Allogeneic Mesenchymal Bone Marrow Cells: A Randomized Controlled Trial

- **Description**: 24 patients with chronic back pain were randomized into either treatment group or control group. Treatment group received 25x10^6 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 25x10^6 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.


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

- **Description**: 10 patients with chronic back pain received a single injection of 20x10^6 and 40x10^6 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.

Impact on Public Health

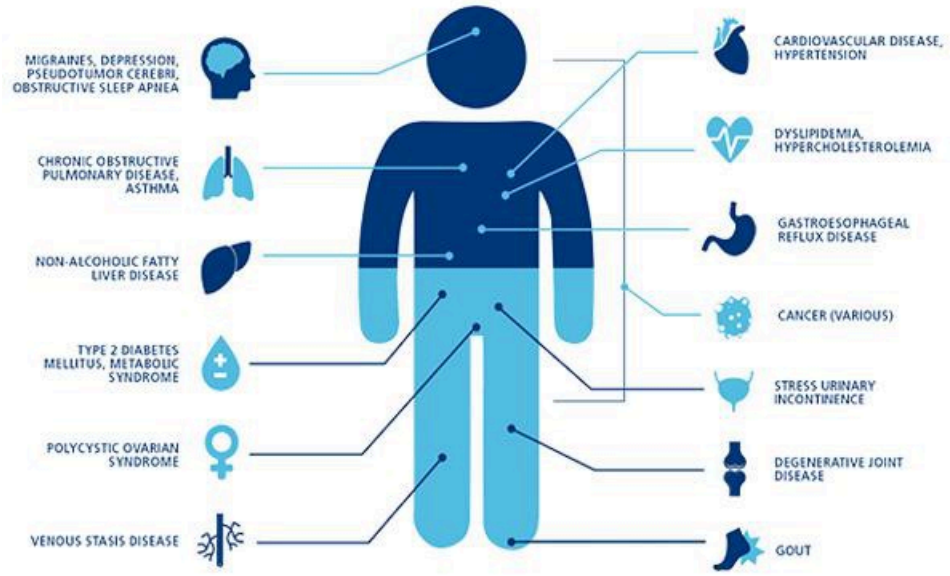
The United States is the world's leading consumer of hydrocodone (99%) and oxycodone (83%) and leads the world in per capital consumption of such drugs (twice as much as second ranked Canada). Each year 42,000 Americans die from overdoses and in 2012 there were enough pain prescriptions in the United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

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

Metabolic Brown Adipose (Fat) Program

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

Brown fat is a specialized adipose (fat) tissue found in the human body that plays a key role in the evolutionarily conserved mechanisms underlying thermogenesis (generation of non-shivering body heat) and energy homeostasis in mammals - long known to be present at high levels in hibernating mammals and human newborns. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of healthy metabolism, thus potentially being involved in caloric regulation. The pre-clinical *ThermoStem Program* involves the use of a cell-based (brown adipose tissue construct) treatment for metabolic disease, such as type 2 diabetes, obesity, hypertension and other metabolic disorders, as well as cardiac deficiencies. The diseases, disorders and syndromes that may be targeted by our *ThermoStem* Program are as follows:



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

Obesity, the abnormal accumulation of white fat tissue, leads to a number of metabolic disorders and is the driving force behind the rise of type 2 diabetes and cardiovascular diseases worldwide. Pharmacological efforts to alter metabolic homeostasis through modulating central control of appetite and satiety have had limited market penetration due to significant psychological and physiological safety concerns directly attributed to modulating these brain centers. Adipose tissue is one of the largest organs in the human body and plays a key role in central energy balance and lipid homeostasis. White and brown adipose tissues are found in mammals. White adipose tissue's function is to store energy, whereas BAT specializes in energy expenditure. As discussed in a 2020 article published in the *International Journal of Molecular Sciences*, recent advancements in unraveling the mechanisms that control the induction, differentiation, proliferation, and thermogenic activity of BAT, along with the application of imaging technologies for human BAT visualization, have generated optimism that these advances may provide novel strategies for targeting BAT activation/thermogenesis, leading to efficacious and safe obesity targeted therapies.

We are developing a cell-based product candidate to target obesity and metabolic disorders using BADSCs. Our goal is to develop a bioengineered implantable brown adipose tissue construct intended to mimic ones naturally occurring in the human body. We have isolated and characterized a human multipotent stem cell population that resides within BAT depots. We have expanded these stem cells to clinically relevant numbers and successfully differentiated them into functional brown adipocytes. We intend to use adult stem cells that may be differentiated into progenitor or fully differentiated brown adipocytes, or a related cell type, which can be used therapeutically in patients. We are focusing on the development of treatment protocols that utilize allogeneic cells (i.e., stem cells from a genetically similar but not identical donor).

In order to deliver these differentiated cells into target locations *in vivo*, we seeded BADSCs onto 3-dimensional biological scaffolds. Pre-clinical animal models of diet-induced obesity, that were transplanted with differentiated BADSCs supported by a biological scaffold, presented significant reductions in weight and blood glucose levels compared to scaffold only controls. We are identifying technology for *in vivo* delivery in small animal models. Having completed our proof of concept using our BAT in small animals, we are currently developing our next generation BAT. It is anticipated that this next version will contain a higher purity of BADSC and a greater percent of functional brown adipocytes, which is expected to increase the therapeutic effect compared to our first generation product. In addition, we are exploring the delivery of the therapeutic using encapsulation technology, which will only allow for reciprocal exchange of small molecules between the host circulation and the BAT implant. We expect that encapsulation may present several advantages over our current biological scaffolds, including prevention of any immune response or implant rejection that might occur in an immunocompetent host and an increase in safety by preventing the implanted cells from invading the host tissues. We have developed promising data on the loading of human stem cell-derived tissue engineered brown fat into an encapsulation device to be used as a cell delivery system for our metabolic platform program for the treatment of type 2 diabetes, obesity, hyperlipidemia and hypertension. This advancement may lead to successful transplantation of brown fat in humans. We are evaluating the next generation of BAT constructs that will first be tested in small animal models. No assurance can be given that this delivery system will be effective *in vivo* in animals or humans. Our allogeneic brown adipose derived stem cell platform potentially provides a therapeutic and commercial model for the cell-based treatment of obesity and related metabolic disorders.

In June 2012, we entered into an Assignment Agreement with the University of Utah Research Foundation, or the Foundation, and a Research Agreement with the University of Utah, or the Utah Research Agreement. Pursuant to the Assignment Agreement, which provides for royalty payments, we acquired the rights to two provisional patent applications that relate to human brown fat cell lines. No royalty amounts are payable to date. The applications have been converted to a utility application in the United States and several foreign jurisdictions. Pursuant to the Utah Research Agreement, the University of Utah provided research services relating to the identification of brown fat tissue and the development and characterization of brown fat cell lines. The Utah Research Agreement provides that all inventions, discoveries, patent rights, information, data, methods and techniques, including all cell lines, cell culture media and derivatives thereof, are owned by us. In February 2019, we entered into a Services Agreement with the University of Utah pursuant to which the university has been retained to provide research services with regard to the *ThermoStem Program*. Pursuant to this agreement, we will initiate preclinical models to study the efficacy of our generation 2 encapsulated brown adipose tissue construct.

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

In March 2014, we entered into a Research Agreement with Pfizer Inc., a global pharmaceutical company. Pursuant to the Research Agreement with Pfizer, we were engaged to provide research and development services with regard to a joint study of the development and validation of a human brown adipose cell model. The Research Agreement with Pfizer provided for an initial payment to us of $250,000 and the payment of up to an additional $525,000 during the two-year term of the Agreement, all of which has been received. The Research Agreement expired upon completion of the services provided for therein.

In August 2015, we entered into a one year research collaboration agreement with the University of Pennsylvania with regard to the understanding of brown adipose biology and its role in metabolic disorders. In September 2018, we entered into a one year material transfer agreement with the University of Pennsylvania pursuant to which the university was provided access to our proprietary brown adipose tissue cells for research purposes. No amounts were payable by or to us pursuant to either agreement.

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

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

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

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

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

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

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

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

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

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

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

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

In May 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.

We have completed proof of concept preclinical animal studies using our first generation brown adipose derived stem cells. We intend to undertake additional preclinical animal studies in order to optimize delivery and explore the feasibility of targeting additional indications. Such studies are planned to begin by the third quarter of 2021 (assuming the receipt of necessary financing). Following the completion of such studies, if successful, we intend to file an IND with the FDA and initiate a clinical trial. The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance.

We anticipate that much of our development work in this area will take place at our laboratory facility, outside core facilities at academic, research or medical institutions, or contractors. See "Laboratory" below.

Curved Needle Device

Pursuant to the Regenerative License Agreement discussed under "Disc/Spine Program-License" above, we have licensed and further developed an investigational curved needle device, or CND, that is a needle system with a curved inner cannula to allow access to difficult-to-locate regions for the delivery or removal of fluids and other substances. The investigational CND is intended to deliver stem cells and/or other therapeutic products or material to the interior of a human intervertebral disc, the spine region, or potentially other areas of the body. The device is designed to rely on the use of pre-curved nested cannulae that allow the cells or material to be deposited in the posterior and lateral aspects of the disc to which direct access is not possible due to outlying structures such as vertebra, spinal cord and spinal nerves. We anticipate that the use of the investigational CND will facilitate the delivery of substances, including living cells, to specific locations within the body and minimize the potential for damage to nearby structures. The investigational device may also have more general use applications. In August 2015, a United States patent for the CND was issued to the licensor, Regenerative. We anticipate that FDA approval or clearance will be necessary for the investigational CND prior to commercialization. We do not intend to utilize the CND in connection with our contemplated Phase 2 clinical trial with regard to *BRTX-100*. The FDA review and approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance.

Laboratory

We have established a laboratory in Melville, New York for research purposes and have built a cleanroom within the laboratory for the possible production of cell-based product candidates, such as *BRTX-100*, for use in a clinical trial, for third party cell products or general research purposes.

As operations grow, our plans include the expansion of our laboratory to perform cellular characterization and culturing, protocol and stem cell-related IP development, translational research and therapeutic outcome analysis. As we develop our business and our stem cell product candidates and obtain regulatory approval, we will seek to establish ourselves as a key provider of adult stem cells for therapies and expand to provide cells in other market areas for stem cell therapy. We may also use outside laboratories specializing in cell therapy services and manufacturing of cell products.

Technology; Research and Development

We intend to utilize our laboratory or a third party laboratory in connection with cellular research activities. We also intend to obtain cellular-based therapeutic technology licenses and increase our IP portfolio. We intend to seek to develop potential stem cell delivery systems or devices. The goal of these specialized delivery systems or devices is to deliver cells into specific areas of the body, control the rate, amount and types of cells used in a treatment, and populate these areas of the body with sufficient stem cells so that there is a successful therapeutic result.

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

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

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

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

Program	Patent Family	I.D.	Jurisdiction	Title
Disc/Spine (brtxDisc)	1	16/441,897*	US	Methods and compositions to facilitate repair of avascular tissue
	1	U.S. Patent No. 9,113,950 B2**	US	Therapeutic delivery device
Metabolic (ThermoStem)	2	U.S. Patent No. 9,133,438	US	Brown fat cell compositions and methods
	2	U.S. Patent No. 10,597,638	US	
	2	U.S. Patent No. 11,066,646	US	
	2	17/348,218	US	
	2	AU Patent No. 2012275335	Australia	
	2	EP Patent No. 2726603 (validated in Belgium, France, Germany, Italy, Poland, Spain, Sweden, Switzerland, and the United Kingdom)	Europe	
	2	IL Patent No. 230237	Israel	
	2	JP Patent No. 6243839	Japan	
	3	U.S. Patent No. 10,167,449	US	Human brown adipose derived stem cells and uses
	3	U.S. Patent No. 10,941,383	US	
	3	17/165,074	US	
	3	AU Patent No. 2014253920	Australia	
	3	2019240634	Australia	
	3	EP Patent No. 2986714 (validated in France, Germany, Italy, Spain, and the United Kingdom)	Europe	
	3	20204990.4	Europe	
	3	IL Patent No. 242150	Israel	
	3	274995	Israel	
	3	JP Patent No. 6887249	Japan	
	3	2019-95972	Japan	
	4	16/862,226	US	Non-naturally occurring three-dimensional (3D) brown adipose-derived stem cell aggregates, and methods of generating and using the same
	4	PCT/US2020/030520	PCT	

*Patent application filed by licensor assignee, Regenexx, LLC
**Patent issued to licensor assignee, Regenexx, LLC

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

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

- biorestorative therapies
- BRTX-100
- THERMOSTEM
- STEM PEARLS

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

We also have federal common law rights in the trademark *BioRestorative Therapies* and other trademarks and trade names used in the conduct of our business that are not registered.

Our success will depend in large part on our ability to develop and protect our proprietary technology. We intend to rely on a combination of patent, trade secret and know-how, copyright and trademark laws, as well as confidentiality agreements, licensing agreements, non-compete agreements and other agreements, to establish and protect our proprietary rights. Our success will also depend upon our ability to avoid infringing upon the proprietary rights of others, for if we are judicially determined to have infringed such rights, we may be required to pay damages, alter our services, products or processes, obtain licenses or cease certain activities.

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

Scientific Advisors

We have established a Scientific Advisory Board whose purpose is to provide advice and guidance in connection with scientific matters relating to our business. The Scientific Advisory Board has established a Disc Advisory Committee which focuses on matters relating to our *Disc/Spine Program*. Our Scientific Advisory Board members are Dr. Wayne Marasco (Chairman), Dr. Naiyer Imam, Dr. Wayne Olan, Dr. Joy Cavagnaro, Dr. Jason Lipetz, Dr. Harvinder Sandhu, Dr. Christopher Plastaras and Dr. Gerard A. Malanga. The Disc Advisory Committee members are Dr. Lipetz (Chairman), Dr. Olan, Dr. Sandhu, Dr. Plastaras and Dr. Malanga. See “Management” for a listing of the principal positions for Drs. Marasco, Imam, Olan, Cavagnaro, Lipetz, Sandhu, Plastaras and Malanga.

Competition

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

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

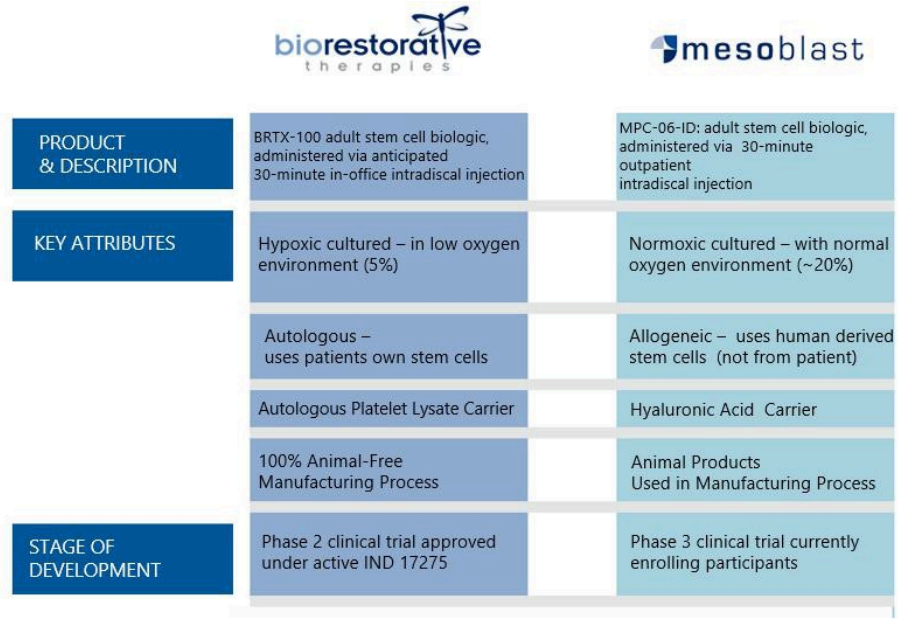
Companies working in the area of regenerative medicine with regard to the disc and spine include, among others, Mesoblast, SpinalCyte, DiscGenics and Isto Biologics. Companies that are developing products and therapies to combat obesity and diabetes, including through the use of brown fat, include, among others, Novo Nordisk, Sanofi, Merck, Eli Lilly, Roche, Pfizer and Regeneron.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. We cannot, with any accuracy, forecast when or if these companies are likely to bring their products and therapies to market in competition with those that we are pursuing.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. For the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and the proposed biosimilar product. Interchangeability requires that a product is biosimilar to the reference product, and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years following approval of the reference product, and it may not be approved by the FDA until 12 years after the original branded product is approved under a biologics license application, or BLA.

We believe that, if any of our product candidates are approved as a biological product under a BLA, it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA could permit biosimilar applicants to reference approved biologics other than our therapeutic candidates, thus circumventing our exclusivity and potentially creating the opportunity for competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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



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

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

Customers

Upon regulatory approval, our cell product candidates are intended to be marketed to physicians, other health care professionals, hospitals, research institutions, pharmaceutical companies and the military. It is anticipated that physicians who are trained and skilled in performing spinal injections will be the physicians most likely to treat discs with injections of *BRTX-100* upon regulatory approval. These physicians would include interventional physiatrists (physical medicine physicians), pain management anesthesiologists, interventional radiologists and neurosurgeons.

Governmental Regulation

U.S. Government Regulation

The health care industry is highly regulated in the United States. The federal government, through various departments and agencies, state and local governments, and private third-party accreditation organizations, regulate and monitor the health care industry, associated products, and operations. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, approval, manufacture, distribution and marketing of medical products, including drugs, biologics, and medical devices. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, post-approval monitoring, advertising, promotion, sampling and import and export of medical products. The following is a general overview of the laws and regulations pertaining to our business.

FDA Regulation of Stem Cell Treatment and Products

The FDA regulates the manufacture of human stem cell treatments and associated products under the authority of the Public Health Service Act, or 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, FDA stated it will exercise enforcement discretion until May 31, 2021 for products that do not comply with the HCT/P Regulations. As of that date, manufacturers of products marketed as HCT/Ps that do not comply with the HCT/P Regulations are subject to immediate FDA enforcement action. If we are not regulated solely under the HCT/P Regulations, we would need to expend significant resources to comply with the FDA's broad regulatory authority under the FDCA. Third party litigation concerning the autologous use of a stem cell mixture to treat musculoskeletal and spinal injuries has increased the likelihood that some of our products and services are likely to be regulated as a drug or biological product and require FDA approval. In past litigation, the FDA asserted that the defendants' use of cultured stem cells without FDA approval is in violation of the FDCA, claiming that the defendants' product is a drug. The defendants asserted that their procedure is part of the practice of medicine and therefore beyond the FDA's regulatory authority. The District Court ruled in favor of the FDA, and in February 2014 the Circuit Court affirmed the District Court's holding.

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

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

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

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

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

Drug and Biological Product Regulation

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

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

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practice, 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 Good Manufacturing Practice, or cGMP, requirements and of selected clinical trial sites to assess compliance with GCP requirements; and
- FDA approval of an NDA or BLA which must occur before a drug or biologic can be marketed or sold.

Approval of an NDA requires a showing that the drug is safe and effective for its intended use and that the methods, facilities, and controls used for the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity. To obtain a BLA, a manufacturer must show that the proposed product is safe, pure, and potent and that the facility in which the product is manufactured, processed, packed, or held meets established quality control standards.

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

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

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

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

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

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

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

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

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

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

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

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

FDA Expedited Review Programs

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

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

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

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

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

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

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

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

Medical Device Regulation

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

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

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

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

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

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

Products that fall outside of the HCT/P regulations and are regulated as drugs, biological products, or devices must comply with applicable cGMP regulations. These cGMPs and related quality standards are designed to ensure the products that are processed at a facility meet the FDA's applicable requirements for identity, strength, quality, sterility, purity, and safety. In the event that our domestic United States operations are subject to the FDA's drug, biological product, or device regulations, we intend to comply with the applicable cGMPs and quality regulations.

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

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

We may establish, or license technology to third parties in connection with their establishment of, adult stem cell therapy facilities outside the United States. We also intend to work with hospitals and physicians to make the stem cell-based therapies available for patients who travel outside the United States for treatment. "Medical tourism" is defined as the practice of traveling across international borders to obtain health care.

The Federal Trade Commission, or the FTC, has the authority to regulate and police advertising of medical treatments, procedures, and regimens in the United States under the Federal Trade Commission Act, or the FTCA. The FTC has regulatory authority to prevent unfair and deceptive practices and false advertising. Specifically, the FTC requires advertisers and promoters to have a reasonable basis to substantiate and support claims. The FTC has many enforcement powers, one of which is the power to order disgorgement by promoters deemed in violation of the FTCA of any profits made from the promoted business and can order injunctions from further violative promotion. Advertising that we may utilize in connection with our medical tourism operations will be subject to FTC regulatory authority, and we intend to comply with such regulatory régime. Similar laws and requirements are likely to exist in other countries and we intend to comply with such requirements.

Federal Regulation of Clinical Laboratories

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

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability, and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. Laboratories that handle stem cells and other biologic matter are, therefore, included under the CLIA program. Under the CLIA program, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections, and pay fees. To the extent that our business activities require CLIA certification, we intend to obtain and maintain such certification. If we are subject to CLIA, the failure to comply with CLIA standards could result in suspension, revocation, or limitation of a laboratory's CLIA certificate. In addition, fines or criminal penalties could also be levied. If any of these events were to occur, it could impact our business operations.

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, including the Final Omnibus Rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information on certain types of individuals and organizations. In addition, certain state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other and from HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts. Further, we may need to also comply with additional federal or state privacy laws and regulations that may apply to certain diagnoses, such as HIV/AIDS, to the extent that they apply to us.

The Department of Health and Human Services, or HHS, through its Office for Civil Rights, investigates breach reports and determines whether administrative or technical modifications are required and whether civil or criminal sanctions should be imposed. Companies failing to comply with HIPAA and the implementing regulations may also be subject to civil money penalties or in the case of knowing violations, potential criminal penalties, including monetary fines, imprisonment, or both. In some cases, the State Attorneys General may seek enforcement and appropriate sanctions in federal court.

Other Applicable U.S. Laws

In addition to the above-described regulation by United States federal and state government, the following are other federal and state laws and regulations that could directly or indirectly affect our ability to operate the business:

- state and local licensure, registration, and regulation of the development of pharmaceuticals and biologics;
- state and local licensure of medical professionals;
- state statutes and regulations related to the corporate practice of medicine;
- laws and regulations administered by U.S. Customs and Border Protection related to the importation of biological material into the United States;
- other laws and regulations administered by the FDA;
- other laws and regulations administered by HHS;
- state and local laws and regulations governing human subject research and clinical trials;
- the federal physician self-referral prohibition, also known as Stark Law, and any state equivalents to Stark Law;
- the federal False Claims Act, or FCA;
- the federal Anti-Kickback Statute, or AKS, and any state equivalent statutes and regulations;
- federal and state coverage and reimbursement laws and regulations;
- state and local laws and regulations for the disposal and handling of medical waste and biohazardous material;
- Occupational Safety and Health Administration, or OSHA, regulations and requirements;
- the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to "excess benefit transactions" with tax-exempt organizations;
- the Physician Payments Sunshine Act (in the event that our products are classified as drugs, biologics, devices or medical supplies and are reimbursed by Medicare, Medicaid or the Children's Health Insurance Program);
- state and other federal laws addressing the privacy of health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare professionals and other potential referral sources, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

Foreign Government Regulation

In general, we will need to comply with the government regulations of each individual country in which our therapy centers are located and products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. Due to the fact that there are new and emerging cell therapy regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not always precisely understood for each country, creating greater uncertainty for the international regulatory process. Furthermore, government regulations can change with little to no notice and may result in up-regulation of our product(s), thereby creating a greater regulatory burden for our cell processing technology products. We have not yet thoroughly explored the applicable laws and regulations that we will need to comply with in foreign jurisdictions. It is possible that we may not be permitted to expand our business into one or more foreign jurisdictions.

We do not have any definitive plans or arrangements with respect to the establishment by us of stem cell therapy clinics in any country. We intend to explore any such opportunities as they arise.

Offices

Our principal executive offices are located at 40 Marcus Drive, Suite One, Melville, New York, and our telephone number is (631) 760-8100. Our website is www.biorestorative.com. Our internet website and the information contained therein or connected thereto are not intended to be incorporated by reference into this prospectus.

Employees

We currently have five employees, all of whom are full-time employees. We believe that our employee relations are good.

MANAGEMENT

Directors and Executive Officers

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

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

Lance Alstodt

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

Francisco Silva

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

Nickolay Kukekov, Ph.D.

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

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

Family Relationships

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

Term of Office

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

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

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

EXECUTIVE COMPENSATION

Summary Compensation Table

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

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

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

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

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

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

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

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

Outstanding Equity Awards at Fiscal Year-End

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

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

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

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

Employment Agreements

Lance Alstodt

2018 Employment Agreement

Effective October 15, 2018, we entered into an at will employment agreement with Lance Alstodt, our then Executive Vice President and Chief Strategy Officer. Pursuant to the employment agreement, Mr. Alstodt was entitled to receive a base annual salary of $350,000. Effective January 1, 2020, his salary was $46,800 per annum (in connection with a salary reduction program for senior management). In addition, pursuant to the employment agreement, Mr. Alstodt was entitled to receive an annual bonus of up to 30% of his annual salary based on the satisfaction of certain performance goals, as determined by our Compensation Committee. Such goals were not satisfied for 2019 (the first year of bonus eligibility). The employment agreement also provided for the payment of six months severance under certain circumstances. Mr. Alstodt's employment with us as Executive Vice President and Chief Strategy Officer ended effective February 24, 2020. Based upon such termination of employment, Mr. Alstodt was entitled to receive six months severance based upon his salary of $350,000 per annum. Such amount was considered an unsecured claim in our Chapter 11 case and Mr. Alstodt received shares of our common stock in exchange for such claim in a manner consistent with other unsecured creditors.

2021 Employment Agreement

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

Francisco Silva

2011 Employment Agreement

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

2021 Employment Agreement

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

Mark Weinreb

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

Director Compensation

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

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

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

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

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

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

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

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

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

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

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

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

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

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The following is a description of each transaction since January 1, 2019 in which we have been a participant in which the amount involved exceeded or will exceed $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our then directors, executive officers or holders of more than 5% of our capital stock, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described under "Executive Compensation."

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

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

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

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

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

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

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

Director Independence

Board of Directors

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

Audit Committee

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

Nominating Committee

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

Compensation Committee

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

PRINCIPAL STOCKHOLDERS

Principal Stockholders

The following table sets forth certain information regarding the beneficial ownership of our common stock, as of July 31, 2021, known by us, through transfer agent records and reports filed with the SEC, to be held by: (i) each person who beneficially owns 5% or more of the shares of common stock then outstanding; (ii) each of our directors; (iii) each of our Named Executive Officers (as defined above); and (iv) all of our directors and executive officers as a group.

The information in this table reflects "beneficial ownership" as defined in Rule 13d-3 of the Exchange Act. To our knowledge, and unless otherwise indicated, each stockholder has sole voting power and investment power over the shares listed as beneficially owned by such stockholder, subject to community property laws where applicable. Percentage ownership is based on 3,350,844,445 shares of common stock outstanding as of July 31, 2021.

Beneficial Owner	Number of Shares Beneficially Owned	Approximate Percent of Class
Lance Alstodt	605,670,653(1)	15.4%
Francisco Silva	595,703,049(2)	15.1%
Nickolay Kukekov	0	-
Mark Weinreb	1,395,500(3)	*
All directors and executive officers as a group (3 persons)	1,201,373,702(1)(2)	26.5%

* Less than 1%

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

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

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

Securities Authorized for Issuance Under Equity Compensation Plans

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

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

Equity Compensation Plan Information

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

DESCRIPTION OF SECURITIES

The following descriptions do not purport to be complete and are subject to, and qualified in their entirety by reference to, the more complete descriptions thereof set forth in our certificate of incorporation, which we refer to as our charter, and our bylaws, each as amended to date.

Authorization

Our authorized capital stock consists of 300,020,000,000 shares of capital stock. We are authorized to issue 300,000,000,000 shares of common stock, par value $0.0001 per share, and 20,000,000 shares of preferred stock, par value $0.01 per share. The number of shares of common stock authorized to be issued may be decreased in connection with contemplated reverse split of our outstanding common stock. See “Nevada Reincorporation; Contemplated Reverse Stock Split” below.

As of July 31, 2021, there were 3,350,844,445 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding.

Common Stock

Dividend Rights. Subject to preferences that may be applicable to any shares of our preferred stock that may be issued, the holders of our common stock are entitled to share ratably in such dividends as may be declared by our Board of Directors out of funds legally available therefor.

As a Delaware corporation, we may not declare and pay dividends on our capital stock if the amount paid exceeds an amount equal to the surplus (which represents the excess of our net assets over paid-in capital) or, if there is no surplus, our net earnings for the current and/or immediately preceding fiscal year. Dividends cannot be paid from our net profits unless the paid-in capital represented by the issued and outstanding stock having a preference upon the distribution of our assets at the market value is intact. Under applicable Delaware case law, dividends may not be paid on our capital stock if we become insolvent or the payment of the dividend will render us insolvent. To the extent we pay dividends and we are deemed to be insolvent or inadequately capitalized, a bankruptcy court could direct the return of any dividends.

Voting Rights. Each share of our common stock entitles its holder to one vote in the election of directors as well as all other matters to be voted on by stockholders.

No Preemptive Rights. Holders of our common stock do not have any preemptive rights to subscribe for additional shares on a pro rata basis or otherwise when additional shares are offered for sale by us.

Liquidation Rights. Subject to preferences that may be applicable to any shares of our preferred stock that may be issued, in the event of our liquidation, dissolution or winding up, the holders of our common stock would be entitled to receive, pro rata, after payment of all of our debts and liabilities, all of our remaining assets available for distribution.

Other Rights. Holders of our common stock have no preferences or conversion or exchange rights. Shares of our common stock will not be liable for further calls or assessments by us and are not subject to redemption.

Preferred Stock

The authorized preferred stock is available for issuance from time to time at the discretion of our Board of Directors without stockholder approval. The Board of Directors has the authority to prescribe, for each series of preferred stock it establishes, the number of shares in that series, the number of votes (if any) to which the shares in that series are entitled, the consideration for the shares in that series, and the designations, powers, preferences and other rights, qualifications, limitations or restrictions of the shares in that series. Depending upon the rights prescribed for a series of preferred stock, the issuance of preferred stock could have an adverse effect on the voting power of the holders of common stock and could adversely affect holders of common stock by delaying or preventing a change in control, making removal of our present management more difficult or imposing restrictions upon the payment of dividends and other distributions to the holders of common stock.

2021 Stock Incentive Plan; Options; Restricted Stock Units

Pursuant to the 2021 Plan, as of July 31, 2021, we were authorized to issue up to 4,700,000,000 shares of common stock pursuant to the grant of stock options, restricted stock units and other incentive awards.

As of March 31, 2021, we had outstanding options under the 2021 Plan to purchase an aggregate of 2,347,835,948 shares of common stock at an exercise price of $0.0119 per share, of which options for the purchase of 1,173,917,974 shares were then exercisable.

In addition, as of March 31, 2021, there were 4,859,617 options outstanding under our 2010 Equity Participation Plan at a weighted average exercise of $0.98 per share, of which options for the purchase of 4,718,287 shares were then exercisable.

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

Options Outstanding			Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$ 0.00 - $0.0119	2,347,835,948	10.0	1,173,917,974
$ 0.26 - $0.74	175,000	8.4	175,000
$ 0.75 - $0.99	4,107,117	6.5	3,965,787
$ 1.00 - $5.99	5,000	3.2	5,000
$ 6.00 - $19.99	37,500	2.8	37,500
$ 20.00 - $30.00	35,000	1.0	35,000
	2,352,195,565	9.99	1,178,136,261

As of March 31, 2021, we had outstanding under the 2021 Plan 1,173,917,974 unvested restricted stock units.

Warrants

As of March 31, 2021, we had outstanding warrants to purchase an aggregate of 14,689,060,954 shares of common stock, all of which were then exercisable.

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

Warrants Outstanding			Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$ 0.00 - $0.015	14,682,649,518	4.6	14,682,649,518
$ 0.20 - $1.99	5,106,746	3.3	5,106,746
$ 2.00 - $2.99	75,000	2.6	75,000
$ 3.00 - $3.99	70,000	2.3	70,000
$ 4.00 - $4.99	1,023,023	1.0	1,023,023
$ 5.00 - $5.99	136,667	0.3	136,667
	14,689,060,954	4.6	14,689,060,954

Of the above, warrants for the purchase of an aggregate of 14,682,649,518 shares of common stock (net of warrants exercised subsequent to March 31, 2021) are contemplated to be exchanged for Units, as described in "Prospectus Summary – Chapter 11 Reorganization; Exchange of Outstanding Debt and Warrants."

Convertible Promissory Notes

As of March 31, 2021, we had outstanding convertible promissory notes in the aggregate principal amount of $9,426,039. Of such aggregate principal amount, the payment of convertible notes in the aggregate principal amount of $5,998,139 is secured by the grant of a security interest in all of our assets. We have had discussions with the holders of secured and unsecured debt in the currently outstanding aggregate principal amount of $9,246,897 to exchange such debt for the Units being offered by this prospectus, as discussed in "Prospectus Summary – Chapter 11 Reorganization; Exchange of Outstanding Debt and Warrants". In the event that agreements are not entered into with regard to the exchange of the outstanding convertible promissory notes for Units, pursuant to the provisions of the notes, the amounts payable pursuant to the notes will automatically convert into the Units offered by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering). Other convertible notes in the aggregate principal amount of $800,000 will automatically convert into the Units offered by this prospectus (assuming that our common stock is listed on Nasdaq in connection with this offering).

Description of Securities in this Offering

Units. Each Unit consists of one share of our common stock, par value $0.0001 per share, and one warrant, or Warrant, to purchase share of our common stock.

Public Warrants. This offering of Units includes shares of our common stock and Warrants to purchase additional shares of our common stock. Accordingly, upon completion of this offering we expect to have an additional common stock purchase Warrants outstanding (if the Units issuable upon exercise of the underwriters' over-allotment option are sold). Each Warrant is exercisable for the purchase of share of common stock at an exercise price of $ per share (% of the price of each Unit sold in the offering) and is immediately exercisable for a period of years from the date of issuance.

The material terms and provisions of the warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the warrants is not complete. For the complete terms of the warrants, you should refer to the form of warrant to be filed as an exhibit to the registration statement of which this prospectus forms a part. The warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

The number of Warrants outstanding, and the exercise price of the Warrants, will be adjusted proportionately in the event of a reverse or forward stock split of our common stock, a recapitalization or reclassification of our common stock, payment of dividends or distributions in common stock to our common stock holders, or similar transactions. In the event that we effect a rights offering to our common stock holders or a pro rata distribution of our assets among our common stock holders, then the holders of the Warrants will have the right to participate in such distribution and rights offering to the extent of their pro rata share of our outstanding common stock as if they owned the number of shares of common stock issuable upon the exercise of their Warrants. In the event of a "Fundamental Transaction" by us, such as a merger or consolidation of us with another company, the sale or other disposition of all or substantially all of our assets in one or a series of related transactions, a purchase offer, tender offer or exchange offer, or any reclassification, reorganization or recapitalization of our common stock, then each Warrant holder will have the right to receive, for each share of common stock issuable upon the exercise of the Warrant, at the option of the holder, the number of shares of common stock of the successor or acquiring corporation or of us (if we are the surviving corporation), and any additional consideration payable as a result of the Fundamental Transaction, that would have been issued or conveyed to the Warrant holder had the holder exercised the Warrant immediately preceding the closing of the Fundamental Transaction. In lieu of receiving such common stock and additional consideration in the Fundamental Transaction, the Warrant holder may elect to have us or the successor entity purchase the Warrant holder's Warrant for its fair market value measured by the Black Scholes method.

We will promptly notify the Warrant holders in writing of any adjustment to the exercise price or to the number of the outstanding Warrants, declaration of a dividend or other distribution, a special non-recurring cash dividend on or a redemption of the common stock, the authorization of a rights offering, the approval of the stockholders required for any proposed reclassification of the common stock, a consolidation or merger by us, the sale of all or substantially all of our assets, any compulsory share exchange, or the authorization of any voluntary or involuntary dissolution, liquidation, or winding up of our company.

The Warrants contain a contractual provision stating that all questions concerning the construction, validity, enforcement and interpretation of the Warrants are governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law.

Representative Warrants. We also expect to have up to an additional common stock purchase warrants outstanding (if the Units issuable upon exercise of the underwriters' over-allotment option are sold), issuable to the representative of the underwriters of this offering, or Representative Warrants. Each Representative Warrant is exercisable for one share of common stock on a cash or cashless basis at an exercise price equal to 120% of the price of each Unit sold in this offering). The Representative Warrants will not be exercisable for six months after the closing of this offering, will expire five years from the commencement of sales of this offering and will be issued in certificated form. Pursuant to FINRA Rule 5110(e), the Representative Warrants and any shares of common stock issued upon exercise of the Representative Warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of reorganization of the issuer; (ii) to any FINRA member firm participating in the offering and the officers, partners, registered persons or affiliates thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the Representative or related persons does not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period; (vi) if we meet the registration requirements of Forms S-3, F-3 or F-10; or (vii) back to us in a transaction exempt from registration with the SEC. The Representative Warrants and the shares of common stock underlying the Representative Warrants are registered on the registration statement of which this prospectus forms a part.

The number of Representative Warrants outstanding and the exercise price of the Representative Warrants will be adjusted proportionately, as permitted by Financial Industry Regulatory Authority, or FINRA, in the event of a reverse or forward stock split of our common stock, a recapitalization or reclassification of our common stock, payment of dividends or distributions in common stock to our common stock holders, or similar transactions. In the event that we effect a rights offering to our common stock holders or a pro rata distribution of our assets among our common stock holders, then the holder of the Representative Warrants will have the right to participate in such distribution and rights offering to the extent of their pro rata share of our outstanding common stock as if they owned the number of shares of common stock issuable upon the exercise of their Representative Warrants. In the event of a "Fundamental Transaction" by us, such as a merger or consolidation of us with another company, the sale or other disposition of all or substantially all of our assets in one or a series of related transactions, a purchase offer, tender offer or exchange offer, or any reclassification, reorganization or recapitalization of our common stock, then the Representative Warrant holder will have the right to receive, for each share of common stock issuable upon the exercise of the Representative Warrant, at the option of the holder, the number of shares of common stock of the successor or acquiring corporation or of us (if we are the surviving corporation), and any additional consideration payable as a result of the Fundamental Transaction that would have been issued or conveyed to the Representative Warrant holder had the holder exercised the Representative Warrant immediately preceding the closing of the Fundamental Transaction. In lieu of receiving such common stock and additional consideration in the Fundamental Transaction, the Representative Warrant holder may elect to have us or the successor entity purchase the Representative Warrant for its fair market value measured by the Black Scholes method.

We will promptly notify the holders of the Representative Warrants in writing of any adjustment to the exercise price or to the number of the outstanding Representative Warrants, declaration of a dividend or other distribution, a special non-recurring cash dividend on or redemption of the common stock, the authorization of a rights offering, the approval of the stockholders required for any proposed reclassification of the common stock, a consolidation or merger by us, the sale of all or substantially all of our assets, any compulsory share exchange, or the authorization of any voluntary or involuntary dissolution, liquidation, or winding up of our company.

Certain Provisions Having Potential Anti-Takeover Effects

General. The following is a summary of the material provisions of the General Corporation Law of the State of Delaware, which we refer to as the DGCL, and our charter and bylaws that address matters of corporate governance and the rights of stockholders. Certain of these provisions may delay or prevent takeover attempts not first approved by our Board of Directors (including takeovers which certain stockholders may deem to be in their best interests). These provisions also could delay or frustrate the removal of incumbent directors or the assumption of control by stockholders. The primary purpose of these provisions is to encourage negotiations with our management by persons interested in acquiring control of our company. All references to the charter and bylaws are to our charter and bylaws in effect on the date of this prospectus.

Authorized But Unissued Shares. Delaware law does not require stockholder approval for any issuance of authorized shares. Authorized but unissued shares may be used for a variety of corporate purposes, including future public or private offerings to raise additional capital or to facilitate corporate acquisitions. One of the effects of the existence of authorized but unissued shares may be to enable our Board of Directors to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management and possibly deprive the stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices.

Preferred Stock. Under the terms of our charter, our Board of Directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our Board of Directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. The purpose of authorizing our Board of Directors to issue preferred stock and determine its rights and preferences is to provide flexibility and eliminate delays associated with a stockholder vote on specific issues. However, the ability of our Board of Directors to issue preferred stock and determine its rights and preferences may have the effect of delaying or preventing a change in control, as described above under "Description of Securities — Preferred Stock."

Classified Board. As discussed above under "Management – Term of Office," we have a classified Board of Directors consisting of three classes of directors. A classified board is one in which a certain number, but not all, of the directors are elected on a rotating basis each year. This method of electing directors makes changes in the composition of our Board more difficult, and thus a potential change in control may be a lengthier process. The existence of our classified Board reduces the possibility that a third party could effect an unsolicited change in control of our Board. Since our classified Board will increase the amount of time required for a takeover bidder to obtain control of us without the cooperation of the Board, even if the takeover bidder were to acquire a majority of our outstanding common stock, the existence of our classified Board could tend to discourage certain tender offers which stockholders might feel would be in their best interests. Our classified Board will likely allow management, if confronted by a proposal from a third party who has acquired a block of our common stock, sufficient time to review the proposal and appropriate alternatives to the proposal and to attempt to negotiate a better transaction, if possible, for our stockholders.

Special Meetings of Stockholders. Our bylaws provide that special meetings of stockholders may be called only by our Board of Directors or the Chairman of the Board.

Stockholder Action by Written Consent. Under the terms of our charter, stockholders are not permitted to act by written consent unless otherwise approved by the Board of Directors.

Filling Vacancies. Vacancies occurring in our Board of Directors and newly created directorships resulting from an increase in the authorized number of directors may be filled by a majority of the remaining directors, even if less than a quorum.

Removal of Directors by Stockholders. Under the terms of our charter, stockholders may only remove directors for cause with the affirmative vote of holders of 75% of the voting power of all of the then-outstanding shares of our capital stock then entitled to vote at an election of directors, voting together as a single class.

Amendment of Bylaws. Our bylaws may be amended by our Board of Directors or by the holders of at least 75% of the voting power of our company.

Amendment of Certain Charter Provisions. Under the terms of our charter, amending certain charter provisions requires the affirmative vote of the holders of at least 75% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote thereon, voting together as a single class. The provisions subject to such heightened requirement include those relating to stockholder action by written consent, the calling of special meetings, board classification, the filling of board vacancies, the removal of directors and the ability to amend our bylaws, among others.

Advance Notification of Stockholder Nominations and Proposals. Our bylaws establish advance notice procedures with respect to the nomination of persons for election as directors, other than nominations made by or at the direction of our Board of Directors, and stockholder proposals for business.

Stockholder Nominees.

In order for a stockholder to nominate a candidate for director at an annual meeting of stockholders, under our bylaws, timely notice of the nomination must be received by us in advance of the meeting. To be timely, a stockholder's notice must be delivered to or mailed and received by our Secretary at our principal executive offices not less than 45 days nor more than 75 days prior to the one-year anniversary of the date on which we first mailed the proxy materials for the preceding year's annual meeting of stockholders; provided, however, that if the meeting is convened more than 30 days prior to or delayed more than 30 days after the anniversary of the preceding year's annual meeting or if no annual meeting was held in the preceding year, to be timely a stockholder's notice must be so received not later than the close of business on the later of (i) the 90^{th} day before such annual meeting or (ii) the 10^{th} day following the day on which public announcement of the date of such meeting is first made.

The stockholder sending the notice of nomination must describe various matters, including the following:

- as to each person whom the stockholder proposes to nominate for election as a director, all information relating to such person as would be required to be disclosed in solicitations of proxies for election of such nominee as a director pursuant to Regulation 14A under the Exchange Act;

- with respect to the stockholder proposing such nomination or the beneficial owner, if any, on whose behalf the nomination is made: (i) the name and address of each such party; (ii) the class and number of shares that are beneficially owned by each such party; (iii) any derivative instruments that are beneficially owned by each such party and any other opportunity to profit or share in any profit derived from any increase or decrease in the value of our capital stock; (iv) any proxy or arrangement pursuant to which either party has a right to vote any shares; (v) any short interest in any of our securities; (vi) any rights to dividends that are separated from our underlying shares; (vii) any proportionate interest in our capital stock or any derivative instruments held by a general or limited partnership in which either party is a general partner or beneficially owns a general partner; (viii) any performance-related fees (other than an asset-based fee) that each such party is entitled to based on any increase or decrease in the value of our capital stock or any derivative instruments; (ix) any other information relating to each such party that would be required to be disclosed in a proxy statement; and (x) a statement as to whether or not each such party will deliver a proxy statement and form of proxy to holders of at least that percentage of voting power of all of the shares of our capital stock reasonably believed to be sufficient to elect the nominee or nominees proposed to be nominated; and

- the written consent by the nominee, agreeing to serve as a director if elected.

Stockholder Proposals.

In order for a stockholder to make a proposal at an annual meeting of stockholders, under our bylaws, timely notice must be received by us in advance of the meeting. To be timely, a stockholder's notice must be delivered to or mailed and received by our Secretary at our principal executive offices not less than 45 days nor more than 75 days prior to the one-year anniversary of the date on which we first mailed the proxy materials for the preceding year's annual meeting of stockholders; provided, however, that if the meeting is convened more than 30 days prior to or delayed more than 30 days after the anniversary of the preceding year's annual meeting or if no annual meeting was held in the preceding year, to be timely a stockholder's notice must be received not later than the close of business on the later of (i) the 90^{th} day before such annual meeting or (ii) the 10^{th} day following the day on which public announcement of the date of such meeting is first made.

A stockholder's notice must set forth as to each matter the stockholder proposes to bring before the annual meeting certain information regarding the proposal, including the following:

- a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting and any material interest (financial or other) of such stockholder in such business; and

- with respect to the stockholder proposing such business or the beneficial owner, if any, on whose behalf the proposal is made: (i) the name and address of each such party; (ii) the class and number of shares that are beneficially owned by each such party; (iii) any derivative instruments that are beneficially owned by each such party and any other opportunity to profit or share in any profit derived from any increase or decrease in the value of our capital stock; (iv) any proxy or arrangement pursuant to which either party has a right to vote any shares; (v) any short interest in any of our securities; (vi) any rights to dividends that are separated from our underlying shares; (vii) any proportionate interest in our capital stock or any derivative instruments held by a general or limited partnership in which either party is a general partner or beneficially owns a general partner; (viii) any performance-related fees (other than an asset-based fee) that each such party is entitled to based on any increase or decrease in the value of our capital stock or any derivative instruments; (ix) any other information relating to each such party that would be required to be disclosed in a proxy statement; and (x) a statement as to whether or not each such party will deliver a proxy statement and form of proxy to holders of at least that percentage of voting power of all of our shares of capital stock required under applicable law to carry the proposal.

Statutory and other Restrictions on Acquisition of our Capital Stock. We are subject to Section 203 of the DGCL, which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any business combination with an interested stockholder, unless:

- prior to the time of the proposed action, the Board of Directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (i) by persons who are directors and also officers and (ii) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to the time of the proposed action, the business combination is approved by the Board of Directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

These provisions are intended to enhance the likelihood of continuity and stability in the composition of the Board and in policies formulated by the Board and to discourage certain types of transactions that may involve an actual or threatened change of control of our company. These provisions are designed to reduce our vulnerability to an unsolicited proposal for a takeover that does not contemplate the acquisition of all of our outstanding shares or an unsolicited proposal for the restructuring or sale of all or part of our company.

Limitations on Director Liability

Our charter provides that our directors shall generally not be liable to us or any of our stockholders for monetary damages for breach of duty as a director. This provision will eliminate such liability except for (i) any breach of the director's duty of loyalty to us or to our stockholders, (ii) acts and omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) liability for unlawful payment of dividends or unlawful stock purchases or redemptions in violation of the DGCL, and (iv) any transaction from which the director derived an improper personal benefit.

Indemnification of Directors and Officers

Section 145 of the DGCL empowers a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or other enterprise. A corporation may indemnify such person against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. A corporation may, in advance of the final disposition of any civil, criminal, administrative or investigative action, suit or proceeding, pay the expenses (including attorneys' fees) incurred by any officer or director in defending such action, provided that the officer or director undertakes to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by the corporation.

A Delaware corporation may indemnify officers and directors in an action by or in the right of the corporation to procure a judgment in its favor under the same conditions, except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses (including attorneys' fees) which he or she actually and reasonably incurred in connection therewith. The indemnification provided by the DGCL is not deemed to be exclusive of any other rights to which those seeking indemnification may be entitled under any corporation's bylaws, agreement, vote or otherwise.

Our bylaws provide that we will indemnify any person made or threatened to be made a party to any action or proceeding by reason of the fact that he or she is or was a director or officer, and any director or officer who served any other company in any capacity at our request, to the fullest extent permitted by Section 145 of the DGCL.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons under the provisions discussed above or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Nevada Reincorporation; Contemplated Reverse Stock Split

At our annual meeting of stockholders scheduled to be held on August 17, 2021, we are seeking stockholder approval of, among other things, the reincorporation of our company from Delaware to Nevada. In addition, at the meeting, in the event the reincorporation is not approved, we are seeking stockholder approval of a reverse split of our common stock at a ratio of not less than 1-for-20 and not more than 1-for-4000 with our Board to have authority to determine whether to effect a reverse split as well as the reverse split ratio. Further, in the event the reverse split proposal is approved, we are seeking stockholder approval of an amendment to our certificate of incorporation pursuant to which the number of shares of common stock authorized to be issued by us can be reduced in a manner proportionate to the reverse split or to a lesser or greater degree. In the event the reincorporation to Nevada is approved, our Board will have the power and authority to effectuate a reverse split of our common stock, as well as to determine the reverse split ratio, without the need for stockholder approval. The share and per share amounts set forth in this prospectus do not give effect to such contemplated reverse stock split.

Transfer Agent

The transfer agent for our common stock is Transhare Corporation.

UNDERWRITING

We have entered into an underwriting agreement, dated _____, 2021, with Roth Capital Partners, LLC, or Roth or the Representative, as the sole representative of the underwriters with respect to the Units being offered. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock and Warrants listed next to its name in the following table:

Name of Underwriter	Number of Shares	Number of Warrants
Roth Capital Partners, LLC		
Total		

The underwriters are committed to purchase all the Units offered by this prospectus if they purchase any Units. The underwriting agreement also provides that, if an underwriter defaults, the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated. The underwriters are not obligated to purchase the Units covered by the underwriters' over-allotment option described below. The underwriters are offering the Units, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-Allotment Option

We have granted to the underwriters an option, exercisable no later than 45 calendar days after the date of the underwriting agreement, to purchase up to Units at the public offering price listed on the cover page of this prospectus, less underwriting discounts. The underwriters may exercise this option only to cover over-allotments, if any, made in connection with this offering. To the extent the option is exercised and the conditions of the underwriting agreement are satisfied, we will be obligated to sell to the underwriters, and the underwriters will be obligated to purchase, these additional Units.

Underwriting Discount, Commissions and Expenses

The Representative has advised us that the underwriters propose to offer the Units directly to the public at the public offering price set forth on the cover of this prospectus. In addition, the underwriters may offer some of the Units to other securities dealers at such price less a concession of up to $ per Unit. After the offering to the public, the offering price and other selling terms may be changed by the Representative without changing our proceeds from the underwriters' purchase of the Units. The underwriters have advised us that they do not expect to confirm sales of Units offered by this prospectus to accounts over which they exercise discretionary authority.

The following table summarizes the public offering price, underwriting discounts and proceeds before expenses to us (assuming either no exercise or the full exercise of the underwriters' over-allotment option to purchase additional Units). The underwriting discounts are equal to the public offering price per Unit less the amount per Unit the underwriters pay us for the Units.

	Per Unit(1)	Total Without Over-Allotment	Total With Over-Allotment(2)
Public offering price	$	$	$
Underwriting discount (7.0%) (1)	$	$	$
Proceeds, before expenses, to us (2)(3)	$	$	$

(1) In addition to the underwriting discount, we have agreed to reimburse the Representative to cover certain accountable expenses of the Representative in connection with this offering in an amount up to $100,000. We have also agreed to issue to the representative of the underwriters the Representative Warrants as described below under "Representative Warrants." With respect to certain investors introduced to the underwriters by us, the underwriting discount shall be 3.5% instead of 7.0%.

(2) We estimate that the total expenses of the offering payable by us, excluding the total underwriting discounts, will be approximately $.

Representative Warrants

We have agreed to issue Representative Warrants to the representative of the underwriters to purchase a number of shares of our common stock equal to 5.0% of the total number of shares of our common stock issued or issuable in this offering, except that, with respect to certain investors introduced to the underwriters by us, the Representative Warrants will be exercisable for the purchase of a number of shares of our common stock equal to 2.5% of the number of shares of our common stock issued or issuable in this offering (in each case, including shares of common stock issuable upon the exercise of the Warrants issued to investors in this offering). The Representative Warrants will have substantially the same terms as the Warrants being offered to investors pursuant to this prospectus, except that the Representative Warrants will be exercisable six months from the date of issuance, have an exercise price equal to 120% of the public offering price of each Unit sold in the offering, and terminate five years from the commencement of sales of the offering. Pursuant to FINRA Rule 5110(e), the Representative Warrants and any shares of common stock issued upon exercise of the Representative Warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of reorganization of the issuer; (ii) to any FINRA member firm participating in the offering and the officers, partners, registered persons or affiliates thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the Representative or related persons does not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period; (vi) if we meet the registration requirements of Forms S-3, F-3 or F-10; or (vii) back to us in a transaction exempt from registration with the SEC. The Representative Warrants and the shares of common stock underlying the Representative Warrants are registered on the registration statement of which this prospectus forms a part.

Lock-Up Agreements

We and each of our officers, directors and 5% stockholders have agreed, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock for a period of six months after this offering is completed without the prior written consent of the Representative.

The Representative may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the Representative will consider, among other factors, the stockholders' reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

Right of First Refusal

We have granted Roth a right of first refusal, for a period of twelve months from the completion of this offering, to act as a placement agent, underwriter and/or sole book-runner, upon certain terms, for each of our future public and private equity and debt offerings, including all equity-linked financings, during such twelve month period, on terms and conditions customary for such transactions.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

OTC and Nasdaq

Our common stock is presently quoted on the OTC under the symbol "BRTX." We have applied to have our common stock and Warrants listed on Nasdaq under the symbols "BRTX" and "BRTXW," respectively. We will not consummate this offering unless our common stock and Warrants are approved for listing on Nasdaq. No assurance can be given that our application will be approved. Trading quotes of securities on an over-the-counter marketplace may not be indicative of the market price of those securities on a national securities exchange. There is no established public trading market for the Warrants. No assurance can be given that a trading market will develop for the Warrants.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Transhare Corporation.

Price Stabilization, Short Positions, and Penalty Bids

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may over-allot in connection with this offering by selling more shares and Warrants than are set forth on the cover page of this prospectus. This creates a short position in our common stock for the underwriters' own account. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares common stock or Warrants over-allotted by the underwriters is not greater than the number of shares of common stock or Warrants that they may purchase in the over-allotment option. In a naked short position, the number of shares of common stock or Warrants involved is greater than the number of shares of common stock or Warrants in the over-allotment option. To close out a short position, the underwriters may elect to exercise all or part of the over-allotment option. The underwriters may also elect to stabilize the price of our common stock and Warrants or reduce any short position by bidding for, and purchasing, common stock and Warrants in the open market.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing a security in this offering because the underwriter repurchases that security in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, shares of our common stock in market making transactions, including "passive" market making transactions as described below.

These activities may stabilize or maintain the market price of our common stock at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice. These transactions may be effected on Nasdaq, in the over-the-counter market, or otherwise.

In connection with this offering, the underwriters and selling group members, if any, or their affiliates may engage in passive market making transactions in our common stock immediately prior to the closing of this offering, in accordance with Rule 103 of Regulation M under the Exchange Act. Rule 103 generally provides that:

- a passive market maker may not effect transactions or display bids for our common stock in excess of the highest independent bid price by persons who are not passive market makers;
- net purchases by a passive market maker on each day are generally limited to 30% of the passive market maker's average daily trading volume in our common stock during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and
- passive market making bids must be identified as such.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the Representative and may also be made available on a website maintained by other underwriters. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the Representative to underwriters that may make Internet distributions on the same basis as other allocations. In connection with this offering, the underwriters or syndicate members may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Certain Relationships

Certain of the underwriters and their affiliates may provide, from time to time, investment banking and financial advisory services to us in the ordinary course of business, for which they may receive customary fees and commissions.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriter is not required to comply with the disclosure requirements of NI33-105 regarding underwriter conflicts of interest in connection with this offering.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area

In relation to each Member State of the European Economic Area (each a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that it may make an offer to the public in that Relevant State of any shares at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2 and D.411-1 to D.411-3, D. 744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Hong Kong

The shares of common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the "SFO") of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong) (the "CO") or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares of common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority ("ISA"), nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with this offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa, "CONSOB") pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors, as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ("Regulation no. 1197l") as amended ("Qualified Investors"); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL") pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor have we received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. We may not render services relating to the securities within the United Arab Emirates, including the receipt of applications and/or the allotment or redemption of such shares.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

In relation to the United Kingdom, no shares have been offered or will be offered pursuant to this offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares that either (i) has been approved by the Financial Conduct Authority, or (ii) is to be treated as if it had been approved by the Financial Conduct Authority in accordance with the transitional provision in Regulation 74 of the Prospectus (Amendment etc.) (EU Exit) Regulations 2019, except that offers of shares may be made to the public in the United Kingdom at any time under the following exemptions under the UK Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000 (the "FSMA"),

provided that no such offer of the shares shall require the Issuer or any representative to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

In addition, this prospectus is only being distributed to, and is only directed at, and any investment or investment activity to which this prospectus relates is available only to, and will be engaged in only with, persons who are outside the United Kingdom or persons in the United Kingdom (i) having professional experience in matters relating to investments who fall within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (ii) who are high net worth entities falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). Persons who are not relevant persons should not take any action on the basis of this prospectus and should not act or rely on it.

LEGAL MATTERS

The validity of the issuance of the securities to be offered by this prospectus will be passed upon for us by Certilman Balin Adler & Hyman, LLP, East Meadow, New York. As of July 31, 2021, Certilman Balin Adler & Hyman, LLP owned 148,500 shares of our common stock. Ellenoff Grossman & Schole LLP, New York, New York is acting as counsel for the underwriters in connection with this offering.

EXPERTS

Our consolidated financial statements as of December 31, 2020 and 2019 and for the years then ended appearing in this prospectus have been included in reliance upon the report of Friedman LLP, an independent registered public accounting firm, included herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities we are offering. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in, or incorporated by reference into, the registration statement, some items of which are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our securities, we refer you to the registration statement, including the exhibits filed as a part of, or incorporated by reference into, the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to, or incorporated by reference into, the registration statement, please see the copy of the contract or document that has been filed or incorporated by reference. Each statement in this prospectus relating to a contract or document filed as an exhibit to, or incorporated by reference into, the registration statement is qualified in all respects by the exhibit so filed or incorporated by reference. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents.

A copy of the registration statement, including the exhibits filed as a part of, or incorporated by reference into, the registration statement, may be inspected without charge at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from the SEC upon the payment of fees prescribed by it. You may call the SEC at 1-800-SEC-0330 for more information on the operation of the public reference facilities. The SEC maintains a website at http://www.sec.gov that contains reports, proxy and information statements and other information regarding companies, such as us, that file electronically with it.

We are subject to the information requirements of the Exchange Act, which means that we are required to file annual, quarterly and current reports, proxy statements and other information with the SEC, all of which are available at the Public Reference Room of the SEC at 100 F Street, NE, Washington D.C. 20549. You may also obtain copies of these reports, proxy statements and other information from the Public Reference Room of the SEC, at prescribed rates, by calling 1-800-SEC-0330. The SEC maintains an Internet website at http://www.sec.gov where you can access reports, proxy statements, information and registration statements, and other information regarding us that we file electronically with the SEC. In addition, we make available, without charge, through our website, www.biorestorative.com, electronic copies of various filings with the SEC, including copies of Annual Reports on Form 10-K. Information on our website should not be considered a part of this prospectus.

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONSOLIDATED FINANCIAL STATEMENTS

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current Assets:		
Cash	$ 2,500,909	$ 3,064,610
Accounts receivable	18,000	17,000
Prepaid expenses	75,452	105,407
Total Current Assets	2,594,361	3,187,017
Equipment, net	16,345	21,914
Right of use asset	444,838	473,849
Intangible assets, net	645,636	664,268
Total Assets	$ 3,701,180	$ 4,347,048
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 245,661	$ 118,851
Accrued expenses and other current liabilities	713,064	718,259
Accrued interest	212,793	49,307
Lease liability	105,459	158,371
PPP loan payable	14,687	-
Total Current Liabilities	1,291,664	1,044,788
Lease liability, net of current portion	392,255	363,519
Notes payable, net of debt discount of $4,949,709 and $5,366,869, respectively	4,476,330	4,270,233
PPP loan payable, net of current portion	235,313	-
Total Liabilities	6,395,562	5,678,540
Commitments and Contingencies		
Stockholders' Deficit:		
Preferred stock, $0.01 par value; Authorized, 20,000,000 shares; none issued and outstanding at March 31, 2021 and December 31, 2020	-	-
Common stock, $0.0001 par value; Authorized, 300,000,000,000 shares; Issued and outstanding 3,175,911,955 and 2,862,174,380, respectively	317,593	286,220
Additional paid in capital	102,484,188	88,225,121
Accumulated deficit	(105,496,163)	(89,842,833)
Total Stockholders' Deficit	(2,694,382)	(1,331,492)
Total Liabilities and Stockholders' Deficit	$ 3,701,180	$ 4,347,048

The accompanying footnotes are an integral part of these unaudited condensed consolidated financial statements.

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended	
	March 31, 2021	**March 31, 2020**
Revenues	$ 18,000	$ 26,000
Operating expenses:		
Marketing and promotion	2,600	22,008
Consulting	8,389	34,012
Research and development	165,254	186,328
General and administrative	14,896,413	602,641
Total operating expenses	15,072,656	844,989
Loss from operations	(15,054,656)	(818,989)
Other expense:		
Interest expense	181,514	285,926
Amortization of debt discount	417,160	1,066,526
Loss on extinguishment of notes payable, net	-	658,152
Change in fair value of derivative liabilites	-	2,141,069
Reorganization items, net	-	2,580,110
Total other expense	598,674	6,731,783
Net loss	$ (15,653,330)	$ (7,550,772)
Net Loss Per Share		
- Basic and Diluted	$ (0.01)	$ (0.01)
Weighted Average Number of Common Shares Outstanding		
- Basic and Diluted	2,919,719,282	960,077,909

The accompanying footnotes are an integral part of these unaudited condensed consolidated financial statements.

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount			
Balance at January 1, 2021	2,862,174,380	$ 286,220	$ 88,225,121	$ (89,842,833)	$ (1,331,492)
Shares issued in exchange of notes payable and accrued interest	19,409,575	1,940	211,733	-	213,673
Shares issued in cashless exercise of warrants	294,328,000	29,433	(29,433)	-	-
Stock-based compensation:					
- restricted share units	-	-	179,098	-	179,098
- options	-	-	13,897,669	-	13,897,669
Net loss	-	-	-	(15,653,330)	(15,653,330)
Balance as of March 31, 2021	3,175,911,955	$ 317,593	$ 102,484,188	$ (105,496,163)	$ (2,694,382)
Balance at January 1, 2020	77,851,633	$ 7,787	$ 65,786,213	$ (78,570,146)	$ (12,776,146)
Shares and warrants issued for cash	1,000,000	100	9,900	-	10,000
Shares issued in exchange for notes payable and accrued interest	1,515,799,750	151,580	2,407,352	-	2,558,932
Stock-based compensation:					
- options	-	-	221,881	-	221,881
Net loss	-	-	-	(7,550,772)	(7,550,772)
Balance as of March 31, 2020	1,594,651,383	$ 159,467	$ 68,425,346	$ (86,120,918)	$ (17,536,105)

The accompanying footnotes are an integral part of these unaudited condensed consolidated financial statements.

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended	
	March 31, 2021	**March 31, 2020**
Cash flows from operating activities:		
Net Loss	$ (15,653,330)	$ (7,550,772)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount	417,160	1,066,526
Accretion of interest expense	-	2,810,973
Depreciation and amortization	24,201	43,764
Stock-based compensation	14,076,767	221,881
Loss on extinguishment of note payables, net	-	658,152
Change in fair value of derivative liabilities	-	2,141,069
Non-cash effect of right of use asset	4,835	8,592
Changes in operating assets and liabilities:		
Accounts receivable	(1,000)	6,000
Prepaid assets and other current assets	29,955	12,978
Accounts payable	126,809	94,349
Accrued interest, expenses and other current liabilities	160,901	37,842
Net cash used in operating activities	(813,702)	(448,646)
Cash flows from financing activities:		
Proceeds from notes payable	-	441,762
Proceeds from PPP Loan	250,000	-
Sales of common stock and warrants for cash	-	10,000
Net cash provided by financing activities	250,000	451,762
Net (decrease) increase in cash and cash equivalents	(563,702)	3,116
Cash and cash equivalents - beginning of period	3,064,610	1,664
Cash and cash equivalents - end of period	$ 2,500,909	$ 4,780
Supplemental cash flow information:		
Cash paid for:		
Interest	$ -	$ -
Non-cash investing and financing activities:		
Shares issued in exchange for notes payable and accrued interest	$ 213,673	$ 2,558,932
Bifurcated embedded conversion options and warrants recorded as derivative liability and debt discount	$ -	$ 2,377,818
Sale of warrants recorded as derivative liabilities	$ -	$ 10,000

The accompanying footnotes are an integral part of these unaudited condensed consolidated financial statements.

NOTE 1 – NATURE OF THE ORGANIZATION, LIQUIDITY, AND BUSINESS

Corporate History

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

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

On August 7, 2020 the Company and Auctus Fund, LLC ("Auctus"), the Company's largest unsecured creditor and a stockholder as of the Petition Date, filed an Amended Joint Plan of Reorganization (the "Plan") and on October 30, 2020, the Bankruptcy Court entered an order (the "Confirmation Order") confirming the Plan, as amended. Amendments to the Plan are reflected in the Confirmation Order. On November 16, 2020 (the "Effective Date"), the Plan became effective. See Note 5 – Notes Payable – Chapter 11 Reorganization.

Nature of the Business

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

Liquidity

The accompanying unaudited condensed 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. At March 31, 2021, the Company had an accumulated deficit of approximately $105,496,000 and working capital surplus of approximately $1,303,000. For the three months ended March 31, 2021, the Company had a loss from operations of approximately $15,055,000 (of which, approximately $14,077,000 was attributable to non-cash stock-based compensation) and negative cash flows from operations of approximately $814,000. The Company's operating activities consume the majority of its cash resources. The Company anticipates that it will continue to incur operating losses as it executes its development plans for 2021, as well as other potential strategic and business development initiatives. In addition, the Company has had and expects to have negative cash flows from operations, at least into the near future. The Company has previously funded, and plans to continue funding, these losses primarily through current cash on hand received subsequent to quarter end and additional infusions of cash from equity and debt financing.

The Company believes the following has been able to mitigate the above factors with regards to its ability to continue as a going concern: (i) as part of its Chapter 11 reorganization approximately $14,700,000 in outstanding debt and other liabilities were exchanged for (a) shares of common stock, (b) new convertible notes or (c) new convertible notes and warrants to purchase shares of common stock; (ii) the Company secured DIP financing during its Chapter 11 Case in the amount of $1,189,413, as well as an aggregate amount of $3,848,548 in debt financing from Auctus and others as part of the Company's Chapter 11 reorganization, to sustain operations; and (iii) pursuant to the plan of reorganization, Auctus is required to loan to the Company, as needed, an additional amount equal to $3,500,000, less the amount of Auctus' DIP financing ($1,226,901, inclusive of accrued interest) and its DIP costs not to exceed approximately $650,000. As a result of the above, and cash on hand of approximately $2,248,000 as of May 11, 2021, the Company believes it has sufficient cash to fund operations for the twelve months subsequent to the filing date. In addition, the Company is seeking further funding to commence and complete a Phase 2 clinical study of the use of *BRTX-100.*

There is no assurance that these funds will be sufficient to enable the Company to fully complete its development activities or attain profitable operations. If the Company is unable to obtain such additional financing on a timely basis the Company may have to curtail its development, marketing and promotional activities, which would have a material adverse effect on the Company's business, financial condition and results of operations, and ultimately the Company could be forced to discontinue its operations and liquidate.

The accompanying unaudited condensed 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 unaudited condensed consolidated financial statements do not necessarily purport to represent realizable or settlement values. The accompanying unaudited condensed consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial information as of and for the three months ended March 31, 2021 and 2020 has been prepared in accordance with GAAP for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the Company's financial position at such dates and the operating results and cash flows for such periods. Operating results for the three months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the entire year or for any other subsequent interim period.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been omitted pursuant to the rules of the U.S. Securities and Exchange Commission (the "SEC"). These unaudited condensed consolidated financial statements and related notes should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K filed with the SEC on April 30, 2021.

Principles of Consolidation

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

Reclassifications

During the three months ended March 31, 2020, the Company reclassified $2,580,110 related to the write-off of unamortizaed debt discount on convertible notes to reorganization items on the unaudited condensed consolidated statements of operations. This amount was previously recorded as interest expense in the Company's Quarterly Report on Form 10-Q filed with the SEC on March 29, 2021. This reclassification had no effect on net loss or cash flows as previously reported.

Chapter 11 Cases

Chapter 11 Accounting

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

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

Reorganization Items, Net

The Company incurred costs after the Petition Date associated with the reorganization, primarily unamortized debt discount and postpetition professional fees. In accordance with applicable guidance, costs associated with the bankruptcy proceedings have been recorded as reorganization items, net within the accompanying unaudited condensed consolidated statements of operations for the three months ended March 31, 2021 and 2020. Reorganization items, net for the three months ended March 31, 2021 and 2020, were $- and $2,580,110, respectively, representing cash used in operating activities.

Reorganization items, net for the three months ended March 31, 2021 and 2020, consisted of the following:

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Unamortized debt discount on convertible notes	$ -	$ 2,580,110
Total reorganization items, net	$ -	$ 2,580,110

Use of Estimates

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

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

Revenue

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

Practical Expedients

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

- Significant Financing Component – the Company does not adjust the promised amount of consideration for the effects of a significant financing component since the Company expects, at contract inception, that the period between when the Company transfers a promised good or service to the customer and when the customer pays for that good or service will be one year or less.
- Unsatisfied Performance Obligations – all performance obligations related to contracts with a duration for less than one year, the Company has elected to apply the optional exemption provided in ASC Topic 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.

Contract Modifications

There were no contract modifications during the three months ended March 31, 2021. Contract modifications are not routine in the performance of the Company's contracts.

Cash

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. There were no cash equivalents as of March 31, 2021 or December 31, 2020.

Accounts Receivable

Accounts receivable are reported at their outstanding unpaid principal balances, net of allowances for doubtful accounts. The Company periodically assesses its accounts and other receivables for collectability on a specific identification basis. The Company provides for allowances for doubtful receivables based on management's estimate of uncollectible amounts considering age, collection history, and any other factors considered appropriate. Payments are generally due within 30 days of invoice. The Company writes off accounts receivable against the allowance for doubtful accounts when a balance is determined to be uncollectible. The Company did not record an allowance for doubtful accounts as of March 31, 2021 and December 31, 2020, respectively.

Property and Equipment

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

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

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including finite-lived intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to the carrying amount. If the operation is determined to be unable to recover the carrying amount of its assets, then these assets are written down first, followed by other long-lived assets of the operation to fair value. Fair value is determined based on discounted cash flows or appraised values, depending on the nature of the assets. During the three months ended March 31, 2021 and 2020, the Company determined that there was no impairment charge for intangible assets.

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.

Advertising and Marketing Costs

The Company expenses advertising and marketing costs as they are incurred. Advertising and marketing expenses were $2,600 and $22,008 for the three months ended March 31, 2021 and 2020, respectively. The above advertising and marketing expenses are recorded in marketing and promotion on the unaudited condensed consolidated statements of operations.

Fair Value Measurements

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

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

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

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

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. All vested outstanding options and warrants are considered potential common stock. The dilutive effect, if any, of stock options, warrants, and unvested restricted stock units ("RSUs") are calculated using the treasury stock method. All outstanding convertible notes are considered common stock at the beginning of the period or at the time of issuance, if later, pursuant to the if-converted method. Since the effect of common stock equivalents is anti-dilutive with respect to losses, options, warrants, RSUs and convertible notes have been excluded from the Company's computation of net loss per common share for the three months ended March 31, 2021 and 2020.

The following table summarizes the securities that were excluded from the diluted per share calculation because the effect of including these potential shares was antidilutive:

	Three Months Ended March 31,	
	2021	**2020**
Options	2,352,695,565	4,874,617
Warrants	14,689,060,954	8,823,490
Unvested RSUs	1,173,917,974	-
Convertible notes – common stock	804,326,396(1)	20,614,707,544(2)
Total	19,020,000,889	20,628,405,651

(1) As of Marh 31, 2021 all of the convertible notes had variable conversion prices and the shares issuable were estimated based on the market conditions. Pursuant to the note agreements, there were 6,078,578,968 shares of common stock reserved for future note conversions as of March 31, 2021.

(2) As of March 31, 2020 many of the convertible notes had variable conversion prices and the shares issuable were estimated based on the market conditions. Pursuant to the note agreements, there were 360,7963,730 shares of common stock reserved for future note conversions as of March 31, 2020.

Stock-based Compensation

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

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

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

Since the shares underlying the Company's 2010 Equity Participation Plan and the 2021 Stock Incentive Plan (the "Plans") are registered, the Company estimates the fair value of the awards granted under the Plans based on the market value of its freely tradable common stock as reported on the OTC Markets. On February 3, 2020, the Company was advised by OTC Markets Group that, based upon the closing bid price of the Company's common stock being less than $0.001 per share for five consecutive trading days, the Company's common stock was moved from the OTCQB Market to the Pink Market effective at market open on February 10, 2020. The fair value of the Company's restricted equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares. Awards granted to directors are treated on the same basis as awards granted to employees. Upon the exercise of an option or warrant, the Company issues new shares of common stock out of its authorized shares.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the unaudited condensed 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 unaudited condensed 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. At March 31, 2021 and December 31, 2020, the Company's net deferred tax asset has been fully reserved.

For uncertain tax positions that meet a "more likely than not" threshold, the Company recognizes the benefit of uncertain tax positions in the unaudited condensed 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 unaudited condensed consolidated statements of operations when a determination is made that such expense is likely.

Derivative Financial Instruments

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

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

Sequencing Policy

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

Leases

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02")). The standard requires all leases that have a term of over 12 months to be recognized on the balance sheet with the liability for lease payments and the corresponding right-of-use ("ROU") asset initially measured at the present value of amounts expected to be paid over the term. Recognition of the costs of these leases on the income statement will be dependent upon their classification as either an operating or a financing lease. Costs of an operating lease will continue to be recognized as a single operating expense on a straight-line basis over the lease term. Costs for a financing lease will be disaggregated and recognized as both an operating expense (for the amortization of the ROU asset) and interest expense (for interest on the lease liability).

A lease is defined as a contract that conveys the right to control the use of identified property, plant or equipment for a period of time in exchange for consideration.

In accordance with ASC 842, *Leases*, the Company recognized an ROU asset and corresponding lease liability on its balance sheets for its office space lease agreement. See Note 8 - Leases for further discussion, including the impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

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

Leases in which the Company is the lessee are comprised of office rental. All of the leases are classified as operating leases. The Company has a lease agreement for office space with a remaining term of 3.75 years as of March 31, 2021.

Subsequent Events

There were no subsequent events or transactions requiring recognition or disclosure in the unaudited condensed consolidated financial statements, and noted thereto, through the date the financial statements were issued.

Recently Issued Accounting Standards

In March 2021, the FASB issued ASU 2021-03, Intangibles – Goodwill and Other (Topic 350) ("ASU 2021-03") which requires an entity to identify and evaluate goodwill impairment triggering events when they occur to determine whether it is more likely than not that the fair value of a reporting unit (or entity, if the entity has elected the accounting alternative for amortizing goodwill and chosen that option) is less than its carrying amount. If an entity determines that it is more likely than not that the goodwill is impaired, it must test goodwill for impairment using the triggering event date as the measurement date. An entity is required to disclose the amount assigned to goodwill in total and by major business combination, or by reorganization event resulting in fresh-start-start reporting. Also, the weighted average amortization period in total and the amortization period by major business combination, or by reorganization event resulting in fresh-start reporting. ASU 2021-03 was effective for the Company on January 1, 2021 and did not have a significant impact on its unaudited condensed consolidated financial statement.

In May 2021, the FASB issued ASU 2021-04 "Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation— Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815- 40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options" which clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. An entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as follows: i) for a modification or an exchange that is a part of or directly related to a modification or an exchange of an existing debt instrument or line-of-credit or revolving-debt arrangements (hereinafter, referred to as a "debt" or "debt instrument"), as the difference between the fair value of the modified or exchanged written call option and the fair value of that written call option immediately before it is modified or exchanged; ii) for all other modifications or exchanges, as the excess, if any, of the fair value of the modified or exchanged written call option over the fair value of that written call option immediately before it is modified or exchanged. The amendments in this Update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. The Company is currently evaluating the impact of this standard on its unaudited condensed consolidated financial statements.

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

NOTE 3 – INTANGIBLE ASSETS

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

Intangible assets consist of the following:

	Patents and Trademarks	Licenses	Accumulated Amortization	Total
Balance as of January 1, 2020	$ 3,676	$ 1,301,500	$ (566,012)	$ 739,164
Amortization expense	-	-	(74,896)	(74,896)
Balance as of December 31, 2020	3,676	1,301,500	(640,908)	664,268
Amortization expense	-	-	(18,632)	(18,632)
Balance as of March 31, 2021	$ 3,676	$ 1,301,500	$ (659,540)	$ 645,636
Weighted average remaining amortization period at March 31, 2021 (in years)	-	8.61		

Amortization of intangible assets consists of the following:

	Patents and Trademarks	Licenses	Accumulated Amortization
Balance as of January 1, 2020	$ 3,312	$ 562,700	$ 566,012
Amortization expense	364	74,532	74,896
Balance as of December 31, 2020	3,676	637,232	640,908
Amortization expense	-	18,632	18,632
Balance as of March 31, 2021	$ 3,676	$ 655,864	$ 659,540

NOTE 4 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of:

	March 31, 2021	December 31, 2020
Accrued payroll	$ 22,898	$ -
Accrued research and development expenses	32,568	-
Accrued general and administrative expenses	-	60,661
Accrued DIP and Plan costs related to DIP Funding and Plan[(1)]	657,598	657,598
Total accrued expenses	$ 713,064	$ 718,259

(1) Amount represents DIP and Plan costs associated with the Auctus DIP Funding and the Plan.

NOTE 5 – NOTES PAYABLE

A summary of the notes payable activity during the three months ended March 31, 2021 is presented below:

	Convertible Notes	Other Loans	Debt Discount	Total
Outstanding, January 1, 2021	$ 9,637,102	$ -	$ (5,366,869)	$ 4,270,233
Issuances	-	250,000	-	250,000
Exchanges for equity	(211,063)	-	-	(211,063)
Amortization of debt discount	-	-	417,160	417,160
Outstanding, March 31, 2021	$ 9,426,039	$ 250,000	$ (4,949,709)	$ 4,726,330

Chapter 11 Reorganization

On March 20, 2020, the Company filed a voluntary petition commencing a case under chapter 11 of title 11 of the U.S. Code in the United States Bankruptcy Court for the Eastern District of New York. On August 7, 2020, the Company and Auctus, the Company's largest unsecured creditor and a stockholder as of the Petition Date, filed an Amended Joint Plan of Reorganization (the "Plan"). Pursuant to the Bankruptcy, for any outstanding principal and interest at the date of the Company's Chapter 11 petition (except for creditors who provided additional debt financing in connection with the Bankruptcy), 100 shares of the Company's common stock were issued for each dollar of allowed claim, with such shares subject to leak-out restrictions prohibiting the holder from selling, without the consent of the Company, more than 33% of the issued shares during each of the three initial 30 day periods following the Effective Date. As a result of the Chapter 11 petition, the conversion rights for the then outstanding notes were rescinded and were subject to the conversion rights outlined above.

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

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

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

ii. Auctus has provided $3,500,000 in funding to the Company (the "Initial Auctus Funding") and is to provide, subject to certain conditions, additional funding to the Company, as needed, in an amount equal to $3,500,000, less the sum of the debtor-in-possession loans made to the Company by Auctus during the Chapter 11 Case (inclusive of accrued interest) (approximately $1,227,000 as of the Effective Date) and the costs incurred by Auctus as the debtor-in-possession lender (the "DIP Costs"). As of March 31, 2021, the DIP Costs and additional Plan costs were not finalized and recorded. The DIP Costs and the additional Plan costs in the aggregate are estimated to total $657,598, of which $500,000 and $157,598 were recorded in debt discount and accrued expenses, respectively, on the consolidated balance sheets. In addition, four other persons and entitles (collectively, the "Other Lenders") who held allowed general unsecured claims provided funding to the Company in the aggregate amount of approximately $348,000 (the "Other Funding" and together with the Initial Auctus Funding, the "Funding"). In consideration of the Funding, the Company has issued the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Company recorded $142,692 and $362,041 of interest expense related to notes payable and convertible note payable for the three months ended March 31, 2021 and 2020, respectively.

Convertible Notes

Conversions, Exchanges and Other

During the three months ended March 31, 2021, certain lenders converted unsecured convertible notes with with an aggegate amount of $213,673 (including $2,611 of accrued interest) for an aggregate of 19,409,575 shares of the Company's common stock at a conversion price of $0.01 per share.

Debtor-in-Possession Financing

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

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

Pursuant to the Plan, the obligation to Auctus with respect to the DIP Funding has been exchanged for two Secured Convertible Notes (See Note 5 – Notes Payable – Chapter 11 Reorganization) for an aggregate principal amount of $1,349,591 which bear interest at 7% per annum with a maturity date of November 16, 2023. In connection with the Secured Convertible Notes, Auctus received warrants to purchase an aggregate of 3,680,703,720 shares of Company's commons stock with exercise prices ranging between $0.0005 and $0.001 per share.

Interest expense for the two Secured Convertible Notes was $23,294 for the three months ended March 31, 2021.

Other Loans

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

Future minimum payments under the above notes payable following the three months ended March 31, 2021, are as follows:

2021	$ -
2022	58,970
2023	9,485,601
2023	60,161
Thereafter	71,307
Total future minimum payments	9,676,039
Less: discount	(4,949,709)
	4,726,330
Less: current	(14,687)
	$ 4,711,643

NOTE 6 – STOCKHOLDERS' DEFICIT

Stock Incentive Plan

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

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.

Warrant Activity Summary

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

	For the Three Months Ended March 31, 2020
Risk free interest rate	1.63%
Contractual term (years)	5.00
Expected volatility	202%

The weighted average estimated fair value of warrants granted during the three months ended March 31, 2020 was $0.01 per share.

During the three months ended March 31, 2021, the Company issued an aggregate of 294,328,000 shares of the Company' common stock, as a result of the cashless exercise of 313,019,749 warrants to Auctus.

A summary of the warrant activity during the three months ended March 31, 2021 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2021	15,002,388,203	$ 0.0011	4.9	95,965,883
Granted	-	-		
Exercised	(313,019,749)	0.001		
Forfeited	(307,500)	4.12		
Outstanding, March 31, 2021	14,689,060,954	$ 0.001	4.6	$ 165,904,440
Exercisable, March 31, 2021	14,689,060,954	$ 0.001	4.6	$ 165,904,440

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

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$0.00 - $0.015	14,682,649,518	4.6	14,682,649,518
$0.20 - $1.99	5,106,746	3.3	5,106,746
$2.00 - $2.99	75,000	2.6	75,000
$3.00 - $3.99	70,000	2.3	70,000
$4.00 - $4.99	1,023,023	1.0	1,023,023
$5.00 - $5.99	136,667	0.3	136,667
	14,689,060,954	4.6	14,689,060,954

Stock Options

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

	For the Three Months Ended March 31, 2021
Risk free interest rate	1.71%
Expected term (years)	5.50
Expected volatility	228%
Expected dividends	0.00%

The Company granted options for the purchase of 2,347,835,948 shares of common stock during the three months ended March 31, 2021.

The Company did not issue stock options during the three months ended March 31, 2020.

The grant date fair value of options issued during the three months ended March 31, 2021 was $27,736,052.

A summary of the option activity during the three months ended March 31, 2021 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2021	4,859,617	$ 0.98	6.2	-
Granted	2,347,835,948	0.0119		
Forfeited	-	-		
Outstanding, March 31, 2021	2,352,695,565	$ 0.0139	10.0	$ -
Exercisable, March 31, 2021	1,178,636,261	$ 0.0158	10.0	$ -

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

Options Outstanding			Options Exercisable
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$0.00 - $0.0119	2,347,835,948	10.0	1,173,917,974
$0.26 - $0.74	175,000	8.4	175,000
$0.75 - $0.99	4,607,117	5.9	4,465,787
$1.00 - $5.99	5,000	3.2	5,000
$6.00 - $19.99	37,500	2.8	37,500
$20.00 - $30.00	35,000	1.0	35,000
	2,352,695,565	9.98	1,178,636,261

On March 18, 2021, the Company, pursuant to two employment agreements, granted to its Chief Executive Officer and Chairman of the Board and its Vice President, Research and Development options to purchase an aggregate of 2,347,835,948 shares of the Company's common stock (See Note 7 – Commitments and Contingencies). The options have an exercise price of $0.0119 per share and vest to the extent of 50% on the date of grant, 25% on the one-year anniversary of the grant date, and 25% on the two-year anniversary of the grant date.

Restricted Stock Units

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

On March 18, 2021, the Company, pursuant to two employment agreements, granted an aggregate of 1,173,917,974 RSUs to its Chief Executive Officer and Chairman of the Board and its Vice President, Research and Development (See Note 7 – Commitments and Contingencies) with a fair value of $0.0119 per share. The RSUs vest to the extent of one-third on the one-year anniversary of the grant date, one-third on the two-year anniversary of the grant date, and one-third on the three-year anniversary of the grant date.

A summary of our unvested RSUs as of March 31, 2021 is as follows:

	Number of Shares
Outstanding, January 1, 2021	-
Granted	1,173,917,974
Forfeited	-
Vested	-
Outstanding, March 31, 2021	1,173,917,974

The following table presents information related to stock compensation expense:

	For the Three Months Ended March 31,		Unrecognized at March 31,	Weighted Average Remaining Amortization Period
	2021	2020	2021	(Years)
Consulting	$ -	$ 34,012	$ -	-
Research and development	25,121	60,104	56,358	0.6
General and administrative	14,051,646	127,765	27,669,103	2.0
	$ 14,076,767	$ 221,881	$ 27,725,461	2.0

NOTE 7 - COMMITMENTS AND CONTINGENCIES

Litigation, Claims and Assessments

Coventry Enterprises, LLC

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

On March 11, 2020, the Court ordered that the Company (i) convene and hold a special meeting, by no later than March 18, 2020, of the Board of Directors of the Company (the "Board"), for approval of certain changes to the shares of the Company, as set forth below; (ii) approve a reverse split and/or a stock consolidation, solely of the Company's outstanding shares, at a ratio of 1,000 to 1, (iii) approve of the continuation of the Company's then total authorized shares of common stock at 2,000,000,000 shares; and (iv) to call a special meeting of stockholders of the Company, within ten days of the special meeting of the Board and by not later than March 25, 2020, to approve the foregoing. On March 18, 2020, the Board considered the matter, and, based upon the Court order, determined to approve the foregoing items, including the 1,000 to 1 reverse split, subject to the Company having available funds to effectuate such items. As discussed above in Note 5 – Notes Payable – Chapter 11 Reorganization on March 20, 2020, the Company filed a petition commencing its Chapter 11 Case. As of the date of this report, the Company has not effected the reverse split.

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

Appointment or Departure of Directors and Certain Officers

On March 18, 2021, the Company and Lance Alstodt, its President, Chief Executive Officer and Chairman of the Board, entered into an employment agreement (the "Alstodt Employment Agreement") which provides for a term ending on March 18, 2026. Pursuant to the Alstodt Employment Agreement, Mr. Alstodt is entitled to receive initially an annual salary of $250,000. Mr. Alstodt's annual salary will increase by $50,000 per year. In addition, in the event certain performance goals are met, Mr. Alstodt's salary will increase by $150,000. The Alstodt Employment Agreement also provides for the grant to Mr. Alstodt pursuant to the Plan of (i) a ten year option for the purchase of 1,173,917,974 shares of common stock of the Company and (ii) 586,958,987 RSUs of the Company (See Note 6 – Stockholders' Deficit) for additional information.

On March 18, 2021, the Company and Francisco Silva, its Vice President, Research and Development, entered into an employment agreement (the "Silva Employment Agreement") which provides for a term ending on March 18, 2026. Pursuant to the Silva Employment Agreement, Mr. Silva is entitled to receive initially an annual salary of $225,000. Mr. Silva's annual salary will increase by $50,000 per year. In addition, in the event certain performance goals are met, Mr. Silva's salary will increase by $150,000. The Silva Employment Agreement also provides for the grant to Mr. Silva pursuant to the Plan of (i) a ten year option for the purchase of 1,173,917,974 shares of common stock of the Company and (ii) 586,958,987 RSUs of the Company (See Note 6 – Stockholders' Deficit) for additional information.

Conversion of Convertible Notes

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

NOTE 8 - LEASES

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

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

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:

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Lease cost		
Operating lease cost (cost resulting from lease payments)	$ 39,593	$ 38,437
Short term lease cost	-	-
Sublease income	-	-
Net lease cost	$ 39,593	$ 38,437
Operating lease – operating cash flows (fixed payments)	$ 39,593	$ 38,437
Operating lease – operating cash flows (liability reduction)	$ 24,176	$ 20,419
Non-current leases – right of use assets	$ 444,838	$ 560,883
Current liabilities – operating lease liabilities	$ 105,459	$ 89,222
Non-current liabilities – operating lease liabilities	$ 392,256	$ 497,714

Future minimum payments under non-cancelable leases for operating leases for the remaining terms of the leases following the three months ended March 31, 2021:

Fiscal Year	Operating Leases
2021 (excluding the three months ended March 31, 2021)	$ 118,779
2022	163,132
2023	168,028
2024	173,060
Total future minimum lease payments	622,999
Amount representing interest	(125,285)
Present value of net future minimum lease payments	$ 497,714

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

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

Basis for Opinion

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

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

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

Critical Audit Matters

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

Valuation of Intangible Asset

Description of the Matter

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

How We Addressed the Matter in Our Audit

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

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

Description of the Matter

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

How We Addressed the Matter in Our Audit

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

/s/ Friedman LLP

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

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

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

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

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

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

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

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

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

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

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

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

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

NOTE 1 – ORGANIZATION AND BUSINESS OPERATIONS

Corporate History

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

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

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

Business Operations

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

NOTE 2 – LIQUIDITY

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

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

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

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Principles of Consolidation

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

Chapter 11 Cases

Chapter 11 Accounting

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

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

Reorganization Items, Net

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

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

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

Use of Estimates

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

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

Concentrations

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

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

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

Revenue

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

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

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

Practical Expedients

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

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

Contract Modifications

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

Cash

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

Accounts Receivable

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

Property and Equipment

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

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

Impairment of Long-Lived Assets

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

Intangible Assets

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

Advertising and Marketing Costs

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

Fair Value Measurements

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

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

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

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

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

Fair Value of Financial Instruments

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

Net Loss per Common Share

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

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

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

(1) As of December 31, 2020 all of the convertible notes had variable conversion prices and the shares issuable were estimated based on the market conditions. Pursuant to the note agreements, there were 52,292,375,355 shares of common stock reserved for future note conversions as of December 31, 2020.
(2) As of December 31, 2019 many of the convertible notes had variable conversion prices and the shares issuable were estimated based on the market conditions. Pursuant to the note agreements, there were 225,023,100 shares of common stock reserved for future note conversions as of December 31, 2019.

Stock-Based Compensation

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

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

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

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

Convertible Instruments

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

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

Income Taxes

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

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

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

Derivative Financial Instruments

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

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

Sequencing Policy

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

Leases

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

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

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

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

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

Recent Accounting Pronouncements

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

NOTE 4 – PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

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

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

NOTE 5 – INTANGIBLE ASSETS

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

Intangible assets consist of the following:

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

Amortization of intangible assets consists of the following:

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

NOTE 6 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of:

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

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

NOTE 7 – NOTES PAYABLE & CHAPTER 11 REORGANIZATION

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

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

Chapter 11 Reorganization

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

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

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

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

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

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

- Maturity date of three years following the Effective Date;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Related Party Notes

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

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

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

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

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

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

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

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

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

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

Convertible Notes

Issuances

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

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

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

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

Embedded Conversion Options and Note Provisions

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

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

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

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

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

Conversions, Exchanges and Other

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

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

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

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

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

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

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

Other Notes

Issuances

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

Exchange and Other

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

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

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

Debtor-in-Possession Financing

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

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

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

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

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

NOTE 8 - STOCKHOLDERS' DEFICIT

Authorized Capital and 2010 Equity Plan

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

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

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

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

Compensatory Common Stock Issuance

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

Warrant and Option Valuation

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

Common Stock and Warrant Offerings

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

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

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

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

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

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

Warrant Compensation

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

Warrant Activity Summary

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

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

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

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

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

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

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

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

Stock Options

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

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

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

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

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

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

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

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

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

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

The following table presents information related to stock option expense:

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

NOTE 9 – DERIVATIVE LIABILITIES

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

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

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

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

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

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

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

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

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

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

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

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

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

NOTE 10 – COMMITMENTS AND CONTINGENCIES

Litigation, Claims and Assessments

Coventry Enterprises, LLC

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

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

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

Appointment or Departure of Directors and Certain Officers

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

Conversion of Convertible Notes

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

NOTE 11 – INCOME TAXES

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

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

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

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

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

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

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

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

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

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

NOTE 12 – LEASES

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

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

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

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

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

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

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

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

NOTE 13 – SUBSEQUENT EVENTS

Exercise of Warrants

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

Conversion of Notes Payable

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

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

Appointment or Departure of Directors and Certain Officers

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

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

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

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

No dealer, salesman or any other person has been authorized to give any information or to make any representation not contained in this prospectus in connection with the offer made by this prospectus. If given or made, such information or representation must not be relied upon as having been authorized by us. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the securities offered by this prospectus, or an offer to sell or a solicitation of an offer to buy any securities by any person in any jurisdiction in which such an offer or solicitation is not authorized or is unlawful. Neither delivery of this prospectus nor any sale made hereunder shall under any circumstances create an implication that information contained herein is correct as of any time subsequent to the date of this prospectus.

UNITS, EACH UNIT COMPRISED OF

ONE SHARE OF COMMON STOCK AND ONE WARRANT
TO PURCHASE SHARE OF COMMON STOCK

PROSPECTUS

Roth Capital Partners

The date of this prospectus is , 2021.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following statement sets forth the amounts of expenses in connection with the offering of the securities of BioRestorative Therapies, Inc. pursuant to this registration statement, all of which shall be borne by the registrant. All amounts shown are estimates, except for the SEC Registration Fee, the FINRA Filing Fee and the Nasdaq Capital Market Listing Fee.

SEC Registration Fee	$	2,182.00
FINRA Filing Fee		3,500.00
Nasdaq Capital Market Listing Fee		*
Legal Fees and Expenses		*
Accounting Fees and Expenses		*
Printing and Engraving Expenses		*
Transfer Agent and Registrar Fees and Expenses		*
Miscellaneous		*
Total	$	*

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers.

Article Eighth of the registrant's certificate of incorporation (the "certificate of incorporation") provides that no director of the registrant shall be personally liable to the registrant or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the registrant or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) under Section 174 of the Delaware General Corporation Law (the "DGCL"); or (iv) for any transaction from which the director derived an improper personal benefit. The certificate of incorporation further provides that if the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the registrant shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

As more fully described below, Section 145 of the DGCL permits Delaware corporations to indemnify each of their present and former directors or officers under certain circumstances, provided that such persons acted in good faith and in a manner which they reasonably believed to be in, or not opposed to, the best interests of the corporation. Our bylaws provide that we will indemnify, to the fullest extent permitted by Delaware law, as the same may be amended from time to time, each of our present and former directors and officers pursuant thereto and in the manner prescribed thereby.

Specifically, Section 145 of the DGCL provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

Section 145 of the DGCL also provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper. Any such indemnification (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the person has met the applicable standard of conduct set forth above.

Section 145 of the DGCL also provides that a corporation may purchase and maintain insurance on behalf of any person who is or was a director or officer of the corporation against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the DGCL. Our bylaws provide that we may maintain such insurance.

The form of Underwriting Agreement included as an exhibit to this registration statement provides for indemnification by the underwriters of the registrant and its officers and directors against certain liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to the registrant's directors, officers and controlling persons under the provisions discussed above or otherwise, the registrant has been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Item 15. Recent Sales of Unregistered Securities.

Since January 1, 2018, the registrant has issued the following securities in transactions not involving any public offering. For each of the following transactions, the registrant relied upon Section 4(a)(2) of the Securities Act, as transactions by an issuer not involving any public offering or Section 3(a)(9) of the Securities Act as a security exchanged by an issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. For each such transaction, the registrant did not use general solicitation to market the securities, the securities were offered to a limited number of persons, the investors had access to information regarding the registrant (including information contained in its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC, and press releases made by the registrant), and the registrant was available to answer questions by prospective investors. The registrant reasonably believes that each of the investors was an accredited investor. The proceeds were used to reduce the registrant's working capital deficiency and for other corporate purposes.

The share and per share amounts shown below do not give effect to the registrant's contemplated reverse split of its shares of common stock at a ratio contemplated to be not less than 1-for-20 and not more than 1-for-4000 to occur prior to or immediately following the effectiveness of this registration statement.

Date Issued	Common Stock	Warrants		Weighted AverageTerm (Years)	Purchaser(s)	Consideration[1]	Weighted Average Price Per Share
		Shares	Weighted Average Exercise Price				
1/1/18 – 12/31/18	207,084	51,771	$ 4.00	2	(2)	$ 414,168(3)	$ 1.60
1/1/18 – 12/31/18	75,250	4,750	$ 4.00	2	(4)	$ 83,000(5)	$ 1.21
1/1/18 – 12/31/18	176,801	-	-	-	(2)	$ 246,593(6)	$ 1.39
1/1/18 – 12/31/18	35,000	140,000	$ 2.92	5	(4)	$ 190,456(7)	$ 1.36
1/1/18 – 12/31/18	39,500	-	-	-	(2)	$ 69,000(8)	$ 1.75
1/1/18 – 12/31/18	4,952,537	10,000	$ 3.50	5	(2)	$ 4,239,764(9)	$ 0.85
1/1/18 – 12/31/18	59,749	-	-	-	(2)	$ 70,545(10)	$ 1.18
1/1/18 – 12/31/18	60,000	60,000	$ 3.50	5	(2)	$ 150,000(11)	$ 1.25
1/1/19 – 12/31/19	85,000	-	-	-	(4)	$ 66,500(7)	$ 0.78
1/1/19 – 12/31/19	10,000	-	-	-	(2)	$ 7,052(8)	$ 0.71
1/1/19 – 12/31/19	63,768,255	-	-	-	(2)	$ 3,326,960(9)	<$0.001
1/1/19 – 12/31/19	68,873	-	-	-	(2)	$ 54,168(10)	$ 0.79
1/1/19 – 12/31/19	2,191,111	2,191,111	$ 0.79	3.07	(2)	$ 1,156,000(11)	$ 0.26
1/1/20 – 12/31/20	1,515,799,750	1,000,000	$ 0.015	5	(2)	$ 948,183(9)	<$0.001
1/1/20 – 12/31/20	1,049,756,797	-	-	-	(2)	$ 14,381,259(14)	$ 0.014
1/1/20 – 12/31/20	-	9,453,802,480	$ 0.0005	5	(2)	$ 2,565,699(15)	<$0.001
1/1/20 – 12/31/20	-	4,726,901,240	$ 0.001	5	(2)	$ 1,282,849(15)	<$0.001
1/1/20 – 12/31/20	217,796,200	-	-	-	(2)	$ 2,157,556(16)	$ 0.01
1/1//21–7/31/21	453,328,000	-	-	-	(2)	$ 4,953,676(16)	$ 0.011
1/1/21 – 7/31/21	19,409,575	-	-	-	(2)	$ 213,674(17)	$ 0.011
1/1/21 – 7/31/21	12,665,735	-	-	-	(2)	$ 100,000(18)	$ 0.008

(1) The value of the non-cash consideration was estimated to be the fair value of our restricted common stock. Since our shares are thinly traded in the open market, the fair value of our equity instruments was estimated by management based on observations of the cash sale prices of both restricted shares and freely tradeable shares.
(2) Accredited investor.
(3) Issued in connection with warrant exercises.
(4) Consultant.
(5) Issued in satisfaction of accrued consulting services.
(6) Issued in connection with the exchange of notes payable.
(7) Issued in consideration of consulting services.
(8) Issued in connection with notes payable maturity extensions.
(9) Issued in connection with the conversion of convertible notes payable.
(10) Issued in connection with issuance of debt.
(11) Issued for cash consideration.
(12) The warrants are exercisable as follows: (i) one-year warrants to purchase an aggregate 500,000 shares of common stock have an exercise price of $0.70 per share and (ii) five-year warrants to purchase an aggregate of 500,000 shares of common stock have an exercise price of $0.85 per share.
(13) The warrants are exercisable as follows: (i) one-year warrants to purchase an aggregate of 555,555 shares of common stock have an exercise price of $0.70 per share and (ii) five-year warrants to purchase an aggregate of 555,556 shares of common stock have an exercise price of $0.80 per share.
(14) Issued in exchange for allowed unsecured claims pursuant to the Plan of Reorganization.
(15) Issued in connection with the issuance of secured convertible notes pursuant to the Plan of Reorganization.
(16) Issued on a cashless net exercise basis pursuant to the exercise of warrants.
(17) Issued upon conversion of unsecured convertible notes.
(18) Issued upon conversion of secured convertible note.

Item 16. Exhibits and Financial Statement Schedules.

(a) The following exhibits are filed as part of this registration statement:

Exhibit No.	
1.1	Form of Underwriting Agreement*
2.1	Order of the Bankruptcy Court for the Eastern District of New York Confirming Amended Joint Plan of Reorganization of BioRestorative Therapies, Inc., and Auctus Fund, LLC (the "Plan of Reorganization"), incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is identified as Exhibit 2.1
2.2	Amended Disclosure Statement with respect to the Plan of Reorganization, together with exhibits thereto, including the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is identified as Exhibit 2.2
2.3	Plan Supplement to the Plan of Reorganization, together with forms of Secured Convertible Note, Unsecured Convertible Note, Class A Warrant, Class B Warrant, Intercreditor Agreement and Security Agreement attached as exhibits thereto, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is identified as Exhibit 2.3.
3.1	Certificate of Incorporation, as amended, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2019, wherein such document is identified as Exhibit 2.3.
3.2	Bylaws, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated December 19, 2014, wherein such document is identified as Exhibit 3.4
4.1	Form of Investor Warrant *
4.2	Form of Warrant Agency Agreement *
4.3	Form of Representative Warrant *
5.1	Opinion of Certilman Balin Adler & Hyman, LLP*
10.1	2010 Equity Participation Plan, as amended, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2019, wherein such document is identified as Exhibit 10.1
10.2	Stock Option Agreement, dated April 5, 2011, between Stem Cell Assurance, Inc. (now BioRestorative Therapies, Inc.) and Francisco Silva, incorporated by reference to the registrant's Form 10, wherein such document is identified as Exhibit 10.24
10.3	License Agreement, dated as of January 27, 2012, between Regenerative Sciences, LLC and BioRestorative Therapies, Inc. ("License Agreement"), incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 10.44

10.4	Amendment to License Agreement, dated March 21, 2012, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 10.45
10.5	Amendment to License Agreement, dated November 30, 2015, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, wherein such document is identified as Exhibit 10.20
10.6	Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 10.46
10.7	Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 10.49
10.8	Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2012, wherein such document is identified as Exhibit 10.58
10.9	Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2012, wherein such document is identified as Exhibit 10.61
10.10	Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.59
10.11	Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.62
10.12	Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.64
10.13	Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.67
10.14	Stock Option Agreement, dated as of March 12, 2014, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.70
10.15	Lease, dated as of August 25, 2014, between BioRestorative Therapies, Inc. and 50 Republic Road, LLC, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated August 25, 2014, wherein such document is identified as Exhibit 99.1

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

10.28	Form of Unsecured Convertible Note issued pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit B to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3
10.29	Form of Class A Warrant issued pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit C to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3
10.30	Form of Class B Warrant issued pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit D to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3
10.31	Form of Intercreditor Agreement entered into pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit E to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3
10.32	Form of Security Agreement entered into pursuant to the Plan of Reorganization, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 30, 2020, wherein such document is Exhibit F to the Plan Supplement to the Plan of Reorganization identified as Exhibit 2.3
10.33	BioRestorative Therapies, Inc. 2021 Stock Incentive Plan, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.1
10.34	Employment Agreement, dated as of March 18, 2021, by and between BioRestorative Therapies, Inc. and Lance Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.2
10.35	Employment Agreement, dated as of March 18, 2021, by and between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.3
10.36	Non-Qualified Stock Option Award Agreement, dated as of March 18, 2021, between BioRestorative Therapies, Inc. and Lance Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.4
10.37	Non-Qualified Stock Option Award Agreement, dated as of March 18, 2021, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.5
10.38	Restricted Stock Unit Award Agreement, dated as of March 18, 2021, between BioRestorative Therapies, Inc. and Lance Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.6

10.39	Restricted Stock Unit Award Agreement, dated as of March 18, 2021, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 18, 2020, wherein such document is identified as Exhibit 99.7
14	Code of Ethics, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2011, wherein such document is identified as Exhibit 14
21	Subsidiaries, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 21
23.1	Independent Registered Public Accounting Firm's Consent**
23.2	Consent of Certilman Balin Adler & Hyman, LLP (included in the opinion of Certilman Balin Adler & Hyman filed as Exhibit 5.1)*
24.1	Power of Attorney (included on signature page)
101.INS	XBRL Instance Document **
101.SCH	XBRL Schema Document **
101.CAL	XBRL Calculation Linkbase Document**
101.DEF	XBRL Definition Linkbase Document**
101.LAB	XBRL Label Linkbase Document**
101.PRE	XBRL Presentation Linkbase Document**

* To be filed by amendment
** Filed herewith

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, *however*, that paragraphs (1)(i), (ii) and (iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) if the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) if the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) That:

(i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the County of Suffolk, State of New York, on August 6, 2021.

BIORESTORATIVE THERAPIES, INC.

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

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints, jointly and severally, Lance Alstodt, as his attorney-in-fact, with full power of substitution, for him in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and any and all registration statements filed pursuant to Rule 462 under the Securities Act of 1933, as amended, in connection with or related to the offering contemplated by this registration statement and its amendments, if any, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorney to any and all amendments to this registration statement.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities indicated as of August 6, 2021.

Signature	Capacity
/s/ Lance Alstodt Lance Alstodt	Chief Executive Officer, President, Chairman of the Board and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)
/s/ Francisco Silva Francisco Silva	Vice President, Research and Development, Secretary and Director
/s/ Nickolay Kukekov Nickolay Kukekov	Director

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement on Form S-1 of our report dated April 29, 2021, with respect to the consolidated financial statements of BioRestorative Therapies, Inc. as of December 31, 2020 and 2019, and for the years then ended. We also consent to the reference to our firm under the heading "Experts" in this Registration Statement.

/s/ Friedman LLP

Marlton, New Jersey
August 6, 2021