Registration No. 333-231079

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### **AMENDMENT NO. 1**

### TO

### FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

### **BIORESTORATIVE THERAPIES, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 8099 (Primary Standard Industrial Classification Code Number) 91-1835664 (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)

Mark Weinreb, 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)

Copies to:

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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	[X]

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**

	Proposed Maximum Aggregate	Amount of
Title of Each Class of Securities to be Registered	Offering Price <sup>(1)</sup>	<b>Registration Fee</b>

Units consisting of shares of Common Stock, par value \$0.001 per share, and Warrants to		
purchase shares of Common Stock, par value \$0.001 per share (2)	\$ 13,800,000	\$ 1,672.56
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	\$ -
Underwriter's Warrants to purchase Common Stock (3)	\$ -	\$ -
Shares of Common Stock issuable upon exercise of the Warrants (4)(5)	\$ 17,250,000	\$ 2,090.70
Shares of Common Stock issuable upon exercise of Underwriter's Warrants (5)(6)	\$ 862,500	\$ 104.54
TOTAL REGISTRATION FEE	\$ 31,912,500	\$ 3,867.80(7)

(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 of 1933, as amended, because the shares of the registrant's common stock underlying the Warrants and Underwriter Warrants are registered hereby, no separate registration fee is required with respect to the warrants registered hereby.
- (4) There will be issued one warrant to purchase one share of common stock for every share of common stock offered. The warrants are exercisable at a per share price of 125% of the Unit 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 125% 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 Underwriter's Warrants is \$862,500, which is equal to 125% of \$690,000 (5% of \$13,800,000).

(7) \$2,369.46 of which previously paid.

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 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 SEPTEMBER 6, 2019



41,379,310 Units Each Unit Consisting of One Share of Common Stock (par value \$0.001) and One Warrant to Purchase One Share of Common Stock

This is a firm commitment public offering of 41,379,310 Units, each Unit consisting of one share of common stock, \$0.001 par value per share, and one warrant to purchase one share of common stock of BioRestorative Therapies, Inc., a Delaware corporation. Each warrant is immediately exercisable for one share of common stock at an exercise price of \$0.3625 per share (or 125% of the price of each Unit sold in this offering) and will expire three years from the date of issuance.

Our common stock is presently traded on the OTCQB market, operated by OTC Markets Group, 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. We believe that, upon completion of this offering contemplated by this prospectus, we will meet the standards for listing on the Nasdaq Capital Market. No assurance can be given that our application will be approved. On August 30, 2019, the last reported sales price for our common stock, as quoted on the OTCQB market, was \$0.29 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 of not less than 1-for-2 and not more than 1-for-20 to occur concurrently with 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 underwriters in the form of warrants to purchase up to 2,379,310 shares of common stock (assuming the underwriters' overallotment option is fully exercised) at an exercise price equal to 125% of the public offering price. We have also agreed to reimburse the underwriters for certain expenses. With respect to investors introduced to the underwriters by us, (a) the underwriting discount will be 5% instead of 7.5% and (b) the number of shares issuable pursuant to the warrant to be issued to the underwriters shall be 2.5% of the number of shares issued pursuant to the offering, instead of 5%. The above table assumes the full 7.5% underwriting discount with respect to all offering proceeds. We have also agreed to pay to the underwriters the amount of \$270,000 (5% of the net proceeds of \$5,400,000 to be received from Arena Investors LP pursuant to the securities purchase agreement described in "Prospectus Summary – Arena Investors Financing"). See "Underwriting" on page 119 of this prospectus for a description of these arrangements.
- (2) We estimate the total expenses of this offering will be approximately \$500,000. 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 6,206,897 additional Units at the initial public offering price, less applicable underwriting discounts. See "Underwriting" on page 119 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 , 2019.

Sole Book-Running Manager

**Maxim Group LLC** 

Co-Manager

Joseph Gunnar & Co., LLC

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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*, the *Dragonfly Logo*, *brtxDISC*, *ThermoStem*, *Stem Cellutrition*, *Stem Pearls* and *Stem the Tides of Time*. The Dragonfly Logo is also registered with the U.S. Copyright Office. This 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 <sup>TM</sup> 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 warrant to be issued to the underwriters of this offering, referred to as the Underwriter Warrants.

The share and per share information in this prospectus do not give effect to a contemplated reverse split of the outstanding common stock at a ratio of not less than 1-for-2 and not more than 1-for-20 to occur concurrently with 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 ("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. 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 Investigational New Drug ("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 the fourth quarter of 2019 (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 ("BADSC") to generate brown adipose tissue ("BAT"). We refer to this as our *ThermoStem Program*. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning, as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. See "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. In addition to raising approximately \$43,000,000 in equity and debt financings since inception, 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 ("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 biotechnology expertise.

• 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 a Clinical Director of our *Disc/Spine Program* who is a Director of Interventional and Endovascular Neurosurgery at George Washington University Medical Center.

- 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.

• We have 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 ("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.
- 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 have 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.

• We have entered into a services agreement with the University of Utah pursuant to which the university is to provide research services with regard to our *ThermoStem Program*.

• United States patents related to the *ThermoStem Program* were issued in September 2015 and January 2019, an Australian patent related to the *ThermoStem Program* was issued in April 2017 and a Japanese patent related to the *ThermoStem Program* was issued in December 2017.

#### Key Risks and Uncertainties

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

• We have a very limited operating history; we have incurred substantial losses since inception; we expect to continue to incur losses for the near term; we have a substantial working capital deficiency and a stockholders' deficiency; and the report of our independent registered public accounting firm contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

• 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 third quarter of 2019 and through the end of 2020, we have the following goals:

- Third quarter of 2019
  - Enter into contracts with a CRO and CMO
  - Initiate pre-clinical animal study for our metabolic program
  - Issuance of new patents relating to our metabolic program
- Fourth quarter of 2019
  - Obtain product manufacturing clearance
  - 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
  - Establish clinical sites for our BRTX-100 clinical trial
  - Have data published from the pre-clinical animal study for our metabolic program
- 2020
  - Have the first patient treated in the clinical trial
  - 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 ("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 OTCQB market ("OTCQB"). 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.

#### **Arena Investors Financing**

On July 26, 2019, we entered into a Securities Purchase Agreement (the "Arena Purchase Agreement") with Arena Investors LP ("Arena") pursuant to which Arena has agreed to acquire 5,500,000 shares of our Series A preferred stock, par value \$0.01 per share, a warrant (the "Arena Warrant") for the purchase of 6,000,000 shares of our common stock and a convertible promissory note in the principal amount of \$500,000 (the "Arena Note") in consideration of a payment by Arena to us of an aggregate of \$5,400,000. We have also agreed to pay to the underwriters the amount of \$270,000 (5% of the net proceeds of \$5,400,000 to be received from Arena pursuant to the Arena Purchase Agreement"). The closing of the Arena Purchase Agreement is subject to, among other things, approval by our stockholders of the Arena Purchase Agreement and the transactions contemplated thereby, the concurrent execution of an underwriting agreement with respect to our shares of common stock. On August 30, 2019, our stockholders approved the Arena Purchase Agreement and the transactions contemplated thereby.

The shares of Series A preferred stock will be convertible, at the option of Arena, into shares of our common stock at a conversion price generally equal to \$0.2175 per share, being 75% of the public offering price for the Units being offered by this prospectus, based upon an assumed offering price of \$0.29 per Unit, except that, with respect to any shares of Series A preferred stock that are outstanding as of the 18 month anniversary of the closing date of the Arena Purchase Agreement (or earlier under certain circumstances), the conversion price will be, if lower, 85% of the market price of the shares of our common stock as of such anniversary date (or such earlier date) (but in no event less than \$0.10 per share). The shares of Series A preferred stock will carry a 12% cumulative dividend and will be redeemable at our option, subject to certain conditions, provided that we pay a redemption premium of 25%. In the event of our liquidation, dissolution or winding-up, the holders of the Series A preferred stock will be entitled to receive the stated value of the shares (\$5,500,000, if all such shares are then outstanding), plus any accrued and unpaid dividends, before any distribution is made to the holders of common stock or other junior securities. Except as required by law, the holders of the Series A preferred stock will not have any voting rights.

The Arena Warrant will be exercisable for a period of three years at an exercise price per share generally equal to the lesser of (i) \$0.271875, being 125% of the conversion price for the shares of Series A preferred stock, or (ii) \$0.3625, being the exercise price of the warrants included as part of the Units being offered by this prospectus (the "Public Warrants") based upon an assumed offering price of \$0.29 per Unit. In the event the ratio of the number of shares of common stock issuable pursuant to the Public Warrants to the number of shares of common stock included as part of the Units being offered by this prospectus is greater than one-to-one, then the number of shares of our common stock underlying the Arena Warrant will be proportionately increased. Arena will be able to exercise the Arena Warrant on a cashless basis if, as of the six month anniversary of the closing date, the shares of common stock underlying the Arena Warrant are not then registered for resale pursuant to an effective registration statement filed with the Securities and Exchange Commission (the "SEC").

The Arena Note will provide for an 18 month maturity date (subject to extension in the event any shares of Series A preferred stock are outstanding as of such date) and interest at the rate of 12% per annum. The principal amount of the Arena Note will be convertible into shares of our Series A preferred stock at a ratio of one share of Series A preferred stock for each dollar of indebtedness converted. We will have the right to prepay the Arena Note, subject to certain conditions, provided that we pay a 30% prepayment premium and concurrently redeem any outstanding shares of Series A preferred stock. The payment of the Arena Note will be secured by the grant by us of a security interest in our tangible and intangible assets.

In connection with the Arena Purchase Agreement, we will enter into a separate registration rights agreement with Arena at the closing pursuant to which we will agree to undertake to file a registration statement with the SEC to register the resale of the shares of common stock underlying the Series A preferred stock and the Arena Warrant. Arena has agreed to enter into a lock-up agreement with the representative of the underwriters pursuant to which it will agree that it will not sell publicly any shares of our common stock for a period of 135 days following the date of this prospectus unless the closing price of the shares of our common stock equals or exceeds, for a period of five consecutive trading days, 150% of the public offering price for the Units being offered by this prospectus. If we fail to file the registration statement with the SEC within 50 days following the date of this prospectus or have it declared effective by the SEC within 135 days following the date of this prospectus, or if we fail to maintain the effectiveness of the registration statement until all of such shares of common stock have been sold or are otherwise able to be sold pursuant to Rule 144 under the Securities Act of 1933, as amended, without any volume or manner of sale restrictions, then we will be obligated to pay to Arena liquidated damages equal to 1% per month of the aggregate amount paid by Arena for its securities (subject to an 8% cap), until such events are satisfied.

In addition, we intend to use the \$5,130,000 net proceeds from the Arena financing (net of the amount payable to the underwriters as described under "Underwriting") to repay indebtedness (as of the date of this prospectus, our outstanding debt is \$8,098,981, and such debt is repayable, with interest at rates ranging between 8% and 15% per annum, on various dates through August 2020).

#### **Exchange of Outstanding Debt**

Pursuant to agreements entered into between us and the holders of \$2,140,000 principal amount of indebtedness, such holders have agreed that, concurrently with this offering (generally upon the execution of the underwriting agreement for this offering), such principal amount of indebtedness, together with accrued interest thereon, will automatically be exchanged for shares of common stock and warrants, as described below, at an exchange price generally equal to \$0.2175 per share, being 75% of the initial public offering price for the Units being offered by this prospectus based upon an assumed offering price of \$0.29 per Unit (or between \$0.50 and \$0.60 per share, depending upon the debtholder, if less). The number of shares of common stock issuable pursuant to the warrants to be issued to the debtholders will be, depending upon the debtholder, either (i) equal to the number of shares of common stock issued upon exchange of the principal amount of the Units being offered by this prospectus. The exercise price of the warrants issued to the debtholders will be 125% of the exchange price for the indebtedness (or between \$0.75 and \$0.80 per share, depending upon the debtholder, if less). The term of such warrants will be the same as the term of the warrants included as part of the Units being offered by this prospectus or five years, depending upon the debtholder.

Each of the debtholders has agreed to enter into a lock-up agreement with the representative of the underwriters pursuant to which it will agree that it will not sell publicly any shares of common stock for a period of 135 days following the date of this prospectus unless the closing price of our shares of common stock equals or exceeds, for a period of five consecutive trading days, 150% of the public offering price of the Units being offered in this offering.

Included as debtholders who will be exchanging indebtedness for shares of common stock and warrants as discussed above are John M. Desmarais, one of our principal stockholders and directors, and Tuxis Trust, a trust for which Mr. Desmarais and his wife serve as trustees and which was established for the benefit of Mr. Desmarais's immediate family. See "Certain Relationships and Related Transactions – John M. Desmarais" for a complete description of the exchange agreements between each of Mr. Desmarais and Tuxis Trust and us.

#### **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 <u>www.biorestorative.com</u>. 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 one share of our common stock. Each warrant will have an exercise price of \$0.3625 per share (125% of the public offering price of each Unit based upon an assumed public offering price of \$0.29 per Unit), will be exercisable immediately and will expire five years from the date of issuance.
Common Stock Outstanding prior to the Offering:	22,092,708 shares
Number of Shares:	41,379,310
Number of Warrants:	41,379,310
Warrant Exercise Price:	\$0.3625 per share (125% of the public offering price of each Unit based upon an assumed public offering price of \$0.29 per Unit)
Common Stock to be Outstanding after the Offering:	75,051,459 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 22,092,708 shares of our common stock outstanding as of August 28, 2019, and includes 11,579,441 shares of common stock issuable upon the exchange of outstanding debt that is to occur concurrently with this offering, as discussed above under "Prospectus Summary – Exchange of Outstanding Debt" but excludes the following:
	<ul> <li>4,739,535 shares of common stock (net of cancellations) issuable upon the exercise of outstanding options granted under our 2010 Equity Participation Plan (the "Plan") as of August 28, 2019, with a weighted average exercise price per share of \$1.04;</li> <li>15,215,465 shares of common stock that are available for future issuance under the Plan as of August 28, 2019;</li> <li>5,811,224 shares of common stock issuable upon the exercise of outstanding warrants as of August 28, 2019, with a weighted average exercise price per share of \$2.29;</li> <li>10,464,259 shares of common stock issuable upon the conversion of outstanding convertible promissory notes that are convertible as of August 28, 2019, with a weighted average conversion price per share of \$1.00, plus an indeterminate number of shares of common stock issuable upon the conversion price per share of \$1.00, plus an indeterminate number of shares of common stock issuable upon the conversion of outstanding convertible promissory notes that are not convertible as of August 28, 2019 and provide for conversion prices based upon the market value of our common stock at the time of conversion;</li> <li>41,379,310 shares of common stock issuable upon the exercise of the warrants issuable upon the exchange of outstanding debt that is to occur concurrently with this offering, as discussed above under "Prospectus Summary – Exchange of Outstanding Debt"; and</li> <li>33,586,207 shares of common stock issuable upon the conversion of shares of Series A preferred stock and a convertible promissory note, and the exercise of warrants, being issued to Arena concurrently with this offering, as discussed above under "Prospectus Summary – Arena Investors Financing".</li> </ul>

Underwriters' Over-Allotment Option:	The underwriting agreement provides that we will grant to the underwriters an option, exercisable within 45 days after the closing of this offering, 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 \$10,600,000 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 <i>BRTX-100</i> and its related collection and delivery procedure; pre- clinical research and development with respect to our <i>ThermoStem Program</i> ; repayment of indebtedness; 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:	\$0.29 per Unit.
Trading Symbol:	Our common stock is presently quoted on the OTCQB market 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.
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, officers and principal stockholders 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. Arena and certain debtholders have also agreed to enter into lock-up agreements with the underwriters, as discussed in "Prospectus Summary – Arena Investors Financing" and "Prospectus Summary – Exchange of Outstanding Debt". See "Underwriting" on page 119.
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#### **Summary Financial Data**

The following table sets forth summary consolidated financial data of BioRestorative Therapies, Inc. The financial data as of June 30, 2019 and for the six months ended June 30, 2019 and 2018 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, 2018 and 2017 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 Six Months Ended June 30,				For The Years Ended December 31,				
		2019 2018				2018 20			
		(unau	dited)						
Revenues	\$	60,000	\$	56,000	\$	111,000	\$	81,000	
Operating Expenses									
Marketing and promotion		124,686		58,554		352,204		65,455	
Consulting		1,133,607		850,884		1,870,829		2,334,212	
Research and development		896,729		779,945		1,513,150		2,152,433	
General and administrative		2,362,118		2,647,690		4,022,469		3,903,184	
Total Operating Expenses		4,517,140		4,337,073		7,758,652		8,455,284	
Loss From Operations		(4,457,140)		(4,281,073)		7,647,652)		(8,374,284)	
Other Expense									
Interest expense		(644,911)		(391,642)		(932,187)		(468,107)	
Amortization of debt discount		(1,734,403)		(1,343,628)	(	2,289,591)		(619,266)	
Loss on extinguishment of notes payable, net		(1,000,595)		(63,788)	(	1,415,950)		(59,938)	
Change in fair value of derivative liabilities		(203,313)		58,048	(	(229,323)		107,039	
Warrant modification expense		(200,010)				(3,100)		(30,099)	
Total Other Expense		(3,583,222)		(1,741,010)	(	4,870,151)		(1,070,371)	
Net Loss	\$		\$	(1,741,010) (6.022.083)			\$		
Net Loss	2	(8,040,362)	\$	(6,022,083)	<u>\$ (1</u>	2,517,803)	\$	(9,444,655)	
Net Loss Per Share									
- Basic and Diluted	\$	(0.52)	\$	(0.93)	\$	(1.64)	\$	(1.74)	
	φ	(0.32)	Ψ	(0.55)	Ψ	(1.01)	Ψ	(1.71)	
Weighted Average Number of Common Shares Outstanding									
- Basic and Diluted		15,599,172		6,485,069		7,630,112		5,422,389	
					Decem	ber 31,			
			ne 30, 2019	_	2018	2	2017		
Balance Sheet Data:		(u	naudited)						
Dalance Sheet Data.									
Cash		\$	1,283,66	6 \$	117,523	\$	451,680		
Working capital deficiency		\$	(9,786,14	4) \$	(9,073,901)	\$	(7,833,592)		
Total assets		\$	2,432,07	9 \$	1,192,381	\$	1,758,607		
Total liabilities		\$	11,374,55		9,833,419	\$	8,595,175		
Total stockholders' deficiency		\$	(8,942,47	1) \$	(8,641,038)	\$	(6,836,568)		
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#### **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; we have a substantial working capital deficiency and a stockholders' deficiency; we believe these conditions indicate that there is substantial doubt about our ability to continue as a going concern within the next twelve months from the date of this prospectus; the report of our independent registered public accounting firm contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

We have a limited operating history. Since our inception, we have incurred net losses. As of June 30, 2019, we had a working capital deficiency of \$9,786,144 and stockholders' deficiency of \$8,942,471. The report of our independent registered public accounting firm with respect to our financial statements as of December 31, 2018 and 2017 and for the years then ended indicates that our financial statements have been prepared assuming that we will continue as a going concern. The report states that, since we have incurred net losses since inception and we need to raise additional funds to meet our obligations and sustain our operations, there is substantial doubt about our ability to continue as a going concern. Our plans in regard to these matters are described in footnote 2 to our audited financial statements as of December 31, 2018 and 2017 and for the years then ended, which are included in this prospectus. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

Since our inception, we have not generated significant revenues from our operations and have funded our operations through the sale of our equity securities (approximately \$16,000,000) and debt securities (approximately \$27,000,000). 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, retire our outstanding debt and otherwise fund our operations. We anticipate that we will require approximately \$20,000,000 in financing to commence and 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 if we determine to establish a manufacturing operation with regard to our *Disc/Spine Program* (as opposed to utilizing a third party manufacturer) and to implement our other programs described in this prospectus under the caption "Business," including our metabolic *ThermoStem Program*. 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 will need to obtain additional financing to satisfy debt obligations.

As described in this prospectus under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Availability of Additional Funds," as of June 30, 2019, our outstanding debt of \$7,759,967, together with interest at rates ranging between 8% and 15% per annum, was due on various dates through June 2020. Subsequent to June 30, 2019, we have received aggregate debt financings of \$1,666,000, debt (inclusive of accrued interest) of \$339,480 has been exchanged for common stock, and \$1,644,778 of debt (inclusive of accrued interest and prepayment premiums) has been repaid, and the due date for the repayment of \$1,053,102 of debt has been extended to dates between July 2019 and July 2020. Giving effect to the above actions, we currently have notes payable in the aggregate principal amount of \$144,000 which are past due. As of the date of this prospectus, the outstanding balance of our debt of \$8,098,981, together with accrued interest, was due and payable either on demand or on various dates through August 2020. We intend to use a portion of the net proceeds of this offering to repay debt (see "Use of Proceeds"). Unless we obtain additional financing or, upon our request, debtholders agree to convert their debt into equity or extend the maturity dates of the remaining debt. Based upon our working capital deficiency and outstanding debt, prior to the receipt of any proceeds from this offering, we expect to be able to fund our operations through September 2019 while we continue to apply efforts to raise additional capital. Even if we are able to satisfy our debt obligations, our cash balance and the revenues for the foreseeable future from our anticipated operations will not be sufficient to fund the development of our business plan.

#### Certain of our notes payable are past due. Such circumstance could trigger the acceleration of the due date of other debt obligations.

As of the date of this prospectus, we currently have notes payable in the aggregate amount of \$144,000 which are past due. Such circumstance could trigger the acceleration of the due date of other outstanding debt obligations which could require us to satisfy such debt obligations earlier than the specified respective maturity dates. In such event, we may be required to use funds for such purpose and not for business operations.

#### Our business strategy is high risk.

We are focusing our resources and efforts primarily on the development of cellular-based products and services which will require extensive cash for research, development and commercialization activities. This is a high-risk strategy because there is no assurance that our products and services, including our *Disc/Spine Program* and our *ThermoStem* metabolic brown fat research initiative, will ever become commercially viable (commercial risk), that we will prevent other companies from depriving us of market share and profit margins by offering services and products based on our inventions and developments (legal risk), that we will successfully manage a company in a new area of business, regenerative medicine, and on a different scale than we have operated in the past (operational risk), that we will be able to achieve the desired therapeutic results using stem and regenerative cells (scientific risk), or that our cash resources will be adequate to develop our products and services until we become profitable, if ever (financial risk). We are using our cash in one of the riskiest industries in the economy (strategic risk). This may make our securities an unsuitable investment for many investors.

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

Except for a certain license agreement with Regenerative Sciences, LLC described in this prospectus under the caption "Business – Disc/Spine Program - License," we do not have any material agreements or understandings in place with respect to the implementation of our business strategy. No assurances can be given that we will be able to enter into any necessary agreements with respect to the development of our business. Our inability to enter into any such agreements would have a material adverse effect on our results of operations and financial condition.

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

Our performance is substantially dependent on the performance of Mark Weinreb, our Chief Executive Officer. We rely upon him for strategic business decisions and guidance. Mr. Weinreb is subject to an employment agreement with us that is scheduled to expire on December 31, 2019. We are also dependent on the performance of Lance Alstodt, our Executive Vice President and Chief Strategy Officer, and Francisco Silva, our Vice President of Research and Development. Messrs. Alstodt and Silva are also subject to employment agreements with us. We do not have any key-man insurance policies on the lives of any of our executive officers. We do not currently have a Chief Financial Officer. Pending the hiring of a Chief Financial Officer, we are utilizing financial consultants with regard to the preparation of our financial statements. We believe that our future success in developing marketable products and services and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel, including a Chief Financial Officer. Competition for such personnel is intense, and there can be no assurance that we will be able to attract and retain such personnel. The loss of the services of Mr. Weinreb, Mr. Alstodt and/or Mr. Silva or the inability to attract and retain additional personnel, including a Chief Financial Officer, and negative effect on our results of operations and financial condition.

#### **<u>Risks Related to Our Cell Therapy Product Development Efforts</u>**

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

We are dependent upon the successful development, approval and commercialization of our product candidates. Before we are able to seek regulatory approval of our product candidates, we must conduct and complete extensive clinical trials to demonstrate their safety and efficacy in humans. Our lead product candidate, *BRTX-100*, is in early stages of development and we only recently received Food and Drug Administration (the "FDA") clearance to commence a Phase 2 clinical trial using *BRTX-100* to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs.

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

- suspensions, delays or changes in the design, initiation, enrollment, implementation or completion of required clinical trials; adverse changes in our financial
  position or significant and unexpected increases in the cost of our clinical development program; changes or uncertainties in, or additions to, the regulatory
  approval process that require us to alter our current development strategy; clinical trial results that are negative, inconclusive or less than desired as to safety
  and/or efficacy, which could result in the need for additional clinical studies or the termination of the product's development; delays in our ability to manufacture
  the product in quantities or in a form that is suitable for any required clinical trials;
- intellectual property constraints that prevent us from making, using, or commercializing any of our cell therapy product candidates;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of these product candidates may be insufficient or inadequate; 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 contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board ("IRB") approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors or approved products post-market for related technology that raise FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's current Good Clinical Practices ("GCP") requirements, or applicable regulatory guidelines in other countries;

- delays in having patients qualify for or complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- transfer of manufacturing processes from any academic collaborators to larger-scale facilities operated by either a contract manufacturing organization ("CMO") or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing;
- the FDA may not accept clinical data from trials that are conducted at clinical sites in countries where the standard of care is potentially different from the United States; and
- failure to raise sufficient funds to complete our clinical trials.

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

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

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

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

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

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

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

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

We have not commenced the clinical trials necessary to obtain FDA approval to market our product candidate, *BRTX-100*, or any of our other product candidates in development. Since our management lacks significant experience in completing clinical trials and bringing a drug through commercialization, we have hired outside consultants with such experience. Clinical trials for *BRTX-100* and other product candidates in development may be delayed or terminated as a result of many factors, including the following:

- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons;
- failure by regulators to authorize us to commence a clinical trial;
- suspension or termination by regulators of clinical research for many reasons, including concerns about patient safety, the failure of study sites and/or investigators
  in our clinical research program to comply with GCP requirements, or our failure, or the failure of our contract manufacturers, to comply with current cGMP
  requirements;
- delays or failure to obtain clinical supply for our products necessary to conduct clinical trials from contract manufacturers;
- treatment candidates demonstrating a lack of efficacy during clinical trials;
- treatment candidates demonstrating significant safety signals; and/or
- inability to continue to fund clinical trials or to find a partner to fund the clinical trials.

Any delay or failure to complete clinical trials and obtain FDA approval for our product candidates could have a material adverse effect on our cost to develop and commercialize, and our ability to generate revenue from, a particular product candidate.

#### The development of our cell therapy product candidates is subject to uncertainty because autologous cell therapy is inherently variable.

When manufacturing an autologous cell therapy, the number and composition of the cell population varies from patient to patient. Such variability in the number and composition of these cells could adversely affect our ability to manufacture autologous cell therapies in a cost-effective or profitable manner and meet acceptable product release specifications for use in a clinical trial or, if approved, for commercial sale. As a consequence, the development and regulatory approval process for autologous cell therapy products could be delayed or may never be completed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pursuant to our license agreement with Regenerative Sciences, LLC, we must complete our Phase 2 clinical trial by a certain date (which we believe to be February 2022) in order to maintain our exclusive rights with regard to the disc/spine technology. No assurances can be given that we will 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.

## Ethical and other concerns surrounding the use of stem cell therapy may negatively impact the public perception of our stem cell products and/or services, thereby suppressing demand for our products and/or services.

Although our contemplated stem cell business pertains to adult stem cells only, and does not involve the more controversial use of embryonic stem cells, the use of adult human stem cells for therapy could give rise to similar ethical, legal and social issues as those associated with embryonic stem cells, which could adversely affect its acceptance by consumers and medical practitioners. Additionally, it is possible that our business could be negatively impacted by any stigma associated with the use of embryonic stem cells if the public fails to appreciate the distinction between adult and embryonic stem cells. Delays in achieving public acceptance may materially and adversely affect the results of our operations and profitability.

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

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

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

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

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

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

The enactment of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated regulatory pathway for the approval of products demonstrated to be biosimilar, or "highly similar," to or "interchangeable" with an FDA-approved innovator (original) biologic product. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a biologics license application ("BLA"). Although the FDA has approved several biosimilar products, complex provisions of the law are still being implemented by the FDA and interpreted by the federal courts. As a result, the ultimate impact, implementation, and meaning of the BPCIA are still subject to some uncertainty and FDA actions and court decisions concerning the law could have a material adverse effect on the future commercial prospects for our biological products.

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

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

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

# We may be subject to significant product liability claims and litigation, including potential exposure from the use of our product candidates in human subjects, and our insurance may be inadequate to cover claims that may arise.

Our business exposes us to potential product liability risks inherent in the testing, processing and marketing of cell therapy products. Such liability claims may be expensive to defend and result in large judgments against us. We face an inherent risk of product liability exposure related to the testing of our current and any future product candidates in human clinical trials and will face an even greater risk with respect to any commercial sales of our products should they be approved. No product candidate has been widely used over an extended period of time, and therefore safety data is limited. Cell therapy companies derive the raw materials for manufacturing of product candidates from human cell sources, and therefore the manufacturing process and handling requirements are extensive, which increases the risk of quality failures and subsequent product liability claims.

We will need to maintain insurance coverage adequate to cover our clinical trials and increase that coverage before commercializing product candidates, if ever. At any time during our clinical trials or after commercialization, if that occurs, we may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all, or if claims against us substantially exceed our coverage, then our financial position could be significantly impaired.

Whether or not we are ultimately successful in any product liability litigation that may arise, such litigation could consume substantial amounts of our financial and managerial resources, result in decreased demand for our products and injure our reputation.

We seek to maintain errors and omissions, directors and officers, workers' compensation and other insurance at levels we believe to be appropriate to our business activities. If, however, we were subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our own limited resources, which could have a material adverse effect on our financial condition, results of operations and business. Additionally, liability or alleged liability could harm our business by diverting the attention and resources of our management and damaging our reputation.

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

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

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

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

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

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

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

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

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

#### **Risks Related to Our Intellectual Property**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### **Risks Related to Government Regulation**

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

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

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

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

- issue a warning or untitled letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- · seize or detain the product or otherwise demand or require the withdrawal or recall of the product from the market;
- refuse to permit the import or export of products;

- request and publicize a voluntary recall of the product; or
- refuse to allow us to enter into supply contracts, including government contracts.

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

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

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

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

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

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

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

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

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

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

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

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

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

To date, we have not received regulatory approval to market any of our product candidates in any jurisdiction. If we seek approval of any of our cell therapy product candidates, we will be required to submit to the FDA and potentially other regulatory authorities extensive pre-clinical and clinical data supporting its safety and efficacy, as well as information about the manufacturing process and to undergo inspection of our manufacturing facility or other contract manufacturing facilities, 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 has 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.

## There is at present only a limited market for our common stock, there is no market for our warrants and there is no assurance that an active trading market for our securities will develop.

Although our common stock is quoted on the OTCQB from time to time, the market for our common stock is extremely limited. 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 shares and 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 honor firm quotations for only a limited number of securities, and are free to withdraw firm quotations at any time. Even with a market for our securities developing in the foreseeable future. Even if a market develops, we cannot assure that a market will continue, or 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 ("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 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 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. Our issuance of additional shares of common stock in the future will dilute the ownership interests of our then existing stockholders.

We have effective registration statements on Form S-8 under the Securities Act registering an aggregate of 20,000,000 shares of our common stock issuable under our 2010 Equity Participation Plan (the "Plan"). As of August 28, 2019, options to purchase 4,739,535 shares of our common stock were outstanding under the Plan. In addition, as of such date, 45,000 shares of common stock were issued as restricted stock pursuant to the Plan and 15,215,465 shares were reserved for future grants under the Plan. 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.

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 equityrelated 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. See "Prospectus Offering – Arena Investors Financing" for a discussion of an agreement with Arena pursuant to which we are issuing shares of Series A preferred stock concurrently with this offering.

## Our principal stockholders currently own a substantial number of shares of our common stock and have the power to significantly influence the vote on all matters submitted to a vote of our stockholders.

As of August 28, 2019, Dale Broadrick beneficially owned 5,725,640 shares of our common stock (including 2,111,111 shares of our common stock issuable pursuant to a currently exercisable warrant), representing 23.7% of the outstanding shares of our common stock. In addition, as of August 28, 2019, SCG Capital, LLC ("SCG") and Steven Geduld beneficially owned 2,231,853 shares of common stock (including 248,162 shares of our common stock issuable pursuant to a currently convertible note), representing 9.99% of the outstanding shares of our common stock. Further as of August 28, 2019, John M. Desmarais, one of our directors, beneficially owned 2,071,240 shares of our common stock (including 1,577,842 shares of our common stock issuable pursuant to currently exercisable options and warrants, but excluding the shares of common stock issuable to him and Tuxis Trust concurrently with this offering in exchange for outstanding indebtedness, as described under "Certain Relationships and Related Transactions – John M. Desmarais"), representing 8.8% of the outstanding shares of our common stock. Moreover, as of August 28, 2019, Westbury (Bermuda), Ltd. ("Westbury") beneficially owned 1,151,661 shares of our common stock (including 199,182 shares of our common stock issuable pursuant to currently exercisable warrants), representing 5.2% of the outstanding shares of our common stock issuable pursuant to currently exercisable warrants), representing 5.2% of the outstanding shares of our common stock issuable pursuant to currently exercisable warrants), representing 5.2% of the outstanding shares of our common stock issuable pursuant to currently exercisable warrants), representing 5.2% of the outstanding shares of our common stock issuable pursuant to currently exercisable warrants), representing 5.2% of the outstanding shares of our common stock.

In addition, as described under "Prospectus Summary – Arena Investors Financing", concurrently with this offering, we will be issuing to Arena 5,500,000 shares of Series A preferred stock, warrants to purchase 6,000,000 shares of common stock (subject to adjustment as described in such section) and a \$500,000 convertible promissory note. The principal amount of the note will be convertible into 500,000 shares of Series A preferred stock. The Series A preferred stock is convertible into common stock at a conversion price equal to 75% of the public offering price for the Units offered pursuant to this prospectus (subject to reset as described in such section). The Series A preferred stock (including the 500,000 shares of Series A preferred stock issuable upon conversion of the principal amount of the Arena convertible promissory note) will be convertible into an aggregate of 27,586,207 shares of common stock, assuming a public offering price of \$0.29 per Unit, and the warrants will be exercisable for the purchase of 6,000,000 shares of common stock (giving effect to the offering being made pursuant to this prospectus and the debt exchange discussed under "Prospectus Summary – Exchange of Outstanding Debt").

Mr. Broadrick, Mr. Desmarais, SCG/Mr. Geduld, Westbury and Arena, through their beneficial ownership of our common stock, will have the power to significantly influence the vote on all matters submitted to a vote of our stockholders, including the election of directors, amendments to our certificate of incorporation or bylaws, mergers or other business combination transactions and certain sales of assets outside the usual and regular course of business. The interests of Mr. Broadrick, Mr. Desmarais, SCG/Steven Geduld, Westbury and Arena may not coincide with the interests of our other stockholders, and they could take actions that advance their own interests to the detriment of our other 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 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 securityholders 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 securityholders.

## In the event that a significant amount of our outstanding debt is converted into equity, the percentage ownership of existing stockholders will be substantially diluted.

As of the date of this prospectus, we had outstanding indebtedness in the amount of \$8,098,981. All or a significant amount of such debt may be converted into equity. In the event of any such conversion, the percentage ownership of existing stockholders will be substantially diluted.

## We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in The Jumpstart Our Business Startups Act (the "JOBS Act"). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus, our annual report on Form 10-K and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could remain as an emerging growth company until December 31, 2020, although circumstances could cause us to lose that status earlier.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation. We cannot predict whether investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and warrants and the prices for our securities may be more volatile.

#### 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 \$0.18 per share, based on the assumed public offering price of \$0.29 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 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 \$0.3625 (125% of the public offering price of the Units in this offering, assuming a public offering price of \$0.29 per Unit), prior to three 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, and, consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

## Substantial future sales of shares of our common stock in the public market could cause our stock and warrant prices to fall.

Shares of our common stock that we have issued directly or that have been issued or are issuable upon the exercise of warrants or upon the conversion of convertible debt may be covered by registration statements which permit the public sale of stock. Other holders of shares of common stock that we have issued, including shares issuable upon the exercise of warrants and the conversion of convertible debt, may be entitled to dispose of their shares subject to the requirements of Rule 144 or other applicable exemption from registration under the Securities Act. The lock-up agreements, which our officers, directors and principal stockholders will be entering into with the underwriters, expire six months after the closing of this offering. Upon the expiration of those lock-up agreements, the outstanding shares of common stock covered by such agreements will become eligible for resale in the open market (subject to Rule 144 volume limitations applicable to executive officers, directors and other affiliates), resulting in more shares eligible for sale and 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.

## We may invest or spend the proceeds from this offering in ways with which you may not agree and in ways that may not earn a profit; in the event of a default with regard to our indebtedness, we may be required to use offering proceeds to repay such debt and not for operational purposes.

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*; (iii) repayment of indebtedness; and (iv) 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, and our use of the proceeds may not yield any profits. In addition, in the event we default with regard to our indebtedness obligations, we may be required to use offering proceeds to satisfy such obligations and not with regard to our clinical trial and research and development activities. 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 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 held on May 30, 2019, in addition to the stockholders approving a reverse stock split at a ratio of not less than 1-for-2 and not more than 1-for-20, the stockholders approved, among other things, an increase in the number of shares of common stock that we will be authorized to issue from 75,000,000 to 150,000,000. Further, the stockholders approved an amendment to our Certificate of Incorporation to reduce the number of shares 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 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, or it determines not to reduce the number of authorized shares of common stock at all, 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 \$10,600,000. If the underwriters' over-allotment option is exercised in full, we estimate that our net proceeds will be approximately \$12,265,000.

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

- undertaking of clinical trials with respect to *BRTX-100* and its related collection and delivery procedure, including seeking clinical trial sites and seeking manufacturing clearance (approximately \$7,000,000);
- pre-clinical research and development with respect to our *ThermoStem Program*, including pre-clinical animal study, pre-IND meeting with the FDA, seeking new
  metabolic patents and seeking to have data published from metabolic study (approximately \$750,000);
- research and development, including preparation for Phase 3 clinical trial with respect to *BRTX-100*, and animal study and continued research and development with respect to *BRTX-100* (approximately \$250,000); and
- general corporate and working capital purposes (approximately \$2,600,000).

In the event we receive additional net proceeds of \$1,665,000 from an exercise of the underwriters' over-allotment option, we anticipate that we will use such additional proceeds for the following purposes: Phase 2 clinical trial (\$1,000,000); metabolic *ThermoStem Program* (\$100,000); research and development (\$100,000); and general corporate and working capital purposes (\$465,000).

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 June 30, 2019 (i) on an actual basis, (ii) pro forma to give retroactive effect to the transactions described in "Prospectus Summary – Arena Investors Financing" and "Prospectus Summary – Exchange of Outstanding Debt" and (iii) pro forma as adjusted to give effect to the offering at the assumed public offering price of \$0.29 per Unit, for total net proceeds of approximately \$10,600,000 (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 June 30, 2019		
	Actual		 Pro Forma(1)(2)	Pro Forma As Adjusted	
Non-Current Liabilities	\$	231,348	\$ 681,348	\$	681,348
Stockholders' (Deficiency) Equity					
Preferred stock, \$0.01 par value; 20,000,000 shares authorized, -0- shares issued and outstanding before the offering, 5,500,000 shares issued and outstanding on a pro forma basis <sup>(1)</sup> and 5,500,000 shares					
issued and outstanding on a pro forma as adjusted basis <sup>(1)</sup>	\$	-	\$ 55,000	\$	55,000
Common stock, \$0.001 par value; 150,000,000 shares authorized; 19,793,477 shares issued and outstanding before the offering; 30,846,459 shares issued and outstanding on a pro forma basis <sup>(2)</sup> and 72,225,769 shares issued and outstanding on a pro forma, as adjusted					
basis <sup>(2)</sup>		10 702	20.946		72 225
Additional paid-in capital		19,793 63,000,354	30,846 70,819,666		72,225 81,378,287
Accumulated deficit		(71,962,618)	(72,621,969)		(72,621,969)
Total stockholders' (deficiency) equity		(8,942,471)	 (1,716,457)	_	8,883,543
Total capitalization	\$	(8,711,123)	\$ (1,035,109)	\$	9,564,891

(1) Gives retroactive effect to the issuance to Arena of (a) 5,500,000 shares of Series A preferred stock and (b) a \$500,000 principal amount convertible promissory note with a \$50,000 original issue discount concurrently with this offering for aggregate net proceeds of \$5,130,000, as described in "Prospectus Summary – Arena Investors Financing."

(2) Gives retroactive effect to the exchange, concurrently with this offering, of indebtedness in the principal amount of \$2,140,000 for shares of common stock and warrants, as described in "Prospectus Summary – Exchange of Outstanding Debt" of which there was \$2,075,000 of principal and \$329,025 of accrued interest outstanding as of June 30, 2019. Also gives effect to the extinguishment of \$141,989 of derivative liabilities (related to bifurcated embedded conversions options) outstanding as of June 30, 2019 to stockholders' deficiency as a result of these exchanges.



#### 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 June 30, 2019, we had a net tangible book value (deficit) of \$(9,719,083), or \$(0.49) per share. As of June 30, 2019, we had a pro forma net tangible book value (deficit) of \$(2,493,069), or \$(0.08) per share, after giving effect to the transactions described in "Prospectus Summary – Arena Investors Financing" and "Prospectus Summary – Exchange of Outstanding Debt". The net tangible book value 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 June 30, 2019. The pro forma net tangible book value per share of common stock is determined by subtracting total pro forma liabilities from the total pro forma tangible assets and dividing the difference by the pro forma number of shares of our common stock deemed to be outstanding as of June 30, 2019. After giving effect to the sale of 41,379,310 Units offered by us in this offering at an assumed offering price of \$0.29 per Unit, which is the last reported sales price of our common stock on the OTCQB market on August 30, 2019, and the application of the estimated net proceeds from this offering, our pro forma as adjusted net tangible book value as of June 30, 2019 would have been \$\$,106,931 or \$0.11 per share. This represents an immediate increase in net tangible book value to existing stockholders of \$0.19 per share and an immediate dilution to new investors of \$0.18 per share, in each case giving effect to the transactions described in "Prospectus Summary – Arena Investors Financing" and "Prospectus Summary – Exchange of Outstanding Debt." The following table illustrates this per share dilution to new investors purchasing Units in this offering.

Assumed offering price per Unit	\$	0.29
Net tangible book value (deficit) per share as of June 30, 2019	\$ (0.49)	
Increase attributable to transactions described in "Prospectus Summary – Arena Investors Financing"	0.24	
Increase attributable to transactions described in "Prospectus Summary – Exchange of Outstanding Debt"	0.17	
Pro forma net tangible book value (deficit) per share as of June 30, 2019	(0.08)	
Increase attributable to new investors in this offering	\$ 0.19	
Pro forma, as adjusted, net tangible book value per share as of June 30, 2019 after the offering	\$	0.11
Dilution per share to new investors	\$	0.18

Each \$0.05 increase (decrease) in the assumed public offering price of \$0.29 per Unit would increase (decrease) our pro forma as adjusted net tangible book value (deficit) per share to new investors by approximately \$0.03 and (\$0.02), respectively, and would increase (decrease) dilution per share to new investors in this offering by approximately \$0.02 and (\$0.03), respectively, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated discounts and commissions and estimated offering expenses payable by us.

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 \$0.14 per share, the increase in net tangible book value per share to existing stockholders would be \$0.22 per share and the dilution to new investors purchasing Units in this offering would be \$0.15 per share.

The following table sets forth on an unaudited pro forma as adjusted basis, as of June 30, 2019, giving effect to the transactions described in "Prospectus Summary – Exchange of Outstanding Debt", 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 \$0.29 per Unit, which is the last reported sales price of our common stock on the OTCQB market on August 30, 2019, before deducting underwriting discounts and estimated offering expenses payable by us:

	Shares Purch	Shares Purchased			Total Consideration		
	Number	Percent	Amount Percent			Share	
			(in	thousands)			
Existing stockholders	30,846,466	43%	\$	42,003	78%	\$	1.36
New investors	41,379,310	57%	\$	12,000	22%	\$	0.29
Totals	72,225,769	100%	\$	54,003	100%	\$	0.75
		48					

The above discussion and table is based on 19,793,477 shares of common stock outstanding as of June 30, 2019, does not reflect the potential sale of up to 6,206,897 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:

- 3,283,205 shares of common stock issuable upon the exercise of stock options that were exercisable as of June 30, 2019 at a weighted-average exercise price of \$1.17 per share;
- 5,852,952 shares of common stock issuable upon the exercise of warrants to purchase common stock that were exercisable as of June 30, 2019 at a weighted average exercise price of \$2.41 per share;
- 15,215,465 shares available for future issuance as of June 30, 2019 under the Plan;
- 11,489,694 shares of common stock issuable upon the conversion of convertible notes that were convertible as of June 30, 2019 at a weighted average conversion price
  of \$0.82 per share (excluding the promissory note described immediately below); and
- 33,586,207 shares of common stock issuable upon the conversion of the promissory note and shares of Series A preferred stock, and the exercise of warrants, that are
  to be issued to Arena pursuant to the transactions described in "Prospectus Summary Arena Investors Financing".

To the extent that outstanding options and warrants are exercised or convertible notes are converted, 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.

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#### SELECTED FINANCIAL DATA

The following table sets forth selected consolidated financial data of BioRestorative Therapies, Inc. The financial data as of June 30, 2019 and for the six months ended June 30, 2019 and 2018 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, 2018 and 2017 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 Six M Jun	Months e 30,	Ended		For The Decer	Years En nber 31,	ded
	 2019	,	2018		2018		2017
	(unau	dited)					
Revenues	\$ 60,000	\$	56,000	\$	111,000	\$	81,000
Operating Expenses							
Marketing and promotion	124,686		58,554		352,204		65,455
Consulting	1,133,607		850,884		1,870,829		2,334,212
Research and development	896,729		779,945		1,513,150		2,152,433
General and administrative	2,362,118		2,647,690		4,022,469		3,903,184
Total Operating Expenses	4,517,140		4,337,073		7,758,652		8,455,284
Loss From Operations	 (4,457,140)		(4,281,073)		(7,647,652)		(8,374,284)
Other Expense							
Interest expense	(644,911)		(391,642)		(932,187)		(468,107)
Amortization of debt discount	(1,734,403)		(1,343,628)		(2,289,591)		(619,266)
Loss on extinguishment of notes payable, net	(1,000,595)		(63,788)		(1,415,950)		(59,938)
Change in fair value of derivative liabilities	(203,313)		(58,048)		(229,323)		107,039
Warrant modification expense	-		-		(3,100)		(30,099)
Total Other Expense	 (3,583,222)		(1,741,010)		(4,870,151)		(1,070,371)
Net Loss	\$ (8,040,362)	\$	(6,022,083)	\$	(12,517,803)	\$	(9,444,655)
		_					
Net Loss Per Share							
- Basic and Diluted	\$ (0.52)	\$	(0.93)	\$	(1.64)	\$	(1.74)
Weighted Average Number of Common Shares Outstanding							
- Basic and Diluted	 15,599,172		6,485,069		7,630,112		5,422,389
					Decembe	er 31,	
		une 30,		2	018	1	2017
Balance Sheet Data:	(	unaudi	ited)				
Duminee Sheet Data.							
Cash	\$		1,283,666 \$		117,523	\$	451,680
Working capital deficiency	\$		(9,786,144) \$		(9,073,901)	\$	(7,833,592)
Total assets	\$		2,432,079 \$		1,192,381	\$	1,758,607
Total liabilities	\$		11,374,550 \$		9,833,419	\$	8,595,175
							. ,

#### DETERMINATION OF OFFERING PRICE

\$

(8,942,471)

\$

(8,641,038)

(6,836,568)

The offering price for the Units offered by this prospectus has been negotiated between the underwriters and us. In determining such offering price, the following factors were considered:

prevailing market conditions;

Total stockholders' deficiency

- 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 OTCQB. 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 September 3, 2019, there were 299 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 subsidiaries as of June 30, 2019 and 2018 and 2018 and as of December 31, 2018 and 2017 and for the years ended December 31, 2018 and 2017 should be read in conjunction with our financial statements and the notes to those financial statements that are included elsewhere in this prospectus under "Index to Financial Statements." 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains forward-looking statements as that term is defined in the federal securities laws. The events described in forward-looking statements contained in this "Management's Discussion and Results of Operations" may not occur. Generally, these statements relate to business plans or strategies, projected or anticipated benefits from acquisitions to be made by us, or projections involving anticipated revenues, earnings or other aspects of our operating results. The words "estimate," "project," "believe," "intend," "anticipate," "expect," "target," "plan," "may" 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 the fourth quarter of 2019 (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 and January 2019, an Australian patent related to the *ThermoStem Program* was issued in December 2017.

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 June 30, 2019, our accumulated deficit was \$71,962,618, our stockholders' deficiency was \$8,942,471 and our working capital deficiency was \$9,786,144. 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. These conditions indicate that there is substantial doubt about our ability to continue as a going concern within one year after the financial statement issuance date.

Based upon our working capital deficiency as of June 30, 2019, and our forecast for continued operating losses, we require equity and/or debt financing to continue our operations. As of June 30, 2019, our outstanding debt of \$7,759,967, together with interest at rates ranging between 8% and 15% per annum, was due on various dates through June 2020. Subsequent to June 30, 2019, we have received aggregate debt financing of \$1,666,000, debt (inclusive of accrued interest) of \$389,480 has been exchanged for common stock, and \$1,644,778 of debt (inclusive of accrued interest and prepayment premiums) has been repaid. Giving effect to the above actions, we currently have notes payable in the aggregate principal amount of \$144,000 which are past due. Based upon our working capital deficiency and outstanding debt, prior to the receipt of any proceeds from this offering, we expect to be able to fund our operations through September 2019 while we continue to apply efforts to raise additional capital. We anticipate that we will require approximately \$20,000,000 in financing to commence and complete a Phase 2 clinical trial with regard to our Disc/Spine Program. We anticipate that we will require 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 if we determine to establish a manufacturing operation with regard to our Disc/Spine Program. No assurance can be given that the anticipated amounts of required funding are correct or that we will be able to accomplish our goals within the timeframes projected. In addition, no assurance can be given that we will be able to obtain any required financing on commercially reasonable terms or otherwise.

We are currently seeking several different financing alternatives to support our future operations and are currently in the process of negotiating extensions or discussing conversions to equity with respect to our outstanding indebtedness. If we are unable to obtain such additional financing on a timely basis or, notwithstanding any request we may make, our debtholders do not agree to convert their notes into equity or extend the maturity dates of their notes, we may have to curtail our development, marketing and promotional activities, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately we could be forced to discontinue our operations and liquidate. See "Liquidity and Capital Resources" below.

Subsequent to June 30, 2019, we entered into a securities purchase agreement with Arena pursuant to which Arena has agreed to acquire from us, concurrently with the offering contemplated by this prospectus, 5,500,000 shares of our Series A preferred stock, a warrant for the purchase of 6,000,000 shares of our common stock and a convertible promissory note in the principal amount of \$500,000, in consideration of a payment by Arena to us of an aggregate of \$5,400,000, as described under "Prospectus Summary – Arena Investors Financing".

In addition, subsequent to June 30, 2019, holders of our notes in the aggregate principal amount of \$2,075,000 have entered into agreements with us pursuant to which the noteholders have agreed to exchange such notes for shares of our common stock and warrants concurrently with the offering contemplated by this prospectus, as described under "Prospectus Summary – Exchange of Outstanding Debt."

#### **Consolidated Results of Operations**

## Six Months Ended June 30, 2019 Compared with Six Months Ended June 30, 2018

The following table presents selected items in our unaudited condensed consolidated statements of operations for the six months ended June 30, 2019 and 2018, respectively:

	For The Six Months Ended June 30,				
	2019		2018		
Revenues	\$ 60,000	\$	56,000		
Operating Expenses:					
Marketing and promotion	124,686		58,554		
Consulting	1,133,607		850,884		
Research and development	896,729		779,945		
General and administrative	2,362,118		2,647,690		
Total Operating Expenses	4,517,140		4,337,073		
Loss From Operations	(4,457,140)		(4,281,073)		
Other (Expense) Income:					
Interest expense	(644,911)		(391,642)		
Amortization of debt discount	(1,734,403)		(1,343,628)		
Loss on extinguishment of notes payable, net	(1,000,595)		(63,788)		
Change in fair value of derivative liabilities	(203,313)		58,048		
Total Other Expense	(3,583,222)		(1,741,010)		
Net Loss	\$ (8,040,362)	\$	(6,022,083)		

Revenues

For the six months ended June 30, 2019 and 2018, we generated \$60,000 and \$56,000, 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 six months ended June 30, 2019, marketing and promotion expenses increased by \$66,132, or 113%, from \$58,554 to \$124,686 as compared to the six months ended June 30, 2018. The increase is primarily due to the hiring of an advertising and promotion firm.

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 six months ended June 30, 2019, consulting expenses increased \$282,723, or 33%, from \$850,884 to \$1,133,607, as compared to the six months ended June 30, 2018. The increase is primarily due to cash consulting fees in connection with clinical trials and strategic planning.

## 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 six months ended June 30, 2019, research and development expenses increased by \$116,784, or 15%, from \$779,945 to \$896,729, as compared to the six months ended June 30, 2018. The increase was primarily a result of an increase of approximately \$101,000 in stock-based compensation expense primarily related to options issued to our Scientific Advisory Board members, incremental modification expense related to an option repricing in 2019, and an increase in laboratory staffing.

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 six months ended June 30, 2019, general and administrative expenses decreased by \$285,572, or 11%, from \$2,647,690 to \$2,362,118, as compared to the six months ended June 30, 2018. The decrease is primarily due to a decrease of approximately \$527,000 in stock-based compensation related primarily to fewer outstanding options in 2019 and a decrease of approximately \$134,000 of performance-based bonuses in 2019, partially offset by an increase of approximately \$259,000 and \$48,000 in legal and financial fees, respectively, due to increased matters regarding fundings and conversions of debt, as well as an increase in corporate expenses.

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 six months ended June 30, 2019, interest expense increased \$253,269, or 65%, as compared to the six months ended June 30, 2018. The increase was due to an increase in interest-bearing short-term borrowings as compared to the six months ended June 30, 2018.

#### Amortization of debt discount

For the six months ended June 30, 2019, amortization of debt discount increased \$390,775, or 29%, as compared to the six months ended June 30, 2018. The increase was primarily due to increased issuances of convertible notes and the timing of the recognition of expense related to the bifurcated embedded conversion options of convertible notes.

#### Loss on extinguishment of notes payable, net

For the six months ended June 30, 2019, we recorded a loss on extinguishment of notes payable, net, of \$1,000,595--, as compared to a loss on extinguishment of notes payable, net of \$63,788 for the six months ended June 30, 2018. The increase is associated with debt repayments and debtholders' exchanges of debt into equity securities resulting in a loss on the exchange.

#### Change in fair value of derivative liabilities

For the six months ended June 30, 2019, we recorded a loss related to the change in fair value of derivative liabilities of \$203,313 due to the increase 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 \$58,048 for the six months ended June 30, 2018.

### Year Ended December 31, 2018 Compared with Year Ended December 31, 2017

The following table presents selected items in our consolidated statements of operations for the years ended December 31, 2018 and 2017, respectively:

	For The Years Ended December 31,				
	2018	2017			
Revenues	\$ 111,000	\$ 81,000			
Operating Expenses					
Marketing and promotion	352,204	65,455			
Consulting	1,870,829	2,334,212			
Research and development	1,513,150	2,152,433			
General and administrative	 4,022,469	3,903,184			
Total Operating Expenses	 7,758,652	8,455,284			
Loss From Operations	 (7,647,652)	(8,374,284)			
Other Expense					
Interest expense	(932,187)	(468,107)			
Amortization of debt discount	(2,289,591)	(619,266)			
Loss on extinguishment of notes payable, net	(1,415,950)	(59,938)			
Change in fair value of derivative liabilities	(229,323)	107,039			
Warrant modification expense	 (3,100)	(30,099)			
Total Other Expense	 (4,870,151)	(1,070,371)			
Net Loss	\$ (12,517,803)	\$ (9,444,655)			

#### Revenues

For the year ended December 31, 2018, we generated \$111,000 from royalty revenue in connection with our sublicense agreement. For the year ended December 31, 2017, we generated \$81,000 from royalty revenue in connection with our sublicense agreement with Regenerative Sciences, LLC (see "Business-Disc/Spine Program – License"). The increase in our revenues for the year ended December 31, 2018 versus 2017 was due to an increase in 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, 2018, marketing and promotion expenses increased by \$286,749, or 438%, to \$352,204 from \$65,455 for the year ended December 31, 2017. The increase is primarily due to the hiring of an advertising and promotion firm in 2018.

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, 2018, consulting expenses decreased \$463,383, or 20%, to \$1,870,829 from \$2,334,212 for the year ended December 31, 2017. The decrease is primarily due to a decrease of approximately \$642,000 in stock-based compensation expense related to options and warrants issued to directors and consultants, partially offset by an increase of approximately \$168,000 in cash consulting fees.

#### 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; (c) our President, Disc/Spine Division (who resigned in July 2017); and (d) 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, 2018, research and development expenses decreased by \$639,283, or 30%, to \$1,513,150 from \$2,152,433 for the year ended December 31, 2017. The decrease was primarily the result of a decrease of approximately \$295,000 in payroll and payroll-related costs due to the resignation of the former President of our Disc/Spine Division and a lab employee in 2017, a decrease of approximately \$150,000 in cash compensation related to the termination of our Chief Medical Advisor for Spine Medicine in February 2018, and a decrease of approximately \$141,000 in stock-based compensation expense related to options issued to our Scientific Advisory Board members.

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

#### General and administrative

General and administrative expenses consist primarily of salaries, bonuses, payroll taxes, severance costs and stock-based compensation to employees (excluding any cash or non-cash compensation of (a) our Vice President of Research and Development; (b) our President, Disc/Spine Division; and (c) our laboratory staff) as well as corporate support expenses such as legal and professional fees, investor relations and occupancy related expenses. For the year ended December 31, 2018, general and administrative expenses increased by \$119,285, or 3%, to \$4,022,469 from \$3,903,184 for the year ended December 31, 2017.

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, 2018, interest expense increased by \$464,080, or 99%, to \$932,187, as compared to \$468,107 during the year ended December 31, 2017. The increase was due to an increase in interest-bearing short-term borrowings as compared to the year ended December 31, 2017.

### Amortization of debt discount

For the year ended December 31, 2018, amortization of debt discount increased by \$1,670,325, or 270%, to \$2,289,591, as compared to \$619,266 during the year ended December 31, 2017. The increase was primarily due to the timing of the recognition of expense related to the bifurcated embedded conversion options of convertible notes and the recognition of the debt discount expense.

## Loss on extinguishment of notes payable, net

For the year ended December 31, 2018, we recorded a loss on extinguishment of notes payable, net, of \$1,415,950, which is associated with debtholders' exchange of debt into equity securities, as compared to a loss on extinguishment of notes payable of \$59,938 for the year ended December 31, 2017.

## Change in fair value of derivative liabilities

For the year ended December 31, 2018, we recorded a loss related to the change in fair value of derivative liabilities of \$229,323 due to the increase 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 \$107,039 for the year ended December 31, 2017.

## Warrant modification expense

During the year ended December 31, 2018, we recorded expense related to the modification of an exercise price of an outstanding warrant of \$3,100, as compared to expense related to the modification of the expiration dates and exercise prices of outstanding warrants of \$30,099 for the year ended December 31, 2017.

## Liquidity and Capital Resources

## Liquidity

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

				December 31,					
	Ju	June 30, 2019 2018				2017			
	(u	naudited)							
Cash	\$	1,283,666	\$	117,523	\$	451,680			
Working Capital Deficiency	\$	(9,786,144)	\$	(9,073,901)	\$	(7,833,592)			
Notes Payable (Gross)	\$	7,759,967	\$	5,161,916	\$	3,999,335			

## Availability of Additional Funds

Based upon our working capital deficiency and stockholders' deficiency of \$9,786,144 and \$8,942,471, respectively, as of June 30, 2019, we require additional equity and/or debt financing to continue our operations. These conditions raise substantial doubt about our ability to continue as a going concern within the next twelve months from the date of this filing.

As of June 30, 2019, our outstanding debt of \$7,759,967, together with interest at rates ranging between 8% and 15% per annum, was due on various dates through June 2020. Subsequent to June 30, 2019, we have received aggregate debt proceeds of \$1,666,000, debt (inclusive of accrued interest) of \$389,480 has been exchanged for common stock, \$1,644,778 of debt (inclusive of accrued interest) has been repaid, and the due date for the repayment of \$1,053,102 of debt has been extended to dates between July 2019 and July 2020. Giving effect to the above actions, we currently have a note payable in the outstanding principal amount of \$144,000 which is past due. As of the date of this prospectus, our outstanding debt was as follows:

	Principal	
Maturity Date	Amount	
Past Due	\$	144,000
QE 9/30/2019	1,	,037,929
QE 12/31/2019	3,	658,226
QE 3/31/2020	1,	478,750
QE 6/30/2020		862,138
QE 9/30/2020		917,938
	\$ 8,	098,981

Subsequent to June 30, 2019, we entered into a securities purchase agreement with Arena pursuant to which Arena has agreed to acquire from us, concurrently with the offering contemplated by this prospectus, 5,500,000 shares of our Series A preferred stock, a warrant for the purchase of 6,000,000 shares of our common stock and a convertible promissory note in the principal amount of \$500,000, in consideration of a payment by Arena to us of an aggregate of \$5,400,000, as described under "Prospectus Summary – Arena Investors Financing." In addition, we intend to use the \$5,130,000 net proceeds from the Arena financing (net of the amount payable to the underwriters as described under "Underwriting") to repay indebtedness (as of the date of this prospectus, our outstanding debt is \$8,098,981, and such debt is repayable, with interest at rates ranging between 8% and 15% per annum, on various dates through August 2020).

In addition, subsequent to June 30, 2019, holders of our notes in the aggregate principal amount of \$2,075,000 have entered into agreements with us pursuant to which the noteholders have agreed to exchange such notes for shares of our common stock and warrants concurrently with the offering contemplated by this prospectus, as described under "Prospectus Summary – Exchange of Outstanding Debt".

Based upon our working capital deficiency, outstanding debt and forecast for continued operating losses we expect that the cash we currently have available will fund our operations through September 2019. Thereafter, we will need to raise further capital, through the sale of additional equity or debt securities, to support our future operations and to repay our debt (unless, if requested, the debt holders agree to convert their notes into equity or extend the maturity dates of their notes). Our operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products and services, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings. We anticipate that the net proceeds of this offering, together with the net proceeds of the Arena financing, will satisfy in substantial part our working capital cash flow requirements at least through the second quarter of 2020.

We may be unable to raise sufficient additional capital when we need it or raise capital on favorable terms. Debt financing may require us to pledge certain assets and enter into covenants that could restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to significantly curtail or discontinue operations or obtain funds by entering into financing agreements on unattractive terms.

Our consolidated financial statements included elsewhere in this 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.

During the six months ended June 30, 2019 and 2018 and the years ended December 31, 2018 and 2017, our sources and uses of cash were as follows:

## Net Cash Used in Operating Activities

We experienced negative cash flows from operating activities for the six months ended June 30, 2019 and 2018 in the amounts of \$3,397,117 and \$2,198,577, respectively. The net cash used in operating activities for the six months ended June 30, 2019 was primarily due to cash used to fund a net loss of \$8,040,362, adjusted for non-cash expenses in the aggregate amount of \$4,508,262 partially offset by \$134,983 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 a decrease in accounts payable. The net cash used in operating activities for the six months ended June 30, 2018 was primarily due to cash used to fund a net loss of \$6,022,083, adjusted for non-cash expenses in the aggregate amount of \$3,514,416 partially offset by \$309,090 of cash generated by changes in the levels of operating assets and liabilities, partially offset by a decrease in accrued interest, expenses, and other current liabilities, primarily as a result of increases in accrued interest, expenses, and other current liabilities, partially offset by \$309,090 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 a decrease in accounts payable.

We experienced negative cash flow from operating activities for the years ended December 31, 2018 and 2017 in the amounts of \$5,104,629 and \$3,853,821, respectively. The net cash used in operating activities for the year ended December 31, 2018 was primarily due to cash used to fund a net loss of \$12,517,803, adjusted for non-cash expenses in the aggregate amount of \$7,458,950 and \$45,776 of cash used in changes in the levels of operating assets and liabilities, primarily as a result of a decrease in accounts payable, partially offset by increases in accrued interest, expenses and other current liabilities. The net cash used in operating activities for the year ended December 31, 2017 was primarily due to cash used to fund a net loss of \$9,444,655, adjusted for non-cash expenses in the aggregate amount of \$4,769,506 partially offset by \$821,328 of cash provided by changes in the levels of operating assets and liabilities, increases in accounts payable, a decrease in security deposit and decreases in prepaid expenses and other current assets, partially offset by increases in accounts receivable, primarily due to cash constraints during the period.

#### Net Cash Used in Investing Activities

During the six months ended June 30, 2019 and 2018, cash used in investing activities was \$29,371 and \$12,869, respectively, due to cash used for the purchase of office and computer equipment.

During the year ended December 31, 2018, net cash used in investing activities was \$12,869 used for the purchase of office and computer equipment. During the year ended December 31, 2017, net cash used in investing activities was \$3,617 used for the purchase of computer equipment.

### Net Cash Provided by Financing Activities

Net cash provided by financing activities during the six months ended June 30, 2019 and 2018 was \$4,592,631 and \$1,763,295, respectively. During the six months ended June 30, 2019, \$3,449,560 of net proceeds were from debt financings, \$1,156,000 of proceeds were from equity financings and \$12,929 was used for incurred offering costs. During the six months ended June 30, 2018, \$1,324,127 of net proceeds were from debt financings and other borrowings and \$439,168 of proceeds were from equity financings (including proceeds received in connection with the exercise of common stock purchase warrants).

Net cash provided by financing activities during the years ended December 31, 2018 and 2017 was \$4,783,341 and \$4,277,296, respectively. During the year ended December 31, 2018, \$4,194,173 of net proceeds were from debt financings and other borrowings and \$589,168 of proceeds were from equity financings (including proceeds received in connection with the exercise of common stock purchase warrants). During the year ended December 31, 2017, \$2,197,046 of net proceeds were from debt financings and other borrowings and \$2,080,250 of proceeds were from equity financings (including proceeds received in connection with the exercise of common stock purchase warrants).

#### **Critical Accounting Policies and Estimates**

## Use of Estimates

The preparation of financial statements in conformity with 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 17.7 years, respectively. Once placed into service, we amortize the cost of the intangible assets over their estimated useful lives on a straight-line basis.

#### Impairment of Long-lived Assets

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

## Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in our financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts, 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 the Plan were registered on May 27, 2014, we estimate the fair value of the awards granted under the Plan based on the market value of our freely tradable common stock as reported on the OTCQB. The fair value of our restricted equity instruments was estimated by management based on observations of the cash sales prices of both restricted shares and freely tradable shares. Awards granted to directors are treated on the same basis as awards granted to employees.

#### **Recently Issued Accounting Pronouncements**

See Note 3 to our unaudited condensed consolidated financial statements for the six months ended June 30, 2019 and 2018 and Note 3 to our consolidated financial statements for the years ended December 31, 2018 and 2017.

#### **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 ("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. 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 Investigational New Drug ("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 the fourth quarter of 2019 (assuming the receipt of necessary funding). See "Disc/Spine Program" below.

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

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

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

#### Overview

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

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



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

Accordingly, we have focused our initial developmental efforts on cellular-based therapeutic products and clinical development programs in selective areas of medicine for which the treatment protocol is minimally invasive. Such areas include the treatment of the disc and spine and metabolic-related disorders. Upon regulatory approval, we will seek to obtain third party reimbursement for our products and procedures; however; patients may be required to pay for our products and procedures out of pocket in full and without the ability to be reimbursed by any governmental and other third party payers.

We have undertaken research and development efforts in connection with the development of investigational therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. See "Disc/Spine Program," "Metabolic Brown Adipose (Fat) Program" and "Curved Needle Device" below. As a result of these programs, we have obtained two United States and two non-United States patents related to research regarding our *ThermoStem Program*, we have obtained licenses for three patent applications related to our *Disc/Spine Program* and we have obtained a license for one United States patent related to a curved needle device.

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

We have not generated any significant revenues from our operations. The implementation of our business plan, as discussed below, will require the receipt of sufficient equity and/or debt financing to purchase necessary equipment, technology and materials, fund our research and development efforts, retire our outstanding debt (see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Availability of Additional Funds") and otherwise fund our operations. We intend to seek such financing from current stockholders and debtholders as well as from other accredited investors. We also intend to seek to raise capital through investment bankers and from biotech funds, strategic partners and other financial institutions. We anticipate that we will require approximately \$20,000,000 in financing to commence and complete a Phase 2 clinical trial and we will require approximately \$45,000,000 in further additional funding to complete our clinical trials using *BRTX-100*, as further described in this section (assuming the receipt of no revenues from operations), repay our outstanding debt (\$7,759,967 as of June 30, 2019) (assuming that no debt is converted into equity) and fund general operations. We will also require a substantial amount of additional funding to implement our other programs described in this section. No assurance can be given that the anticipated amounts of required financing on commercially reasonable terms or otherwise. We may also seek to have our debtholders convert all or a portion of their debt into equity. No assurance can be given that we will be able to obtain adequate funding, we may be required to significantly curtail or discontinue our proposed operations. See "Risk Factors – Factors That May Affect Future Results and Financial Condition – We will need to obtain a significant amount of financing to initiate and complete our clinical trials and implement our business plan. – We will need to obtain additional financing to satisfy debt o

#### **Disc/Spine** Program

#### General

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

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

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

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

We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We have received such authorization from the FDA. We intend to commence such clinical trial during the fourth quarter of 2019 (assuming the receipt of necessary funding). The net proceeds of this offering would be sufficient for us to commence the clinical trial.

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

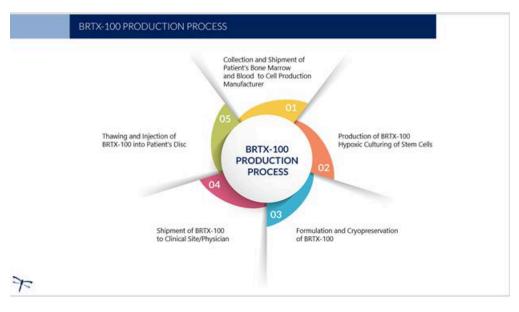
Our lead product candidate, *BRTX-100*, is an autologous hypoxic (low oxygen) cultured mesenchymal stem cell product derived from a patient's own bone marrow and formulated with a proprietary biomaterial carrier (platelet lysate) to increase potency, viability and survivability. We have designed the 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 marrowderived 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 marrowderived 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 applied is intended to result in the selection of a cell population that is suitable for an improved possibility of survival in the internal disc environment. We anticipate that the cell culturing process and product formulation will take approximately three weeks, with an additional two weeks required for quality control testing required to meet product release criteria. We will then send the therapeutic cryopreserved stem cells (*BRTX-100*) in a sterile vial back to the physician's offices where it will undergo a controlled thaw prior to the procedure. The price structure for the procedure and our services has not been determined and no assurances can be given as to the effect that such price structure will have on the marketability of such procedure and services. The following illustrates the process:



#### License

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

#### Animal Study

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

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

- There was no evidence or observation of gross toxicity related to the administration of *BRTX-100* at either time point. The clinical pathology across both groups and time points were within expected normal historical ranges and under the conditions of the test. No abnormalities (including fractures or overt signs of lumbar disc disease) were identified after review of the radiographic images taken at both endpoints for both groups. No toxicity or adverse finding was evident in the systemic tissues or the discs of animals receiving *BRTX-100*.
- There was no detectable presence of human cells (*BRTX-100*) observed at the day 56 interim time point. This is consistent with the proposed mechanism of action that *BRTX-100* acts through a paracrine effect of secreted growth and immunomodulation factors.

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

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

# Clinical Trial

We submitted an IND application to the FDA to obtain authorization to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We have received such authorization from the FDA. We intend to commence such clinical trial during the fourth quarter of 2019 (assuming the receipt of necessary funding).

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

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

- General
  - 99 patients; randomized 2:1, BRTX-100 to control, 40 million cells/dose
  - 10-20 clinical trial sites
  - Primary efficacy endpoint at 12 months
  - Patient safety and efficacy follow up at 24 months
  - Included subjects must have only one symptomatic diseased disc
  - Included subjects must have current diagnosis of chronic lumbar disc disease typical pain with degeneration of a single disc confirmed by history, exam, radiography, or other acceptable means
  - Included subjects must have exhausted previous conservative non-operative therapies
- Primary Efficacy Endpoint
  - Responder endpoint % of patients that meet the improvement in function and reduction in pain threshold
  - Improvement in function defined as at least a 30% increase in function based on the Oswestry questionnaires (ODI)
  - Reduction of pain defined as at least a 30% decrease in pain as measured using the Visual Analogue Scale (VAS)
- Additional or Secondary Endpoints
  - Clinical response at 12 months
  - Changes from baseline in pain as assessed with the VAS score and ODI at weeks 2, 12, 26, 52 and 104
  - Changes from baseline in function as assessed with the ODI at weeks 2, 12, 26, 52 and 104
  - Changes from baseline in function as assessed by Roland Morris Disability Questionnaire (RMDQ) at weeks 26, 52 and 104
  - Changes from baseline function as assessed by Functional Rating Index (FRI) at weeks 12, 52 and 104
  - Changes from baseline Quality of Life assessment (SF-12 questionnaire) scores at weeks 2, 12, 26, 52 and 104

The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee that the clinical trial(s) will be commenced or completed or that the product will ultimately receive approval or clearance. See "Government Regulation" below and "Risk Factors– Risks Related to Our Cell Therapy Product Development Efforts; and – Risks Related to Government Regulation."

As an alternative to undertaking the Phase 2 clinical trial ourselves, we are exploring the possible licensing of our rights with respect to our product candidate, *BRTX-100*, to a strategic partner. Such an arrangement could possibly eliminate or significantly reduce the need to raise the substantial capital needed to commence and complete the clinical trials and undertake the commercialization of *BRTX-100* and would provide licensing-related revenue to us. No assurance can be given that any licensing agreement will be entered into, whether upon commercially reasonable terms or otherwise.



## Defined Health Report

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

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

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

# Similar Therapies

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

Description: 33 patients diagnosed with degenerative disc disease received an intradiscal injection of auto Sourceal of Translational Medicine ogous, 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 . Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy Results: Study results on the use of hypoxic cultured autologous MSCs demonstrated no safety issues, substa pain, increased function, and reduced disc bulge size. Pain change score relative to baseline were significant at 3, 36, 48, 60 and Theoretics introduced one using static ran bundle bore relative to done the system over system as 3, 50, expression and 2, monthly and 2, monthly system as 3, 50, expression and 2, monthly system and 2, monthly syste Description: 24 patients with chronic back pain were randomized into either treatment group or control group. Treatment 1 group received 25x10<sup>6</sup> bone marrow-derived MSCs. Clinical outcomes were followed up for 1 year and included evaluation of pain, disability and quality of life. ertebral Disc Repair by Allogeneic schymal Bone Marrow Cells: A Ra olled Trial Results: Feasibility and safety of a 25x10<sup>6</sup> cell dose was confirmed and clinical efficacy was identified. MSC-treated patients displayed a guick and significant improvement in algo-functional indices versus controls. VAS and ODI were significantly Teres, ML reduced at 3 months after MSC transplantation and the improvement maintained at 6 and 12 months. Degeneration quantified by Pfirmann grading, improved in the MSC-treated patients and worsened in the co Safety and tolerability of intradiscal . Description: 10 patients with chronic back pain received a single injection of 20x10<sup>6</sup> and 40x10<sup>6</sup> of autolo implantation of combined autologous adipose-derived mesenchymal stem cells and hyaluronic acid in patients with 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 study were determined to have increased water content based on an increased diffusion coefficient on diffusion MRI. chronic discogenic low back pain: 1-year follow-up of a phase I study

#### Impact on Public Health

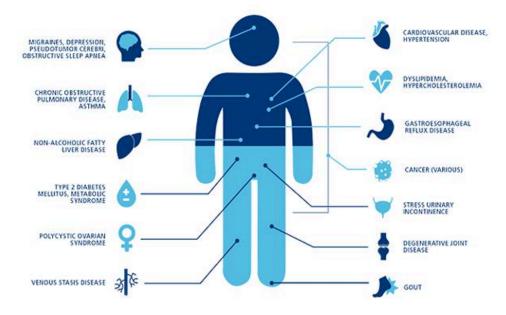
The United States is the world's leading consumer of hydrocodone (99%) and oxycodone (83%) and leads the world in per capital consumption of such drugs (twice as much as second ranked Canada). Each year 30,000 Americans die from overdoses and in 2012 there were enough pain prescriptions in the United States for every adult to obtain a bottle of pills.

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

#### Metabolic Brown Adipose (Fat) Program

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

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



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

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

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

In order to deliver these differentiated cells into target locations *in vivo*, we seeded BADSCs onto 3-dimensional biological scaffolds. Pre-clinical animal models of dietinduced obesity, that were transplanted with differentiated BADSCs supported by a biological scaffold, presented significant reductions in weight and blood glucose levels compared to saline injected controls. We are identifying technology for *in vivo* delivery in small animal models. Having completed our proof of concept using our BAT in small animals, we are currently developing our next generation BAT. It is anticipated that this next version will contain a higher purity of BADSC 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 and forming tumors. 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 trea

In June 2012, we entered into an Assignment Agreement with the University of Utah Research Foundation (the "Foundation") and a Research Agreement with the University of Utah (the "Utah Research Agreement"). Pursuant to the Assignment Agreement, which provides for royalty payments, we acquired the rights to two provisional patent applications that relate to human brown fat cell lines. No royalty amounts are payable to date. The applications have been converted to a utility application in the 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, we will initiate preclinical models to study the efficacy of our generation 2 encapsulated brown adipose tissue construct.

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

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

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

Following our research activities, we intend to undertake preclinical animal studies in order to determine whether our proposed treatment protocol is feasible. Such studies are planned to begin by the third quarter of 2019 (assuming the receipt of necessary financing). Following the completion of such studies, we intend to file an IND with the FDA and initiate a clinical trial. See "Government Regulation" below and "Risk Factors – Risks Related to Our Cell Therapy Product Development Efforts; and – Risks Related to Government Regulation." The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance.

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

# **Curved Needle Device**

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

# Laboratory

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

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

### Technology; Research and Development

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

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

In our *Disc/Spine Program*, four 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 three applications remain pending. The patents that are the subject of the Regenerative License Agreement have been assigned to Regenexx, LLC which we have been advised is an affiliate of Regenerative.

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

Program	Patent Family	I.D.	Jurisdiction	Title
Disc/Spine	1	13/132,840*	US	Methods and compositions to facilitate repair of avascular tissue
(brtxDisc)	1	15/891,852*	US	Surgical methods and compositions to facilitate repair of avascular tissue
	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	2	U.S. Patent No. 9,133,438	US	Brown fat cell compositions and methods
(ThermoStem)	2	13/932,468	US	
	2	15/910,625	US	
	2	AU Patent No. 2012275335	Australia	
	2	12743811.7	Europe	
	2	230237	Israel	
	2	JP Patent No. 6243839	Japan	
	3	U.S. Patent No. 10,167,449	ÛS	Human brown adipose derived stem cells and uses
	3	16/183,370	US	
	3	2014253920	Australia	
	3	14729769.1	Europe	
	3	242150	Israel	
	3	2016-509105	Japan	
	3	2019-95972	Japan	
	4	62/840,096***	ÛS	Non-naturally occurring three-dimensional (3D) brown adipose-derived ster cell aggregates, and methods of generating and using the same

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

\*\*\*U.S. provisional application

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

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

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





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

We own a published application in the U.S. Patent and Trademark Office for the trademark BRTX and an allowed application in the U.S. Patent and Trademark Office for the trademark BRTX-100.

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, 2018 and 2017, we incurred \$1,513,150 and \$2,152,433, 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 –Scientific Advisors" for a listing of the principal positions for Drs. Marasco, Imam, Olan, Cavagnaro, Lipetz, Sandhu, Plastaras and Malanga.

# Competition

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

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

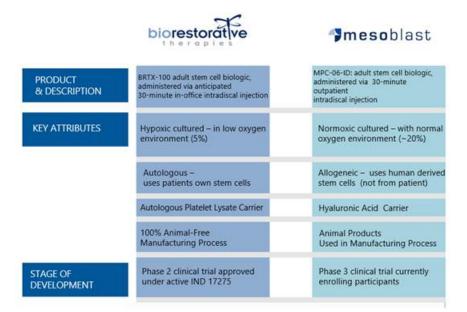
Companies working in the area of regenerative medicine with regard to the disc and spine include, among others, Mesoblast, SpinalCyte, DiscGenics and Isto Biologics. Companies that are developing products and therapies to combat obesity and diabetes, including through the use of brown fat, include, among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

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

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

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

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



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

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

#### Customers

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

# **Governmental Regulation**

#### U.S. Government Regulation

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

# FDA Regulation of Stem Cell Treatment and Products

The FDA regulates the manufacture of human stem cell treatments and associated products under the authority of the Public Health Service Act ("PHSA") and the Federal Food, Drug, and Cosmetic Act ("FDCA"). Stem cells can be regulated under the FDA's Human Cells, Tissues, and Cellular and Tissue-Based Products Regulations ("HCT/Ps") or may also be subject to the FDA's drug, biologic, or medical device regulations, each as discussed below.

### Human Cells, Tissues, and Cellular and Tissue-Based Products Regulation

Under Section 361 of the PHSA, the FDA issued specific regulations governing the use of HCT/Ps in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations ("CFR"), the FDA established a unified registration and listing system for establishments that manufacture and process HCT/Ps. The regulations also include provisions pertaining to donor eligibility determinations; current good tissue practices covering all stages of production, including harvesting, processing, manufacture, storage, labeling, packaging, and distribution; and other procedures to prevent the introduction, transmission, and spread of communicable diseases.

The HCT/P regulations strictly constrain the types of products that may be regulated solely under these regulations. Factors considered include the degree of manipulation, whether the product is intended for a homologous function, whether the product has been combined with noncellular or non-tissue components, and the product's effect or dependence on the body's metabolic function. In those instances where cells, tissues, and cellular and tissue-based products have been only minimally manipulated, are intended strictly for homologous use, have not been combined with noncellular or nontissue substances, and do not depend on or have any effect on the body's metabolism, the manufacturer is only required to register with the FDA, submit a list of manufactured products, and adopt and implement procedures for the control of communicable diseases. If one or more of the above factors has been exceeded, the product would be regulated as a drug, biological product, or medical device rather than an HCT/P.

Because we are an enterprise in the early stages of operations and have not generated significant revenues from operations, it is difficult to anticipate the likely regulatory status of the array of products and services that we may offer. We believe that some of the adult autologous (self derived) stem cells that will be used in our cellular therapy products and services, including the brown adipose (fat) tissue that we intend to use in our *ThermoStem Program*, may be regulated by the FDA as HCT/Ps under 21 C.F.R. Part 1271. This regulation defines HCT/Ps as articles "containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient." However, the FDA may disagree with this position or conclude that some or all of our stem cell therapy products or services do not meet the applicable definitions and exemptions to the regulation. If we are not regulated solely under the HCT/P provisions, we would need to expend significant resources to comply with the FDA's broad regulatory authority under the FDCA. Third party litigation concerning the autologous use of a stem cell mixture to treat musculoskeletal and spinal injuries has increased the likelihood that some of our products and services are likely to be regulated as a drug or biological product and require FDA approval. In past litigation, the FDA asserted that the defendants' product is a drug. The defendants asserted that their procedure is part of the practice of medicine and therefore beyond the FDCA's regulatory authority. The District Court affirmed the District Court's holding.

On November 16, 2017, the FDA announced a comprehensive policy framework for the regulation of regenerative medicine products and issued a final guidance document entitled, "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use", which provides the FDA's current thinking on how to apply the existing regulatory criteria for regulation of HCT/Ps. The final guidance also stated that the FDA intends to exercise enforcement discretion under limited conditions with respect to application and pre-market approval requirements for certain HCT/Ps for a period of 36 months from the date the guidance was issued in order to provide sponsors with time to evaluate their products, have a dialogue with the agency and, if necessary, begin clinical trials and file the appropriate pre-market applications. The FDA's enforcement approach is risk-based, and the guidance clarified that high-risk products and uses could be subject to immediate enforcement action. In addition, on June 12, 2019, the FDA issued a press release announcing the establishment of the Tissue Reference Group Rapid Inquiry Program ("TRIP") through which manufacturers of HCT/Ps may seek a preliminary, informal, non-binding assessment from the FDA regarding how specific HCT/Ps might be regulated.

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

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

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

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

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

# Drug and Biological Product Regulation

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

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

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

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

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

- registration of clinical trials of FDA-regulated products and certain clinical trial information;
- preparation and submission to the FDA of a new drug application ("NDA"), in the case of a drug or BLA in the case of a biologic;
- review of the product by an FDA advisory committee, where appropriate or if applicable;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## FDA Expedited Review Programs

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

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

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

• Breakthrough therapy designation. To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or lifethreatening 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 crossdisciplinary review, and rolling review.

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

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

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

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

#### Medical Device Regulation

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

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

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

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

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

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

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

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

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

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

The Federal Trade Commission (the "FTC") has the authority to regulate and police advertising of medical treatments, procedures, and regimens in the United States under the Federal Trade Commission Act, 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 ("CMS") authority over all laboratory testing, except research, that is performed on humans in the United States. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations ("CMSO") has the responsibility for implementing the CLIA program.

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

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

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

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

# Other Applicable U.S. Laws

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

- state and local licensure, registration, and regulation of the development of pharmaceuticals and biologics;
- state and local licensure of medical professionals;
- state statutes and regulations related to the corporate practice of medicine;
- laws and regulations administered by U.S. Customs and Border Protection related to the importation of biological material into the United States;
- other laws and regulations administered by the FDA;
- other laws and regulations administered by HHS;
- state and local laws and regulations governing human subject research and clinical trials;
- the federal physician self-referral prohibition, also known as Stark Law, and any state equivalents to Stark Law;
- the federal False Claims Act ("FCA");
- the federal Anti-Kickback Statute ("AKS") and any state equivalent statutes and regulations;

- federal and state coverage and reimbursement laws and regulations;
- state and local laws and regulations for the disposal and handling of medical waste and biohazardous material;
- Occupational Safety and Health Administration ("OSHA") regulations and requirements;
- the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to "excess benefit transactions" with tax-exempt organizations;
- the Physician Payments Sunshine Act (in the event that our products are classified as drugs, biologics, devices or medical supplies and are reimbursed by Medicare, Medicaid or the Children's Health Insurance Program);
- state and other federal laws addressing the privacy of health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare professionals and other potential referral sources, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

### Foreign Government Regulation

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

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

# Offices

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

# Employees

We currently have eight 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 or her full business time in providing services on our behalf.

Name	Age	Positions Held
Mark Weinreb	66	Chief Executive Officer, President and Chairman of the Board
Lance Alstodt	48	Executive Vice President and Chief Strategy Officer
Francisco Silva	44	Vice President of Research and Development
Robert Paccasassi	50	Vice President of Quality and Compliance
Mandy D. Clyde	37	Vice President of Operations and Secretary
Robert B. Catell	82	Director
John M. Desmarais	55	Director
A. Jeffrey Radov	67	Director
Charles S. Ryan	55	Director
Paul Jude Tonna	61	Director

#### **Mark Weinreb**

Mark Weinreb has served as our Chief Executive Officer since October 2010, as our President since February 2012 and as our Chairman of the Board since April 2011. From February 2003 to January 2006, he served as the Chief Executive Officer and Chairman of the Board of Directors of Phase III Medical, Inc. where he orchestrated the acquisition of an adult stem cell collection company that became NeoStem, Inc. (now Caladrius Biosciences, Inc. - NASDAQ: CLBS), a public international biopharmaceutical company engaged in, among other things, adult stem cell-related science. From June 2006 through October 2009, Mr. Weinreb served as President and a director of NeoStem. In 1976, Mr. Weinreb joined Bio Health Laboratories, Inc., a state-of-the-art medical diagnostic laboratory providing clinical testing services for physicians, hospitals, and other medical laboratories. He became the laboratory administrator in 1978 and then an owner and the laboratory's Chief Operating Officer in 1982. In such capacity, he oversaw all technical and business facets, including finance and laboratory science technology. In 1989, Bio Health Laboratories was acquired by Enzo Biochem (NYSE: ENZ). From 1992 to 2002, Mr. Weinreb pursued entrepreneurial and consulting interests. Mr. Weinreb received a Bachelor of Arts degree from Northwestern University and a Master of Science degree in Medical Biology from C.W. Post, Long Island University. We believe that Mr. Weinreb's executive-level management experience, his extensive experience in the adult stem cell sector and his service on our Board since October 2010 give him the qualifications and skills to serve as one of our directors.

### Lance Alstodt

Lance Alstodt has served as our Executive Vice President and Chief Strategy Officer since October 2018. From 2013 until 2018, Mr. Alstodt served as Chief Executive Officer of MedVest Consulting Corporation, an advisory and capital firm that focused exclusively on the healthcare industry. Prior to MedVest, he was an investment banker with over 20 years of experience with respect to healthcare investment banking, including mergers and acquisitions. From 2011 to 2013, Mr. Alstodt was a Managing Director at Lerrink 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.

#### 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. 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.

#### **Robert Paccasassi**

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

# Mandy D. Clyde

Mandy D. Clyde has been our Vice President of Operations since August 2009. She has served as our Secretary since December 2010 and served on our Board from September 2010 to April 2011. From 2006 to 2009, Ms. Clyde served as Educational Envoy and then CME/CE Coordinator for Professional Resources in Management Education, an accredited provider of continuing medical education. She conducted needs assessments nationally to determine in which areas clinicians most needed current education. She also oversaw onsite educational meetings and analyzed data for outcomes reporting. From 2005 to 2006, Ms. Clyde served as surgical coordinator for Eye Surgery Associates and the Rand Eye Institute, two prominent physician practices in Florida. Ms. Clyde has experience in medical editing for educational programs and is a published author of advanced scientific and clinical content on topics including Alzheimer's disease, breast cancer, sleep apnea and adult learning. She received a degree in Biology from Mercyhurst College.

#### **Robert B. Catell**

Robert B. Catell became a member of our Board of Directors in February 2016. Mr. Catell served as Chairman and Chief Executive Officer of KeySpan Corporation and KeySpan Energy Delivery, the former Brooklyn Union Gas, from 1998 to 2007. His career with Brooklyn Union Gas started in 1958. Following National Grid's acquisition of KeySpan Corporation in 2007, Mr. Catell became Chairman of National Grid, U.S. and Deputy Chairman of National Grid plc. Mr. Catell currently serves as Chairman of the Board of the Advanced Energy Research and Technology Center (AERTC) at Stony Brook University, New York State Smart Grid Consortium, Cristo Rey Brooklyn High School, Futures in Education Endowment Fund, and the National Offshore Wind Research and Development Consortium. He also serves on the Board of Directors of Applied DNA Sciences, Inc., a company that uses biotechnology as a forensic foundation in creating unique security solutions addressing the challenges of modern commerce. In addition, Mr. Catell serves as a board member of a number of other business, governmental and not-for-profit organizations. Mr. Catell holds both a Master's and Bachelor's degree in Mechanical Engineering from City College of New York. We believe that Mr. Catell's executive-level management experience and his extensive experience in the Long Island community give him the qualifications and skills to serve as one of our directors.

# John M. Desmarais

John M. Desmarais became a member of our Board of Directors in December 2015. Mr. Desmarais is the founding partner of Desmarais LLP, an intellectual property trial boutique established in 2010, and the founder and owner of Round Rock Research LLC, and Sound View Innovations LLC, patent licensing companies. From 1997 to 2009, he was a partner at the international law firm of Kirkland & Ellis LLP and served as a member of the firm's Management Committee from 2004 to 2009. Prior to joining Kirkland, and after practicing in the area of intellectual property litigation and counseling for several years, he left private practice to serve as an Assistant United States Attorney in the Southern District of New York, where for three years he represented the federal government in criminal jury trials. Mr. Desmarais is a member of the bars of California, New York and Washington, D.C., the United States Supreme Court, the Federal Circuit Court of Appeals, and various other federal district courts and courts of appeal. He is also registered to practice before the United States Patent and Trademark Office. Mr. Desmarais has been recognized by numerous publications as one of the nation's leading intellectual property litigators. Mr. Desmarais obtained a degree in Chemical Engineering from Manhattan College and a law degree from New York University. We believe that Mr. Desmarais' business and legal experience, including his extensive experience in the area of intellectual property, give him the qualifications and skills to serve as one of our directors.

### A. Jeffrey Radov

A. Jeffrey Radov became a member of our Board and Chair of our Audit Committee in April 2011. Mr. Radov is an entrepreneur and businessman with more than 35 years of experience in media, communications and financial endeavors. Since 2002, he has served as the Managing Partner of Walworth Group, which provides consulting and advisory services to a variety of businesses, including hedge funds, media, entertainment and Internet companies, financial services firms and early stage ventures. Mr. Radov is also a registered representative of Young America Capital, LLC, a broker-dealer. From 2008 to 2010, Mr. Radov was a Principal and Chief Operating Officer at Aldebaran Investments, LLC, a registered investment advisor. From 2005 to 2008, Mr. Radov was Chief Operating Officer at EagleRock Capital Management, a group of hedge funds. Prior to joining EagleRock, Mr. Radov was a founding investor in and Board member of Edusoft, Inc., an educational software company. From 2001 to 2002, Mr. Radov was a Founder-in-Residence at SAS Investors, an early-stage venture fund. From 1999 to 2001, Mr. Radov was CEO and co-founder of VocaLoca, Inc., an innovator in consumer-generated audio content on the Internet. Mr. Radov was a founding executive of About.Com, Inc., an online information source, and was its EVP of Business Development and Chief Financial Officer from its inception. In 1996, prior to founding About.Com, Mr. Radov was a Director at Prodigy Systems Company, a joint venture of IBM and Sears. Mr. Radov was also a principal in the management of a series of public limited partnerships that invested in the production and distribution of more than 130 major motion pictures. From 1982 to 1984, Mr. Radov was the Director of Finance at Rainbow Programming Enterprises, a joint venture anong Cablevision Systems Corporation, Cox Broadcasting and Daniels & Associates. From 1977 to 1981, Mr. Radov was Director of Marketing at Winklevoss & Associates. Mr. Radov earned a Masters of Business Administration from The Wharton School of the

#### Charles S. Ryan

Dr. Charles S. Ryan became a member of our Board in April 2015 and has served as Chair of our Nominating Committee since August 2018. Since February 2018, Dr. Ryan has served as Chief Executive Officer of Neurotrope Bioscience, Inc., a company that develops novel therapies for the treatment of neurodegenerative diseases and developmental disorders. From October 2016 to February 2018, Dr. Ryan served as Chief Executive Officer of Orthobond, Inc., a company that seeks to improve the performance and safety of medical devices through the use of proprietary non-polymer technology. From March 2015 to May 2016, Dr. Ryan served as Vice President, General Counsel of Cold Spring Harbor Laboratory, a not-for-profit research and education institution at the forefront of molecular biology and genetics, with research programs focusing on cancer, neuroscience, plant biology, genomics and quantitative biology. From 2003 to 2014, he served as Senior Vice President and Chief Intellectual Property Counsel at Forest Laboratories, Inc., a New York Stock Exchange company that developed and marketed pharmaceutical products in a variety of therapeutic categories including central nervous system, cardiovascular, anti-infective, respiratory, gastrointestinal, and pain management medicine. Dr. Ryan has over 20 years experience in managing all aspects of intellectual property litigation, conducting due diligence investigations and prosecuting patent and trademark applications in the pharmaceutical and biotechnology industries. He also serves as a director of Applied DNA Sciences, Inc., a company that uses biotechnology from Stony Brook University and a law degree from Western New England University. We believe that Dr. Ryan's executive-level management and legal experience give him the qualifications and skills to serve as one of our directors.

### **Paul Jude Tonna**

Paul Jude Tonna became a member of our Board and Chair of our Compensation Committee in June 2014. Mr. Tonna is a highly regarded community leader and an accomplished businessman with an extensive history of public service. From 1994 to 2005 he served as a Suffolk County, New York Legislator, and from 2000 through 2002 was its Presiding Officer. He currently serves as Executive Director and a member of the Board of Advisors for The Energeia Partnership at Molloy College, a leadership academy based in Rockville Centre, New York, dedicated to identifying and addressing the serious, complex and multi-dimensional issues challenging the Long Island region. Mr. Tonna is a former Adjunct Professor in Theology & Religious Studies at St. John's University. He served as Chairman of the Suffolk County Industrial Development Agency, and currently serves as Trustee of the Long Island State Parks & Recreation Commission and as Public Trustee of the Stationary Engineers Industry Stabilization Fund. Mr. Tonna is a board member of The Advanced Energy Research & Technology Center at Stony Brook University, The Long Island Index Advisory Board and Erase Racism's College of Advisors. He also serves as the Executive Director of the Suffolk County Village Officials Association and the United States Green Building Council-Long Island Chairman and Commissioner of the South Huntington Water District. Mr. Tonna holds an undergraduate degree in Philosophy from New York University and a Master's degree in Theology from Immaculate Conception Seminary, and he conducted doctoral studies in Systemic Theology at Fordham University. We believe that Mr. Tonna's executive-level management experience and his extensive experience in the Long Island community give him the qualifications and skills to serve as one of our directors.

# **Scientific Advisors**

# Scientific Advisory Board

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

Name	Principal Positions
Wayne Marasco, M.D., Ph.D. 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
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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

# Clinical Director, Regenerative Disc/Spine Program

Dr. Olan also serves as Clinical Director of our Regenerative Disc/Spine Program.

# 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
Mark Weinreb	III	2020
Robert B. Catell	Ι	2021
John M. Desmarais	II	2022
A. Jeffrey Radov	III	2020
Charles S. Ryan	Ι	2021
Paul Jude Tonna	II	2022

Each executive officer will hold office until the initial meeting of the Board of Directors following the next annual meeting of stockholders and until his or her 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, 2018 and 2017 by (i) our principal executive officer, (ii) our two most highly compensated executive officers, other than our principal executive officer, who were serving as executive officers as of December 31, 2018 and whose total compensation for the 2018 fiscal year, as determined by Regulation S-K, Item 402, exceeded \$100,000, and (iii) a person who would have been included as one of our two most highly compensated executive officers, other than our principal executive officer, but for the fact that he was not serving as one of our executive officers as of December 31, 2018 (the individuals falling within categories (i), (ii) and (iii) are collectively referred to as the "Named Executive Officers"):

Name and Principal							Option Awards		All Other		
Position	Year	Salary			Bonus (1)	Earned (2)			mpensation	 Total	
Mark Weinreb,	2018	\$	400,000	\$	-	\$	291,800(3)	\$	7,200(4)	\$ 699,000(4)	
Chief Executive Officer	2017	\$	400,000	\$	32,000	\$	784,700(5)	\$	7,200(6)	\$ 1,223,900(6)	
Adam Bergstein	2018	\$	264,538	\$	-	\$	1,491,300(7)	\$	-	\$ 1,755,838	
Senior VP, Planning and Business Development (8)	2017	\$	-	\$	-	\$	-	\$	-	\$ -	
Francisco Silva,	2018	\$	287,500	\$	23,000	\$	107,800(9)	\$	-	\$ 418,300	
VP, Research and Development	2017	\$	250,000	\$	6,000	\$	200,400(10)	\$	-	\$ 456,400	
Robert Paccasassi,	2018	\$	201,250	\$	32,703	\$	53,900(11)	\$	-	\$ 287,853	
VP, Quality and Compliance (12)	2017	\$	-	\$	-	\$	-	\$	-	\$ -	
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- (2) The amounts reported in this column represent the grant date fair value of the option awards granted during the years ended December 31, 2018 and 2017, calculated in accordance with FASB ASC Topic 718. For a detailed discussion of the assumptions used in estimating fair values, see Note 10 Stockholders' Deficiency in the notes that accompany our consolidated financial statements included in this prospectus.
- (3) During 2018, Mr. Weinreb was granted a ten-year option under the Plan for the purchase of 275,000 shares of common stock at an exercise price of \$1.23 per share. Such option is exercisable to the extent of 91,667 shares as of each of the date of grant and the first anniversary of the date of grant and 91,666 shares as of the second anniversary of the date of grant. See "Employment Agreements" below for a discussion of certain provisions relating to the options granted to Mr. Weinreb.
- (4) Of the aggregate \$699,000 earned during 2018, \$291,800 represents the grant date value of non-cash stock-based compensation awards, irrespective of the vesting period of those awards. Of the \$407,200 earned cash compensation, \$406,761 and \$439 were paid in cash during 2018 and 2019 (prior to the date of this prospectus), respectively, and none remains unpaid for 2018. All Other Compensation represents an automobile allowance paid to Mr. Weinreb in 2018.
- (5) During 2017, Mr. Weinreb was granted a ten-year option under the Plan for the purchase of 275,000 shares of common stock at an exercise price of \$3.35 per share. Such option is exercisable to the extent of 91,667 shares as of each of the date of grant and the first anniversary of the date of grant and 91,666 shares as of the second anniversary of the date of grant. See "Employment Agreements" below for a discussion of certain provisions relating to the options granted to Mr. Weinreb.
- (6) Of the aggregate \$1,223,900 earned during 2017, \$784,700 represents the grant date value of non-cash stock-based compensation awards, irrespective of the vesting period of those awards. Of the \$439,200 earned cash compensation, \$178,113 and \$261,087 were paid in cash during 2017 and 2018, respectively, and none remains unpaid for 2017. All Other Compensation represents an automobile allowance paid to Mr. Weinreb in 2017.
- (7) During 2018, Mr. Bergstein was granted a ten-year option under the Plan for the purchase of 500,000 shares of common stock at an exercise price of \$3.40 per share. Such option was exercisable upon the satisfaction of a certain condition. As a result of Mr. Bergstein's resignation on October 28, 2018, such option has terminated.
- (8) Mr. Bergstein resigned as an officer on October 28, 2018.
- (9) During 2018, Mr. Silva was granted a ten-year option under the Plan for the purchase of 100,000 shares of common stock at an exercise price of \$1.23 per share. Such option is exercisable to the extent of 33,334 shares as of the first anniversary of the date of the grant and 33,333 shares as of each of the second and third anniversaries of the date of grant.
- (10) During 2017, Mr. Silva was granted a ten-year option under the Plan for the purchase of 80,000 shares of common stock at an exercise price of \$2.80 per share. Such option is exercisable to the extent of 26,667 shares as of each of the first and second anniversaries of the date of grant and 26,666 shares as of the third anniversary of the date of grant.
- (11) During 2018, Mr. Paccasassi was granted a ten-year option under the Plan for the purchase of 50,000 shares of common stock at an exercise price of \$1.23 per share. Such option is exercisable to the extent of 16,667 shares as of each of the first and second anniversaries of the date of grant and 16,666 shares as of the third anniversary of the date of grant.

(12) Mr. Paccasassi was not a Named Executive Officer during 2017.



<sup>(1)</sup> Represents bonus amounts earned pursuant to the achievement of certain performance goals.

# Outstanding Equity Awards at Fiscal Year-End

The following table provides information on outstanding equity awards as of December 31, 2018 to the Named Executive Officers:

		Ор	tion 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	ex Pi	Option ercise :ice(1)	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
Mark Weinreb	4,000	-	-	\$	4.70	12/14/2020	-	\$	-	-	\$ -
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	183,334	91,666(2)	-	\$	3.35	6/23/2027		\$	-	-	
Mark Weinreb	91,667	183,333(3)	-	\$	1.23	10/29/2028		\$	-	-	
Adam D. Bergstein	-	500,000(4)	-	\$	3.40	1/19/2028		\$	-	-	\$ -
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(5)	\$	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	40,000	20,000(6)	-	\$	3.73	6/10/2026	-	\$	-	-	\$ -
Francisco Silva	26,667	53,333(7)	-	\$	2.80	7/12/2027	-	\$	-	-	\$ -
Francisco Silva	-	100,000(8)	-	\$	1.23	10/29/2028	-	\$	-	-	\$ -
Robert Paccasassi	5,000	-	-	\$	4.70	8/13/2025	-	\$	-	-	\$-
Robert Paccasassi	10,000	5,000(9)	-	\$	3.73	6/10/2026	-	\$	-	-	\$-
Robert Paccasassi	13,334	26,666(10)	-	\$	2.80	7/12/2027	-	\$	-	-	\$-
Robert Paccasassi	-	50,000(11)	-	\$	1.23	10/29/2028	-	\$	-	-	\$ -

- (1) In March 2019, the exercise price for each of the options was reduced to \$0.75 per share.
- (2) Option became exercisable on June 23, 2019.
- (3) Option is exercisable to the extent of 91,667 shares on October 29, 2019 and 91,666 shares on October 29, 2020.
- (4) Option was exercisable subject to the satisfaction of a certain condition. As a result of Mr. Bergstein's resignation on October 28, 2018, such option has terminated.
- (5) Options are 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.
- (6) Option became exercisable on June 10, 2019.
- (7) Option became exercisable to the extent of 26,667 shares on July 12, 2019 and is exercisable to the extent of 26,666 shares on July 12, 2020.
- (8) Option is exercisable to the extent of 33,334 shares on October 29, 2019 and 33,333 shares on each of October 29, 2020 and October 29, 2021.
- (9) Option became exercisable on June 10, 2019.
- (10) Option became exercisable to the extent of 13,333 shares on July 12, 2019 and is exercisable to the extent of 13,333 shares on July 12, 2020.
- (11) Option is exercisable to the extent of 16,667 shares on each of October 29, 2019 and October 29, 2020 and 16,666 shares on October 29, 2021.

#### **Employment Agreements**

In March 2015, we entered into an employment agreement with Mark Weinreb, our Chief Executive Officer. Pursuant to the employment agreement, which expires on December 31, 2019, Mr. Weinreb is entitled to receive a salary of \$400,000 per annum. Mr. Weinreb was entitled to receive an annual bonus for 2015 equal to 50% of his annual base salary and was entitled to receive an annual bonus for 2016, 2017 and 2018 of up to 40%, 50% and 50%, respectively, of his annual base salary, in the event certain performance goals, as determined by our Compensation Committee, were satisfied. Mr. Weinreb is entitled to receive an annual bonus for 2019 of up to 50% of his annual base salary in the event certain performance goals, as determined by our Compensation Committee, are satisfied. Pursuant to the employment agreement, in the event that Mr. Weinreb's employment is terminated by us without "cause," or Mr. Weinreb terminates his employment for "good reason" (each as defined in the employment agreement), Mr. Weinreb would be entitled to receive severance in an amount equal to one time his then annual base salary and certain benefits, plus \$100,000 (in lieu of bonus). In addition, pursuant to the employment agreement, Mr. Weinreb would be entitled to receive such severance in the event that the term of his employment agreement is not extended beyond December 31, 2019 and, within three months of such expiration date, his employment is terminated by us without "cause" or if Mr. Weinreb terminates his employment for any reason. Further, in the event that Mr. Weinreb's employment is terminated by us without "cause," or Mr. Weinreb terminates his employment for "good reason," following a "change in control" (as defined in the employment agreement), Mr. Weinreb 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). Pursuant to the employment agreement, with respect to options granted to Mr. Weinreb during the term of his employment with us, such options shall vest and become exercisable if Mr. Weinreb is 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 becomes exercisable (whether due to the passage of time or otherwise), such option shall remain exercisable until its expiration date notwithstanding any termination of employment with us.



Effective January 16, 2018, we entered into an at will employment agreement with Adam D. Bergstein, Senior Vice President, Planning and Business Development. Pursuant to the employment agreement, Mr. Bergstein was entitled to receive a base annual salary of \$250,000 during the initial three months of employment. Thereafter, his base salary increased to \$350,000. In addition, pursuant to the employment agreement, Mr. Bergstein was entitled to receive an annual bonus of up to 30% of his annual salary based on the satisfaction of certain performance goals. The employment agreement also provided for the payment of three months severance under certain circumstances. Mr. Bergstein resigned his employment with us effective October 28, 2018.

Effective April 5, 2011, we entered into an at will employment agreement with Francisco Silva, our Vice President of Research and Development. Pursuant to the employment agreement, as amended, Mr. Silva is currently entitled to receive a salary of \$287,500 per annum. In addition, pursuant to the employment agreement, as amended, Mr. Silva is entitled to receive an annual bonus of up to 20% of his annual salary (up to 16% of his annual salary for 2016) based on the satisfaction of certain performance goals. Further, pursuant to the employment agreement, as amended, in the event that Mr. Silva's employment with us is terminated without cause, Mr. Silva would be entitled to receive severance in an amount equal to 50% of his then annual base salary.

Effective September 2, 2015, we entered into an at will employment agreement with Robert Paccasassi, our Vice President of Quality and Compliance. Pursuant to the employment agreement, as amended, Mr. Paccasassi is currently entitled to receive a salary of \$201,250 per annum. In addition, pursuant to the employment agreement, Mr. Paccasassi is entitled to receive an annual bonus of up to 25% of his annual salary based upon the satisfaction of certain performance goals

# **Director Compensation**

The following table sets forth certain information concerning the compensation of our non-employee directors for the fiscal year ended December 31, 2018:

Name	s Earned Paid in Cash	Stock Awards	I	Option Awards (1)	Non-Equity Incentive Plan Compensation		Def Comp	ualified erred ensation mings	ll Other	 Total
Robert B. Catell	\$ 40,000	\$ -	\$	79,600(2)	\$	-	\$	-	\$ -	\$ 119,600
John M. Desmarais	\$ 40,000	\$ -	\$	79,600(3)	\$	-	\$	-	\$ -	\$ 119,600
A. Jeffrey Radov	\$ 40,000	\$ -	\$	79,600(4)	\$	-	\$	-	\$ -	\$ 119,600
Charles S. Ryan	\$ 40,000	\$ -	\$	79,600(5)	\$	-	\$	-	\$ -	\$ 119,600
Paul Jude Tonna	\$ 40,000	\$ -	\$	79,600(6)	\$	-	\$	-	\$ -	\$ 119,600

(1) The amounts reported in this column represent the grant date fair value of the option awards granted during the year ended December 31, 2018, calculated in accordance with FASB ASC Topic 718. For a detailed discussion of the assumptions used in estimating fair values, see Note 10 – Stockholders' Deficiency in the notes that accompany our consolidated financial statements included in this prospectus for the fiscal year ended December 31, 2018.

(2) As of December 31, 2018, Mr. Catell held options for the purchase of 219,000 shares of common stock.

(3) As of December 31, 2018, Mr. Desmarais held options for the purchase of 250,000 shares of common stock.

(4) As of December 31, 2018, Mr. Radov held options for the purchase of 566,000 shares of common stock.

(5) As of December 31, 2018, Dr. Ryan held options for the purchase of 256,000 shares of common stock.

(6) As of December 31, 2018, 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 non-employee directors, is 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 receive stock options, from time to time, in consideration of their services.

### CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

# John M. Desmarais

In June 2016, we borrowed \$500,000 from Tuxis Trust, a trust for which John M. Desmarais, one of our non-employee directors and principal stockholders, and his wife serve as the trustees and which was established for the benefit of Mr. Desmarais's immediate family. The promissory note evidencing the loan (the "Tuxis Trust Note") provided for the payment of the principal amount, together with interest at the rate of 10% per annum, in July 2017. In July 2017, we and Tuxis Trust agreed to amend the Tuxis Trust Note to provide for a maturity date of December 1, 2017 and an increase in the interest rate to 15% per annum effective July 1, 2017. In the event that, prior to the maturity date of the Tuxis Trust Note, we receive net proceeds of \$10,000,000 from a single equity or debt financing (as opposed to a series of related or unrelated financings), Tuxis Trust has the right to require that we prepay the amount due under the Tuxis Trust Note (subject to the consent of the party that provided the particular financing). In consideration of the loan, we issued to Tuxis Trust a five-year warrant for the purchase of 40,000 shares of our common stock at an exercise price of \$4.00 per share.

In December 2016, we borrowed \$60,000 from Mr. Desmarais. The promissory note evidencing the loan provided for the payment of \$65,000 on January 31, 2017. In consideration of the loan, we further extended the expiration dates of the warrants held by Mr. Desmarais for the purchase of 444,444 and 400,000 shares of our common stock to December 31, 2018. In February 2017, we entered into an exchange agreement with Mr. Desmarais pursuant to which Mr. Desmarais exchanged the principal amount of the promissory note, together with accrued interest, for 21,731 shares of our common stock at an exchange price of \$3.00 per share and, in consideration thereof, received a five year warrant for the purchase of 21,731 shares of our common stock at an exercise price of \$4.00 per share.

In July 2017, we borrowed \$175,000 from Mr. Desmarais. The promissory note evidencing the loan (the "Desmarais Note") provides for the payment of the principal amount, together with interest at the rate of 15% per annum, on December 1, 2017. In the event that, prior to the maturity date of the Desmarais Note, we receive net proceeds of \$10,000,000 from a single equity or debt financing (as opposed to a series of related or unrelated financings), Mr. Desmarais has the right to require that we prepay the amount due under the Desmarais Note (subject to the consent of the party that provided the particular financing). The payment of the Desmarais Note is secured by the grant of a security interest in our equipment and intellectual property. Concurrently, we agreed that the payment of the Desmarais Trust Note is also secured by the grant of such security interest.

In November 2017, we and Mr. Desmarais agreed that the due date for the payment of the Desmarais Note was extended to December 1, 2018. Concurrently, we agreed with Tuxis Trust that the due date for the payment of the Tuxis Trust Note was also extended to December 1, 2018. In consideration of the note extensions by Mr. Desmarais and Tuxis Trust, we agreed to reduce the exercise prices of certain warrants held by Mr. Desmarais for the purchase of an aggregate of 775,000 shares of our common stock from \$5.00 per share to \$4.00 per share and the exercise price of a certain warrant held by Mr. Desmarais for the purchase of 444,444 shares of our common stock from \$4.50 per share to \$4.00 per share.

In November 2018, we and Mr. Desmarais agreed that the due date for the payment of the Desmarais Note was extended to December 31, 2019. Concurrently, we agreed with Tuxis Trust that the due date for the payment of the Tuxis Trust Note was also extended to December 31, 2019. In consideration of the note extensions by Mr. Desmarais and Tuxis Trust, we agreed to reduce the exercise prices of certain warrants held by Mr. Desmarais for the purchase of an aggregate of 844,444 shares of our common stock from \$4.00 per share to \$1.50 per share and to extend the expiration date of such warrants from December 31, 2018 to December 31, 2019.

In July 2019, we, Mr. Desmarais and Tuxis Trust agreed that the outstanding principal amounts of the Desmarais Note and the Tuxis Trust Note, together with accrued interest, will be exchanged for shares of common stock and warrants, as described below, concurrently with the offering contemplated by this prospectus (subject to our stockholders having approved such exchange agreements; on August 30, 2019, our stockholders approved such exchange agreements). The exchange price will be equal to 75% of the public offering price of the Units offered by this prospectus. The number of shares of common stock issuable pursuant to the warrants issued to Mr. Desmarais and Tuxis Trust will 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 issued as part of the Units being offered by this prospectus. The exercise price of the warrants will be 125% of the exchange price and the term of the warrants will be the same term as the Public Warrants. Mr. Desmarais and Tuxis Trust have agreed to enter into a lock-up agreement with the representative of the underwriters pursuant to which they will agree that they will not sell publicly any shares of common stock for a period of 135 days following the date of this prospectus unless the closing price of our shares of common stock equals or exceeds, for a period of five consecutive trading days, 150% of the public offering price as discussed under "Underwriting-Lock-Up Agreements". 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 will be reduced from between \$1.50 and \$4.00 per share to \$0.75 per share and the expiration dates of such warrants will be exchange, Mr. Desmarais and Tuxis Trust will release the security interest they held in our equipment and intellectual property.

#### Others

In August 2016, we borrowed \$100,000 from Robert B. Catell, one of our non-employee directors. The promissory note evidencing the loan (the "Catell Note") provided for the payment of the principal amount, together with interest at the rate of 10% per annum, on February 5, 2017. In consideration of the loan, we issued to Mr. Catell a fiveyear warrant for the purchase of 8,000 shares of our common stock at an exercise price of \$4.00 per share. In August 2017, we and Mr. Catell agreed that the outstanding principal amount of the Catell Note of \$50,000 would be payable on February 5, 2018. In consideration of such extension of the maturity date, we issued to Mr. Catell a fiveyear warrant for the purchase of 5,000 shares of our common stock at an exercise price of \$4.00 per share. In April 2018, we and Mr. Catell agreed that the outstanding principal amount of the Catell Note of \$45,000 would be payable on December 31, 2018. In February 2019, we and Mr. Catell agreed that the outstanding principal amount of the Catell Note of \$45,000 would be payable on December 31, 2018. In February 2019, we and Mr. Catell agreed that the outstanding principal amount of the Catell Note of \$30,000 will be payable on December 31, 2019. In August 2019, we paid the balance of the Catell Note.

In December 2016, we borrowed \$30,000 from Mr. Catell. The promissory note evidencing the loan provided for the payment of \$32,500 on January 31, 2017. In February 2017, we entered into an exchange agreement with Mr. Catell pursuant to which Mr. Catell exchanged the principal amount of the promissory note, together with accrued interest, for 10,866 shares of our common stock at an exchange price of \$3.00 per share and, in consideration thereof, received a five year warrant for the purchase of 10,866 shares of our common stock at an exercise price of \$4.00 per share.

In February 2017, the Compensation Committee of our Board of Directors reduced the exercise price of outstanding options for the purchase of an aggregate of 1,219,450 shares of our common stock (with exercise prices ranging between \$5.70 and \$30.00 per share) to \$4.70 per share, which was the closing price for our common stock on the day prior to the determination, as reported by the OTCQB. The exercise price reduction related to options held by, among others, our Named Executive Officers and directors with respect to the following number of shares: (i) Mark Weinreb, our President, Chief Executive Officer and Chairman of the Board: 494,500 shares, (ii) A. Jeffrey Radov, one of our directors: 238,000 shares, (iii) Paul Jude Tonna, one of our directors: 100,000 shares, (iv) Dr. Charles S. Ryan, one of our directors: 35,000 shares, (v) Francisco Silva, our Vice President of Research and Development: 100,650 shares, and (vi) Edward L. Field, then President of our Disc/Spine Division: 50,000 shares.

In March 2017, we entered into exchange agreements with Messrs. Catell, Desmarais and Tonna and Dr. Ryan, each a non-employee director, pursuant to which accrued director fees were exchanged for our common stock at an exchange price of \$3.00 per share and, in consideration thereof, we issued to them five year warrants for the purchase of our common stock at an exercise price of \$4.00 per share as follows: (i) Mr. Catell: \$45,000 for 15,000 shares and 15,000 warrants; (ii) Mr. Desmarais: \$50,000 for 16,667 shares and 16,667 warrants; (iii) Dr. Ryan: \$80,000 for 26,667 shares and 26,667 warrants; and (iv) Mr. Tonna: \$90,000 for 30,000 shares and 30,000 warrants.

In August 2017, we borrowed \$125,000 from Robert Austin Sperling, Jr., one of our then principal stockholders. The promissory note evidencing the loan provided for the payment of the principal amount, together with interest at the rate of 12% per annum, on May 23, 2018. The note provided that, in the event, prior to the maturity date of the note, we received net proceeds of \$10,000,000 from a single equity or debt financing (as opposed to a series of related or unrelated financings), Mr. Sperling had the right to require that we prepay the amount due under the note (subject to the consent of the party that provided the particular financing). The note issued to Mr. Sperling is no longer outstanding. In consideration of the loan, we issued to Mr. Sperling a five-year warrant for the purchase of 15,000 shares of our common stock at an exercise price of \$4.00 per share.

In February 2019, we borrowed \$450,000 from Harvey P. Alstodt and Melody Alstodt. The convertible promissory note issued to the lenders provides 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 is 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 provides for an exercise price of \$0.80 per share, subject to adjustment. The lenders are the parents of Lance Alstodt, our Executive Vice President and Chief Strategy Officer. The principal amount of the note is convertible into 750,000 shares of our common stock and a warrant for the purchase of 750,000 shares of our common stock. Such aggregate of 1,500,000 shares would represent approximately 6.6% of our outstanding common stock as of August 28, 2019 (based on 22,092,708 shares of common stock outstanding as of such date); however, the note provides that, except upon 61 days prior written notice, the lenders may not convert the note into our common stock and warrant to the extent that, after giving effect to the conversion, they would beneficially own in excess of 4.99% of our outstanding common stock. In August 2019, the lenders 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, will be exchanged for shares of common stock and warrants concurrently with the offering contemplated by this prospectus, as described below. The exchange price will be equal to the lesser of (i) \$0.2175 (75% of the public offering price of the Units offered by this prospectus at an assumed offering price of \$0.29 per Unit) and (ii) \$0.60 per share. The number of shares of common stock issuable pursuant to the warrant to be issued to the lenders will 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 will be equal to the lesser of (i) \$0.271875 (125% of the exchange price) or (ii) \$0.80 per share. The term of the warrant will be five years. The lenders have agreed to enter into a lock-up agreement with the representative of the underwriters pursuant to which they will agree that they will not sell publicly any shares of common stock for a period of 135 days following the date of this prospectus unless the closing price of our shares of common stock equals or exceeds, for a period of five consecutive trading days, 150% of the public offering price for the Units offered pursuant to this prospectus.

In March 2019, our Board of Directors reduced the exercise price of outstanding options for the purchase of an aggregate of 4,631,700 shares of our common stock (with exercise prices ranging between \$1.00 and \$4.70 per share) to \$0.75 per share, which was the closing price for our common stock on the day prior to the determination, as reported by the OTCQB. The exercise price reduction related to options held by, among others, our Named Executive Officers and directors with respect to the following number of shares: (i) Mr. Weinreb: 1,319,500 shares, (ii) Mr. Radov: 566,000 shares, (iii) Mr. Tonna: 364,000 shares, (iv) Dr. Ryan: 256,000 shares, (v) Mr. Desmarais: 250,000 shares, (vi) Mr. Catell: 219,000 shares, (vii) Mr. Silva: 340,650 shares, and (viii) Robert Paccasassi, our Vice President of Quality and Compliance: 110,000 shares.

#### **Director Independence**

### Board of Directors

Our Board of Directors is currently comprised of Mark Weinreb (Chairman), Robert B. Catell, John M. Desmarais, A. Jeffrey Radov, Charles S. Ryan and Paul Jude Tonna. Each of Messrs. Catell, Desmarais, Radov and Tonna and Dr. Ryan is currently an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of the listing standards of The NASDAQ Stock Market.

### Audit Committee

The members of our Board's Audit Committee currently are Messrs. Radov (Chairman) and Tonna and Dr. Ryan, each of whom is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of the listing standards of The NASDAQ Stock Market and Rule 10A-3(b)(1) under the Exchange Act.

#### Nominating Committee

The members of our Board's Nominating Committee currently are Dr. Ryan (Chairman) and Messrs. Radov and Tonna, each of whom is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of the listing standards of The NASDAQ Stock Market.

# Compensation Committee

The members of our Board's Compensation Committee currently are Messrs. Tonna (Chairman), Catell and Radov, each of whom is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of the listing standards 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 August 28, 2019, known by us, through transfer agent records, 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, and as adjusted to give effect to the issuance of the shares of common stock in this offering (without giving effect to the potential sale of up to additional shares of our common stock which may be issued in the event the underwriters exercise their over-allotment option) and the issuance of shares of common stock pursuant to the exchange of indebtedness described in "Prospectus Summary – Exchange of Outstanding Debt".

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 22,092,708 shares of common stock outstanding as of August 28, 2019, and 75,051,459 shares of common stock outstanding after giving effect to the sale of the shares of common stock in this offering, respectively (without giving effect to the potential sale of up to 6,206,897 additional shares of our common stock which may be issued in the event the underwriters exercise their over-allotment option but giving effect to the issuance of shares of common stock and warrants pursuant to the exchange of indebtedness described in "Prospectus Summary – Exchange of Outstanding Debt").

		Approximate Perce	ent of Class
Beneficial Owner	Number of Shares Beneficially Owned	Prior to the Offering	After the Offering <sup>(14)</sup>
Dale Broadrick			
3003 Brick Church Pike			
Nashville, Tennessee	5,725,640(1)	23.7%	
SCG Capital, LLC			
Steven Geduld			
21200 NE 38th Avenue			
Aventura, Florida	2,231,853(2)	9.99%	
John M. Desmarais			
230 Park Avenue		0.00/	
New York, New York Mark Weinreb	2,071,240(3)(4)	8.8%	(4)
40 Marcus Drive, Suite One			
Melville, New York	1 221 1(7(5)	5.3%	
Westbury (Bermuda) Ltd.	1,231,167(5)	5.5%	
Westbury Trust			
Victoria Hall			
11 Victoria Street			
Hamilton, HMEX Bermuda	1,151,661(6)	5.2%	
A. Jeffrey Radov	540,500(7)	2.4%	
Paul Jude Tonna	450,000(8)	2.0%	
Robert B. Catell	338,732(9)	1.5%	
Charles S. Ryan	284,334(10)	1.3%	
Francisco Silva	240,103(11)	1.1%	
Robert Paccasassi	46,667(12)	*	
Adam Bergstein	2	*	
All directors and executive officers	2	· · · · · · · · · · · · · · · · · · ·	
as a group (10 persons)	5,600,127(4)(13)	20.9%	
	5,000,127(4)(15)	20.970	

\*Less than 1%.

(1) Based upon Schedule 13D filed with the SEC. Includes 2,111,111 shares of common stock issuable upon the exercise of currently exercisable warrants.

(2) Based upon Schedule 13G filed with the SEC and other information known to us. Includes 248,162 shares of common stock issuable upon the conversion of a currently convertible note. The shares and convertible note are owned directly by SCG Capital, LLC ("SCG"). Steven Geduld as President of SCG has an indirect beneficial ownership in the securities held by SCG. SCG has rights, under the convertible promissory note, to own an aggregate number of shares of our common stock which, except for a contractual cap on the amount of outstanding shares of the common stock that SCG may own, could exceed such a cap. SCG's ownership cap under the convertible promissory note is 9.99% of the outstanding shares of our common stock. Therefore, based on 22,092,708 shares of common stock outstanding as of August 28, 2019 (22,573,885 shares of common stock outstanding giving effect to the shares issuable pursuant to the convertible note, subject to the cap), the number of shares of our common stock beneficially owned by SCG as of August 28, 2019 was 2,231,853 shares of common stock.

- (3) Based upon Schedule 13D filed with the SEC and other information known to us. Includes 1,577,842 shares of common stock issuable upon the exercise of options and warrants that are exercisable currently or within 60 days (including warrants for the purchase of 40,000 shares of common stock held by a trust for which Mr. Desmarais and his wife serve as the trustees and which was established for the benefit of his immediate family).
- (4) The "Number of Shares Beneficially Owned" by Mr. Desmarais does not give effect to the issuance of shares of common stock and warrants upon the exchange of outstanding indebtedness held by Mr. Desmarais and his related trust, as described in "Certain Relationships and Related Transactions – John M. Desmarais"; however, the "Approximate Percent of Class After the Offering" does give effect to such issuance.
- (5) Includes 1,136,167 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.
- (6) Based upon Schedule 13D filed with the SEC and other information known to us. Includes 199,182 shares of common stock issuable upon the exercise of currently exercisable warrants. The shares and warrants are owned directly by Westbury (Bermuda) Ltd. which is 100% owned by Westbury Trust.
- (7) Includes 516,000 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.
- (8) Represents (i) 1,500 shares of common stock held jointly with Mr. Tonna's wife and (ii) 344,000 shares of common stock issuable upon the exercise of options and warrants that are exercisable currently or within 60 days.
- (9) Includes 257,866 shares of common stock issuable upon the exercise of options and warrants that are exercisable currently or within 60 days.
- (10) Includes 241,417 shares of common stock issuable upon the exercise of options and warrants that are exercisable currently or within 60 days.
- (11) Includes (i) 12,116 shares of common stock held in an individual retirement account for the benefit of Mr. Silva and (ii) 210,984 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.
- (12) Represents shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.
- (13) Includes 4,708,327 shares of common stock issuable upon the exercise of options and warrants that are exercisable currently or within 60 days.
- (14) Gives effect to the issuance of shares of common stock (and, in the case of Mr. Desmarais, warrants) upon the exchange of outstanding indebtedness for common stock and warrants by, among others, Mr. Desmarais and his related trust, as described in "Prospectus Summary Exchange of Outstanding Debt".

# **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 170,000,000 shares of capital stock. We are authorized to issue 150,000,000 shares of common stock, par value \$0.001 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 the contemplated reverse split of our outstanding common stock. See "Contemplated Reverse Stock Split" below.

As of August 28, 2019, there were 22,092,708 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding; however, see "Prospectus Summary – Arena Investors Financing" for a discussion of the issuance of shares of Series A preferred stock to Arena concurrently with this offering.

### **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. See "Prospectus Summary – Arena Investors Financing" for a discussion of the issuance of shares of Series A preferred stock to Arena concurrently with this offering.

# 2010 Equity Participation Plan; Options

Pursuant to the Plan, we are authorized to issue up to 20,000,000 shares of common stock pursuant to the grant of stock options and stock appreciation rights, restricted stock grants and stock bonus grants.

As of June 30, 2019, we had outstanding options under the Plan to purchase an aggregate of 4,739,535 shares of common stock, of which options for the purchase of 3,283,205 shares were then exercisable.

The following table presents information related to stock options at June 30, 2019:

Options Outstanding	Options Outstanding		rcisable
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
\$0.75 - \$0.99	4,623,367	6.9	3,167,037
\$1.00 - \$5.99	43,668	0.8	43,668
\$6.00 - \$19.99	37,500	4.5	37,500
\$20.00 - \$30.00	35,000	2.7	35,000
	4,739,535	6.8	3,283,205

# Warrants

As of June 30, 2019, we had outstanding warrants to purchase an aggregate of 5,852,952 shares of common stock, all of which were then exercisable.

### The following table presents information related to stock warrants at June 30, 2019:

Warrants Outstanding		Warrants Exe	rcisable
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
\$0.56 - \$0.99	2,456,111	3.0	2,456,111
\$1.00 - \$1.99	844,444	0.5	844,444
\$2.00 - \$2.99	75,000	4.3	75,000
\$3.00 - \$3.99	70,000	4.0	70,000
\$4.00 - \$4.99	2,102,135	2.0	2,102,135
\$5.00 - \$5.99	195,989	2.0	195,989
\$6.00 - \$7.99	40,000	1.1	40,000
\$8.00 - \$9.99	2,500	0.4	2,500
\$10.00 - \$15.00	66,773	0.6	66,773
	5,852,952	2.3	5,852,952

Subsequent to June 30, 2019, as described in "Prospectus Summary – Arena Investors Financing", concurrently with this offering, we are issuing to Arena warrants to purchase 6,000,000 shares of common stock (subject to increase as described in such section), which warrants are exercisable at an exercise price equal to the lesser of (i) 0.271875 (93.75% of the public offering price for the Units offered by this prospectus, assuming a public offering price of \$0.29 per Unit) or (ii) \$0.3625 (100% of the exercise price of the warrants included as part of the Units offered by this prospectus, assuming a public offering price of \$0.29 per Unit). Further, concurrently with this offering, the exercise price of warrants held by John M. Desmarais and Tuxis Trust for the purchase of an aggregate of 1,377,842 shares of common stock will be reduced from between \$1.50 and \$4.00 per share to \$0.75 per share and the expiration dates of the warrants will be extended from between December 31, 2019 to March 1, 2022 to December 31, 2023.

### **Description of Securities in this Offering**

Units. Each Unit consists of one share of our common stock, par value \$0.001 per share, and one warrant ("Warrant") to purchase one 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 41,379,310 common stock purchase Warrants outstanding (47,586,207 if the Units issuable upon exercise of the underwriters' over-allotment option are sold). Each Warrant is exercisable for the purchase of 1 share of common stock at an exercise price of \$0.3625 per share (125% of the price of each Unit sold in the offering based upon an assumed offering price of \$0.29 per Unit) and is exercisable for a period of three years from the initial exercise date.

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 holder 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 the 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. In lieu of receiving such common stock and additional consideration in the Fundamental Transaction. The 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.

Underwriter's Warrants. We also expect to have up to an additional 2,068,966 common stock purchase warrants outstanding (2,379,310 if the Units issuable upon exercise of the underwriters' over-allotment option are sold), issuable to the underwriters of this offering ("Underwriter's Warrants") (assuming that the number of Underwriter's Warrants equals 5% of the number of shares of common stock issued pursuant to this offering). Each Underwriter's Warrant is exercisable for one share of common stock on a cash or cashless basis at an exercise price of 125% of the price of each Unit sold in this offering). The Underwriter's Warrants will not be exercisable for six months after the closing of this offering, and will expire five (5) years after the closing of this offering. The Underwriter's Warrants will not be redeemable. The Underwriter's Warrants may not be transferred, assigned, pledged or hypothecated for six months following the effective date of the registration statement for this offering, except that the underwriters may assign the Underwriter's Warrants in whole or in part to any successor, officer, manager or member of such underwriter (or to officers, managers or members of any such successor or member) and to other underwriters of this offering. The Underwriter's Warrants will contain provisions for one demand registration of the shares underlying the Underwriter's Warrants at our expense and unlimited piggyback registration rights for a period of five (5) years after the closing of this offering at our expense.

The number of Underwriter's Warrants outstanding and the exercise price of the Underwriter Warrants will be adjusted proportionately, as permitted by Financial Industry Regulatory Authority ("FINRA") Rule 5110(f)(2)(G), 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 Underwriter's 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 Underwriter's 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 Underwriter's Warrant holder will have the right to receive, for each share of common stock issuable upon the exercise of the Underwriter's Warrant, at the option of the holder, the number of shares of common stock of the successor or acquiring corporation or or us (if we are the surviving corporation), and any additional consideration payable as a result of the Fundamental Transaction. In lieu of receiving such common stock and additional consideration in the Fundamental Transaction, the Underwriter's Warrant for its fair market value measured by the Black Scholes method.

We will promptly notify the holders of the Underwriter's Warrants in writing of any adjustment to the exercise price or to the number of the outstanding Underwriter's 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.

# **Registration Rights**

Holders of 2,506,861 shares of our common stock and warrants for the purchase of 2,151,111 shares of our common stock have certain piggyback registration rights with regard to the resale of such shares and the shares underlying such warrants. In addition, we have granted registration rights with regard to the resale of shares of common stock as described in "Prospectus Summary – Arena Investors Financing" and "Prospectus Summary – Exchange of Outstanding Debt". Further, outstanding convertible promissory notes in the aggregate principal amount of \$3,078,374 have registration rights with regard to the shares of common stock issuable upon conversion (such number being presently indeterminate since the conversion prices are based upon the market price of our common stock at the time of conversion). However, all such registration rights are subject to the qualification that, if the managing underwriter of an underwritten offering determines that, in its good faith judgment, the inclusion of the shares would adversely affect the success of the offering or the price at which the securities can be sold, then the number of shares subject to such piggyback registration rights are subject to the qualification, substantially all of the registration rights are subject to the qualification that they do not apply if the shares can be sold pursuant to Rule 144.

### **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<sup>th</sup> day before such annual meeting or (ii) the 10<sup>th</sup> 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 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<sup>th</sup> day before such annual meeting or (ii) the 10<sup>th</sup> 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 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.

#### **Contemplated Reverse Stock Split**

At our annual meeting of stockholders held on May 30, 2019, our stockholders approved amendments to our charter, and the authorization of our Board of Directors to select and file one such amendment, to effect a reverse stock split of our common stock at a ratio of not less than 1-for-2 and not more than 1-for-20. In addition, at such meeting, our stockholders authorized our Board of Directors, in its discretion, to reduce the number of shares of common stock authorized to be issued by us 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 our Board of Directors in its discretion). The share and per share amounts set forth in this prospectus do not give effect to such contemplated reverse split.

### **Transfer Agent**

The transfer agent for our common stock is Transhare Corporation.

### UNDERWRITING

We have entered into an underwriting agreement with Maxim Group LLC ("Maxim" or the "Representative"), as the sole representative of the underwriters with respect to the Units being offered. Maxim is the sole book-running manager for the offering. 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
Maxim Group LLC		
Joseph Gunnar & Co., 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 6,206,897 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.

# **Underwriter's Warrants**

We have agreed to issue Underwriter's Warrants to the underwriters to purchase a number of shares of our common stock equal to 5% of the total number of shares of our common stock sold in this offering, except that, with respect to investors introduced to the underwriters by us, the Underwriter's 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 sold in this offering. Each Underwriter's Warrant is exercisable for one share of common stock on a cash or cashless basis at an exercise price equal to 125% of the price of each Unit sold in the offering. The Underwriter's Warrants will not be exercisable for six months after the closing of this offering, and will expire five years after the effective date of the registration statement for this offering. The Underwriter's Warrants may 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 six months following the effective adate of the registration statement for this offering, except that the underwriters may assign the Underwriter's Warrants in whole or in part to any officer or partner of such underwriter and to the other underwriters (or their officers or partners) of this offering. The Underwriter's Warrants will contain provisions for one demand registration statement for this offering at our expense and unlimited piggyback registration rights for a period of five (5) years after the effective date of the registration statement for the shares underlying the Underwriter's Warrants at our expense.

The number of Underwriter's Warrants that are issued, and the exercise price of the Underwriter's Warrants, will be adjusted proportionately, as permitted by FINRA Rule 5110(f)(2)(G).

### **Underwriting Discounts and Commissions**

We have agreed to sell the Units to the underwriters at a discount equal to 7.5% of the public offering price for the Units, except that, with respect to investors introduced to the underwriters by us, the discount shall be equal to 5% of the public offering price for the Units.

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 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 discounts (7.5%) (1)	\$	\$	\$
Proceeds, before expenses, to us $(2)(3)$	\$	\$	\$

(1) In addition to the underwriting discount, we have agreed to pay to the underwriters the amount of \$270,000 in connection with the closing of the Arena private financing and reimburse the underwriters to cover certain accountable expenses of the underwriters in connection with this offering in an amount up to \$90,000. We have also agreed to issue to the underwriters the Underwriter's Warrants as described above under "Underwriter's Warrants." With respect to investors introduced to the underwriters by us, the underwriting discount shall be 5% instead of 7.5%.

(2) We estimate that the total expenses of the offering payable by us, excluding the total underwriting discounts, will be approximately \$500,000.

(3) We have paid a \$25,000 advance to the underwriters to be applied against the accountable expenses that will be paid by us to the underwriters in connection with this offering; any amount not offset by actual expenses will be returned to us.

### 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. In addition, see "Prospectus Summary – Arena Investors Financing", "Prospectus Summary – Exchange of Outstanding Debt" and "Certain Relationships and Related Transactions – John M. Desmarais" for a discussion of certain lock-up agreements to be entered into with Arena, the debtholders, Mr. Desmarais and Tuxis Trust.

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 Maxim a right of first refusal, for a period of twelve months from the commencement of sales of this offering (assuming the closing of this offering occurs), to act as sole lead managing underwriter and sole book-runner, at Maxim's sole and exclusive discretion, for each and every of our future public and private equity and debt offerings, including all equity-linked financings, during such twelve month period for which we engage an investment banker or other intermediary for such purpose, 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.

# **OTCQB** and NASDAQ

Our common stock is presently quoted on the OTCQB under the symbol "BRTX." We have applied to have our common stock and Warrants listed on NASDAQ under the symbols "BRTX" and "BRTXW," respectively. 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.

### 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 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.

The underwriters have informed us that they do not expect to confirm sales of Units offered by this prospectus to accounts over which they exercise discretionary authority.

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.

#### Notice to Prospective Investors in Canada

This prospectus constitutes an "exempt offering document" as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the Units. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this prospectus or on the merits of the Units and any representation to the contrary is an offence.

Canadian investors are advised that this prospectus has been prepared in reliance on section 3A.3 of National Instrument 33-105 Underwriting Conflicts ("NI 33-105"). Pursuant to section 3A.3 of NI 33-105, this prospectus is exempt from the requirement that we and the underwriters provide Canadian investors with certain conflicts of interest disclosure pertaining to "connected issuer" and/or "related issuer" relationships that may exist between us and the underwriters as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

#### **Resale Restrictions**

The offer and sale of the Units in Canada is being made on a private placement basis only and is exempt from the requirement that we prepare and file a prospectus under applicable Canadian securities laws. Any resale of shares and/or Warrants acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, pursuant to a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements regulatory authority. These resale restrictions may under certain circumstances apply to resales of the shares and/or Warrants outside of Canada.

### **Representations of Purchasers**

Each Canadian investor who purchases Units will be deemed to have represented to us, the underwriters and to each dealer from whom a purchase confirmation is received, as applicable, that the investor is (i) purchasing as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) an "accredited investor" as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions* or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a "permitted client" as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

### **Taxation and Eligibility for Investment**

Any discussion of taxation and related matters contained in this prospectus does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the Units and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the Units or with respect to the eligibility of the shares and/or Warrants for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

### **Rights of Action for Damages or Rescission**

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum (such as this prospectus), including where the distribution involves an "eligible foreign security" as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a "misrepresentation" as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defenses under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

### Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.

### 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 August 28, 2019, 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, 2018 and 2017 and for the years then ended appearing in this prospectus have been included in reliance upon the report, which includes an explanatory paragraph as to our ability to continue as a going concern, of Marcum 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 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 exhibits 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 <u>http://www.sec.gov</u> 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 <u>http://www.sec.gov</u> 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, <u>www.biorestorative.com</u>, 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, and we do not intend to incorporate into this prospectus any information contained on our website.

# CONSOLIDATED FINANCIAL STATEMENTS

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# **Condensed Consolidated Balance Sheets**

	June 30, 2019 (unaudited)		December 31, 2018		
Assets					
Current Assets:					
Cash	\$ 1,283,666	\$	117,523		
Accounts receivable	31,000		29,000		
Prepaid expenses and other current assets	42,392		34,464		
Total Current Assets	1,357,058		180,987		
Property and equipment, net	136,406		175,235		
Intangible assets, net	776,612		814,059		
Security deposit	-		22,100		
Deferred offering costs	 162,003		-		
Total Assets	\$ 2,432,079	\$	1,192,381		
Liabilities and Stockholders' Deficiency					
Current Liabilities:					
Accounts payable	\$ 1,526,957	\$	1,893,827		
Accrued expenses and other current liabilities	2,665,677		2,302,176		
Accrued interest	505,210		338,619		
Current portion of notes payable, net of debt discount of \$2,035,578 and \$936,866 at June 30, 2019 and December 31, 2018, respectively	5,499,287		3,625,659		
Derivative liabilities	946,071		1,094,607		
Total Current Liabilities	11,143,202		9,254,888		
Accrued expenses, non-current portion	-		36,500		
Accrued interest, non-current portion	30,548		18,137		
Notes payable, non-current portion, net of debt discount of \$24,302 and \$75,497 at June 30, 2019 and December 31, 2018, respectively	200,800		523,894		
Total Liabilities	11,374,550		9,833,419		
Commitments and contingencies (See Note 6)					
Stockholders' Deficiency:					
Preferred stock, \$0.01 par value;					
Authorized, 20,000,000 shares; None issued and outstanding at June 30, 2019 and December 31, 2018	-				
Common stock, \$0.001 par value;					
Authorized, 150,000,000 shares;					
Issued and outstanding 19,793,477 and 11,728,394 shares					
at June 30, 2019 and December 31, 2018, respectively	19,793		11,728		
Additional paid-in capital	63,000,354		55,269,490		
Accumulated deficit	 (71,962,618)		(63,922,256		
Total Stockholders' Deficiency	 (8,942,471)		(8,641,038		
Total Liabilities and Stockholders' Deficiency	\$ 2,432,079	\$	1,192,381		

See Notes to these Condensed Consolidated Financial Statements

# **Condensed Consolidated Statements of Operations**

# (unaudited)

	For The Three Months Ended June 30,					Months Ended ne 30,		
		2019		2018		2019		2018
Revenues	\$	31,000	\$	37,000	\$	60,000	\$	56,000
Operating Expenses:								
Marketing and promotion		108,849		17,531		124,686		58,554
Consulting		533,873		417,954		1,133,607		850,884
Research and development		441,723		372,815		896,729		779,945
General and administrative		1,075,359		1,279,035		2,362,118		2,647,690
Total Operating Expenses		2,159,804	-	2,087,335	-	4,517,140		4,337,073
Loss-From Operations		(2,128,804)		(2,050,335)		(4,457,140)		(4,281,073)
Other (Expense) Income:								
Interest expense		(327,967)		(230,383)		(644,911)		(391,642)
Amortization of debt discount		(991,261)		(1,081,982)		(1,734,403)		(1,343,628)
Loss on extinguishment of notes payable, net		(552,109)		(44,951)		(1,000,595)		(63,788)
Change in fair value of derivative liabilities		(157,049)		(106,772)		(203,313)		58,048
Total Other Expense		(2,028,386)		(1,464,088)		(3,583,222)		(1,741,010)
Net Loss	\$	(4,157,190)	\$	(3,514,423)	\$	(8,040,362)	\$	(6,022,083)
Net Loss Per Share								
- Basic and Diluted	\$	(0.24)	\$	(0.53)	\$	(0.52)	\$	(0.93)
Weighted Average Number of Common Shares Outstanding		<u> </u>						
- Basic and Diluted		17,509,453		6,576,327		15,599,172		6,485,069
San Notas to these Condensed Consolidated Financial Statements								

See Notes to these Condensed Consolidated Financial Statements

# Condensed Consolidated Statements of Changes in Stockholders' Deficiency

# (unaudited)

		Six Months Ended June 30, 2019						
	Commo Shares	on Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total			
Balance - January 1, 2019	11,728,394	\$ 11,728	\$ 55,269,490	\$ (63,922,256)	\$ (8,641,038)			
Shares and warrants issued for cash	1,000,000	1,000	99,000	-	100,000			
Shares issued in satisfaction of accrued consulting services	10,000	10	7,190	-	7,200			
Shares issued in exchange for notes payable and accrued interest	1,984,017	1,984	1,508,298	-	1,510,282			
Shares issued and recorded as debt discount in connection with a note payable extension	10,000	10	7,042	-	7,052			
Reclassification of derivative liabilities to equity	-	-	2,517,254	-	2,517,254			
Stock-based compensation: - options	-	-	729,678	-	729,678			
Net loss	-	-	-	(3,883,172)	(3,883,172)			
Balance - March 31, 2019	14,732,411	14,732	60,137,952	(67,805,428)	(7,652,744)			
Shares and warrants issued for cash	1,191,111	1,191	155,120	-	156,311			
Shares issued in exchange for notes payable and accrued interest	3,726,082	3,726	2,059,712	-	2,063,438			
Shares issued and recorded as debt discount in connection with a note payable issuance	68,873	69	54,099	-	54,168			
Reclassification of derivative liabilities to equity	-	-	120,742	-	120,742			
Stock-based compensation: - common stock - options	75,000	75	29,925 442,804	- -	30,000 442,804			
Net loss				(4,157,190)	(4,157,190)			
Balance - June 30, 2019	19,793,477	\$ 19,793	\$ 63,000,354	\$ (71,962,618)	\$ (8,942,471)			

	Six Months Ended June 30, 2018					
	Comme Shares	on Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total	
Balance - January 1, 2018	6,112,473	\$ 6,112	\$ 44,561,773	\$ (51,404,453)	\$ (6,836,568)	
Exercise of warrants for purchase of common stock	207,084	207	413,961	-	414,168	
Shares and warrants issued in satisfaction of accrued consulting services	19,000	19	37,981	-	38,000	
Conversion of notes payable and accrued interest into common stock	27,018	27	52,877	-	52,904	
Shares issued in exchange for notes payable and accrued interest	84,678	85	173,841	-	173,926	
Shares issued and recorded as debt discount in connection with note payable issuances or extensions	33,000	33	61,174	-	61,207	
Reclassification of derivative liabilities to equity	-	-	9,397	-	9,397	
Beneficial conversion features related to convertible notes payable	-	-	21,518	-	21,518	
Stock-based compensation: - options and warrants			882,812	-	882,812	
Net loss Balance - March 31, 2018	6,483,253	6,483	46,215,334	(2,507,660) (53,912,113)	(2,507,660) (7,690,296)	
Shares and warrants issued for cash	10,000	10	24,990	-	25,000	
Shares issued in exchange for notes payable and accrued interest	236,248	236	467,430	-	467,666	
Shares issued and recorded as debt discount in connection with note payable issuances or extensions	18,000	18	26,232	-	26,250	
Reclassification of derivative liabilities to equity	-	-	(9,397)	-	(9,397)	
Stock-based compensation: - options	-	-	827,187	-	827,187	
Net loss Balance - June 30, 2018	6,747,501	\$ 6,747	\$ 47,551,776	(3,514,423) \$ (57,426,536)	(3,514,423) \$ (9,868,013)	

# **Condensed Consolidated Statements of Cash Flows**

# (unaudited)

	For The Six Months Ended June 30,		
		2019	2018
Cash Flows From Operating Activities			
Net loss	\$	(8,040,362) \$	(6,022,083)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt discount		1,734,403	1,343,628
Accretion of interest expense		235,122	333,425
Depreciation and amortization		105,647	121,624
Stock-based compensation		1,258,482	1,709,999
Loss on extinguishment of note payables, net		1,000,595	63,788
Gain on settlement of payables		(29,300)	-
Change in fair value of derivative liabilities		203,313	(58,048)
Changes in operating assets and liabilities:			
Accounts receivable		(2,000)	1,000
Prepaid expenses and other current assets		(7,928)	(5,065)
Security deposit		22,100	-
Accounts payable		(457,444)	(177,666)
Accrued interest, expenses and other current liabilities		580,255	490,821
Total adjustments		4,643,245	3,823,506
Net Cash Used In Operating Activities		(3,397,117)	(2,198,577)
Cash Flows From Investing Activities			
Purchases of property and equipment		(29,371)	(12,869)
Net Cash Used In Investing Activities		(29,371)	(12,869)
Cash Flows From Financing Activities			
Offering costs incurred		(12,929)	-
Proceeds from notes payable		5,991,198	1,473,552
Repayments of notes payable - principal		(2,201,629)	(149,425)
Repayments of notes payable - prepayment premiums		(340,009)	-
Advances from officers and a family member of an officer		-	32,000
Repayments of advances from officers and a family member of an officer		-	(32,000)
Proceeds from exercise of warrants		-	414,168
Sales of common stock and warrants for cash		1,156,000	25,000
Net Cash Provided By Financing Activities		4,592,631	1,763,295
Net Increase (Decrease) In Cash		1,166,143	(448,151)
Cash at beginning of period		117,523	451,680
Cash at end of period	\$	1,283,666 \$	3,529

See Notes to these Condensed Consolidated Financial Statements

# Condensed Consolidated Statements of Cash Flows - Continued

# (unaudited)

	For The Six Months Ended June 30,			nded
		2019		2018
Supplemental Disclosures of Cash Flow Information:				
Cash paid during the period for:				
Interest	\$	134,536	\$	9,355
Income tax	\$	-	\$	-
Non-cash investing and financing activities:				
Shares issued and recorded as debt discount in connection with notes payable issuances or				
extensions	\$	61,220	\$	87,457
Shares issued in exchange for notes payable and accrued interest	\$	3,573,720	\$	641,592
Conversion of notes payable and accrued interest into common stock	\$	-	\$	52,904
Shares and warrants issued in satisfaction of accrued consulting services	\$	7,200	\$	38,000
Bifurcated embedded conversion options and warrants recorded as derivative liability and debt				
discount	\$	3,168,462	\$	1,233,410
Beneficial conversion features set up as debt discount	\$	-	\$	21,518
Reclassification of derivative liabilities to equity	\$	2,637,996	\$	-
Warrants issued for consulting services recorded as derivative liabilities	\$	56,000	\$	-
Accrued interest reclassified to notes payable principal	\$	23,013	\$	-
Offering costs in accounts payable and accrued expenses	\$	149,074	\$	-
Original issue discount in connection with notes payable	\$	355,940	\$	150,948

See Notes to these Condensed Consolidated Financial Statements

# Notes to Condensed Consolidated Financial Statements (unaudited)

# Note 1 - Business Organization and Nature of Operations

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" (See Note 3 – Summary of Significant Accounting Policies – Principles of Consolidation). BRT develops therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. BRT's website is at <u>www.biorestorative.com</u>. 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. 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.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information. Accordingly, they do not include all of the information and disclosures required by GAAP for annual financial statements. In the opinion of management, such statements include all adjustments (consisting only of normal recurring items) which are considered necessary for a fair presentation of the unaudited condensed consolidated financial statements of the Company as of June 30, 2019 and for the three and six months ended June 30, 2019 and 2018. The results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the operating results for the full year ending December 31, 2019 or any other period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related disclosures of the Company as of December 31, 2018 and for the year then ended, which are include elsewhere in this filing.

### Note 2 – Going Concern and Management's Plans

As of June 30, 2019, the Company had a working capital deficiency and a stockholders' deficiency of \$9,786,144 and \$8,942,471, respectively. During the three and six months ended June 30, 2019, the Company incurred net losses of \$4,157,190 and \$8,040,362, respectively. These conditions indicate that there is substantial doubt about the Company's ability to continue as a going concern within the next twelve months from the filing date of this report.

The Company's primary source of operating funds since inception has been equity and debt financings. The Company intends to continue to raise additional capital through debt and equity financings. 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 or, notwithstanding any request the Company may make, the Company's debt holders do not agree to convert their notes into equity or extend the maturity dates of their notes, 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 U.S. 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 financial statements do not necessarily purport to represent realizable or settlement values. The unaudited condensed consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

### Notes to Condensed Consolidated Financial Statements (unaudited)

Subsequent to June 30, 2019, the Company has received aggregate debt proceeds of \$1,666,000, debt (inclusive of accrued interest) of \$339,480 has been exchanged for common stock, \$1,644,778 of debt (inclusive of accrued interest and prepayment premiums) has been repaid, and the due date for the repayment of \$1,053,102 of debt has been further extended to dates ranging between July 2019 (each of which were subsequently exchanged for common stock or further extended) and July 2020. As a result, the Company expects to have the cash required to fund its operations through September 2019 while it continues to apply efforts to raise additional capital. While there can be no assurance that it will be successful, the Company is in negotiations to raise additional capital. As of the filing date of this report, the Company has a note payable with a principal balance of \$144,000 which is past due. The Company is currently in the process of negotiating an extension with respect to this note, though there can be no assurance that the Company will be successful. See Note 9 – Subsequent Events for details regarding the Company entering into a securities purchase agreement with an investor for the purchase of preferred stock, a warrant and a convertible note and exchange agreements with respect to the exchange of debt for common stock and warrants.

### Note 3 - Summary of Significant Accounting Policies

### Principles of Consolidation

The unaudited condensed consolidated financial statements of the Company include the accounts of Stem Pearls. All significant intercompany transactions have been eliminated in the consolidation.

# 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 the dates of the financial statements and the reported amounts of revenue and expenses during the periods. The Company's significant estimates and assumptions include the recoverability and useful lives of long-lived assets, the fair value of the Company's stock, stock-based compensation, warrants issued in connection with notes payable, derivative liabilities and the valuation allowance related to the Company's deferred tax assets. Certain of the Company's estimates, including the carrying amount of the intangible assets, could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and could cause actual results to differ from those estimates.

# Deferred Offering Costs

Deferred offering costs, which primarily consist of direct, incremental professional fees incurred in connection with preparing for a contemplated public offering of the Company's equity securities (as described in Note 9 – Subsequent Events), are capitalized as non-current assets on the balance sheet. Upon the consummation of such contemplated offering, the deferred offering costs will be offset against the equity offering proceeds. As of June 30, 2019, the Company incurred deferred offering costs in the amount of \$162,003, of which \$127,074 and \$22,000 are included in accounts payable and accrued expenses, respectively, on the June 30, 2019 condensed consolidated balance sheet, in connection with such contemplated public offering.

### Revenue Recognition

On January 1, 2019, the Company adopted Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers" ("ASC 606"). The core principle of ASC 606 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing U.S. GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

# The five-step process outlined in the ASC 606 is as follows:

Step 1 - Identify the Contract with the Customer – A contract exists when (a) the parties to the contract have approved the contract and are committed to perform their respective obligations, (b) the entity can identify each party's rights regarding the goods or services to be transferred, (c) the entity can identify the payment terms for the goods or services to be transferred, (d) the contract has commercial substance and it is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.



## Notes to Condensed Consolidated Financial Statements (unaudited)

Step 2 - Identify Performance Obligations in the Contract – Upon execution of a contract, the Company identifies as performance obligations each promise to transfer to the customer either (a) goods or services that are distinct or (b) a series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer. To the extent a contract includes multiple promised goods or services, the Company must apply judgement to determine whether the goods or services are capable of being distinct within the context of the contract. If these criteria are not met, the goods or services are accounted for as a combined performance obligation.

Step 3 – Determine the Transaction Price – When (or as) a performance obligation is satisfied, the Company shall recognize as revenue the amount of the transaction price that is allocated to the performance obligation. The contract terms are used to determine the transaction price. Generally, all contracts include fixed consideration. If a contract did include variable consideration, the Company would determine the amount of variable consideration that should be included in the transaction price based on expected value method. Variable consideration would be included in the transaction price, if in the Company's judgement, it is probable that a significant future reversal of cumulative revenue under the contract would not occur.

Step 4 - Allocate the Transaction Price – After the transaction price has been determined, the next step is to allocate the transaction price to each performance obligation in the contract. If the contract only has one performance obligation, the entire transaction price will be applied to that obligation. If the contract has multiple performance obligations, the transaction price is allocated to the performance obligations based on the relative standalone selling price (SSP) at contract inception.

Step 5 – Satisfaction of the Performance Obligations (and Recognize Revenue) – Revenue is recognized when (or as) goods or services are transferred to a customer. The Company satisfies each of its performance obligations by transferring control of the promised good or service underlying that performance obligation to the customer. Control is the ability to direct the use of, and obtain substantially all of the remaining benefits from, an asset. It includes the ability to prevent other entities from directing the use of, and obtaining the benefits from, an asset. Indicators that control has passed to the customer include: a present obligation to pay; physical possession of the asset; legal title; risks and rewards of ownership; and acceptance of the asset. Performance obligations can be satisfied at a point in time or over time.

The Company recognizes 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 non-exclusive 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 recognizes sublicensing and royalty revenue on a per disc procedure basis when the third-party sale occurs. 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 three and six months ended June 30, 2019, the Company recognized \$31,000 and \$60,000, respectively, of revenue related to the Company's sublicenses. During the three and six months ended June 30, 2018, the Company recognized \$37,000 and \$56,000, respectively, of revenue related to the Company's sublicenses.

The Company adopted ASC 606 for all applicable contracts using the modified retrospective method, which would have required a cumulative-effect adjustment, if any, as of the date of adoption. The adoption of ASC 606 did not have a material impact on the Company's unaudited condensed consolidated financial statements as of the date of adoption. As a result, a cumulative-effect adjustment was not required.

### Notes to Condensed Consolidated Financial Statements (unaudited)

# Net Loss Per Common Share

Basic loss per common share is computed by dividing net loss by the weighted average number of vested common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	June 30,	June 30,	
	2019	2018	
Options	4,739,535	3,615,119	
Warrants	5,852,952	3,318,403	
Convertible notes - common stock [1]	21,525,021	2,713,717	
Convertible notes - warrants	2,555,318	-	
Total potentially dilutive shares	34,672,826	9,647,239	

[1] As of June 30, 2019 and June 30, 2018, many of the convertible notes had variable conversion prices and the shares were estimated based on market conditions. Pursuant to the note agreements, on June 30, 2019 and June 30, 2018 there were 105,349,305 and 15,771,133 shares of common stock reserved for future note conversions, respectively.

### Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. The Company estimates the fair value of the awards granted based on the market value of its freely tradable common stock as reported on the OTCQB market. Upon the exercise of an option or warrant, the Company issues new shares of common stock out of its authorized shares.

# 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 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 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.

### Notes to Condensed Consolidated Financial Statements (unaudited)

### 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 or directors are not subject to the sequencing policy.

### Reclassification

Certain amounts in prior periods have been reclassified to conform to the current period presentation. These reclassifications had no effect on previously reported net loss.

### Subsequent Events

The Company evaluates events that have occurred after the balance sheet date but before the financial statements are issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the unaudited condensed consolidated financial statements, except as disclosed.

### Recently Issued Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)" ("ASU 2016-02"). ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This amendment will be effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The FASB issued ASU No. 2018-10 "Codification Improvements to Topic 842, Leases" ("ASU 2018-10"), ASU No. 2018-11 "Leases (Topic 842) Targeted Improvements" ("ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adoption ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently evaluating these ASUs and their impact on its unaudited condensed consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments". The new standard will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2018. The Company has adopted this standard as of January 1, 2019. The adoption of this standard did not have a material impact on the Company's unaudited condensed consolidated financial statements and financial statement disclosures.

# Notes to Condensed Consolidated Financial Statements (unaudited)

In June 2018, the FASB issued ASU No. 2018-07, "Compensation — Stock Compensation (Topic 718)" ("ASU 2018-07"). ASU 2018-07 is intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. Currently, the accounting requirements for nonemployee and employee share-based payment transactions are significantly different. ASU 2018-07 expands the scope of Topic 718, Compensation — Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, Equity — Equity-Based Payments to Nonemployees. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019 and including interim periods within that fiscal year. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606, Revenue from Contracts with Customers. The Company early adopted this accounting standard as of January 1, 2019. The adoption of this standard did not have a material impact on the Company's unaudited condensed consolidated financial statements and financial statement disclosures.

In March 2019, the FASB issued ASU 2019-01, "Leases (Topic 842): Codification Improvements" ("Topic 842") ("ASU 2019-01"). These amendments align the guidance for fair value of the underlying asset by lessors that are not manufacturers or dealers in Topic 842 with that of existing guidance. As a result, the fair value of the underlying asset at lease commencement is its cost, reflecting any volume or trade discounts that may apply. However, if there has been a significant lapse of time between when the underlying asset is acquired and when the lease commences, the definition of fair value (in Topic 820, Fair Value Measurement) should be applied. (Issue 1). The ASU also requires lessors within the scope of Topic 942, Financial Services—Depository and Lending, to present all "principal payments received under leases" within investing activities. (Issue 2). Finally, the ASU exempts both lessees and lessors from having to provide certain interim disclosures in the fiscal year in which a company adopts the new lease standard. (Issue 3). The transition and effective date provisions apply to Issue 1 and Issue 2. They do not apply to Issue 3 because the amendments for that Issue are to the original transition requirements in Topic 842. The effective date of those amendments is for fiscal years beginning after December 15, 2019. The Company is currently evaluating ASU 2019-01 and its impact on its unaudited condensed consolidated financial statements and financial statement disclosures.

In July 2019, the FASB issued ASU 2019-07, "Codification Updates to SEC Sections — Amendments to SEC Paragraphs Pursuant to SEC Final Rule Releases No. 33-10532, Disclosure Update and Simplification, and Nos. 33-10231 and 33-10442, Investment Company Reporting Modernization and Miscellaneous Updates (SEC Update)" ("ASU 2019-07"). ASU 2019-07 aligns the guidance in various SEC sections of the Codification with the requirements of certain SEC final rules. ASU 2019-07 is effective immediately. The adoption of ASU 2019-07 did not have a material impact on the Company's unaudited condensed consolidated financial statements.

# Note 4 - Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities are comprised of the following:

	Ju	ne 30, 2019		December 31, 2018
Accrued payroll and other accrued expenses	\$	61,884	\$	91,560
Accrued research and development expenses		696,175		646,175
Accrued general and administrative expenses		1,360,545		1,084,831
Accrued director compensation		532,500		482,500
Deferred rent		14,573		33,610
Total accrued expenses		2,665,677	_	2,338,676
Less: accrued expenses, current portion		2,665,677		2,302,176
Accrued expenses, non-current portion	\$	-	\$	36,500

During the six months ended June 30, 2019, the Company entered into a settlement agreement with a certain consultant, pursuant to which \$46,500 of previously accrued consulting fees were exchanged for 10,000 shares of the Company's common stock and a \$10,000 cash payment. The value of the shares was \$7,200, and accordingly the Company recorded a gain on settlement of payables of \$29,300 which is reflected within general and administrative expenses in the unaudited condensed consolidated statements of operations.

# Notes to Condensed Consolidated Financial Statements (unaudited)

# Note 5 - Notes Payable

A summary of the notes payable activity during the six months ended June 30, 2019 is presented below:

	Related Party Notes		Convertible Notes		Other Notes		Debt Discount		Total
Outstanding, January 1, 2019	\$	720,000	\$	4,309,415	\$	132,501	\$	(1,012,363)	\$ 4,149,553
Issuances		475,000		6,000,152[1]		-		-	6,475,152
Exchanges for equity		-		(1,550,471)		-		354,900	(1,195,571)
Repayments		(15,000)		(2,186,629)		-		187,484	(2,014,145)
Extinguishment of notes payable		-		-		(148,014)[1]		6,196	(141,818)
Recognition of debt discount		-		-		-		(3,565,622)	(3,565,622)
Accretion of interest expense		-		-		-		235,122	235,122
Accrued interest reclassified to notes payable principal		-		-		23,013		-	23,013
Amortization of debt discount		-		-		-		1,734,403	 1,734,403
Outstanding, June 30, 2019 [2]	\$	1,180,000	\$	6,572,467[3]	\$	7,500	\$	(2,059,880)	\$ 5,700,087

[1] During the six months ended June 30, 2019, a convertible note in the principal amount of \$148,014 was issued concurrently with the extinguishment of a certain note payable in the same aggregate principal amount. See below within Note 5 – Notes Payable – Conversions, Exchanges and Other for additional details.

- [2] As of June 30, 2019, outstanding related party notes, convertible notes and other notes in the aggregate principal amounts of \$0, \$168,000 and \$7,500, respectively, were considered past due.
- [3] As of June 30, 2019, a portion of convertible notes with an aggregate principal balance of \$3,808,241 were convertible into shares of common stock at the election of the holder any time until the balance has been paid in full. As of June 30, 2019, a portion of convertible notes with an aggregate principal balance of \$2,764,226, which are not currently convertible, will become convertible into shares of the Company's common stock at the election of the respective holder subsequent to June 30, 2019.

#### Related Party Notes

During the six months ended June 30, 2019, the Company issued to family members of an officer of the Company and a Scientific Advisory Board member (the "SAB Member") notes payable in the aggregate principal amount of \$475,000, which bear interest at the rate of 15% per annum and provide for maturity dates between July 2019 and August 2019.

During the six months ended June 30, 2019, the Company partially repaid a certain related party note in the principal amount of \$15,000.

During the six months ended June 30, 2019, the Company and a certain related party agreed to further extend the maturity date of a note payable with a principal balance of \$30,000 from January 2019 to December 2019.

As of June 30, 2019, related party notes consisted of notes payable issued to certain directors of the Company, family members of an officer of the Company, the SAB Member, and Tuxis Trust (the "Trust"). A director and principal shareholder of the Company serves as a trustee of the Trust, which was established for the benefit of his immediate family.

As of June 30, 2019, certain related party notes in the aggregate principal amount of \$475,000 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 (the "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 provides for an exercise price of \$0.80 per share, subject to adjustment. As of June 30, 2019, the other related party notes in the aggregate principal amount of \$705,000 were not convertible. See Note 9 – Subsequent Events for details regarding amendments to notes held by a director of the Company, and the Trust.

# Notes to Condensed Consolidated Financial Statements (unaudited)

# Convertible Notes

#### Issuances

During the six months ended June 30, 2019, the Company issued certain lenders convertible notes payable in the aggregate principal amount of \$5,852,138 for aggregate cash proceeds of \$5,516,198. The difference of \$335,940 was recorded as a debt discount and will be amortized over the terms of the respective notes. The convertible notes bear interest at rates ranging between 8% to 15% per annum payable at maturity with original maturity dates ranging between July 2019 through June 2020. In connection with the issuance of a certain convertible note, the Company issued the lender 68,873 shares of the Company's common stock and the relative fair value of \$54,168 was recorded as debt discount and is being amortized over the term of the note. In connection with the issuance of certain convertible notes, the Company issued the lenders five-year warrants to purchase an aggregate of 165,000 shares of the Company's common stock at exercise prices ranging from \$0.56 per share to \$1.00 per share. The aggregate grant date value of the warrants was \$66,500, 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 Note 5 – Notes Payable – Conversions, Exchanges and Other and Note 8 – Derivative Liabilities for additional details regarding the ECOs of the convertible notes.

During the six months ended June 30, 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 Note 5 – Notes Payable – Convertible Notes – Conversions, Exchanges and Other for additional details.

## Embedded Conversion Options and Note Provisions

As of June 30, 2019, outstanding convertible notes in the aggregate principal amount of \$3,808,241 were convertible into shares of common stock of the Company as follows: (i) \$2,007,139 of aggregate convertible notes were convertible at a fixed price ranging from \$1.00 to \$2.00 per share for the first six months following the respective issue date, and thereafter at a conversion price generally equal to a range of \$8% to 65% of the fair value of the Company's stock, subject to adjustment, until the respective note has been paid in full, (ii) \$876,102 of aggregate convertible notes were convertible generally at a range of \$8% to 65% of the fair value of the Company's stock, subject to adjustment, depending on the note, and (iii) \$925,000 of aggregate 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 \$275,000 provide for a mandatory conversion into common stock of the Company and warrants to purchase common stock of the Company in the same ratio. The warrants public offering by the Company of its securities whereby the conversion price shall 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 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 Note 5 - Notes Payable – Convertible Notes – Embedded Conversion Options and Note Provisions and Note \$ - Deriva

As of June 30, 2019, a portion of convertible notes with an aggregate principal balance of \$2,764,226, which were not yet convertible, will generally become convertible into shares of the Company's common stock subsequent to June 30, 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 have been paid in full.

As of June 30, 2019, outstanding convertible notes in the aggregate principal amount of \$4,096,363 have prepayment premiums, whereby, in the event that the Company elects to prepay certain notes during the one hundred eighty-day period following the issue date, the respective holder is entitled to receive a prepayment premium of up to 35%, depending on the note, on the then outstanding principal balance including accrued interest.



# Notes to Condensed Consolidated Financial Statements (unaudited)

As of June 30, 2019, outstanding convertible notes in the aggregate principal amount of \$3,082,328 have most favored nation ("MFN") provisions, whereby, so long as such respective note is 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 shall become a part of the transaction documents with the holder. As of June 30, 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 six months ended June 30, 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 \$3,186,760, of which \$3,101,962 was recorded as a debt discount and is being amortized over the terms of the respective convertible notes and \$84,798 was recognized as part of an extinguishment loss as described below. See Note 8 – Derivative Liabilities for additional details.

#### Conversions, Exchanges and Other

During the six months ended June 30, 2019, the Company and certain lenders exchanged certain convertible notes with bifurcated ECOs with an aggregate net carrying amount of 33,191,611 (including an aggregate of 1,550,471 of principal less debt discount of 3354,900, 573,238 of accrued interest and 1,922,802 related to the separated ECOs accounted for as derivative liabilities) for an aggregate of 5,710,099 shares of the Company's common stock at conversion prices ranging from 0.17 to 0.43 per share. The common stock had an aggregate exchange date value of 3,573,720 and, as a result, the Company recorded a loss on extinguishment of notes payable of 3382,109. See Note 8 - Derivative Liabilities for additional details.

During the six months ended June 30, 2019, the Company repaid an aggregate principal amount of \$2,186,629 of convertible notes payable, \$131,935 of the respective aggregate accrued interest and an aggregate of \$340,009 of prepayment premiums. As a result of the repayments, the Company recorded a loss on extinguishment of notes payable of \$527,492 and an aggregate of \$187,484 of the related debt discounts were extinguished.

During the six months ended June 30, 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 accrues 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 8 – 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 new note's ECO of an aggregate of \$84,798.

During the six months ended June 30, 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 \$100,000 from a maturity date in June 2019 to a new maturity date in December 2019. In consideration of the extension, the Company modified the conversion terms of the lender's note 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 shall 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.

## Other Notes

#### Exchange and Other

During the six months ended June 30, 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 is being amortized over the remaining term of the note.

# Notes to Condensed Consolidated Financial Statements (unaudited)

During the six months ended June 30, 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 5 – Notes Payable – Conversions, Exchanges and Other for additional details.

#### Note 6 – Commitments and Contingencies

#### Consulting Agreements

#### Business Advisory Services

In January 2019, an agreement for business advisory services that had expired on December 31, 2018 was further extended and now provides for an expiration date of December 31, 2019. In consideration of the extension of the term of the consulting agreement, the Company issued to the consultant a five-year, immediately vested warrant for the purchase of 100,000 shares of the Company's common stock at an exercise price of \$1.00 per share. The grant date value of the warrant of \$56,000 was recognized immediately as stock-based compensation expense which is reflected as consulting expense in the unaudited condensed consolidated financial statements. The warrant was subject to the Company's sequencing policy and, as a result, was recorded as a derivative liability. See Note 8 - Derivative Liabilities for additional details.

#### Operating Lease

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 calls 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 will commence on January 1, 2020 with annual base rent ranging between \$153,748 and \$173,060.

The Company's rent expense amounted to approximately \$24,000 and \$54,000 for the three and six months ended June 30, 2019, respectively. The Company's rent expense amounted to approximately \$31,000 and \$61,000 for the three and six months ended June 30, 2018, respectively. Rent expense is reflected in general and administrative expenses and research and development expenses in the unaudited condensed consolidated statements of operations.

# Litigations, Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims or assessments arising from the ordinary course of business, and as of June 30, 2019, none are expected to materially impact the Company's financial position.

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

# Bonus Accruals

As of December 31, 2018, the Company had remaining accruals of approximately \$91,000 for bonus milestones that were achieved in prior years and remained unpaid. As of June 30, 2019, the remaining accruals for bonus milestones achieved in prior years had been paid in full. In April 2019, the Company's Compensation Committee and Board of Directors approved performance goals associated with cash bonuses payable to certain officers for the year ending December 31, 2019 and, as a result, the Company accrued \$61,290 for 2019 cash bonuses as of June 30, 2019.

# Notes to Condensed Consolidated Financial Statements (unaudited)

# Note 7 – Stockholders' Deficiency

# 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 shareholder 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 shareholder approval. In May 2019, such shareholder approval was obtained.

In March 2019, the Board of Directors determined to submit to the Company's shareholders 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-20, with the Board of Directors having the discretion as to whether or not the reverse stock split is 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 shareholders for their approval a proposal to authorize the Board of Directors, in the event the reverse stock split proposal is approved by the shareholders, 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 shareholders approved the foregoing proposals.

#### Compensatory Common Stock Issuance

During the six months ended June 30, 2019, the Company issued 75,000 shares of immediately vested common stock valued 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 six months ended June 30, 2019, the Company issued an aggregate of 2,191,111 shares of common stock of the Company, five-year immediately vested warrants to purchase an aggregate of 1,135,556 shares of common stock of the Company at exercise prices ranging from \$0.85 per share to \$1.00 per share and one-year immediately vested warrants to purchase an aggregate of 1,055,555 shares of common stock of the Company at an exercise price of \$0.70 per share to certain investors for aggregate gross proceeds of \$1,156,000. The warrants had an aggregate grant date fair value of \$899,689. The warrants were subject to the Company's sequencing policy and, as a result, were initially recorded as derivative liabilities. See Note 8 – Derivative Liabilities for additional details.

# Stock Warrants

Warrant Compensation

See Note 6 - Commitments and Contingences for additional details associated with the issuance of a warrant in connection with a consulting agreement extension.

# Notes to Condensed Consolidated Financial Statements (unaudited)

The Company recorded stock-based compensation expense of \$0 and \$56,000 for the three and six months ended June 30, 2019, respectively, related to stock warrants issued as compensation, which is reflected as consulting expense in the unaudited condensed consolidated statements of operations. For the three and six months ended June 30, 2018, the Company recorded stock-based compensation expense of \$0 and \$48,192, respectively, related to stock warrants issued as compensation.

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 Mon June 30,		For the Six Mon June 30	
	2019	2018	2019	2018
Risk free interest rate	1.84% - 2.37%	2.83%	1.84% - 2.62%	1.92% - 2.83 %
Contractual term (years)	1.00 - 5.00	5.00	1.00 - 5.00	1.98 - 5.00
Expected volatility	136% - 139%	136%	136% - 150%	128% - 136%
Expected dividends	0.00%	0.00%	0.00%	0.00%

The weighted average estimated fair value of the warrants granted during the three and six months ended June 30, 2019 was approximately \$0.34 and \$0.42 per share, respectively. The weighted average estimated fair value of the warrants granted during the three and six months ended June 30, 2018 was approximately \$1.23 and \$1.22 per share, respectively.

A summary of the warrant activity during the six months ended June 30, 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		
Issued	2,456,111	0.78		
Expired	(86,562)	5.15		
Outstanding, June 30, 2019	5,852,952	\$ 2.41	2.3	<u>\$</u>
Exercisable, June 30, 2019	5,852,952	\$ 2.41	2.3	<u>\$</u>
	F-18			

# Notes to Condensed Consolidated Financial Statements (unaudited)

The following table presents information related to stock warrants at June 30, 2019:

Warrants (	Dutstanding	Warrants E	xercisable
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
\$0.56 - \$0.99	2,456,111	3.0	2,456,111
\$1.00 - \$1.99	844,444	0.5	844,444
\$2.00 - \$2.99	75,000	4.3	75,000
\$3.00 - \$3.99	70,000	4.0	70,000
\$4.00 - \$4.99	2,102,135	2.0	2,102,135
\$5.00 - \$5.99	195,989	2.0	195,989
\$6.00 - \$7.99	40,000	1.1	40,000
\$8.00 - \$9.99	2,500	0.4	2,500
\$10.00 - \$15.00	66,773	0.6	66,773
	5,852,952	2.3	5,852,952

# Stock Options

In March 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.

The following table presents information related to stock options at June 30, 2019:

Options Outs	tanding	Options Exercisable						
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options					
\$0.75 - \$0.99	4,623,367	6.9	3,167,037					
\$1.00 - \$5.99	43,668	0.8	43,668					
\$6.00 - \$19.99	37,500	4.5	37,500					
\$20.00 - \$30.00	35,000	2.7	35,000					
	4,739,535	6.8	3,283,205					
		F-19						

## Notes to Condensed Consolidated Financial Statements (unaudited)

The following table presents information related to stock option expense:

	For the Three ! June	Ended	For the Six M June	Ended	Unrecognized at June 30,	Weighted Average Remaining Amortization Period
	 2019	 2018	 2019	 2018	 2019	(Years)
Consulting	\$ 175,567	\$ 241,590	\$ 471,649	\$ 505,817	\$ 181,413	1.3
Research and development	96,138	68,593	245,932	144,438	398,589	1.8
General and administrative	 171,099	 517,004	 454,901	 1,011,552	 633,859	1.4
	\$ 442,804	\$ 827,187	\$ 1,172,482	\$ 1,661,807	\$ 1,213,861	1.5

# Note 8 - 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	4,208,949
Extinguishment of derivative liabilities in connection with convertible note repayments and exchanges	(1,922,802)
Change in fair value of derivative liabilities	203,313
Reclassification of derivative liabilities to equity	(2,637,996)
Ending balance as of June 30, 2019	\$ 946,071

In applying the Multinomial Lattice and Black-Scholes option pricing models to derivatives issued and outstanding during the three and six months ended June 30, 2019 and 2018, the Company used the following assumptions:

	For the Three Mon June 30,	ths Ended	For the Six Month June 30,			
	2019	2018	2019	2018		
Risk free interest rate	1.71% - 2.42%	2.24% - 2.73%	1.71% - 2.62%	1.22% - 2.56 %		
Expected term (years)	0.02 - 5.00	0.26 - 4.41	0.02 - 5.00	0.26 - 4.91		
Expected volatility	98% - 139%	100% - 164%	98% - 156%	100% - 164%		
Expected dividends	0.00%	0.00%	0.00%	0.00%		

During the six months ended June 30, 2019, the Company recorded new derivative liabilities in the aggregate amounts of \$3,186,760 and \$1,022,189 related to the ECOs of certain convertible notes payable and warrants subject to sequencing, respectively. See Note 5 – Notes Payable – Convertible Notes for additional details. See Note 6 – Commitments and Contingencies and Note 7 – Stockholders' Deficiency for warrants issued and deemed to be derivative liabilities.

During the six months ended June 30, 2019, the Company extinguished an aggregate of 1,922,802 of derivative liabilities in connection with repayments and exchanges of certain convertible notes payable into shares of the Company's common stock. See Note 5 - Notes Payable - Convertible Notes for additional details.

During the six months ended June 30, 2019, the Company reclassified an aggregate of \$2,637,996 of derivative liabilities to equity as a result of a change in the sequencing status.

On June 30, 2019, the Company recorded a loss on the change in fair value of ECOs recorded as derivative liabilities to be \$688,738. The Company recorded a loss on the change in fair value of these derivative liabilities of \$342,765 and \$439,602 for the three and six months ended June 30, 2019, respectively.

# Notes to Condensed Consolidated Financial Statements (unaudited)

On June 30, 2019, the Company recomputed the fair value of the derivative liabilities related to outstanding warrants to be \$257,333. 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 \$185,716 and \$236,289 for the three and six months ended June 30, 2019, respectively.

# Note 9 – Subsequent Events

# Arena Investors

Subsequent to June 30, 2019, the Company entered into a securities purchase agreement (the "Arena Purchase Agreement") with Arena Investors LP ("Arena") pursuant to which Arena has agreed to acquire 5,500,000 shares of Series A preferred stock, par value \$0.01 per share, of the Company, a warrant for the purchase of 6,000,000 shares of common stock, par value \$0.001 per share, of the Company in the principal amount of \$500,000 (the "Arena Note"), in consideration of a payment by Arena to the Company of an aggregate of \$5,400,000. The closing of the Arena Purchase Agreement is subject to, among other things, approval by the shareholders of the Company of the Arena Purchase Agreement and the transactions contemplated thereby, the concurrent execution of an underwriting agreement with regard to a public offering of the Company's securities with gross proceeds to the Company of at least \$7,500,000 (the "Public Offering") and approval by the Nasdaq Stock Market of the Company's pending listing application with respect to its shares of common stock. The number of shares of common stock subject to the Arena Warrant is subject to adjustment for the Company's contemplated reverse stock split in connection with the Public Offering.

The shares of Series A preferred stock will be convertible, at the option of Arena, into shares of common stock of the Company at a conversion price generally equal to 75% of the public offering price for the common stock, or units of common stock and warrants, as the case may be, offered pursuant to the Public Offering, except that, with respect to any shares of Series A preferred stock that are outstanding as of the 18 month anniversary of the closing date of the Arena Purchase Agreement (or earlier under certain circumstances), the conversion price will be, if lower, 85% of the market price of the shares of common stock of the Company as of such anniversary date (or such earlier date) (but in no event less than \$0.10 per share, subject to adjustment for reverse stock splits and the like). The shares of Series A preferred stock will carry a 12% cumulative dividend and will be redeemable at the Company's option, subject to certain conditions, provided that the Company pays a redemption premium of 25%. In the event of a liquidation, dissolution or winding-up of the Company, the holders of the Series A preferred stock will be entitled to receive the stated value of the shares of \$5,500,000, plus any accrued and unpaid dividends, before any distribution is made to the holders of common stock or other junior securities. Except as required by law, the holders of the Series A preferred stock will not have any voting rights.

The Arena Warrant will be exercisable for a period of three years at an exercise price per share generally equal to the lesser of 125% of the conversion price for the shares of Series A preferred stock or 100% of the exercise price of any warrants included as part of units offered pursuant to the Public Offering (the "Public Warrants"). In the event the ratio of the number of shares of common stock issuable pursuant to the Public Warrants to the number of shares of common stock included as part of such units is greater than one-to-one, then the number of shares of common stock of the Company underlying the Arena Warrant will be proportionately increased. Arena will be able to exercise the Arena Warrant on a cashless basis if, as of the six month anniversary of the closing date, the shares of common stock underlying the Arena Warrant are not then registered for resale pursuant to an effective registration statement filed with the Securities and Exchange Commission (the "SEC").

The Arena Note will provide for an 18-month maturity date (subject to extension in the event any shares of Series A preferred stock are outstanding as of such date) and interest at the rate of 12% per annum. The principal amount of the Arena Note will be convertible into shares of Series A preferred stock of the Company at a ratio of one share of Series A preferred stock for each dollar of indebtedness converted. The Company will have the right to prepay the Arena Note, subject to certain conditions, provided that the Company pays a 30% prepayment premium and concurrently redeems any outstanding shares of Series A preferred stock. The payment of the Arena Note will be secured by the grant by the Company of a security interest in its tangible and intangible assets.



# Notes to Condensed Consolidated Financial Statements (unaudited)

In connection with the Arena Purchase Agreement, the Company will enter into a separate registration rights agreement with Arena at closing pursuant to which the Company will agree to undertake to file a registration statement with the SEC to register the resale of the shares underlying the Series A preferred stock and the Arena Warrant. Arena has agreed to enter into a lock-up agreement with the representative of the underwriters of the Public Offering pursuant to which it will agree that it will not sell publicly any shares of common stock of the Company for a period of 135 days following the Public Offering unless the closing price of the shares of common stock of the Company equals or exceeds, for a period of five consecutive trading days, 150% of the public offering or have it declared effective by the SEC within 135 days following the Public Offering or have it declared effective by the SEC within 135 days following the Public Offering, or if the Company fails to maintain the effectiveness of the registration statement until all of such shares of common stock have been sold or are otherwise able to be sold pursuant to Rue 144 under the Securities Act of 1933, as amended, without any volume or manner of sale restrictions, then the Company will be obligated to pay to Arena liquidated damages equal to 1% per month of the aggregate amount paid by Arena for its securities (subject to an 8% cap), until such events are satisfied.

## Notes Payable

Subsequent to June 30, 2019, the Company issued convertible promissory notes in the aggregate principal amount of \$1,792,938 to certain lenders for aggregate cash proceeds of \$1,666,000. The difference of \$126,938 was recorded as a debt discount and will be amortized over the terms of the respective notes. The convertible notes bear interest at a rate of 12% per annum, payable at maturity, with original maturity dates ranging from December 2019 to August 2020. The notes are convertible as follows: (i) \$\$10,000 of aggregate convertible notes and the respective accrued interest are convertible into shares of the Company's common stock at the election of the holder after the 180th day following the issue date at a conversion price generally equal to 58% of the fair value of the Company's common stock, (ii) \$917,938 of aggregate convertible notes are convertible at either a fixed price of \$0.25, \$1.00 or \$2.00 per share, depending on the note, 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 has been paid in full, and (iii) \$65,000 of aggregate convertible notes are convertible into shares of common stock of the Company at a conversion price of \$0.50 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 of \$0.75 per share, subject to adjustment. Convertible notes in the aggregate principal amount of \$65,000 are mandatorily convertible 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 shall be equal to the lower of the respective original conversion price, 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, sold pursuant to the Public Offering. In connection with the issuance of certain convertible promissory notes, the Company issued to the respective lenders warrants for the purchase of an aggregate of 130,000 shares of the Company's common stock. The grant date fair value of the warrants will be recorded as a debt discount and will be amortized over the terms of the respective notes. In the event that the Company elects to prepay certain notes during the 180 period following the issue date, the holder will be entitled to receive a prepayment premium up to 35%, depending on the note, of the then outstanding principal balance plus accrued interest.

# Notes to Condensed Consolidated Financial Statements (unaudited)

Subsequent to June 30, 2019, the Company, a 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, will be exchanged for shares of common stock and warrants, as described below, in connection with the Public Offering. The exchange price for the indebtedness will 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 will 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 issued as part of the Public Offering units. The exercise price of the warrants to be issued to the director and the Trust will be 125% of the Director/Trust Exchange Price and the term of the warrants will 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 will be reduced from between \$1.50 and \$4.00 per share to \$0.75 per share and the expiration dates of such warrants will be extended from between December 2019 and March 2022 to December 2023. The exchange agreements will be submitted for approval by the shareholders of the Company. In the event that such shareholder approval is not obtained prior to the Public Offering, then, in connection with the Public Offering, the promissory notes held by the director and the Trust will be paid.

Subsequent to June 30, 2019, the holders of notes in the aggregate principal amount \$1,053,102 entered into agreements with the Company pursuant to which the parties agreed that the maturity of the promissory notes held by such holders will be further extended to dates ranging between July 2019 to July 2020. Such notes in the aggregate amount of \$1,025,000 will be exchanged for shares of common stock and warrants, as described below, in connection with the Public Offering. The exchange price for the indebtedness will 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 "Other Indebtedness Exchange Price"). The number of shares of common stock issuable pursuant to the warrants to be issued to such holders will 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 will be the lesser of (i) 125% of the Other Indebtedness Exchange Price or (ii) \$0.80 per share (subject to adjustment for reverse stock splits and the like).

Subsequent to June 30, 2019, the Company and certain lenders agreed to the exchange of convertible notes in the aggregate principal amount of \$301,173 and aggregate accrued interest of \$38,307 for an aggregate of 2,299,231 shares of the Company's common stock at exchange prices ranging from \$0.11 to \$0.19 per share.

Subsequent to June 30, 2019, the Company repaid an aggregate principal amount of \$1,152,750 of convertible notes payable, \$85,078 of the respective aggregate accrued interest and an aggregate of \$406,950 of prepayment premium

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

# **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of BioRestorative Therapies, Inc. (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, changes in stockholders' deficiency and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

#### **Explanatory Paragraph – Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### **Basis for Opinion**

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

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

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

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2011.

New York, NY March 29, 2019

# **Consolidated Balance Sheets**

Current Assets:	2	018	
Assets Current Assets:			2017
Cook			
	\$	117,523	\$ 451,680
Accounts receivable		29,000	38,000
Prepaid expenses and other current assets		34,464	 30,030
Total Current Assets		180,987	519,710
Property and equipment, net		175,235	327,847
Intangible assets, net		814,059	888,950
Security deposit		22,100	 22,100
Total Assets	\$	1,192,381	\$ 1,758,607
Liabilities and Stockholders' Deficiency			
Current Liabilities:			
Accounts payable	\$	1,893,827	\$ 2,454,944
Accrued expenses and other current liabilities		2,302,176	1,885,551
Accrued interest		338,619	329,160
Current portion of notes payable, net of debt discount of \$936,866 and \$336,229 at December 31, 2018 and			
2017, respectively		3,625,659	3,467,568
Derivative liabilities		1,094,607	216,073
Total Current Liabilities		9,254,888	8,353,302
Accrued expenses, non-current portion		36,500	38,000
Accrued interest, non-current portion		18,137	9,591
Notes payable, non-current portion, net of debt discount of \$75,497 and \$1,256 at December 31, 2018 and 2017,			
respectively		523,894	 194,282
Total Liabilities		9,833,419	 8,595,175
Commitments and contingencies			
Stockholders' Deficiency:			
Preferred stock, \$0.01 par value; Authorized, 20,000,000 shares; None issued and outstanding at December 31, 2018 and 2017		-	
Common stock, \$0.001 par value; Authorized, 75,000,000 shares; Issued and outstanding 11,728,394 and			
6,112,473 shares at December 31, 2018 and 2017, respectively		11,728	6,112
Additional paid-in capital		55,269,490	44,561,773
Accumulated deficit		(63,922,256)	(51,404,453
Total Stockholders' Deficiency		(8,641,038)	(6,836,568
Total Liabilities and Stockholders' Deficiency	\$	1,192,381	\$ 1,758,607

See Notes to these Consolidated Financial Statements

# **Consolidated Statements of Operations**

		For The Year Decembe	
	2	2018	2017
Revenues	\$	111,000	\$ 81,000
Operating Expenses			
Marketing and promotion		352,204	65,455
Consulting		1,870,829	2,334,212
Research and development		1,513,150	2,152,433
General and administrative		4,022,469	3,903,184
Total Operating Expenses		7,758,652	8,455,284
Loss From Operations		(7,647,652)	(8,374,284)
Other Expense			
Interest expense		(932,187)	(468,107)
Amortization of debt discount		(2,289,591)	(619,266)
Loss on extinguishment of notes payable, net		(1,415,950)	(59,938)
Change in fair value of derivative liabilities		(229,323)	107,039
Warrant modification expense		(3,100)	 (30,099)
Total Other Expense		(4,870,151)	 (1,070,371)
Net Loss	\$	(12,517,803)	\$ (9,444,655)
Net Loss Per Share			
- Basic and Diluted	\$	(1.64)	\$ (1.74)
Weighted Average Number of Common Shares Outstanding			
- Basic and Diluted		7,630,112	 5,422,389
See Notes to these Consolidated Financial Statements			

# Consolidated Statements of Changes in Stockholders' Deficiency For the Years Ended December 31, 2018 and 2017

	Comme	on Stock			Additional Paid-In		Accumulated	
	Shares	A	Amount	_	Capital	_	Deficit	 Total
Balance - December 31, 2016	4,699,035	\$	4,699	\$	36,954,817	\$	(41,959,798)	\$ (5,000,282)
Shares and warrants issued for cash	361,335		361		1,083,639		-	1,084,000
Exercise of warrants for purchase of common stock	460,625		461		995,789		-	996,250
Conversion of notes payable and accrued interest into common stock	243,441		243		524,291		-	524,534
Shares and warrants issued in exchange for notes payable and accrued interest	132,082		132		421,170		-	421,302
Shares and warrants issued in satisfaction of accrued services	165,002		165		588,427		-	588,592
Shares and warrants issued or modified and recorded as debt discount in connection with notes payable	40,953		41		257,015		-	257,056
Reclassification of derivative liabilities to equity	-		-		9,019		-	9,019
Beneficial conversion features related to convertible notes payable	-		-		11,991		-	11,991
Warrant modifications	-		-		114,821		-	114,821
Stock-based compensation:								
- common stock - options and warrants	10,000 -		10		19,990 3,580,804		-	20,000 3,580,804
Net loss			_				(9,444,655)	 (9,444,655)
Balance - December 31, 2017	6,112,473	\$	6,112	\$	44,561,773	\$	(51,404,453)	\$ (6,836,568)
Shares and warrants issued for cash	70,000		70		99,930		-	100,000
Exercise of warrants for purchase of common stock	207,084		207		413,961		-	414,168
Shares and warrants issued in satisfaction of accrued services	75,250		75		80,113		-	80,188
Conversion of notes payable and accrued interest into common stock	97,424		97		110,539		-	110,636
Shares issued in exchange of notes payable and accrued interest	5,031,914		5,033		7,210,333		-	7,215,366
Shares and warrants issued or modified and recorded as debt discount in connection with notes payable issuances or extensions	99,249		99		384,336		-	384,435
Beneficial conversion features related to convertible notes payable	-		-		69,394		-	69,394
Warrant modifications	-		-		3,100		-	3,100
Reclassification of derivative liabilities to equity	-		-		105,187		-	105,187
Stock-based compensation: - common stock	35,000		35		52,465		-	52,500
- options and warrants	-		-		2,178,359		-	2,178,359
Net loss	-		-	_			(12,517,803)	 (12,517,803)
Balance - December 31, 2018	11,728,394	\$	11,728	\$	55,269,490	\$	(63,922,256)	\$ (8,641,038)

See Notes to these Consolidated Financial Statements

# **Consolidated Statements of Cash Flows**

	For The Years Ended December 31,				
	 2018	2017			
Cash Flows From Operating Activities					
Net loss	\$ (12,517,803)	\$ (	(9,444,655		
Adjustments to reconcile net loss to net cash used in operating activities:					
Amortization of debt discount	2,289,591		619,266		
Accretion of interest expense	624,041		206,284		
Depreciation and amortization	240,372		259,259		
Stock-based compensation	2,399,385		3,600,804		
Loss on extinguishment of note payables, net	1,415,950		59,938		
Gain (loss) on settlement of payables	(2,812)		100,895		
Change in fair value of derivative liabilities	229,323		(107,039		
Consulting services provided in exchange for notes payable	260,000				
Warrant modification expense	3,100		30,099		
Changes in operating assets and liabilities:					
Accounts receivable	9,000		(32,000		
Prepaid expenses and other current assets	(4,434)		5,548		
Security deposit	-		12,076		
Accounts payable	(516,117)		185,963		
Accrued interest, expenses and other current liabilities	 465,775		649,741		
Total Adjustments	 7,413,174		5,590,834		
Net Cash Used In Operating Activities	 (5,104,629)	(	(3,853,821		
Cash Flows From Investing Activities					
Purchases of property and equipment	 (12,869)		(3,617		
Net Cash Used In Investing Activities	 (12,869)		(3,617		
Cash Flows From Financing Activities					
Proceeds from notes payable	5,057,475		2,542,222		
Repayments of notes payable	(863,302)		(330,176		
Advances from officers and a family member of an officer	38,500		43,515		
Repayments of advances from officers, a director and a family member of an officer	(38,500)		(58,515		
Proceeds from exercise of warrants	414,168		996,250		
Sales of common stock and warrants for cash	 175,000		1,084,000		
Net Cash Provided By Financing Activities	 4,783,341		4,277,29		
Net (Decrease) Increase In Cash	(334,157)		419,858		
Cash - Beginning	451,680		31,822		
Cash - Ending	 		451,680		

See Notes to these Consolidated Financial Statements

# **Consolidated Statements of Cash Flows - Continued**

		For The Years Ended December 31,				
	_	2018		2017		
Supplemental Disclosures of Cash Flow Information:						
Cash paid during the period for:						
Interest	\$	44,787	\$	17,538		
Non-cash investing and financing activities:						
Warrant modifications	\$	3,100	\$	114,821		
Shares and warrants issued or modified and recorded as debt discount in connection with notes payable						
issuances or extensions	\$	384,435	\$	257,056		
Shares issued in exchange for notes payable and accrued interest	\$	7,215,366	\$	421,302		
Conversion of notes payable and accrued interest into common stock	\$	110,636	\$	524,534		
Shares and warrants issued in satisfaction of accrued consulting and director services	\$	80,188	\$	588,592		
Reclassification of derivative liabilities to equity	\$	105,187	\$	9,019		
Bifurcated embedded conversion options recorded as debt discount	\$	3,181,376	\$	332,131		
Beneficial conversion features recorded as debt discount	\$	69,394	\$	11,991		
Consulting services provided in exchange for notes payable	\$	260,000	\$	-		
Sale of warrants recorded as derivative liabilities	\$	75,000	\$	-		
Warrants and options issued for consulting services recorded as derivative liabilities	\$	168,526	\$	-		
Write-offs of fully depreciated property recorded as derivative liabilities and equipment	\$	101,423	\$	-		

See Notes to these Consolidated Financial Statements

## Notes to Consolidated Financial Statements

# Note 1 - Business Organization and Nature of Operations

BioRestorative Therapies, Inc. has one wholly-owned subsidiary, Stem Pearls, LLC ("Stem Pearls"). Stem Cell Cayman Ltd. ("Cayman"), which was formed in the Cayman Islands as a wholly-owned subsidiary of the Company, was dissolved in March 2017. BioRestorative Therapies, Inc. and its subsidiaries are referred to collectively as "BRT" or the "Company" (See Note 3 – Summary of Significant Accounting Policies – Principles of Consolidation). 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. 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 - Going Concern and Management's Plans

As of December 31, 2018, the Company had a working capital deficiency and a stockholders' deficiency of \$9,073,901 and \$8,641,038, respectively. During the years ended December 31, 2018 and 2017, the Company incurred net losses of \$12,517,803 and \$9,444,655, respectively. These conditions indicate that there is substantial doubt about the Company's ability to continue as a going concern within one year after the financial statement issuance date.

The Company's primary source of operating funds since inception has been equity and debt financings. The Company intends to continue to raise additional capital through debt and equity financings. 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 or, notwithstanding any request the Company may make, the Company's debt holders do not agree to convert their notes into equity or extend the maturity dates of their notes, the Company may have to curtail its development, marketing and promotional activities, which would have a material adverse effect on the Company's business, financial condition and results of operations, and ultimately the Company could be forced to discontinue its operations and liquidate.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. 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 financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

Subsequent to December 31, 2018, the Company has received aggregate equity financings and debt financings of \$600,000 and \$3,073,918, respectively, debt (inclusive of accrued interest) of \$643,900 has been exchanged for common stock, \$1,254,805 of debt (inclusive of accrued interest and prepayment premiums) has been repaid, and the due date for the repayment of an aggregate \$155,000 of debt has been extended to December 2020. As a result, the Company expects to have the cash required to fund its operations through April 2019 while it continues to apply efforts to raise additional capital. While there can be no assurance that it will be successful, the Company is in negotiations to raise additional capital. As of the filing date of this report, the Company has notes payable with an aggregate principal balance of \$107,500 which are past due. The Company is currently in the process of negotiating repayments or discussing conversions to equity with respect to one of these notes. However, there can be no assurance that the Company will be successful in repaying or converting the note. See Note 12 – Subsequent Events for additional details.

## Notes to Consolidated Financial Statements

### Note 3 - Summary of Significant Accounting Policies

#### Principles of Consolidation

The consolidated financial statements of the Company include the accounts of Cayman and Stem Pearls. All significant intercompany transactions have been eliminated in the consolidation. As discussed above, Cayman, which had no material assets, liabilities or operations (other than intercompany balances) and is no longer needed to facilitate certain financings, was dissolved in March 2017.

## 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 the dates of the financial statements and the reported amounts of revenue and expenses during the periods. The Company's significant estimates and assumptions include the recoverability and useful lives of long-lived assets, the fair value of the Company's stock, stock-based compensation, warrants issued in connection with notes payable, derivative liabilities and the valuation allowance related to the Company's deferred tax assets. Certain of the Company's estimates, including the carrying amount of the intangible assets, could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and could cause actual results to differ from those estimates.

# Concentrations

One license and the related royalties comprised all of the Company's revenue during the years ended December 31, 2018 and 2017. See "Revenue Recognition" below.

During the year ended December 31, 2018, 23.1% of the Company's debt financings were from one lender. During the year ended December 31, 2017, 30.9% and 13.7% respectively, of the Company's debt financings were from two lenders.

#### Cash

The Company maintains cash in bank accounts, which, at times, may exceed Federal Deposit Insurance Corporation ("FDIC") insured limits. The Company has not experienced any losses in such accounts, periodically evaluates the creditworthiness of the financial institutions and has determined the credit exposure to be negligible. As of December 31, 2018, the Company did not have cash balances in excess of FDIC insured limits. As of December 31, 2017, the Company had cash balances in excess of FDIC insured limits of \$205,302. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of December 31, 2018, and 2017 the Company did not have any cash equivalents.

## Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation which is recorded commencing at the in-service date using the straight-line method at rates sufficient to charge the cost of depreciable assets to operations over their estimated useful lives, which range from 3 to 5 years. Leasehold improvements are amortized over the lesser of (a) the useful life of the asset; or (b) the remaining lease term. Maintenance and repairs are charged to operations as incurred. The Company capitalizes cost attributable to the betterment of property and equipment when such betterment extends the useful life of the assets.

# Intangible Assets

Intangible assets are comprised of patents and trademarks and licenses with original estimated useful lives of 10 and 17.7 years, respectively. Once placed into service, the Company amortizes the cost of the intangible assets over their estimated useful lives on a straight-line basis.



## Notes to Consolidated Financial Statements

# Note 3 - Summary of Significant Accounting Policies - Continued

#### Impairment of Long-lived Assets

The Company reviews 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. The Company measures the carrying amount of the asset against the estimated undiscounted future cash flows associated with it. Should the sum of the expected future net cash flows be less than the carrying value of the asset being evaluated, an impairment loss would be recognized for the amount by which the carrying value of the asset exceeds its fair value. The evaluation of asset impairment requires the Company to make assumptions about future cash flows over the life of the asset being evaluated. These assumptions require significant judgment and actual results may differ from assumed and estimated amounts. While the Company's near-term liquidity is tight, historically the Company has been successful in raising capital as needed (although there can be no assurance that the Company will continue to be successful in raising capital as needed. The Company has not identified any impairment losses at December 31, 2018 and 2017.

#### Revenue Recognition

The Company recognizes sublicensing and royalty revenue when all of the following have occurred: (i) persuasive evidence of an arrangement exists, (ii) the service is completed without further obligation, (iii) the sales price to the customer is fixed or determinable, and (iv) collectability is reasonably assured. In November 2015, the Company and a stem cell treatment company ("SCTC") entered into an amendment to a January 27, 2012 license agreement between them. Pursuant to the amendment, effective November 30, 2015, the Company granted to the SCTC (i) a non-exclusive sublicense to use certain of the licensed intellectual property in one location outside the United States and (ii) a non-exclusive sublicense to use, and the right to sublicense to third parties the right to use, in certain locations in the United States, 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. During the years ended December 31, 2018 and 2017, the Company recognized \$111,000 and \$81,000, respectively, of revenue related to the Company's sublicense agreement.

#### Income Taxes

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

The Company utilizes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's consolidated financial statements as of December 31, 2018 and 2017. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the consolidated statements of operations.



#### Notes to Consolidated Financial Statements

## Note 3 - Summary of Significant Accounting Policies - Continued

#### Net Loss Per Common Share

Basic loss per common share is computed by dividing net loss by the weighted average number of vested common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	December 31	December 31,				
	2018	2017				
Options	4,703,785	3,122,202				
Warrants	3,483,403	3,435,134				
Convertible notes	9,200,062[1]	1,411,762				
Total potentially dilutive shares	17,387,250	7,969,098				

[1] As of December 31, 2018, many of the convertible notes had variable conversion prices and the shares issuable were estimated based on market conditions. Pursuant to the note agreements, there were 57,019,880 shares of common stock reserved for future note conversions.

#### Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees, 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 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. 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 employees. Upon the exercise of an option or warrant, the Company issues new shares of common stock out of its authorized shares.

#### Advertising

Advertising costs are charged to operations as incurred. For the years ended December 31, 2018 and 2017, the Company incurred advertising costs of \$288,986 and \$26,840, respectively. Advertising expense is reflected in marketing and promotion expenses in the consolidated statements of operations.

## Research and Development

Research and development expenses are charged to operations as incurred. For the years ended December 31, 2018 and 2017, the Company incurred research and development expenses of \$1,513,150 and \$2,152,433, respectively.

# Notes to Consolidated Financial Statements

# Note 3 - Summary of Significant Accounting Policies - Continued

#### Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 820 "Fair Value Measurements and Disclosures" ("ASC 820").

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 - quoted prices in active markets for identical assets or liabilities

Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 — inputs that are unobservable (for example, cash flow modeling inputs based on assumptions)

The carrying amounts of accrued liabilities approximate fair value due to the short-term nature of these instruments. The carrying amounts of our short-term credit obligations approximate fair value because the effective yields on these obligations, which include contractual interest rates, taken together with other features such as concurrent issuance of warrants, are comparable to rates of returns for instruments of similar credit risk.

See Note 11 - Derivative Liabilities for additional details regarding the valuation technique and assumptions used in valuing Level 3 inputs.

#### 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 FASB ASC 815 "Derivatives and Hedging" ("ASC 815"). 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 statements of operations 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 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, the Company follows 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, issuance of securities to the Company's employees or directors are not subject to the sequencing policy.

## Notes to Consolidated Financial Statements

#### Note 3 - Summary of Significant Accounting Policies - Continued

#### 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.

#### Reclassification

Certain amounts in prior periods have been reclassified to conform to the current period presentation. These reclassifications had no effect on previously reported net loss.

#### Subsequent Events

The Company evaluates events that have occurred after the balance sheet date but before the financial statements are issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the consolidated financial statements, except as disclosed.

# Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers (Topic 606)" ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements in ASC 605 - Revenue Recognition ("ASC 605") and most industry-specific guidance throughout ASC 605. The FASB has issued numerous updates that provide clarification on a number of specific issues as well as requiring additional disclosures. The core principle of ASU 2014-09 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing U.S. GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The guidance may be adopted through either retrospective application to all periods presented in the financial statements (full retrospective approach) or through a cumulative effect adjustment to retained earnings at the effective date (modified retrospective approach). The Company expects to adopt ASU 2014-09 using a modified retrospective approach effective as of January 1, 2019. The Company has completed an analysis and concluded that the adoption of ASU 2014-09 will not have an impact on the Company's financial statements.



## Notes to Consolidated Financial Statements

# Note 3 - Summary of Significant Accounting Policies - Continued

#### Recently Issued Accounting Pronouncements - Continued

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)" ("ASU 2016-02"). ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lesse should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This amendment will be effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The FASB issued ASU No. 2018-10 "Codification Improvements to Topic 842, Leases" ("ASU 2018-10"), ASU No. 2018-11 "Leases (Topic 842) Targeted Improvements" ("ASU 2018-11") in July 2018, and ASU No. 2018-20 "Leases (Topic 842) - Narrow Scope Improvements for Lessors" ("ASU 2018-20") in December 2018. ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently evaluating these ASUs and their impact on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation – Stock Compensation (Topic 718)" ("ASU 2016-09"). ASU 2016-09 requires an entity to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. The Company adopted this guidance on January 1, 2017. The adoption of this standard did not have a material impact on the Company's financial statement disclosures.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments" ("ASU 2016-15"). The new standard will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2018. The Company will require adoption on a retrospective basis unless it is impracticable to apply, in which case the Company would be required to apply the amendments prospectively as of the earliest date practicable. The Company does not believe the adoption of ASU 2016-15 will have a material impact on its consolidated financial statements or disclosures.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation—Stock Compensation (Topic 718)" ("ASU 2017-09"). ASU 2017-09 provides clarity on the accounting for modifications of stock-based awards. ASU 2017-09 requires adoption on a prospective basis in the annual and interim periods for the Company's fiscal year ending December 31, 2017 for share-based payment awards modified on or after the adoption date. The adoption of this standard did not have a material impact on the Company's financial statement disclosures.

In July 2017, the FASB issued ASU No. 2017-11, "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815)": (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The guidance in ASU 2017-11 can be applied using a full or modified retrospective approach. The Company does not believe the adoption of ASU 2017-11 will have a material impact on its consolidated financial statements or disclosures.

## Notes to Consolidated Financial Statements

# Note 3 - Summary of Significant Accounting Policies - Continued

#### Recently Issued Accounting Pronouncements - Continued

In June 2018, the FASB issued ASU No. 2018-07, "Compensation — Stock Compensation (Topic 718)" ("ASU 2018-07"). ASU 2018-07 is intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. Currently, the accounting requirements for nonemployee and employee share-based payment transactions are significantly different. ASU 2018-07 expands the scope of Topic 718, Compensation — Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, Equity — Equity-Based Payments to Nonemployees. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019, and including interim periods within that fiscal year. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606, Revenue from Contracts with Customers. The Company is currently evaluating ASU 2018-07 and its impact on its consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-09, "Codification Improvements" ("ASU 2018-09"). These amendments provide clarifications and corrections to certain ASC subtopics including the following: Income Statement - Reporting Comprehensive Income – Overall (Topic 220-10), Debt - Modifications and Extinguishments (Topic 470-50), Distinguishing Liabilities from Equity – Overall (Topic 480-10), Compensation - Stock Compensation - Income Taxes (Topic 718-740), Business Combinations - Income Taxes (Topic 805-740), Derivatives and Hedging – Overall (Topic 815-10), and Fair Value Measurement – Overall (Topic 820-10). The majority of the amendments in ASU 2018-09 will be effective in annual periods beginning after December 15, 2019. The Company is currently evaluating and assessing the impact this guidance will have on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements associated with fair value measurements based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating ASU 2018-13 and its impact on its consolidated financial statements.

## Note 4 - Property and Equipment, net

Property and equipment include the following:

		December 31,						
		2017						
Medical equipment	\$	345,963	\$	446,506				
Furniture and fixtures		120,925		121,625				
Computer software and equipment		80,748		78,190				
Office equipment		12,979		2,848				
Leasehold improvements		304,661		304,661				
		865,276		953,830				
Less: accumulated depreciation		(690,041)		(625,983)				
Property and equipment, net	\$	175,235	\$	327,847				

During the years ended December 31, 2018 and 2017, depreciation expense amounted to \$165,481 and \$184,365, respectively. Depreciation expense is reflected in general and administrative expenses and research and development expenses in the consolidated statements of operations. During the year ended December 31, 2018, the Company disposed of an aggregate of \$101,423 of fully depreciated property and equipment.

# Notes to Consolidated Financial Statements

# Note 5 - Intangible Assets, net

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 will be required to pay to the SCTC 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 February 2022 to complete the Phase 2 clinical trial in order to satisfy the final performance milestone such that the Company would not be 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:

	tents and demarks	Licenses	cumulated nortization	Total		
Balance as of January 1, 2017	\$ 3,676	\$ 1,301,500	\$ (341,331)	\$	963,845	
Amortization expense	-	-	(74,895)		(74,895)	
Balance as of December 31, 2017	3,676	1,301,500	(416,226)		888,950	
Amortization expense	-	-	(74,891)		(74,891)	
Balance as of December 31, 2018	\$ 3,676	\$ 1,301,500	\$ (491,117)	\$	814,059	
Weighted average remaining amortization period at December 31, 2018 (in years)	2.0	 10.9	 			

Amortization of intangible assets consists of the following:

	Patents and Trademarks Licenses			 Accumulated Amortization
Balance as of January 1, 2017	\$ 2,208	\$	339,123	\$ 341,331
Amortization expense	368		74,527	74,895
Balance as of December 31, 2017	 2,576		413,650	 416,226
Amortization expense	368		74,523	74,891
Balance as of December 31, 2018	\$ 2,944	\$	488,173	\$ 491,117

Amortization expense is reflected in general and administrative expenses in the consolidated statements of operations. Based upon the current intangible assets as of December 31, 2018, amortization expense is projected to be approximately \$75,000 per annum through 2029.

## Notes to Consolidated Financial Statements

# Note 6 - Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities are comprised of the following:

		December 31,					
	2	2018					
Accrued payroll	\$	91,560	\$	349,163			
Accrued research and development expenses		646,175		636,175			
Accrued general and administrative expenses		1,084,831		605,318			
Accrued director compensation		482,500		282,500			
Deferred rent		33,610		50,395			
Total accrued expenses		2,338,676		1,923,551			
Less: accrued expenses, current portion		2,302,176		1,885,551			
Accrued expenses, non-current portion	\$	36,500	\$	38,000			

During the year ended December 31, 2018, the Company received non-interest bearing advances in the aggregate amount of \$38,500 from officers and a family member of an officer of the Company and repaid an aggregate of \$38,500 of non-interest bearing advances from officers and a family member of an officer of the Company. During the year ended December 31, 2017, the Company received non-interest bearing advances in the amount of \$43,515 from an officer and a family member of an officer of the Company and repaid an aggregate of \$58,515, of which \$15,000 was in accounts payable at December 31, 2016, of non-interest bearing advances from a director, an officer and a family member of an officer of the Company.

Effective March 1, 2017, the Company entered into an exchange agreement with the Chairman of the Company's Scientific Advisory Board, pursuant to which an aggregate of \$175,000 of accrued consulting fees were exchanged for 58,334 shares of common stock of the Company and, in consideration thereof, the Company issued to such person an immediately vested five-year warrant for the purchase of 58,334 shares of common stock of the Company at an exercise price of \$4.00 per share. The common stock and warrants had an aggregate grant date value of \$211,752 and, as a result, the Company recorded a loss on settlement of payables of \$36,752 which is reflected within general and administrative expenses in the consolidated statements of operations.

Effective March 1, 2017, the Company entered into exchange agreements with four non-employee directors of the Company, pursuant to which an aggregate of \$265,000 of accrued director fees were exchanged for an aggregate of 88,334 shares of common stock of the Company and, in consideration thereof, the Company issued to the directors immediately vested five-year warrants for the purchase of an aggregate of 88,334 shares of common stock of the Company at an exercise price of \$4.00 per share. The aggregate value of the shares and warrants was \$320,652, and accordingly the Company recorded a loss on settlement of payables of \$55,652 which is reflected within general and administrative expenses in the consolidated statements of operations.

Effective July 18, 2017, the Company entered into an exchange agreement with a certain vendor of the Company, pursuant to which \$17,697 of accounts payable were exchanged for 8,334 shares of common stock of the Company. In consideration thereof, the Company issued to the vendor immediately vested five-year warrants for the purchase of 2,000 shares of common stock of the Company at an exercise price of \$4.00 per share. The aggregate value of the shares and warrants was \$19,888, and accordingly the Company recorded a loss on settlement of payables of \$2,191 which is reflected within general and administrative expenses in the consolidated statements of operations.

Effective December 12, 2018, the Company entered into an exchange agreement with a certain consultant of the Company, pursuant to which \$45,000 of accounts payable were exchanged for 56,250 shares of common stock of the Company. The value of the shares was \$42,188, and accordingly the Company recorded a gain on settlement of payables of \$2,812 which is reflected within general and administrative expenses in the consolidated statements of operations.

See Note 9 - Commitments and Contingencies - Consulting Agreements and Note 12 - Subsequent Events for details regarding additional exchanges of accrued consulting fees for shares of common stock and warrants.

# Notes to Consolidated Financial Statements

# Note 7 – Notes Payable

A summary of the notes payable activity during the years ended December 31, 2018 and 2017 is presented below:

	Rela	ated Party Notes	(	Convertible Notes	Other Notes		Debt Discount	Total
Outstanding, December 31, 2016	\$	827,500	\$	390,000	\$	1,119,065	\$ (179,964)	\$ 2,156,601
Issuances		175,000		1,612,333		1,033,900	-	2,821,233
Indebtedness satisfied via settlement		-		637,250[1]		(637,250)	-	-
Exchanges for equity		(97,500)		(50,000)		(203,750)	-	(351,250)
Conversions to equity		-		(495,197)		-	-	(495,197)
Repayments		(60,000)		(69,176)		(201,000)	-	(330,176)
Recognition of debt discount		-		-		-	(964,911)	(964,911)
Accretion of interest expense		-		4,660		13,500	188,124	206,284
Amortization of debt discount		-		-		-	619,266	619,266
Outstanding, December 31, 2017	\$	845,000	\$	2,029,870[2]	\$	1,124,465	\$ (337,485)	\$ 3,661,850
Issuances		-		6,357,286[3]		128,000	-	6,485,286
Exchanges for equity		(95,000)		(2,739,926)		(1,047,247)	681,281	(3,200,892)
Conversions to equity		-		(105,000)		-	-	(105,000)
Repayments		(30,000)		(833,302)		-	61,001	(802,301)
Extinguishment of notes payable		-		(407,295)[3]		(318,493)[3]	-	(725,788)
Recognition of debt discount		-		-		-	(4,077,234)	(4,077,234)
Accretion of interest expense		-		7,782		245,776	370,483	624,041
Amortization of debt discount		-		-		-	2,289,591	2,289,591
Outstanding, December 31, 2018	\$	720,000	\$	4,309,415[2]	\$	132,501	\$ (1,012,363)	\$ 4,149,553
Outstanding, December 31, 2017	\$	845,000	\$	2,029,870[2]	\$	1,124,465	\$ (337,485)	\$ 3,661,850
Less: current portion, December 31, 2017		(845,000)		(1,834,332)		(1,124,465)	336,229	(3,467,568)
Non-current portion, December 31, 2017 [4]	\$	-	\$	195,538	\$		\$ (1,256)	\$ 194,282
Outstanding, December 31, 2018	\$	720,000	\$	4,309,415[2]	\$	132,501	\$ (1,012,363)	\$ 4,149,553
Less: current portion, December 31, 2018		(720,000)		(3,710,024)		(132,501)	936,866	(3,625,659)
Non-current portion, December 31, 2018 [4]	\$	-	\$	599,391	\$	-	\$ (75,497)	\$ 523,894
			ł	-40				

# Notes to Consolidated Financial Statements

#### Note 7 - Notes Payable - Continued

- [1] In connection with certain note extensions during the year ended December 31, 2017, the Company and a certain lender agreed to add embedded conversion options, permitting principal and the respective accrued interest to be convertible into shares of the Company's common stock at the election of the lender any time until the balance has been paid in full. See Note 7 Notes Payable Convertible Notes and Note 11 Derivative Liabilities for additional details regarding the embedded conversion options.
- [2] As of December 31, 2018 and 2017, a portion of convertible notes with an aggregate principal balance of \$2,374,415 and \$1,777,788, respectively, was convertible into shares of common stock at the election of the holder any time immediately until the balance has been paid in full. As of December 31, 2018 and 2017, a portion of convertible notes with an aggregate principal balance of \$0 and \$252,082, respectively, was convertible into shares of common stock at the election of the Company near maturity. In the event the Company exercised that conversion right, the respective holder had the right to accelerate the conversion of up to \$0 and \$196,666 of principal into shares of common stock at December 31, 2018 and 2017, respectively, at the same conversion price. As of December 31, 2018, a portion of convertible notes with an aggregate principal balance of \$1,935,000, which were not yet convertible, will become convertible into shares of the Company's common stock at the election of the respective holder subsequent to December 31, 2018.
- [3] During the year ended December 31, 2018, convertible notes in the aggregate principal amount of \$725,788 were issued concurrently with the extinguishment of certain notes payable in the same aggregate principal amount. See below within Note 7 – Notes Payable – Conversions, Exchanges and Other for additional details.
- [4] As of December 31, 2018 and 2017, the Company reclassified principal in the aggregate amount of \$523,894 and \$194,282, respectively (net of debt discount of \$75,497 and \$1,256, respectively), and accrued interest in the aggregate amount of \$18,137 and \$9,591, respectively, to notes payable, non-current portion, net of debt discount and accrued interest, non-current portion, respectively, on the consolidated balance sheets related to outstanding notes payable that were converted into or exchanged for shares of common stock subsequent to December 31, 2018 and 2017, respectively. See Note 12 Subsequent Events for additional details regarding notes payable.

# Related Party Notes

As of December 31, 2018 and 2017, 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 director and principal shareholder of the Company (the "Director/Principal Shareholder") serves as a trustee of Trust, which was established for the benefit of his immediate family.

During the year ended December 31, 2017, the Company issued to the Director/Principal Shareholder a note in the principal amount of \$175,000, which bears interest at a rate of 15% per annum payable and provided for a maturity date of December 1, 2017. In November 2017, the maturity date of the note was extended to December 1, 2018 as described below (subject to a Financing Acceleration, as defined below). The note is secured by the grant of a security interest in the Company's equipment and intellectual property. In connection with the borrowing, the Company agreed that the payment of a note in the principal amount of \$500,000 issued to the Trust (the "Trust Note") is also secured by such security interest.

During the year ended December 31, 2017, the Company and the Trust agreed to extend the maturity date of the Trust Note from July 2017 to December 2017. As consideration of the extension, the Company increased the interest rate payable on the Trust Note from 10% to 15% per annum. During the year ended December 31, 2017, the maturity date of the Trust Note was further extended to December 1, 2018 as described below. In the event that, prior to maturity, the Company receives net proceeds of \$10,000,000 from a single equity or debt financing (as opposed to a series of related or unrelated financings), the Trust has the right to require that the Company prepay the amount due under the Trust Note (subject to the consent of the party that provided the particular financing) (a "Financing Acceleration").

# Notes to Consolidated Financial Statements

# Note 7 – Notes Payable – Continued

# Related Party Notes - Continued

During the year ended December 31, 2017, the Company, the Trust and the Director/Principal Shareholder agreed to extend the maturity dates of the above notes payable with an aggregate principal balance of \$675,000, that were near maturity, to December 1, 2018 (subject to a Financing Acceleration). In consideration of the note extensions, the Company reduced the exercise prices for an aggregate of 1,219,444 previously issued five-year warrants to purchase the Company's common stock at prices ranging from \$4.50 to \$5.00 per share to a reduced exercise price of \$4.00 per share. The incremental modification expense of \$84,722 has been recorded as debt discount and is being amortized over the extended term of the notes. During the year ended December 31, 2018, the Company, the Trust and the Director/Principal Shareholder agreed to further extend the maturity dates of the above notes payable with an aggregate principal balance of \$675,000, that were near maturity, to December 31, 2019 (subject to a Financing Acceleration). In consideration of one of the note extensions, the Company reduced the exercise prices for an aggregate principal balance of \$675,000, that were near maturity, to December 31, 2019 (subject to a Financing Acceleration). In consideration of one of the note extensions, the Company reduced the exercise prices for an aggregate of \$44,444 previously issued five-year warrants to purchase the Company's common stock from an exercise price of \$4.00 per share to a reduced exercise price of \$1.50 per share. The incremental modification expense of \$244,889 has been recorded as debt discount and is being amortized over the extended term of the respective note. See Note 10 – Stockholders' Deficiency for additional details regarding the warrant modification.

During the year ended December 31, 2017, the Company and a director of the Company agreed to extend the maturity date of a note payable with a principal balance of \$50,000 from February 2017 to February 2018. In connection with the extension, the Company issued the director a five-year, immediately vested warrant to purchase 5,000 shares of common stock at an exercise price of \$4.00 per share. The grant date fair value of the warrant of \$8,050 was recorded as debt discount and is being amortized over the remaining term of the note.

During the year ended December 31, 2018, the Company and certain related parties agreed to further extend the maturity dates of notes payable with an aggregate principal balance of \$140,000 from maturity dates ranging between August 2016 to February 2018 to new maturity dates ranging from July 2018 to December 2018. As of December 31, 2018, a certain related party note in the outstanding principal amount of \$45,000 was past maturity.

During the year ended December 31, 2017, the Company and certain related party lenders agreed to exchange certain related party notes with an aggregate principal balance of \$97,500 and aggregate accrued interest of \$288 into an aggregate of 32,597 shares of common stock and immediately vested five-year warrants to purchase an aggregate of 32,597 shares of common stock and warrants had an aggregate exchange date value of \$118,328 and, as a result, the Company recorded a loss on extinguishment of notes payable of \$20,540.

During the year ended December 31, 2018, the Company and certain related parties agreed to exchange certain notes with an aggregate principal balance of \$95,000 for an aggregate of 76,000 shares of the Company's common stock. The common stock had an aggregate exchange date value of \$114,000 and, as a result, the Company recorded a loss on extinguishment of notes payable of \$19,000.

During the years ended December 31, 2018 and 2017, the Company partially repaid certain related party notes in the aggregate principal amount of \$30,000 and \$60,000, respectively.



#### Notes to Consolidated Financial Statements

#### Note 7 – Notes Payable – Continued

#### Convertible Notes

#### Issuances

During the year ended December 31, 2017, the Company issued lenders convertible notes in the aggregate principal amount of \$1,554,000, for aggregate gross proceeds of \$1,415,970. The difference of \$138,030 was recorded as an original issue discount and is being amortized over the terms of the respective notes. The convertible notes bore interest at rates ranging between 6% to 10% per annum payable at maturity with maturity dates ranging between November 2017 through July 2018. In connection with the issuance of these convertible notes, the Company issued a certain lender 8,000 shares of common stock. Additionally, in connection with the issuance of certain convertible notes, the Company issued certain lenders five-year warrants to purchase an aggregate 62,019 shares of the Company's common stock at exercise prices ranging from \$4.00 to \$4.15 per share, subject to a mandatory redemption provision depending on the warrant. The aggregate relative fair value of the common stock and warrants was \$104,402, which was recorded as a debt discount and is being amortized over the terms of the respective notes. In connection with certain convertible notes, the Company incurred \$13,750 of debt issuance costs which is being amortized over the terms of the respective notes.

During the year ended December 31, 2017, the Company issued a lender a note payable in the principal amount of \$83,333 of which \$25,000 of principal bore no interest and \$58,333 of principal bore interest at 10% per annum and was convertible into common stock. In connection with the issuance of the note, the Company received gross proceeds of \$75,000, and the difference of \$8,333 has been recorded as an original issue discount and will be amortized over the term of the note. The note provided for payment as follows: (i) \$25,000 of principal (classified as an other note herein), which bore no interest and was not convertible into common stock, was payable three weeks from the issuance date, (ii) \$11,667 of principal and the respective interest on such principal was payable six months from the issuance date (the "First Maturity Date"), (iii) \$11,667 of principal and the respective interest on such principal was payable two weeks following the First Maturity Date, (iv) \$11,667 of principal and the respective accrued interest on such principal was payable four weeks following the First Maturity Date, (v) \$11,667 of principal and the respective interest on such principal was payable four weeks following the First Maturity Date, (v) \$11,667 of principal and the respective interest on such principal was payable six weeks following the First Maturity Date, (v) \$11,667 of principal and the respective interest on such principal was payable weeks following the First Maturity Date, (v) \$11,667 of principal and the respective interest on such principal was payable six weeks following the First Maturity Date, (v) \$11,667 of principal and the respective interest on such principal was payable weeks following the First Maturity Date. In connection with the issuance of this note, the Company issued the lender 3,500 shares of common stock with a rel

During the year ended December 31, 2018, the Company issued certain lenders and a consultant convertible notes payable in the aggregate principal amount of \$5,631,498 for aggregate cash proceeds of \$4,947,475. The difference of \$684,025 was recorded as follows: (i) \$424,023 was recorded as a debt discount and will be amortized over the terms of the respective notes and (ii) \$260,000 was recognized as consulting expense in the consolidated financial statements for services performed during the period. See Note 9 – Commitments and Contingencies for additional details regarding convertible notes issued in connection with consulting services. The convertible notes bear interest at rates ranging between 6% and 15% per annum payable at maturity with original maturity dates ranging between June 2018 through December 2019. In connection with the issuance of certain convertible notes, the Company issued the lenders an aggregate of 53,249 shares of the Company's common stock and the relative fair value of \$60,925 was recorded as debt discount and is being amortized over the terms of the respective notes. See below within Note 7 – Notes Payable – Conversions, Exchanges and Other and Note 11 – Derivative Liabilities for additional details regarding the ECOs of the convertible notes.

During the year ended December 31, 2018, convertible notes in the aggregate principal amount of 725,788 were issued concurrently with the extinguishment of certain convertible and other notes payable in the same aggregate principal amount. See below within Note 7 – Notes Payable – Conversions, Exchanges and Other for additional details.

#### Notes to Consolidated Financial Statements

#### Note 7 – Notes Payable – Continued

#### Convertible Notes - Continued

#### Embedded Conversion Options and Note Provisions

As of December 31, 2018, outstanding convertible notes in the aggregate principal amount of \$2,374,415 were convertible into shares of common stock of the Company as follows: (i) \$920,000 of aggregate convertible notes were convertible at a fixed price ranging from \$1.00 to \$2.00 per share for the first six months following the respective issue date, thereafter, at a conversion price equal to 58% of the fair value of the Company's stock, subject to adjustment, until the respective note has been paid in full, (ii) \$350,000 of convertible notes were convertible at a fixed conversion price of \$2.15 per share, (iii) \$100,000 of convertible notes were convertible at the greater of (a) 60% of the fair value of the Company's stock (subject to adjustment), depending on the note, and (v) \$100,000 of convertible notes 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 (the "Warrant") for the purchase of a number of shares equal to the number of shares issued upon the 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 Note 7 – Notes Payable – Convertible Notes and Note 11 – Derivative Liabilities for additional details regarding the embedded conversion options of the convertible notes.

As of December 31, 2018, a portion of convertible notes with an aggregate principal balance of \$1,935,000, which were not yet convertible, will become convertible into shares of the Company's common stock subsequent to December 31, 2018, as follows: (i) \$1,835,000 of aggregate convertible notes will generally become convertible at a conversion price equal to 58% of the fair value of the Company's stock, subject to adjustment, until the respective note has been paid in full and (ii) \$100,000 of convertible notes will become convertible at the greater of (a) 58% of the fair value of the Company's stock or (b) \$1.50 per share.

As of December 31, 2018, outstanding convertible notes in the aggregate principal amount of \$69,978 have mandatory prepayment terms at the option of the holder ("MPOs"). Convertible notes issued with MPOs permit the respective holder to demand prepayment of the note, in cash, at a premium of 35% of the then outstanding principal balance and accrued interest during the period between 150 days to 179 days following the respective issuance date.

As of December 31, 2018, outstanding convertible notes in the aggregate principal amount of \$2,798,493 have prepayment premiums, whereby, in the event that the Company elects to prepay certain notes during the first ninety-day period following the issue date, the respective holder is entitled to receive a prepayment premium of up to 35%, depending on the note, on the then outstanding principal balance including accrued interest. In the event that the Company prepays any of the notes during the second ninety-day period following the issue date, the respective holder is entitled to receive a prepayment premium of up to 40%, depending on the note, on the then outstanding principal balance including accrued interest. In the event that the Company prepays a certain note after the 180<sup>th</sup> day period following the issue date and prior to maturity, the holder is entitled to receive a prepayment premium of 50% on the then outstanding principal balance including accrued interest.

As of December 31, 2018, outstanding convertible notes in the aggregate principal amount of \$1,849,978 have most favored nation ("MFN") provisions, whereby, so long as such respective note is 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 shall become a part of the transaction documents with the holder. As of December 31, 2018, 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, 2018, 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 \$3,631,702, of which \$3,181,376 was recorded as a debt discount and is being amortized over the terms of the respective convertible notes and \$450,326 was recognized as part of an extinguishment loss as described below. See Note 11 – Derivative Liabilities for additional details.

#### Notes to Consolidated Financial Statements

#### Note 7 – Notes Payable – Continued

#### Convertible Notes - Continued

#### Embedded Conversion Options and Note Provisions - Continued

During the years ended December 31, 2018 and 2017, the contingently adjustable non-bifurcated, beneficial conversion features associated with certain convertible notes were resolved and such notes became convertible during the period. The Company estimated the intrinsic value of the beneficial conversion features based upon the difference between the fair value of the underlying common stock at the commitment date of the note transaction and the adjusted conversion price embedded in the convertible note. During the years ended December 31, 2018 and 2017, the Company recognized \$69,394 and \$11,991, respectively, related to the beneficial conversion feature as debt discount which was immediately amortized.

#### Conversions, Exchanges and Other

During the year ended December 31, 2017, the Company and a certain lender agreed to exchange a certain convertible note with a principal balance of \$50,000 and accrued interest of \$2,712 into 29,280 shares of common stock. The common stock had an exchange date value of \$58,560 and, as a result, the Company recorded a loss on extinguishment of notes payable of \$5,848.

During the year ended December 31, 2017, certain convertible notes with an aggregate principal balance of \$495,197 and aggregate accrued interest of \$29,338 were converted into an aggregate of 243,441 shares of common stock at conversion prices ranging from \$1.75 to \$2.77 per share at the election of either the Company or the respective lender.

During the year ended December 31, 2017, the Company and a lender agreed to multiple extensions of the maturity dates of notes payable with an aggregate principal balance of \$637,250 with maturity dates that were near or at maturity to maturity dates ranging from December 1, 2017 through February 10, 2018. In connection with one of the note extensions, the Company issued the lender 2,500 shares of common stock. The issuance date fair value of the common stock of \$5,000 has been recorded as a debt discount and is being amortized over the term of the note. Additionally, in connection with one of the extensions, the Company incurred an extension fee in the amount \$8,500 which was accreted as interest expense and added to the principal balance of the note. Also, in connection with the note extensions, the Company increased the effective rate at which the notes bore interest from 0% to 8% on dates effective between August 2, 2017 and September 7, 2017. Furthermore, in connection with the note extensions, the Company added embedded conversion options, pursuant to which each payment of principal and the respective notes. Further, in connection with the note extension, such a aggregate \$4,660 of incurred interest to the principal and the respective accrued interest is convertible into shares of the Company's common stock at the election of the lender at any time until the balance has been paid in full at a conversion price equal to 80% of the fair market value of the Company's stock (subject to reduction to 70% under certain circumstances); however, generally the conversion price could not be less than \$1.00 per share. The embedded conversion options of the notes were determined to be derivative liabilities. The aggregate issuance date value of the embedded conversion options was \$252,117, which was recorded as a debt discount and is being amortized over the terms of the respective notes. See Note 11 – Derivative Liabilities for additional details.

During the year ended December 31, 2017, the Company repaid an aggregate principal amount of \$69,176 of convertible notes.

During the year ended December 31, 2018, the Company and certain lenders exchanged certain convertible notes with bifurcated ECOs with an aggregate net carrying amount of \$5,144,063 (including an aggregate of \$2,058,645 of principal net of debt discount, \$166,022 of accrued interest and \$2,919,396 related to the separated ECOs accounted for as derivative liabilities) for an aggregate of 3,734,664 shares of the Company's common stock at conversion prices ranging from \$0.28 to \$2.38 per share. The common stock had an aggregate exchange date value of \$5,846,809 and, as a result, the Company recorded a loss on extinguishment of notes payable of \$702,746. See Note 11 – Derivative Liabilities for additional details.

During the year ended December 31, 2018, the Company elected to convert certain convertible notes with an aggregate principal balance of \$105,000 and aggregate accrued interest of \$5,636 into an aggregate of 97,424 shares of the Company's common stock at conversion prices ranging from \$0.82 to \$2.02 per share.

#### Notes to Consolidated Financial Statements

#### Note 7 – Notes Payable – Continued

#### Convertible Notes - Continued

#### Conversions, Exchanges and Other - Continued

During the year ended December 31, 2018, the Company repaid an aggregate principal amount of \$833,302 of convertible notes payable, \$44,787 of the respective aggregate accrued interest and an aggregate of \$238,808 of prepayment premiums. As a result of the repayments, the Company recorded a loss on extinguishment of notes payable of \$299,809 and an aggregate of \$61,001 of the related debt discounts were extinguished.

During the year ended December 31, 2018, the Company and certain lenders agreed to multiple extensions of the maturity dates of notes payable with an aggregate principal balance of 681,445 from maturity dates ranging between December 2017 to July 2018 to new maturity dates ranging from April 2018 to September 2018. In consideration of the extensions, the Company issued a lender 4,500 shares of the Company's common stock. The issuance date fair value of the common stock of 9,000 was recorded as debt discount and is being amortized over the remaining term of the note. See below within this Note 7 – Notes Payable – Conversions, Exchanges and Other and Note – 11 Derivative Liabilities for additional details regarding the ECOs of the convertible notes. As of December 31, 2018, there were no convertible notes payable past due.

During the year ended December 31, 2018, certain lenders to the Company acquired other promissory notes issued by the Company in the aggregate outstanding amount of \$725,788 (inclusive of accreted interest of \$76,272) from different lenders to the Company. The Company exchanged the acquired notes for new convertible notes in the aggregate principal amount of \$725,788 which accrue interest at rates ranging between 8% to 12% per annum, payable on the respective maturity date ranging between August 2019 and November 2019. The ECOs of the notes were subject to sequencing and their issuance date fair value of \$450,326 was accounted for as derivative liabilities (see Note 11 – Derivative Liabilities for additional details). Since the fair value of the new ECOs exceeded 10% of the respective principal amounts of the new notes, the note exchanges were accounted for as extinguishments, and accordingly the Company recognized a net loss on extinguishment of \$248,891 in connection with the derecognition of the net carrying amount of \$927,223 of the extinguished debt (\$725,788 of aggregate principal amount \$725,788 plus the fair value of the new notes' ECOs of an aggregate of \$450,326.

#### Other Notes

Issuances

During the year ended December 31, 2017, the Company issued lenders other notes in the aggregate principal amount of 1,033,900 for aggregate gross proceeds of 915,000, and the difference of 118,900 has been recorded as an original issue discount and will be amortized over the terms of the respective notes (inclusive of 25,000 of principal of a note payable as discussed above in Note 7 – Notes Payable – Convertible Notes). The other notes bear interest at rates between 0% to 12% per annum payable at maturity. The other notes matured between dates in May 2017 to July 2018. In connection with the issuance of these other notes, the Company issued to certain lenders 22,653 shares of common stock and certain other lenders five-year warrants to purchase an aggregate of 55,000 shares of common stock at an exercise price of 4.00 per share. The aggregate relative fair value of the common stock and warrants of 116,248 was recorded as an original issue discount and is being amortized over the terms of the respective notes.

During the year ended December 31, 2018, the Company issued a lender three-month notes payable in the aggregate principal amount of \$128,000, which bear no interest, for aggregate cash proceeds of \$110,000. The \$18,000 difference was recorded as debt discount and is being amortized over the terms of the respective notes. In connection with the issuances of the promissory notes, the Company issued the lender an aggregate of 6,500 shares of the Company's common stock. The issuance date fair value of the common stock of \$9,627 was recorded as debt discount and is being amortized over the terms of the respective notes.

#### Notes to Consolidated Financial Statements

#### Note 7 – Notes Payable – Continued

#### Other Notes - Continued

# Exchanges and Other

During the year ended December 31, 2017, the Company and certain lenders agreed to exchange certain other notes with an aggregate principal balance of \$203,750 and aggregate accrued interest of \$7,114 into an aggregate of 70,205 shares of common stock and immediately vested five-year warrants to purchase an aggregate of 63,205 shares of common stock at an exercise price of \$4.00 per share. In addition, in consideration of the exchange by certain lenders, the Company agreed to extend the expiration dates of certain warrants held by the lenders for the purchase of an aggregate of 18,000 shares of common stock of the Company at an exercise price of \$4.00 per share, from expiration dates of addees ranging from April 27, 2021 to January 31, 2022 to a new expiration date of February 8, 2022. The common stock, warrants, and warrant modification (which represents the incremental value of the modified warrant as compared to the original warrant value, both valued as of the modification date) had an aggregate exchange date value of \$244,414 and, as a result, the Company recorded a loss on extinguishment of notes payable of \$33,550.

During the year ended December 31, 2017, the Company and certain lenders agreed to extend other notes with an aggregate principal balance of \$984,063, that were near or at maturity, to various dates through October 2018. In consideration of the extensions, the Company issued certain lenders an aggregate 4,300 shares of the Company's common stock. Also, in connection with the extensions, the Company issued certain lenders five-year, immediately vested warrants to purchase an aggregate of 56,118 shares of the Company's common stock at exercise prices ranging between \$4.00 to \$5.00 per share. The aggregate grant date fair value of the common stock and warrants of \$96,910 has been recorded as debt discount and is being amortized over the terms of the respective notes. Additionally, in connection with one of the extensions, the Company incurred debt issuance costs in the amount \$5,000 which was accreted as interest expense and added to the principal balance of the note.

During the year ended December 31, 2017, the Company and a lender agreed to extend other notes with an aggregate principal balance of 637,250 such that the notes also became convertible into shares of the Company's common stock. See Note 7 – Notes Payable – Convertible Notes for additional details.

During the year ended December 31, 2017, the Company repaid an aggregate principal amount of \$201,000 of other notes.

During the year ended December 31, 2018, the Company and certain lenders agreed to exchange certain notes with an aggregate principal balance of \$1,047,247 and aggregate accrued interest of \$61,802 for an aggregate of 1,221,250 shares of the Company's common stock at exchange prices ranging from \$0.72 to \$1.50 per share. The common stock had an aggregate exchange date value of \$1,254,557 and, as a result, the Company recorded a loss on extinguishment of notes payable of \$145,508.

During the year ended December 31, 2018, the Company and certain lenders agreed to multiple extensions of the maturity dates of notes payable with an aggregate principal balance of \$1,309,747 from maturity dates ranging between December 2017 to October 2018 to new maturity dates ranging from March 2018 to January 2019. In consideration of the extensions, the Company issued certain lenders an aggregate of 35,000 shares of the Company's common stock. The aggregate issuance date fair value of the common stock of \$60,000 was recorded as debt discount and is being amortized over the remaining terms of the respective notes. Additionally, in connection with a certain extension, the Company increased the stated rate at which the note bears interest, from 0% to 8% per annum, effective June 2018. Furthermore, in connection with certain of the extensions, the Company accreted an aggregate of \$177,286 as interest expense to the principal balance of the respective note. As of December 31, 2018, principal of \$7,500 of a certain other note payable was past due.

During the year ended December 31, 2018, a convertible promissory note in the principal amount of 318,493 was issued concurrently with the extinguishment of a certain other note payable in the same principal amount. See above within Note 7 – Notes Payable – Conversions, Exchanges and Other for additional details.

# Notes to Consolidated Financial Statements

# Note 8 – Income Taxes

The tax effects of temporary differences that give rise to deferred tax assets and liabilities are presented below:

		For The Years Ended December 31,			
		2018		2017	
Deferred Tax Assets:					
Net operating loss carryforwards	\$	4,401,000	\$	2,176,000	
Stock-based compensation		3,433,000		2,873,000	
Accruals		6,000		48,000	
Research & development tax credits		358,000		340,000	
Other		1,000		1,000	
Gross deferred tax assets		8,199,000		5,438,000	
Deferred Tax Liabilities:					
Fixed assets		(2,000)		(34,000)	
Intangible assets		(19,000)		(16,000)	
Gross deferred tax liabilities		(21,000)		(50,000)	
Net deferred tax assets		8,178,000		5,388,000	
Valuation allowance		(8,178,000)		(5,388,000)	
Deferred tax asset, net of valuation allowance	\$		\$	<u> </u>	
Changes in valuation allowance	<u>\$</u>	2,790,000	\$	(1,291,000)	

The income tax provision (benefit) consists of the following:

		For The Years Ended December 31,		
		2018		2017
Federal:				
Current	\$	-	\$	-
Deferred		(2,253,000)		1,385,000
State and local:				
Current		-		-
Deferred		(537,000)		(94,000)
		(2,790,000)	-	1,291,000
Change in valuation allowance		2,790,000		(1,291,000)
Income tax provision (benefit)	\$	-	\$	-
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### Notes to Consolidated Financial Statements

# Note 8 - Income Taxes - Continued

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

		For The Years Ended December 31,		
	2018	2017		
Tax benefit at federal statutory rate	(21.0)%	(34.0)%		
State income taxes, net of federal benefit	(5.0)%	(4.0)%		
Permanent differences	3.8%	0.0%		
Change in tax rates	0.0%	24.7%		
Research & development tax credits	(0.1)%	(1.6)%		
Impact of Section 382 limits	0.0%	28.3%		
True-ups and other	0.0%	0.3%		
Change in valuation allowance	22.3%	(13.7)%		
Effective income tax rate	0.0%	0.0%		

The Company assesses the likelihood that deferred tax assets will be realized. To the extent that realization is not likely, a valuation allowance is established. Based upon the Company's history of losses since inception, management believes that it is more likely than not that future benefits of deferred tax assets will not be realized.

At December 31, 2018 and 2017, the Company had approximately \$16,900,000 and \$8,400,000, respectively, of federal and state net operating losses that may be available to offset future taxable income. At December 31, 2018 approximately \$8,400,000 of federal net operating losses will expire from 2029 to 2037 and approximately \$8,500,000 have no expiration. In accordance with Section 382 of the Internal Revenue Code, the usage of the Company's net operating loss carry forwards are subject to annual limitations due to several greater than 50% ownership changes. The Section 382 limitations result 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 files income tax returns in the U.S. federal jurisdiction and the state of New York (also formerly Florida where the Company filed its final return in 2015), which remain subject to examination by the various taxing authorities beginning with the tax year ended December 31, 2015 (or the tax year ended December 31, 2009 if the Company were to utilize its NOLs). No tax audits were commenced or were in process during the years ended December 31, 2018 and 2017.

The Tax Cuts and Jobs Act tax reform legislation (the "Act") was enacted in December 2017 making significant changes to the Internal Revenue Code. Changes include but are not limited to (a) the reduction of the U.S. corporate income tax rate from 35% to 21% for tax years beginning after December 31, 2017; (b) the transition of U.S. international taxation from a worldwide tax system to a territorial system; and (c) a one-time transition tax on the mandatory deemed repatriation of foreign earnings. The latter two changes are not expected to impact the Company as its Cayman subsidiary generated cumulative losses and was dissolved in March 2017. The change in tax law required the Company to remeasure existing net deferred tax assets using the lower rate in the period of enactment resulting in an income tax expense of approximately \$2.3 million which is fully offset by the corresponding tax benefit of \$2.3 million from the reduction in the valuation allowance in the year ended December 31, 2017. There were no specific impacts of the Act that could not be reasonably estimated which the Company accounted for under the prior tax law.

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### Notes to Consolidated Financial Statements

## Note 9 - Commitments and Contingencies

## **Operating** Lease

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 expires in March 2020 (subject to extension at the option of the Company for a period of five years) and calls for an annual base rental during the initial term ranging between \$132,600 and \$149,260. The aggregate base rent payable over the lease term will be recognized on a straight-line basis. In connection with the operating lease, the Company paid the landlord a security deposit of \$45,900, of which \$12,076 and \$11,724 were applied as rent payments in 2018 and 2017, respectively.

During the years ended December 31, 2018 and 2017, the Company received a credit of \$12,991 and \$21,237, respectively, towards its rent payments in connection with a tax rebate received by the landlord. The Company's rent expense amounted to \$122,739 and \$115,885 for the years ended December 31, 2018 and 2017, respectively. Rent expense is reflected in general and administrative expenses and research and development expenses in the consolidated statements of operations.

Future minimum payments under this operating lease agreement is as follows:

For the Years Ending		
December 31,	A	mount
2019	\$	147,257
2020		37,315
	\$	184,572

# Consulting Agreements

In March 2017, a previously expired agreement for business advisory services was further amended and the agreement was reinstated effective January 1, 2017. The agreement provided for an expiration date of December 31, 2017 (the "New Business Advisory Extended Term"). In consideration of the extension of the term of the consulting agreement, the Company issued to the consultant an immediately vested five-year warrant for the purchase of 25,000 shares of common stock of the Company. See Note 10 – Stockholders' Deficiency – Stock Warrants for details associated with the issuance of warrants as compensation. Concurrently, the Company entered into an exchange agreement with the consultant pursuant to which \$30,000 of accrued consulting fees were exchanged for 10,000 shares of common stock of the Company and, in consideration thereof, the Company issued to the consultant an immediately vested five-year warrant for the purchase of 10,000 shares of common stock of the Company at an exercise price of \$4.00 per share. The aggregate value of the shares and warrant was \$36,300, and accordingly the Company recorded a loss on settlement of payables of \$6,300 which is reflected within general and administrative expenses in the consolidated statements of operations. During each of the years ended December 31, 2018 and 2017, the Company recorded cash consulting fee expense of \$180,000 related to the business advisory agreement. In January 2018, the term of the business advisory agreement was recognized immediately vested five-year warrant for the purchase of 30,000 per share. The aggregate grant date value of the Company at an exercise price of \$4.00 per share. The aggregate grant date value of the term of the business advisory agreement. In January 2018, the term of the business advisory agreement was extended to December 31, 2018. In consideration of the extension of the term of the business advisory agreement, the Company issued to the consultant an immediately vested five-year warrant for the purchase of 30,000 shares of c



### Notes to Consolidated Financial Statements

#### Note 9 – Commitments and Contingencies – Continued

### Consulting Agreements - Continued

On July 10, 2018, as further amended on August 22, 2018 and October 25, 2018, the Company entered into a consulting agreement with a consultant for services through March 31, 2019. In consideration of the consulting services, the Company issued the consultant convertible notes in the aggregate principal amount of \$260,000 which will be earned and recognized ratably over their respective consulting agreement term. During the year ended December 31, 2018, the Company recorded an aggregate \$260,000 of marketing and promotion expense for services rendered with a corresponding credit to notes payable. The notes mature at dates between January 2019 and April 2019 and bear interest at the rate of 10% per annum, payable at maturity. Pursuant to the notes, the holder has the right, from time to time following the respective issue date, at its election, to convert all or part of the outstanding and earned principal and accrued interest into shares of common stock of the Company, at a price generally equal to the lesser of (i) \$1.27 or \$1.75 per share, depending on the note, and (ii) 65% of the fair market value of the Company's common stock, as defined. The Company may prepay the notes prior to the maturity date provided the principal is prepaid in full, plus interest, plus a prepayment premium of 25% on the principal.

In July 2018, the Company and a consultant agreed to further extend a previously expired consulting agreement from May 2018 to December 2018. In consideration of the extension of the term of the consulting agreement, the Company issued to the consultant an immediately vested five-year warrant for the purchase of 35,000 shares of common stock of the Company at an exercise price of \$4.00 per share. The aggregate grant date value of the warrant of \$43,106 was recognized immediately as stock-based compensation expense which is reflected as consulting expense in the consolidated financial statements.

See Note 10 – Stockholders' Deficiency – Warrant and Option Valuation and Note 10 – Stockholders' Deficiency – Stock Warrants regarding details for the valuation of warrants and the Black-Scholes valuation assumptions.

# Scientific Advisory Services

In July 2018 and December 2018, the Company entered into agreements with certain consultants to serve as members of its Scientific Advisory Board and provide advice and guidance in connection with scientific matters relating to the Company's business. The agreements will continue until terminated by either the Company or the respective party for any reason upon ten days written notice. In connection with the agreements, the Company issued the advisors five-year and ten-year options to purchase up to an aggregate 100,000 shares of the Company's common stock at exercise prices ranging between \$1.25 to \$1.70 per share. The options vest as follows: (i) an aggregate 50,000 options vested immediately and (ii) an aggregate 50,000 options vest on the one-year anniversary of the grant date. The options had an aggregate grant date value of \$92,100 which is being amortized over the vesting term of the respective options. The options were subject to the Company's sequencing policy and, as a result, were recorded as derivative liabilities. In addition, on each one-year anniversary of the respective agreement date (as long as the consultant remains engaged), options to purchase an additional 5,000 shares are to be granted to the respective consultant which shall be exercisable for a period of five years from the respective dates of grant at exercise prices equal to the fair market value of the Company's common stock.

In October 2018, the Company entered into an agreement with a consultant to serve as Chairman of the Disc Advisory Committee of its Scientific Advisory Board (the "Disc Committee Chairman") and provide advice and guidance in connection with scientific matters relating to the Company's business. The agreement will continue until terminated by either party for any reason upon thirty days written notice. In connection with the agreement, the Company issued the Disc Committee Chairman a ten-year option to purchase up to 75,000 shares of the Company's common stock at an exercise price of \$1.80 per share. The option vests as follows: (i) 25,000 options vested immediately and (ii) 50,000 options vest upon the achievement of certain performance conditions. The option had a grant date value of \$129,800 which is being recognized over the respective expected vesting period. The option was subject to the Company's sequencing policy and, as a result, was recorded as a derivative liability.

See Note 10 - Stockholders' Deficiency - Options and Note 11 - Derivative Liabilities for additional details.

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## Notes to Consolidated Financial Statements

#### Note 9 - Commitments and Contingencies - Continued

#### Litigations, Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business, and as of December 31, 2018, none are expected to materially impact the Company's financial position.

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

### Employment Agreements

# Chief Executive Officer

The Company and its Chief Executive Officer ("CEO") are parties to an employment agreement that expires on December 31, 2019. Pursuant to the employment agreement, as amended, in the event that (a) the CEO's employment is terminated by the Company without cause, or (b) the CEO terminates his employment for "good reason" (each as defined in the employment agreement), or (c) the term of the CEO's employment agreement is not extended beyond December 31, 2019 and within three months of such expiration date, his employment is terminated by the Company without "cause" or the CEO terminates his employment for any reason, the CEO would 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 CEO's employment agreement), the 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 \$100,000 (in lieu of bonus). Further, in the event that the CEO's employment agreement), the 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 CEO is 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 CEO's then annual base salary per annum could be earned for such year pursuant to the satisfaction of such goals. See below Note 9 – Commitments and Contingencies – Employment Agreements – Other for details regarding the CEO's bonus accruals.

#### Former Senior VP

In January 2018, the Company entered into an employment agreement with its then Senior Vice President of Planning and Business Development (the "Former Senior VP"). In October 2018, the Former Senior VP resigned from the Company. The Former Senior VP was entitled to any accrued unpaid salary and unused vacation days that was payable to him through his termination date pursuant to his employment agreement. As of December 31, 2018, the Company paid such liability due to the Former Senior VP. Additionally, the Former Senior VP's unvested option to purchase 500,000 shares was forfeited as of the termination date. See Note 10 – Stockholders' Deficiency – Stock Options for additional details.

#### Executive Vice President

In October 2018, the Company entered into an employment agreement with its new Executive Vice President and Chief Strategy Officer (the "Executive VP"). Pursuant to the employment agreement, in the event of the termination of the Executive VP's employment by the Company without "cause" or the resignation by the Executive VP for "good reason" (each as defined in the employment agreement), the Executive VP would be entitled to receive severance in an amount equal to six months of his then annual base salary. Additionally, in connection with the employment agreement, the Executive VP was granted a ten-year option to purchase up to 500,000 shares of the Company's common stock at an exercise price of \$1.42 per share. The option vests as follows: (i) 100,000 options vested immediately, (ii) 150,000 options vest upon the earlier of (a) the achievement of a certain performance condition or (b) the first anniversary of the date of grant, and (iii) 250,000 options vest on the second anniversary of the date of grant. The option had a grant date value of \$677,200 which is being recognized over the respective expected vesting period.

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## Notes to Consolidated Financial Statements

#### Note 9 - Commitments and Contingencies - Continued

### Employment Agreements - Continued

Other

In February 2017 and March 2017, the Company's Compensation Committee and Board of Directors, respectively, approved the following associated with performance-based cash bonuses for certain of the Company's officers and current employees: (i) new performance-based cash bonuses payable for the year ending December 31, 2017 such that an aggregate of up to \$402,500 could be earned for such year pursuant to the satisfaction of such goals; and (ii) the amendment of the performance-based cash bonuses for the year ended December 31, 2016 such that an aggregate of up to \$322,000 could be earned for such year pursuant to the satisfaction of such year pursuant to the satisfaction of such year pursuant to the amendment of the performance-based cash bonuses, the Company's officers and certain employees' achievement date of 2016 milestones was extended from January 31, 2017 to July 31, 2017. As of December 31, 2018 and 2017, the Company accrued approximately \$35,000 and \$87,000, respectively, for 2016 bonus milestones which were achieved and \$0 for 2017 bonus milestones since such milestones were deemed not probable to be achieved.

In May 2018, the Company's Compensation Committee and Board of Directors, respectively, approved new performance-based cash bonuses payable for the year ending December 31, 2018 for certain of the Company's officers and employees, such that, an aggregate of up to \$400,938 could be earned for 2018 pursuant to the satisfaction of such goals. As of December 31, 2018, the Company accrued approximately \$56,000 for 2018 bonus milestones which were achieved but remain unpaid.

As of December 31, 2018, three employees other than the CEO have "at-will" employment agreements with the Company that provide for aggregate cash severance payments of \$368,750, payable over twelve months, upon involuntary termination. As of December 31, 2017, two employees other than the CEO have "at-will" employment agreements with the Company that provide for aggregate cash severance payments of \$175,000, payable over twelve months, upon involuntary termination.

#### Note 10 - Stockholders' Deficiency

### Authorized Capital

As of December 31, 2018, the Company was authorized to issue 75,000,000 shares of common stock, \$0.001 par value, and 20,000,000 shares of preferred stock, \$0.01 par value. The holders of the Company's common stock are entitled to one vote per share. Subject to the rights of holders of preferred stock, if any, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors out of legally available funds. Subject to the rights of holders of preferred stock, if any, upon liquidation, dissolution or winding up of the Company, holders of common stock are entitled to share ratably in all assets of the Company that are legally available for distribution. No preferred stock has been issued through December 31, 2018.

### 2010 Equity Participation Plan

During the year ended December 31, 2018, the Compensation Committee and the Company's stockholders, respectively, approved an increase in the number of shares authorized to be issued pursuant to the Company's 2010 Equity Participation Plan from 4,250,000 to 10,000,000. As of December 31, 2018, 5,204,132 shares were reserved for future grant under the Company's 2010 Equity Participation Plan.

## Notes to Consolidated Financial Statements

### Note 10 - Stockholders' Deficiency - Continued

#### Warrant and Option Valuation

The Company has computed the fair value of warrants and options granted using the Black-Scholes option pricing model. Option forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate will be adjusted periodically based on the extent to which actual option forfeitures differ, or are expected to differ, from the previous estimate, when it is material. The Company estimated forfeitures related to option grants at an annual rate ranging from 0% to 5% for options granted during the years ended December 31, 2018 and 2017. 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, 2017, the Company issued an aggregate of 361,335 shares of common stock of the Company and five-year immediately vested warrants to purchase an aggregate of 371,335 shares of common stock of the Company at an exercise price of \$4.00 per share to investors for aggregate gross proceeds of \$1,084,000. The warrants had an aggregate grant date fair value of \$601,595.

During the year ended December 31, 2018, the Company issued an aggregate of 70,000 shares of common stock of the Company and five-year immediately vested warrants to purchase an aggregate of 70,000 shares of common stock of the Company at an exercise price of \$3.50 per share to investors for aggregate gross proceeds of \$175,000. The warrants had an aggregate grant date fair value of \$87,300.

#### Compensatory Common Stock Issuances

See Note 6 – Accrued Expenses and Other Current Liabilities for details regarding exchanges of accrued expenses for shares of common stock and warrants to a consultant and certain directors of the Company. See Note 9 – Commitments and Contingencies for details regarding an exchange of accrued consulting fees for shares of common stock and warrants.

During the year ended December 31, 2017, the Company issued 10,000 shares of immediately vested common stock valued at \$20,000 to a consultant for services rendered during the year.

During the year ended December 31, 2018, the Company issued 35,000 shares of immediately vested common stock valued at \$52,500 to a consultant for services rendered during the year.

### Stock Warrants

### Warrant Compensation

During the year ended December 31, 2017, the Company extended a previously expired agreement with a consultant from January 1, 2017 to December 31, 2017. In connection with this extension, the Company issued to the consultant an immediately vested five-year warrant to purchase 25,000 shares of common stock at an exercise price of \$4.00 per share. The issuance date fair value of \$40,763 was immediately recognized as stock-based compensation expense which is reflected in consulting expense in the consolidated statements of operations.

During the year ended December 31, 2017, the Company extended a previously expired agreement with a consultant from January 1, 2017 to June 30, 2017. In connection with this extension, the Company issued a five-year immediately vested warrant to purchase 20,000 shares of common stock at an exercise price of \$4.50 per share. The warrant grant date fair value of \$30,440 was recognized immediately as stock-based compensation expense which is reflected as consulting expense in the consolidated statements of operations.



### Notes to Consolidated Financial Statements

### Note 10 - Stockholders' Deficiency - Continued

### Stock Warrants - Continued

### Warrant Compensation - Continued

During the year ended December 31, 2017, the Company issued an immediately vested five-year warrant to purchase 25,000 shares of common stock at an exercise price of \$4.00 per share to a consultant for services rendered. The warrant grant date fair value of \$40,275 was recognized immediately as stock-based compensation expense and is reflected as consulting expense in the consolidated statements of operations.

During the year ended December 31, 2017, the Company extended a previously expired agreement with a consultant from October 1, 2017 to May 31, 2018. In connection with this extension, the Company issued a five-year immediately vested warrant to purchase 35,000 shares of common stock at an exercise price of \$4.00 per share. The warrant grant date fair value of \$56,434 was recognized immediately as stock-based compensation expense which is reflected as consulting expense in the consolidated statements of operations.

During the year ended December 31, 2018, the Company issued an immediately vested five-year warrant to purchase 75,000 shares of common stock of the Company at an exercise price of \$2.00 per share to a consultant for services rendered. The warrant grant date fair value of \$46,658 was recognized immediately as stock-based compensation expense and is reflected as consulting expense in the consolidated statements of operations with a corresponding credit to derivative liabilities as a result of the warrant being subject to the Company's sequencing policy. See Note 11 – Derivative Liabilities for additional details.

See Note 9 - Commitments and Contingencies for additional details associated with the issuance of common stock and warrants in connection with consulting agreement extensions.

The Company recorded stock-based compensation expense of \$137,956 and \$167,912 during the years ended December 31, 2018 and 2017, respectively, related to stock warrants issued as compensation, which is reflected as consulting expense in the consolidated statements of operations. As of December 31, 2018, there was no unrecognized stock-based compensation expense related to stock warrants.

## Warrant Modifications and Exercises

During the year ended December 31, 2017, the Company issued an aggregate of 410,625 shares of common stock pursuant to the exercise of warrants for aggregate gross proceeds of \$821,250. The shares were issued pursuant to a warrant repricing program under which the exercise price for certain outstanding and exercisable warrants for the purchase of shares of common stock of the Company was reduced to \$2.00 per share (reduced from exercises prices ranging from \$4.00 to \$30.00 per share). In connection with the share issuances, the Company issued to the purchasers of such shares additional two-year warrants for the purchase of an aggregate of 102,656 shares of common stock of the Company recognized a warrant modification charge of \$6,618 during the year ended December 31, 2017, which represents the incremental value of the modified warrants and additional warrants issued as compared to the original warrants, both valued as of the respective modification dates.

During the year ended December 31, 2017, with respect to a warrant held by an investor, the Company agreed that (i) the conditions to the exercisability of the warrant for tranches to purchase an aggregate of 35,000 shares were eliminated, such that the entire warrant to purchase 50,000 shares of common stock was exercisable, and (ii) the exercise price of the warrant was reduced from an exercise price of \$30.00 per share to \$3.50 per share. Concurrent with the modification of the warrant, the investor exercised the warrant in full for aggregate gross proceeds to the Company of \$175,000. The Company recognized a warrant modification charge of \$4,500 during the year ended December 31, 2017, which represents the incremental value of the modified warrant as compared to the original warrant, both valued as of the respective modification dates which is reflected in warrant modification expense in the consolidated statement of operations.

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### Notes to Consolidated Financial Statements

### Note 10 - Stockholders' Deficiency - Continued

#### Stock Warrants - Continued

#### Warrant Modifications and Exercises - Continued

During the year ended December 31, 2017, with respect to warrants held by certain lenders, the Company agreed to extend the expiration dates of certain warrants to purchase an aggregate of 53,291 shares of the Company's common stock and reduce the exercise price of certain warrants to purchase an aggregate of 1,233,931 shares of the Company's common stock. The expiration dates of the warrants were extended from dates ranging between December 31, 2017 through December 29, 2021 to new expiration dates ranging between December 31, 2019 and June 28, 2022. The exercise price of certain warrants was reduced from an exercise price ranging between \$4.50 and \$10.00 per share to \$4.00 per share. The Company recognized a warrant modification charge of \$18,962 during the year ended December 31, 2017, which represents the incremental value of the modified warrants as compared to the original warrants, both valued as of the respective modification dates. The charge is reflected in warrant modification expense in the consolidated statements of operations. Of the warrants with the reduced exercise prices to purchase an aggregate 1,233,931 shares of the Company's common stock, were reduced as consideration of extending the maturity dates of certain related party notes payable and are reflected as debt discount, net of notes payable in the consolidated balance sheet. See Note 7 - Notes Payable - Related Party Notes for details.

During the year ended December 31, 2018, the Company issued an aggregate of 207,084 shares of common stock pursuant to the exercise of warrants for aggregate gross proceeds of \$414,168. The shares were issued pursuant to a warrant repricing program under which the exercise price for certain outstanding and exercisable warrants for the purchase of shares of common stock of the Company was reduced to \$2.00 per share (reduced from exercises prices ranging from \$4.00 to \$5.00 per share). In connection with the share issuances, the Company issued to the purchasers of such shares additional two-year warrants for the purchase of an aggregate of 51,771 shares of common stock of the Company did not recognize a warrant modification charge as there was no incremental value of the modified warrants and additional warrants issued as compared to the original warrants, both valued as of the respective modification dates.

During the year ended December 31, 2018, the Company reduced the exercise price and extended the expiration date of a certain warrant held by an investor for the purchase of 10,000 shares of common stock of the Company. The exercise price of the warrant was reduced from \$5.00 per share to \$4.00 per share and the expiration date of the warrant was extended from May 2021 to May 2023. The Company recognized a warrant modification charge of \$3,100, which represents the incremental value of the modified warrants as compared to the original warrants, both valued as of the respective modification dates which is reflected in warrant modification expense in the consolidated statements of operations.

During the year ended December 31, 2018, with respect to warrants held by a certain related party, the Company agreed to extend the expiration dates and reduce the exercise price of certain warrants to purchase an aggregate 844,444 shares of the Company's common stock as consideration of extending the maturity dates of certain notes payable. The expiration dates of the warrants were extended from December 2018 to December 2019. The exercise prices of the warrants were reduced from \$4.00 per share to \$1.50 per share. The Company recognized a warrant modification charge of \$244,889 during the year ended December 31, 2018, which represents the incremental value of the modified warrants as compared to the original warrants, both valued as of the respective modification dates. The incremental modification expense has been recorded as debt discount and is being amortized over the remaining extended term of the respective note. See Note 7 – Notes Payable – Related Party Notes for details.

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# Notes to Consolidated Financial Statements

# Note 10 - Stockholders' Deficiency - Continued

Stock Warrants - Continued

## Warrant Activity Summary

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

	For the Years En December 31	
	2018	2017
Risk free interest rate	1.92% - 2.91%	1.74% - 2.07%
Contractual term (years)	1.98 - 5.00	2.00 - 5.00
Expected volatility	128% - 141%	120% - 132%
Expected dividends	0.00%	0.00%

The weighted average estimated fair value of the warrants granted during the years ended December 31, 2018 and 2017 was approximately \$1.06 and \$1.54 per share, respectively.

See Note 6 – Accrued Expenses and Other Current Liabilities for details regarding exchanges of accrued expenses for shares of common stock and warrants to a consultant and certain directors of the Company. See Note 7 – Notes Payable for details associated with the issuance of warrants in connection with note issuances and the exchange of notes payable. See Note 9 – Commitments and Contingencies – Consulting Agreements for details associated with the issuance of warrants as compensation. See Note 10 – Stockholders' Deficiency – Common Stock and Warrant Offerings for details associated with the issuance of warrants in connection with common stock and warrant offerings.

A summary of the warrant activity during the year ended December 31, 2018 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years		Aggregate Intrinsic Value
Outstanding, December 31, 2017	3,435,134	\$ 4.47		-	
Issued	266,521	3.31			
Exercised	(207,084)	2.00			
Expired	(11,168)	42.72			
Outstanding, December 31, 2018	3,483,403	\$ 3.63	2.1	\$	-
Exercisable, December 31, 2018	3,483,403	\$ 3.63	2.1	\$	-
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# Notes to Consolidated Financial Statements

### Note 10 - Stockholders' Deficiency - Continued

Stock Warrants - Continued

# Warrant Activity Summary - Continued

The following table presents information related to stock warrants at December 31, 2018:

Warrants Outstanding		Warrants Ex	ercisable
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
\$1.50 - \$1.99	844,444	1.0	844,444
\$2.00 - \$2.99	75,000	4.8	75,000
\$3.00 - \$3.99	70,000	4.5	70,000
\$4.00 - \$4.99	2,179,635	2.4	2,179,635
\$5.00 - \$5.99	195,989	2.5	195,989
\$6.00 - \$7.99	40,000	1.6	40,000
\$8.00 - \$9.99	2,500	0.9	2,500
\$10.00 - \$14.99	40,400	1.2	40,400
\$15.00 - \$19.99	35,435	0.7	35,435
	3,483,403	2.1	3,483,403

# Stock Options

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

	For the Years En December 31,	
	2018	2017
Risk free interest rate	2.44% - 3.15%	1.77% - 1.88%
Expected term (years)	5.00 - 10.00	5.50 - 6.00
Expected volatility	129% - 141%	120% - 130%
Expected dividends	0.00%	0.00%

The weighted average estimated fair value of the stock options granted during the years ended December 31, 2018 and 2017 was approximately \$1.60 and \$2.75 per share, respectively.

On February 14, 2017, the Compensation Committee reduced the exercise price of outstanding options for the purchase of an aggregate of 1,219,450 shares of common stock of the Company (with exercise prices ranging between \$5.70 and \$30.00 per share) to \$4.70 per share, which was the closing price for the Company's common stock on February 13, 2017, as reported by the OTCQB. The exercise price reduction related to options held by, among others, the Company's executive officers and directors. The incremental value of the modified options compared to the original options, both valued as of the respective modification date, of \$430,394 is being recognized over the vesting term of the options.

During the year ended December 31, 2017, the Company issued ten-year options to employees, directors, and an advisor of the Company to purchase an aggregate of 1,117,000 shares of common stock at exercise prices ranging between \$2.80 to \$3.35 per share. The options vest as follows: (i) options for the purchase of 283,336 shares vested immediately, (ii) options for the purchase of 372,338 shares vested on the one-year anniversary of the issuance date, (iii) options for the purchase of 372,332 shares vest on the two-year anniversary of the issuance date and (iv) options for the purchase of 88,994 shares vest on the three-year anniversary of the issuance date. The options had an aggregate grant date value of \$3,070,600 which is being amortized over the vesting term of the respective options.

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# Notes to Consolidated Financial Statements

### Note 10 - Stockholders' Deficiency - Continued

#### Stock Options - Continued

In January 2018, the Company granted a ten-year option to a consultant of the Company to purchase 10,000 shares of the Company's common stock at an exercise price of \$3.20 per share. The option vested ratably over three years on the issuance date anniversaries. The option had an aggregate grant date value of \$33,700. During the year ended December 31, 2018, the option was forfeited in connection with the consultant's termination and accordingly, no expense related to the option was recognized.

In January 2018, the Company granted the Former Senior VP a ten-year option to purchase 500,000 shares of the Company's common stock at an exercise price of \$3.40 per share. The option grant provided for vesting based upon the achievement of a certain performance condition. The grant date value of the option was \$1,491,300, which was recognizable to the extent such milestone was deemed probable to occur. See Note 9 – Commitments and Contingencies for additional details regarding the Former Senior VP's resignation and termination of the option.

In October 2018, the Company issued ten-year options to employees and directors of the Company to purchase an aggregate of 885,000 shares of common stock at an exercise price of \$1.23 per share. The options vest as follows: (i) options for the purchase of 216,667 shares vested immediately, (ii) options for the purchase of 295,002 shares vest on the one-year anniversary of the issuance date, (iii) options for the purchase of 295,000 shares vest on the two-year anniversary of the issuance date and (iv) options for the purchase of 78,331 shares vest on the three-year anniversary of the issuance date. The options had an aggregate grant date value of \$943,100 which is being amortized over the vesting term of the respective options.

In October 2018 and December 2018, the Company entered into agreements with certain members of its Scientific Advisory Board to provide advice and guidance in connection with scientific matters relating to the Company's business. In connection with the agreements, the Company issued the advisors ten-year options to purchase up to an aggregate 110,000 shares of the Company's common stock at an exercise price of 1.23 per share. The options vest ratably over three years on the issuance date anniversaries. The options had an aggregate grant date value of 125,800. The Company recognizes the fair value of the options as consulting expenses over the respective vesting terms of the options. The options were subject to the Company's sequencing policy and, as a result, were recorded as derivative liabilities. The Company See Note 11 - Derivative Liabilities for additional details.

See Note 9 - Commitments and Contingencies for details regarding the issuance of options to certain Scientific Advisory Board members and the Executive VP.

A summary of the option activity during the year ended December 31, 2018 is presented below:

	Number of Options	Veighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, December 31, 2017	3,122,202	\$ 4.25		
Granted	2,180,000	1.81		
Forfeited	(598,417)	3.50		
Outstanding, December 31, 2018	4,703,785	\$ 3.21	8.0	<u> </u>
Exercisable, December 31, 2018	2,952,460	\$ 4.03	7.1	<u>\$</u>
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# Notes to Consolidated Financial Statements

# Note 10 - Stockholders' Deficiency - Continued

# Stock Options - Continued

# The following table presents information related to stock options at December 31, 2018:

Options Outstanding		<b>Options Exe</b>	ercisable
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
\$1.00 - \$1.99	1,670,000	9.6	391,667
\$2.00 - \$2.99	187,834	8.2	64,503
\$3.00 - \$3.99	1,615,334	7.9	1,268,673
\$4.00 - \$4.99	1,153,117	5.5	1,150,117
\$5.00 - \$5.99	5,000	5.5	5,000
\$6.00 - \$19.99	37,500	5.0	37,500
\$20.00 - \$30.00	35,000	3.2	35,000
	4,703,785	7.1	2,952,460

The following table presents information related to stock option expense:

	For the Ye Decem	ears En Iber 31,		recognized at ecember 31,	Weighted Average Remaining Amortization Period
	 2018		2017	2018	(Years)
Consulting	\$ 965,916	\$	1,558,392	\$ 502,144	0.6
Research and development	340,471		481,041	551,073	1.5
General and administrative	902,542		1,373,459	963,729	1.0
	\$ 2,208,929	\$	3,412,892	\$ 2,016,946	1.0
			F-60		

# Notes to Consolidated Financial Statements

## Note 11 - 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, 2017	\$ -
Issuance of derivative liabilities	332,131
Reclassification of derivative liabilities to equity	(9,019)
Change in fair value of derivative liabilities	(107,039)
Ending balance as of December 31, 2017	\$ 216,073
Issuance of derivative liabilities	3,875,231
Extinguishment of derivative liabilities in connection with convertible note repayments	
and exchanges	(3,120,833)
Change in fair value of derivative liabilities	229,323
Reclassification of derivative liabilities to equity	(105,187)
Ending balance as of December 31, 2018	\$ 1,094,607

In applying the Multinomial Lattice and Black-Scholes option pricing models to derivatives issued and outstanding during the years ended December 31, 2018 and 2017, the Company used the following assumptions:

		For the Years Ended December 31,		
	2018	2017		
Risk free interest rate	1.22% - 2.94%	1.22% - 2.07%		
Expected term (years)	0.01 - 5.00	0.00 - 5.00		
Expected volatility	100% - 208%	123% - 130%		
Expected dividends	0.00%	0.00%		

During the year ended December 31, 2018, the Company recorded new derivative liabilities in the aggregate amounts of 3,631,705, 121,657 and 121,869 related to the ECOs of certain convertible notes payable, warrants and stock options subject to sequencing, respectively. During the year ended December 31, 2017, the Company recorded new derivative liabilities in the aggregate amounts of 252,117 and 80,014 related to the ECOs of certain convertible notes payable and warrants, respectively. See Note 7 - Notes Payable – Convertible Notes and Other Notes for additional details. See Note 9 - Commitments and Contingencies for a stock option issued and deemed to be a derivative liability. See Note 10 - Stockholders' Deficiency for warrants issued and deemed to be derivative liabilities.

During the year ended December 31, 2018, the Company extinguished an aggregate of 3,120,833 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 - N or Payable – Convertible Notes and Other Notes for additional details.

During the year ended December 31, 2017, the Company reclassified \$9,019 of derivative liabilities to equity in connection with the conversion of convertible notes payable into shares of common stock.

During the year ended December 31, 2018, the Company reclassified an aggregate of \$105,187 of derivative liabilities to equity as a result of a change in the sequencing status.

On December 31, 2018, the Company recorded the fair value of ECOs recorded as derivative liabilities to be \$852,454. The Company recorded a loss on the change in fair value of these derivative liabilities of \$310,710 for the year ended December 31, 2018.

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## Notes to Consolidated Financial Statements

# Note 11 - Derivative Liabilities - Continued

On December 31, 2018, the Company recomputed the fair value of the derivative liabilities related to outstanding warrants to be \$120,284. 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 \$81,387 for the year ended December 31, 2018.

On December 31, 2018, the Company recomputed the fair value of the derivative liabilities related to outstanding consultant stock options to be \$121,869. The stock options were issued subsequent to the commencement of sequencing and the fair value of the options are being recorded in consulting expenses in the consolidated statements of operations over the respective expected vesting period with a corresponding credit to derivative liabilities. See Note 10 - Stockholders' Deficiency -Stock Options for additional details.

# Note 12 – Subsequent Events

## Stock Options

Subsequent to December 31, 2018, the Company issued a ten-year option to a certain Scientific Advisory Board member of the Company to purchase 70,000 shares of common stock of the Company at an exercise price of \$1.00 per share. The option vests as follows: (i) an option for the purchase of 23,334 shares vested immediately, (ii) an option for the purchase of 23,333 shares will vest on the one-year anniversary of the issuance date, and (iii) an option for the purchase of 23,333 shares will vest on the two-year anniversary of the issuance date. The fair value of the option will be recognized over the vesting period.

Subsequent to December 31, 2018, 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 directors, advisors and employees. The incremental value of the modified options compared to the original options, both valued as of the respective modification date, will be recognized over the vesting term of the options.

# Consulting Agreement

Subsequent to December 31, 2018, the Company and a consultant agreed to further extend a previously expired consulting agreement from January 2019 to December 2019. In connection with the extension, the Company issued to the consultant a five-year, immediately vested warrant for the purchase of 100,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

### Settlement Agreement

Subsequent to December 31, 2018, the Company entered into a settlement agreement with a certain consultant, pursuant to which \$46,500 of previously recorded consulting fees were exchanged for 10,000 shares of the Company's common stock and a \$10,000 cash payment.

# Common Stock and Warrant Offering

Subsequent to December 31, 2018, the Company issued 1,000,000 shares of common stock of the Company, a five-year immediately vested warrant to purchase 500,000 shares of common stock of the Company at an exercise price of \$0.85 per share and a one-year immediately vested warrant to purchase 500,000 shares of common stock of the Company at an exercise price of \$0.70 per share to an investor for gross proceeds of \$600,000.



## Notes to Consolidated Financial Statements

#### Note 12 - Subsequent Events - Continued

### Notes Payable

Subsequent to December 31, 2018, the Company issued a convertible promissory note in the principal amount of \$450,000 to certain related parties. The convertible note bears interest at the rate of 15% per annum, payable at maturity, with an original maturity date in August 2019. The note is convertible, at the option of the lenders, 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 amount of the note. The warrant provides for an exercise price of \$0.80 per share, subject to adjustment.

Subsequent to December 31, 2018, the Company issued convertible promissory notes in the aggregate principal amount of \$575,000 to certain lenders for aggregate cash proceeds of \$575,000. The convertible notes bear interest at the rate of 15% per annum, payable at maturity, with original maturity dates in July 2019. Each note is convertible, at the option of the lender, 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 amount of the respective note. The warrant provides for an exercise price of \$0.80 per share, subject to adjustment.

Subsequent to December 31, 2018, the Company issued convertible promissory notes in the aggregate principal amount of \$2,205,000 for aggregate cash proceeds of \$2,048,918. The convertible notes bear interest at rates ranging from 8% to 12% per annum, payable at maturity, with original maturity dates ranging between July 2019 to March 2020. The convertible notes are convertible as follows: (i) \$805,000 of aggregate principal and the respective accrued interest is convertible into shares of the Company's common stock at the election of the holder after the 180th day following the issue date at a conversion price generally equal to 58% of the fair value of the Company's common stock, (ii) \$170,000 of aggregate principal and the respective accrued interest is convertible into shares of the Company's common stock, (ii) \$170,000 of aggregate principal and the respective accrued interest is convertible into shares of the Company's common stock at the election of the holder at any time immediately on or after the issue date until the 180<sup>th</sup> day following issuance at a conversion price equal to 58% of the fair value of the Company's common stock, and (iii) \$1,230,000 of aggregate principal and the respective accrued interest is convertible into shares of the Company's common stock at the election of the holder for the first six months at a fixed conversion price ranging from \$1.00 to \$2.00 per share, and thereafter, at a conversion price generally equal to 58% of the fair value of the Company's common stock. In connection with the issuance of a certain convertible promissory note, the Company issued to the lender a five-year, immediately vested warrant for the purchase of 40,000 shares of the Company's common stock at an exercise price of \$1.00 per share. The grant date fair value of the warrant will be recorded as a debt discount and will be amortized over the term of the note. In the event that the Company elects to prepay any of the respective notes during the first ninety-day period following the issue date, the ho

Subsequent to December 31, 2018, a certain lender to the Company acquired another promissory note issued by the Company in the outstanding amount of \$148,014 (inclusive of accreted interest of \$23,014) from a different lender to the Company. The Company exchanged the acquired note for a new convertible note in the principal amount of \$148,014 which accrues interest at a rate of 12% per annum, payable on the maturity date in March 2020.

Subsequent to December 31, 2018, the Company and a certain related party agreed to extend the maturity date of a certain promissory note with a principal balance of \$30,000 that was past maturity from December 2018 to December 2019.

Subsequent to December 31, 2018, the Company and a certain lender agreed to extend the maturity date of a certain promissory note with a principal balance of \$125,000 that was past maturity from January 2019 to December 2019. In connection with 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 will be recorded as debt discount and will be amortized over the term of the note.

Subsequent to December 31, 2018, the Company and certain lenders agreed to exchange an aggregate principal amount of \$619,391 and aggregate accrued interest of \$24,509 of certain convertible notes payable for an aggregate of 1,928,400 shares of the Company's common stock at exchange prices ranging from \$0.28 to \$0.42 per share.

Subsequent to December 31, 2018, the Company repaid an aggregate principal amount of \$1,065,000 of notes payable, \$55,169 of the respective aggregate accrued interest and an aggregate of \$134,636 of prepayment premiums.



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.



41,379,310 UNITS EACH UNIT CONSISTING OF ONE SHARE OF COMMON STOCK AND ONE WARRANT TO PURCHASE ONE SHARE OF COMMON STOCK

# PROSPECTUS

Sole Book-Running Manager

**Maxim Group LLC** 

Co-Manager

Joseph Gunnar & Co., LLC

### 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.

	 Amount	
SEC Registration Fee	\$ 3,868	
FINRA Filing Fee	5,287	
NASDAQ Capital Market Listing Fee	50,000	
Legal Fees and Expenses	315,000	
Accounting Fees and Expenses	75,000	
Printing and Engraving Expenses	10,000	
Transfer Agent and Registrar Fees and Expenses	5,000	
Miscellaneous	35,845	
Total	\$ 500,000	

### 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 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, 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 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, 2016, 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 or advertising 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 is 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 of not less than 1-for-2 and not more than 1-for-20 to occur immediately following the effectiveness of this registration statement.

			v	Warrants					eighted verage
Date Issued	Common Stock	Shares	I	Exercise Price	Term (Years)	Purchaser(s)	Co	nsideration (1)	 ice Per Share
01/04/2016 - 01/19/2018	728,540	154,427	\$	4.00	2.0	(2)	\$	1,623,316(3)	\$ 2.23(4)
01/20/2016 - 06/04/2019	180,609	-	\$	-	-	(5)	\$	230,135(6)	\$ 1.27(7)
01/25/2016 - 05/07/2019	3,579,279	4,433,623	\$	2.68(8)	3.3(9)	(2)	\$	5,913,338	\$ 1.65(10)
01/26/2016 - 09/20/2018	489,360	-	\$	-	-	(2)	\$	994,155(11)	\$ 2.03(12)
03/07/2016 - 09/04/2019	13,942,007	95,802	\$	4.00	5.0	(2)	\$	6,821,864	\$ 0.49(13)
05/11/2016 - 02/21/2019	62,300	-	\$	-	-	(2)	\$	103,100(14)	\$ 1.65(15)
03/01/2017 - 02/25/2019	250,252	163,418	\$	4.00	5.0	(5)	\$	607,197(16)	\$ 2.43(17)
04/26/2017 - 04/08/2019	162,775	-	\$	-	-	(2)	\$	189,480(18)	\$ 1.16(19)

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

(3) Issued pursuant to the exercise of warrants.

(4) Shares of common stock were issued at the following prices per share: (i) 617,709 shares of common stock were issued at a price of \$2.00 per share and (ii) 110,831 shares of common stock were issued at a price of \$3.50 per share.

(5) Consultant.

- (6) Issued in consideration of consulting services.
- (7) Shares of common stock were issued at the following prices per share: (i) 75,000 shares of common stock were issued at a price of \$0.40 per share, (ii) 35,000 shares of common stock were issued at a price of \$2.00 per share, (iv) 12,455 shares of common stock were issued at a price of \$2.02 per share, (v) 15,000 shares of common stock were issued at a price of \$2.25 per share, (vi) 753 shares of common stock were issued at a price of \$3.10 per share, and (vii) 901 shares of common stock were issued at a price of \$3.70 per share.
- (8) The warrants are exercisable as follows: (i) warrants to purchase an aggregate 1,055,555 shares of common stock have an exercise price of \$0.70 per share, (ii) warrants to purchase an aggregate 1,055,556 shares of common stock have an exercise price of \$0.85 per share, (iii) warrants to purchase an aggregate 80,000 shares of common stock have an exercise price of \$1.00 per share, (iv) warrants to purchase an aggregate 70,000 shares of common stock have an exercise price of \$3.50 per share, (v) warrants to purchase an aggregate 697,325 shares of common stock have an exercise price of \$4.00 per share, (vi) warrants to purchase an aggregate 444,444 shares of common stock have an exercise price of \$4.50 per share, and (vii) warrants to purchase an aggregate 1,030,743 shares of common stock have an exercise price of \$5.00 per share.
- (9) Warrants to purchase an aggregate 1,344,444 and 1,978,068 shares of common stock have terms of 1 and 5 years, respectively.
- (10) Shares of common stock were issued at the following prices per share: (i) 1,111,111 shares of common stock were issued at a price of \$0.45 per share, (ii) 1,000,000 shares of common stock were issued at a price of \$0.70 per share, (iv) 70,000 shares of common stock were issued at a price of \$2.50 per share, (v) 11,000 shares of common stock were issued at a price of \$2.73 per share, (vi) 676,325 shares of common stock were issued at a price of \$3.00 per share, and (vii) 630,843 shares of common stock were issued at a price of \$4.00 per share.
- (11) Issued in connection with the conversion of convertible notes payable.
- (12) Shares of common stock were issued at the following prices: (i) 70,406 shares of common stock were issued at a price of \$0.82 per share, (ii) 11,439 shares of common stock were issued at a price of \$1.75 per share, (iii) 14,814 shares of common stock were issued at a price of \$1.70 per share, (vi) 14,616 shares of common stock were issued at a price of \$1.80 per share, (vi) 27,894 shares of common stock were issued at a price of \$1.90 per share, (vii) 10,461 shares of common stock were issued at a price of \$1.92 per share, (viii) 10,874 shares of common stock were issued at a price of \$1.94 per share, (xii) 10,174 shares of common stock were issued at a price of \$1.96 per share, (xi) 10,232 shares of common stock were issued at a price of \$2.01 per share, (xii) 13,071 shares of common stock were issued at a price of \$2.02 per share, (xii) 22,927 shares of common stock were issued at a price of \$2.03 per share, (xii) 13,071 shares of common stock were issued at a price of \$2.06 per share, (xii) 12,410 shares of common stock were issued at a price of \$2.12 per share, (xxii) 13,053 shares of common stock were issued at a price of \$2.26 per share, (xii) 12,546 shares of common stock were issued at a price of \$2.30 per share, (xiii) 13,053 shares of common stock were issued at a price of \$2.38 per share, (xiii) 13,053 shares of common stock were issued at a price of \$2.39 per share, (xxii) 8,288 shares of common stock were issued at a price of \$2.41 per share, (xxii) 6,279 shares of common stock were issued at a price of \$2.41 per share, (xxiii) 11,653 shares of common stock were issued at a price of \$2.53 per share, (xxiii) 13,053 shares of common stock were issued at a price of \$2.49 per share, (xxii) 11,653 shares of common stock were issued at a price of \$2.40 per share, (xxiii) 6,279 shares of common stock were issued at a price of \$2.40 per share, (xxiii) 6,279 shares of common stock were issued at a price of \$2.40 per share, (xxii) 6,279 shares of common stock were issued at a price of \$2.40 per share

(13) Shares of common stock were issued at the following prices per share: (i) 395,929 shares of common stock were issued at a price of \$0.11 per share, (ii) 1,109,512 shares of common stock were issued at a price of \$0.12 per share, (iii) 71,556 shares of common stock were issued at a price of \$0.14 per share, (iv) 297,375 shares of common stock were issued at a price of \$0.15 per share, (v) 405,764 shares of common stock were issued at a price of \$0.16 per share, (vi) 647,996 shares of common stock were issued at a price of \$0.17 per share, (vii) 27,472 shares of common stock were issued at a price of \$0.18 per share, (viii) 835,276 shares of common stock were issued at a price of \$0.19 per share, (ix) 1,392,903 shares of common stock were issued at a price of \$0.20 per share, (x) 36,000 shares of common stock were issued at a price of \$0.22 per share, (xi) 113,040 shares of common stock were issued at a price of \$0.23 per share, (xii) 649,796 shares of common stock were issued at a price of \$0.28 per share, (xiii) 108,734 shares of common stock were issued at a price of \$0.29 per share, (xiv) 74,455 shares of common stock were issued at a price of \$0.31 per share, (xv) 659,433 shares of common stock were issued at a price of \$0.32 per share, (xvi) 108,805 shares of common stock were issued at a price of \$0.33 per share, (xvii) 327,153 shares of common stock were issued at a price of \$0.34 per share, (xviii) 167,752 shares of common stock were issued at a price of \$0.35 per share, (xix) 701,111 shares of common stock were issued at a price of \$0.36 per share, (xx) 400,215 shares of common stock were issued at a price of \$0.38 per share, (xxi) 521,265 shares of common stock were issued at a price of \$0.39 per share, (xxii) 130,530 shares of common stock were issued at a price of \$0.40 per share, (xxiii) 172,724 shares of common stock were issued at a price of \$0.41 per share, (xxiv) 123,125 shares of common stock were issued at a price of \$0.42 per share, (xxv) 249,578 shares of common stock were issued at a price of \$0.43 per share, (xxvi) 72,398 shares of common stock were issued at a price of \$0.55 per share, (xxvii) 40,784 shares of common stock were issued at a price of \$0.58 per share, (xxviii) 54,815 shares of common stock were issued at a price of \$0.59 per share, (xxix) 13,000 shares of common stock were issued at a price of \$0.61 per share, (xxx) 133,826 shares of common stock were issued at a price of \$0.65 per share, (xxxi) 180,457 shares of common stock were issued at a price of \$0.71 per share, (xxxii) 769,757 shares of common stock were issued at a price of \$0.72 per share, (xxxiii) 81,000 shares of common stock were issued at a price of \$0.77 per share, (xxxi) 113,972 shares of common stock were issued at a price of \$0.78 per share, (xxxii) 92,706 shares of common stock were issued at a price of \$0.83 per share, (xxxii) 167,552 shares of common stock were issued at a price of \$0.89 per share, (xxxiv) 102,747 shares of common stock were issued at a price of \$0.90 per share, (xxxii) 80,000 shares of common stock were issued at a price of \$0.92 per share, (xxxiii) 20,921 shares of common stock were issued at a price of \$0.94 per share, (xxxiv) 100,000 shares of common stock were issued at a price of \$0.98 per share, (xxxii) 591,588 shares of common stock were issued at a price of \$1.00 per share, (xxxiii) 364,878 shares of common stock were issued at a price of \$1.01 per share, (xxxiv) 20,000 shares of common stock were issued at a price of \$1.02 per share, (xxxii) 193,639 shares of common stock were issued at a price of \$1.03 per share, (xxxiii) 46,620 shares of common stock were issued at a price of \$1.07 per share, (xxxiv) 430,655 shares of common stock were issued at a price of \$1.25 per share, (xxxii) 53,294 shares of common stock were issued at a price of \$1.31 per share, (xxxiii) 18,939 shares of common stock were issued at a price of \$1.32 per share, (xxxiv) 13,975 shares of common stock were issued at a price of \$1.43 per share, (xxxii) 25,000 shares of common stock were issued at a price of \$1.48 per share, (xxxiii) 47,051 shares of common stock were issued at a price of \$1.50 per share, (xxxiv) 45,984 shares of common stock were issued at a price of \$1.58 per share, (xxxii) 15,000 shares of common stock were issued at a price of \$1.74 per share, (xxxiii) 29,280 shares of common stock were issued at a price of \$1.80 per share, (xxxiv) 10,938 shares of common stock were issued at a price of \$1.83 per share, (xxxii) 13,512 shares of common stock were issued at a price of \$1.94 per share, (xxxiii) 13,127 shares of common stock were issued at a price of \$2.00 per share, (xxxii) 12,901 shares of common stock were issued at a price of \$2.04 per share, (xxxii) 12,912 shares of common stock were issued at a price of \$2.05 per share, (xxxiii) 78,955 shares of common stock were issued at a price of \$2.10 per share, (xxxiv) 12,468 shares of common stock were issued at a price of \$2.11 per share, (xxxii) 6,402 shares of common stock were issued at a price of \$2.34 per share, (xxxiii) 14,728 shares of common stock were issued at a price of \$2.38 per share, (xxxii) 15,925 shares of common stock were issued at a price of \$2.45 per share, (xxxii) 95,802 shares of common stock were issued at a price of \$3.00 per share, and (xxxiii) 7,000 shares of common stock were issued at a price of \$3.04 per share.

(14) Issued as debt discount in connection with loans.

- (15) Shares of common stock were issued at the following prices per share: (i) 10,000 shares of common stock were issued at a price of \$0.70 per share, (ii) 20,000 shares of common stock were issued at a price of \$1.50 per share, (iii) 26,300 shares of common stock were issued at a price of \$2.00 per share, and (iv) 6,000 shares of common stock were issued at a price of \$2.25 per share.
- (16) Issued in consideration of accrued compensation.
- (17) Shares of common stock were issued at the following prices: (i) 56,250 shares of common stock were issued at a price of \$0.80 per share, (ii) 19,000 shares of common stock were issued at a price of \$2.00 per share, (iii) 8,334 shares of common stock were issued at a price of \$2.12 per share, (iv) 156,668 shares of common stock were issued at a price of \$3.00 per share, and (v)10,000 shares of common stock were issued at a price of \$3.65 per share.
- (18) Issued as debt discount in connection with loans.
- (19) The common stock and warrants were issued as follows: (i) 7,000 shares of common stock were issued at a price of \$0.71 per share, (ii) 16,666 shares of common stock were issued at a price of \$0.73 per share, (iii) 12,50 shares of common stock were issued at a price of \$0.74 per share, (iv) 68,873 shares of common stock were issued at a price of \$0.75 per share, (iv) 5,000 shares of common stock were issued at a price of \$0.75 per share, (vi) 5,000 shares of common stock were issued at a price of \$0.75 per share, (vi) 750 shares of common stock were issued at a price of \$1.45 per share, (vii) 2,500 shares of common stock were issued at a price of \$1.45 per share, (viii) 2,500 shares of common stock were issued at a price of \$1.45 per share, (ix) 8,333 shares of common stock were issued at a price of \$1.47 per share, (x) 12,000 shares of common stock were issued at a price of \$1.61 per share, (xi) 8,000 shares of common stock were issued at a price of \$1.72 per share, (xii) 7,353 shares of common stock were issued at a price of \$1.74 per share, (xii) 7,800 shares of common stock were issued at a price of \$1.85 per share, (xii) 7,800 shares of common stock were issued at a price of \$1.85 per share, (xii) 1,500 shares of common stock were issued at a price of \$1.86 per share, (xvi) 1,500 shares of common stock were issued at a price of \$1.90 per share.

### 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\*
- 3.1 Certificate of Incorporation, 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 3.3
- 3.2 Certificate of Amendment of Certificate of Incorporation filed with the State of Delaware on July 2, 2015, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 6, 2015, wherein such document is identified as Exhibit 3.1
- 3.4 Certificate of Amendment of Certificate of Incorporation filed with the State of Delaware on May 31, 2019, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated May 30, 2019, wherein such document is identified as Exhibit 3.1
- 3.5 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 Underwriter 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, 2016, wherein such document is identified as Exhibit 10.1
- 10.2 Executive Employment Agreement, dated as of March 9, 2015, between BioRestorative Therapies, Inc. and Mark Weinreb ("Weinreb Employment Agreement"), incorporated by reference to the registrant's Annual Report for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.2
- 10.3 Amendment to Weinreb Employment Agreement, dated February 14, 2017, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 8, 2017, wherein such document is identified as Exhibit 10.1.
- 10.4 Letter agreement, dated March 29, 2018, with regard to Weinreb Employment Agreement, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.4
- 10.5 Amendment to Weinreb Employment Agreement, dated May 30, 2018, 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 10.5

- 10.6 Stock Option Agreement, dated December 15, 2010, between Stem Cell Assurance, Inc. (now BioRestorative Therapies, Inc.) and Mark Weinreb, incorporated by reference to the registrant's Form 10, wherein such document is identified as Exhibit 10.17
- 10.7 Amended and Restated Executive Employment Agreement, dated May 10, 2011, between Stem Cell Assurance, Inc. (now BioRestorative Therapies, Inc.) and Francisco Silva ("Silva Employment Agreement"), incorporated by reference to the registrant's Form 10, wherein such document is identified as Exhibit 10.23
   10.8 Amendment to Silva Employment Agreement dated November 4, 2011, incorporated by reference to the registrant's Annual Report on Form 10-K for the year
- 10.8 Amendment to Silva Employment Agreement, dated November 4, 2011, 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 10.27
  10.0 Amondment to Silva Employment Agreement, dated May 2, 2012, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended
- 10.9 Amendment to Silva Employment Agreement, dated May 3, 2012, 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 10.29
- 10.10 Amendment to Silva Employment Agreement, dated December 7, 2012, 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 10.30
- 10.11 Amendment to Silva Employment Agreement, dated March 9, 2015, incorporated by reference to the registrant's Annual Report for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.20
- 10.12 Amendment to Silva Employment Agreement, dated March 1, 2017, 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 10.10
- 10.13 Amendment to Silva Employment Agreement, dated January 5, 2018, 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 10.13
- 10.14 Amendment to Silva Employment Agreement, dated May 31, 2018, 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 10.14
- 10.15 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
- 10.16
   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
- 10.17 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
- 10.18 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
- 10.19 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

10.20 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, 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 10.47 10.21 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 Consulting Agreement, dated as of August 16, 2012, between Wayne A. Marasco, M.D., Ph.D. and BioRestorative Therapies, Inc., incorporated by reference to 10.22 the registrant's Annual Report on Form 10-K for the year ended December 31, 2012, wherein such document is identified as Exhibit 10.56 10.23 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 Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, incorporated by reference to the 10.24registrant's Annual Report on Form 10-K for the year ended December 31, 2012, wherein such document is identified as Exhibit 10.59 10.25 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 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's 10.26 Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.59 10.27 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, 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 10.60 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's 10.28 Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.62 10.29 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 10.30 Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, 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 10.65 10.31 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

- 10.32 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
- 10.33 Stock Option Agreement, dated as of June 27, 2014, between BioRestorative Therapies, Inc. and Paul Jude Tonna, incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2014, wherein such document is identified as Exhibit 10.2
- 10.34 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
- 10.35 Amendment to Lease, dated June 4, 2019, 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 10.1
- 10.36 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 for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.65
- 10.37 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, incorporated by reference to the registrant's Annual Report for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.66
- 10.38 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 for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.67
- 10.39 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and Paul Jude Tonna, incorporated by reference to the registrant's Annual Report for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.70
- 10.40 Stock Option Agreement, dated as of April 6, 2015, between BioRestorative Therapies, Inc. and Charles S. Ryan, J.D., Ph.D., incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-204672), wherein such document is identified as Exhibit 10.74
- 10.41 Stock Option Agreement, dated as of August 13, 2015, between BioRestorative Therapies, Inc. and Robert Paccasassi, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.40
- 10.42 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
- 10.43 Stock Option Agreement, dated as of September 4, 2015, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, 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 10.78

10.44 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 Stock Option Agreement, dated as of September 4, 2015, between BioRestorative Therapies, Inc. and Paul Jude Tonna, incorporated by reference to the 10.45 registrant's Amendment No. 1 to Form S-1 Registration Statement (Registration No. 333-204672), wherein such document is identified as Exhibit 10.82 Stock Option Agreement, dated as of September 4, 2015, between BioRestorative Therapies, Inc. and Charles S. Ryan, J.D., Ph.D., incorporated by reference to 10.46 the registrant's Amendment No. 1 to Form S-1 Registration Statement (Registration No. 333-204672), wherein such document is identified as Exhibit 10.83 Warrant, dated November 17, 2015, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 125,000 shares of common stock, 10.47 incorporated by reference to Mr. Desmarais' Schedule 13D, wherein such document is identified as Exhibit 7.2 Stock Option Agreement, dated as of December 1, 2015, between BioRestorative Therapies, Inc. and John M. Desmarais, incorporated by reference to the 1048 registrant's Annual Report on Form 10-K for the year ended December 31, 2015, wherein such document is identified as Exhibit 10.64 10.49 Stock Option Agreement, dated as of February 19, 2016, between BioRestorative Therapies, Inc. and Robert B. Catell, 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 10.65 Warrant, dated February 29, 2016, issued by BioRestorative Therapies, Inc. to Robert B. Catell for the purchase of 37,500 shares of common stock incorporated 10.50 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 10.66 10.51 Warrant, dated March 18, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 250,000 shares of common stock, incorporated by reference to Amendment No. 1 to Mr. Desmarais' Schedule 13D, wherein such document is identified as Exhibit 7.2 Warrant, dated March 18, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 444,444 shares of common stock, 10.52 incorporated by reference to Amendment No. 1 to Mr. Desmarais' Schedule 13D, wherein such document is identified as Exhibit 7.3 10 53 Warrant, dated March 18, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 400,000 shares of common stock, incorporated by reference to Amendment No. 1 to Mr. Desmarais' Schedule 13D, wherein such document is identified as Exhibit 7.4 Form of Stock Option Agreement, dated as of June 10, 2016, between BioRestorative Therapies, Inc. and each of Robert B. Catell, John M. Desmarais, A. Jeffrey, 10.54Radov, Charles S. Ryan and Paul Jude Tonna, 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 10.58

- 10.55 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
- 10.56
   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
- 10.57 Stock Option Agreement, dated as of June 10, 2016, between BioRestorative Therapies, Inc. and Robert Paccasassi, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.56
- 10.58 Promissory Note, dated June 30, 2016, issued by BioRestorative Therapies, Inc. to Tuxis Trust in the principal amount of \$500,000 ("Tuxis Trust Note"), 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 10.61
- 10.59 Warrant, dated June 30, 2016, issued by BioRestorative Therapies, Inc. to Tuxis Trust for the purchase of 40,000 shares of common stock, 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 10.62
- 10.60 Letter agreement, dated November 17, 2017, with regard to Tuxis Trust Note incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.56
- 10.61
   Promissory Note, dated August 5, 2016, issued by BioRestorative Therapies, Inc. to Robert B. Catell in the principal amount of \$100,000, 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 10.63
- 10.62 Warrant, dated August 5, 2016, issued by BioRestorative Therapies, Inc. to Robert B. Catell for the purchase of 8,000 shares of common stock, 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 10.64
- 10.63 Warrant, dated September 26, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 80,000 shares of common stock, 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 10.65
- 10.64
   Letter agreement, dated September 26, 2016, between BioRestorative Therapies, Inc. and John M. Desmarais, 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 10.66
- 10.65 Promissory Note, dated December 14, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais in the principal amount of \$65,000, 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 10.67
- 10.66
   Letter agreement, dated December 14, 2016, between BioRestorative Therapies, Inc. and John M. Desmarais, 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 10.68

- 10.67 Form of Warrant, dated March 1, 2017, issued by BioRestorative Therapies, Inc. to each of Robert B. Catell, John M. Desmarais, Charles S. Ryan and Paul Jude Tonna, 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 10.70
- 10.68 Convertible Promissory Note, with an original issue date of August 4, 2016, issued by BioRestorative Therapies, Inc. to St. George Investments LLC in the principal amount of \$215,250 ("St. George August 2016 Note"), incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.63
- 10.69 Amendment to Convertible Promissory Note, dated January 15, 2018, with regard to St. George August 2016 Note, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.65
- 10.70
   Convertible Promissory Note, with an original issue date of January 3, 2017, issued by BioRestorative Therapies, Inc. to St. George Investments LLC in the principal amount of \$242,000 ("St. George January 2017 Note"), incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.70
- 10.71 Amendment to Convertible Promissory Note, dated January 15, 2018, with regard to St. George January 2017 Note, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.67
- 10.72 Convertible Promissory Note, with an original issue date of May 10, 2017, issued by BioRestorative Therapies, Inc. to St. George Investments LLC in the principal amount of \$180,000 ("St. George May 2017 Note"), incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.72
- 10.73 Amendment to Convertible Promissory Note, dated February 15, 2018, with regard to St. George May 2017 Note, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.69
- 10.74 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
- 10.75 Form of Stock Option Agreement, dated as of June 23, 2017, between BioRestorative Therapies, Inc. and each of Robert B. Catell, John M. Desmarais, A. Jeffrey Radov, Charles S. Ryan and Paul Jude Tonna, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.74
- 10.76 Letter agreement, dated as of July 5, 2017, between BioRestorative Therapies, Inc. and Tuxis Trust, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.75

- 10.77 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
- 10.78
   Stock Option Agreement, dated as of July 12, 2017, between BioRestorative Therapies, Inc. and Robert Paccasassi, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.77
- 10.79 Promissory Note, dated as of July 13, 2017, issued by BioRestorative Therapies, Inc. to John M. Desmarais in the principal amount of \$175,000 ("Desmarais Note"), incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.77
- 10.80 Security Agreement, dated as of July 13, 2017, by and among BioRestorative Therapies, Inc., Tuxis Trust and John M. Desmarais, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.78
- 10.81 Letter agreement, dated November 17, 2017, with regard to Desmarais Note incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.76
- 10.82 Warrant, dated as of August 11, 2017, issued by BioRestorative Therapies, Inc. to Robert B. Catell for the purchase of 5,000 shares of common stock, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.79
- 10.83 Convertible Promissory Note, dated October 25, 2017, issued by BioRestorative Therapies, Inc. to Tangiers Global, LLC, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 27, 2017, wherein such document is identified as Exhibit 10.1
- 10.84 Executive Employment Agreement, dated as of September 2, 2015, between BioRestorative Therapies, Inc. and Robert Paccasassi ("Paccasassi Employment Agreement"), 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 10.83
- 10.85 Amendment to Paccasassi Employment Agreement, dated March 24, 2016, 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 10.84
- 10.86 Amendment to Paccasassi Employment Agreement, dated March 1, 2017, 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 10.85
- 10.87 Amendment to Paccasassi Employment Agreement, dated May 30, 2018, 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 10.86
- 10.88
   Executive Employment Agreement, dated as of January 16, 2018, between BioRestorative Therapies, Inc. and Adam D. Bergstein, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated January 16, 2018, wherein such document is identified as Exhibit 10.1
- 10.89 Stock Option Agreement, dated as of January 19, 2018, between BioRestorative Therapies, Inc. and Adam D. Bergstein, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated January 16, 2018, wherein such document is identified as Exhibit 10.2

- 10.90 <u>Convertible Promissory Note, dated March 27, 2018, issued by BioRestorative Therapies, Inc. to Auctus Fund, LLC incorporated by reference to the registrant's</u> Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.83
- 10.91 Convertible Promissory Note, dated August 31, 2018, issued by BioRestorative Therapies, Inc. to Tangiers Global, LLC, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated September 6, 2018, wherein such document is identified as Exhibit 10.1
- 10.92 Executive Employment Agreement, dated as of October 15, 2018, 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 15, 2018, wherein such document is identified as Exhibit 10.1
- 10.93
   Stock Option Agreement, dated as of October 15, 2018, 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 15, 2018, wherein such document is identified as Exhibit 10.2
- 10.94
   Convertible Promissory Note, dated October 19, 2018, issued by BioRestorative Therapies, Inc. to Labrys Fund, L.P., 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 10.93
- 10.95
   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
- 10.96
   Form of Stock Option Agreement, dated as of October 29, 2018, between BioRestorative Therapies, Inc. and each of Robert B. Catell, John M Desmarais, A. Jeffrey Radoy, Charles S. Ryan and Paul Jude Tonna, 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 10.95
- 10.97 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
- 10.98 Stock Option Agreement, dated as of October 29, 2018, between BioRestorative Therapies, Inc., and Robert Paccasassi, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.97
- 10.99 Convertible Promissory Note, dated November 12, 2018, issued by BioRestorative Therapies, Inc. to SCG Capital, LLC, 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 10.98
- 10.100 Letter agreement, dated November 20, 2018, with regard to Desmarais Note, 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 10.99
- 10.101 12% Convertible Redeemable Note, dated November 28, 2018, issued by BioRestorative Therapies, Inc to Eagle Equities, LLC, 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 10.100

- 10.102 Form of Convertible Promissory Note issued by BioRestorative Therapies, Inc. in connection with \$675,000 debt financing, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated January 4, 2019, wherein such document is identified as Exhibit 10.1
- 10.103 Convertible Promissory Note, dated January 18, 2019, issued by BioRestorative Therapies, Inc. to Auctus Fund, LLC, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.102
- 10.104 Convertible Promissory Note, dated February 6, 2019, issued by BioRestorative Therapies, Inc. to Harvey P. Alstodt and Melody Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 6, 2019, wherein such document is identified as Exhibit 10.1
- 10.105 Amendment to Convertible Promissory Note, dated February 6, 2019, between BioRestorative Therapies, Inc. and Harvey P. Alstodt and Melody Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 6, 2019, wherein such document is identified as Exhibit 10.2
- 10.106
   Warrant, dated February 19, 2019, issued by BioRestorative Therapies, Inc. to Dale Broadrick, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 19, 2019, wherein such document is identified as Exhibit 10.1
- 10.107 Warrant, dated February 19, 2019, issued by BioRestorative Therapies, Inc. to Dale Broadrick, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 19, 2019, wherein such document is identified as Exhibit 10.2
- 10.108
   Warrant, dated May 7, 2019, issued by BioRestorative Therapies, Inc. to Dale Broadrick, incorporated by reference to Amendment No. 1 to Schedule 13D filed by Mr. Broadrick with the Securities and Exchange Commission on May 9, 2019, wherein such document is identified as Exhibit A
- 10.109 Warrant, dated May 7, 2019, issued by BioRestorative Therapies, Inc. to Dale Broadrick, incorporated by reference to Amendment No. 1 to Schedule 13D filed by Mr. Broadrick with the Securities and Exchange Commission on May 9, 2019, wherein such document is identified as Exhibit B
- 10.110 Convertible Promissory Note, dated June 13, 2019, issued by BioRestorative Therapies, Inc. to Auctus Fund, LLC, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated June 18, 2019, wherein such document is identified as Exhibit 10.2
- 10.111 Amended and Restated Exchange Agreement, dated as of July 26, 2019, between BioRestorative Therapies, Inc. and John M. Desmarais, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 26, 2019, wherein such document is identified as Exhibit 10.2
- 10.112 Amended and Restated Exchange Agreement, dated as of July 26, 2019, between BioRestorative Therapies, Inc. and Tuxis Trust, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 26, 2019, wherein such document is identified as Exhibit 10.3
- 10.113 Securities Purchase Agreement, dated as of July 26, 2019, between BioRestorative Therapies, Inc. and Arena Investors, LP, including exhibits thereto, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 26, 2019, wherein such document is identified as Exhibit 10.1
- 10.114 Form of Exchange Agreement between BioRestorative Therapies, Inc. and the holders of \$675,000 principal amount of indebtedness, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 26, 2019, wherein such document is identified as Exhibit 10.4
- 10.115 Exchange Agreement, dated as of August 8, 2019, between BioRestorative Therapies, Inc. and Harvey P. Alstodt and Merry Alstodt\*\*
- 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 <u>Power of Attorney (included on signature page)</u>
- 101.INS XBRL Instance Document \*\*
- 101.SCH XBRL Schema Document \*\*
- 101.CAL XBRL Calculation Linkbase Document\*\*
- 101.DEFXBRL Definition Linkbase Document\*\*101.LABXBRL Label 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 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 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 September 6, 2019.

# **BIORESTORATIVE THERAPIES, INC.**

By: /s/ Mark Weinreb

Chief Executive Officer

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 September 6, 2019.

Signature	Capacity				
/s/ Mark Weinreb Mark Weinreb	Chief Executive Officer, President, Chairman of the Board and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)				
* Robert B. Catell	Director				
* John M. Desmarais	Director				
* A. Jeffrey Radov	Director				
* Charles S. Ryan	Director				
* Paul Jude Tonna	Director				
*/s/ Mark Weinreb Mark Weinreb Attorney-in-Fact					
	[Signature Page to Amendment No. 1 to Registration Statement on Form S-1]				

#### EXHIBITS TO AMENDMENT NO. 1 TO REGISTRATION STATEMENT ON FORM S-1 BIORESTORATIVE THERAPIES, INC.

#### EXHIBIT INDEX

## Exhibit No.

- 1.1 Form of Underwriting Agreement\*
- 3.1 Certificate of Incorporation, 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 3.3
- 3.2 Certificate of Amendment of Certificate of Incorporation filed with the State of Delaware on July 2, 2015, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 6, 2015, wherein such document is identified as Exhibit 3.1
- 3.4 Certificate of Amendment of Certificate of Incorporation filed with the State of Delaware on May 31, 2019, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated May 30, 2019, wherein such document is identified as Exhibit 3.1
- 3.5 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 Underwriter 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, 2016, wherein such document is identified as Exhibit 10.1
- 10.2 Executive Employment Agreement, dated as of March 9, 2015, between BioRestorative Therapies, Inc. and Mark Weinreb ("Weinreb Employment Agreement"), incorporated by reference to the registrant's Annual Report for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.2
   10.3 Amendment to Weinreb Employment Agreement, dated February 14, 2017, incorporated by reference to the registrant's Current Report on Form 8-K for an event
- 10.3 Amendment to Weinreb Employment Agreement, dated February 14, 2017, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 8, 2017, wherein such document is identified as Exhibit 10.1.
- 10.4 Letter agreement, dated March 29, 2018, with regard to Weinreb Employment Agreement, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.4
- 10.5 Amendment to Weinreb Employment Agreement, dated May 30, 2018, 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 10.5

- 10.6 Stock Option Agreement, dated December 15, 2010, between Stem Cell Assurance, Inc. (now BioRestorative Therapies, Inc.) and Mark Weinreb, incorporated by reference to the registrant's Form 10, wherein such document is identified as Exhibit 10.17
- 10.7 Amended and Restated Executive Employment Agreement, dated May 10, 2011, between Stem Cell Assurance, Inc. (now BioRestorative Therapies, Inc.) and Francisco Silva ("Silva Employment Agreement"), incorporated by reference to the registrant's Form 10, wherein such document is identified as Exhibit 10.23
   10.8 Amendment to Silva Employment Agreement, dated November 4, 2011, incorporated by reference to the registrant's Annual Report on Form 10-K for the year
- 10.8 Amendment to Silva Employment Agreement, dated November 4, 2011, 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 10.27
  Amendment to Silva Employment Agreement dated May 2, 2012, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended
- 10.9 <u>Amendment to Silva Employment Agreement, dated May 3, 2012, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended</u> December 31, 2012, wherein such document is identified as Exhibit 10.29
- 10.10 Amendment to Silva Employment Agreement, dated December 7, 2012, 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 10.30
- 10.11 Amendment to Silva Employment Agreement, dated March 9, 2015, incorporated by reference to the registrant's Annual Report for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.20
- 10.12 Amendment to Silva Employment Agreement, dated March 1, 2017, 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 10.10
- 10.13 Amendment to Silva Employment Agreement, dated January 5, 2018, 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 10.13
- 10.14 Amendment to Silva Employment Agreement, dated May 31, 2018, 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 10.14
- 10.15 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
- 10.16
   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
- 10.17 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
- 10.18 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
- 10.19 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

- 10.20 Stock Option Agreement, dated as of February 10, 2012, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, 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 10.47 10.21 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 Consulting Agreement, dated as of August 16, 2012, between Wayne A. Marasco, M.D., Ph.D. and BioRestorative Therapies, Inc., incorporated by reference to 10.22 the registrant's Annual Report on Form 10-K for the year ended December 31, 2012, wherein such document is identified as Exhibit 10.56 10.23 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 Stock Option Agreement, dated as of December 7, 2012, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, incorporated by reference to the 10.24registrant's Annual Report on Form 10-K for the year ended December 31, 2012, wherein such document is identified as Exhibit 10.59 10.25 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 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's 10.26 Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10.59 10.27 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, 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 10.60 Stock Option Agreement, dated as of October 4, 2013, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's 10.28
- 10.28 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
- 10.29
   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
- 10.30 Stock Option Agreement, dated as of February 18, 2014, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, 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 10.65
- 10.31 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

- 10.32 <u>Stock Option Agreement, dated as of March 12, 2014, between BioRestorative Therapies, Inc. and Francisco Silva, incorporated by reference to the registrant's</u> <u>Annual Report on Form 10-K for the year ended December 31, 2013, wherein such document is identified as Exhibit 10,70</u>
- 10.33 Stock Option Agreement, dated as of June 27, 2014, between BioRestorative Therapies, Inc. and Paul Jude Tonna, incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2014, wherein such document is identified as Exhibit 10.2
- 10.34 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
- 10.35
   Amendment to Lease, dated June 4, 2019, 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 10.1
- 10.36 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 for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.65
- 10.37 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, incorporated by reference to the registrant's Annual Report for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.66
- 10.38 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 for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.67
- 10.39 Stock Option Agreement, dated as of October 23, 2014, between BioRestorative Therapies, Inc. and Paul Jude Tonna, incorporated by reference to the registrant's Annual Report for the year ended December 31, 2014, wherein such document is identified as Exhibit 10.70
- 10.40 Stock Option Agreement, dated as of April 6, 2015, between BioRestorative Therapies, Inc. and Charles S. Ryan, J.D., Ph.D., incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-204672), wherein such document is identified as Exhibit 10.74
- 10.41 Stock Option Agreement, dated as of August 13, 2015, between BioRestorative Therapies, Inc. and Robert Paccasassi, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.40
- 10.42
   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
- 10.43 Stock Option Agreement, dated as of September 4, 2015, between BioRestorative Therapies, Inc. and A. Jeffrey Radov, 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 10.78
- 10.44 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

- 10.45 Stock Option Agreement, dated as of September 4, 2015, between BioRestorative Therapies, Inc. and Paul Jude Tonna, 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 10.82
- 10.46 Stock Option Agreement, dated as of September 4, 2015, between BioRestorative Therapies, Inc. and Charles S. Ryan, J.D., Ph.D., 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 10.83
- 10.47 Warrant, dated November 17, 2015, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 125,000 shares of common stock, incorporated by reference to Mr. Desmarais' Schedule 13D, wherein such document is identified as Exhibit 7.2
- 10.48 Stock Option Agreement, dated as of December 1, 2015, between BioRestorative Therapies, Inc. and John M. Desmarais, 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 10.64
- 10.49
   Stock Option Agreement, dated as of February 19, 2016, between BioRestorative Therapies, Inc. and Robert B. Catell, 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 10.65
- 10.50 Warrant, dated February 29, 2016, issued by BioRestorative Therapies, Inc. to Robert B. Catell for the purchase of 37,500 shares of common stock 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 10.66
- 10.51 Warrant, dated March 18, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 250,000 shares of common stock, incorporated by reference to Amendment No. 1 to Mr. Desmarais' Schedule 13D, wherein such document is identified as Exhibit 7.2
- 10.52 Warrant, dated March 18, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 444,444 shares of common stock, incorporated by reference to Amendment No. 1 to Mr. Desmarais' Schedule 13D, wherein such document is identified as Exhibit 7.3
- 10.53 Warrant, dated March 18, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 400,000 shares of common stock, incorporated by reference to Amendment No. 1 to Mr. Desmarais' Schedule 13D, wherein such document is identified as Exhibit 7.4
- 10.54 Form of Stock Option Agreement, dated as of June 10, 2016, between BioRestorative Therapies, Inc. and each of Robert B. Catell, John M. Desmarais, A. Jeffrey Radov, Charles S. Ryan and Paul Jude Tonna, 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 10.58
- 10.55 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

- 10.56
   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
- 10.57
   Stock Option Agreement, dated as of June 10, 2016, between BioRestorative Therapies, Inc. and Robert Paccasassi, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.56
- 10.58 Promissory Note, dated June 30, 2016, issued by BioRestorative Therapies, Inc. to Tuxis Trust in the principal amount of \$500,000 ("Tuxis Trust Note"), 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 10.61
- 10.59 Warrant, dated June 30, 2016, issued by BioRestorative Therapies, Inc. to Tuxis Trust for the purchase of 40,000 shares of common stock, 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 10.62
- 10.60
   Letter agreement, dated November 17, 2017, with regard to Tuxis Trust Note incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.56
- 10.61 Promissory Note, dated August 5, 2016, issued by BioRestorative Therapies, Inc. to Robert B. Catell in the principal amount of \$100,000, 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 10.63
- 10.62 Warrant, dated August 5, 2016, issued by BioRestorative Therapies, Inc. to Robert B. Catell for the purchase of 8,000 shares of common stock, 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 10.64
- 10.63 Warrant, dated September 26, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais for the purchase of 80,000 shares of common stock, 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 10.65
- 10.64
   Letter agreement, dated September 26, 2016, between BioRestorative Therapies, Inc. and John M. Desmarais, 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 10.66
- 10.65
   Promissory Note, dated December 14, 2016, issued by BioRestorative Therapies, Inc. to John M. Desmarais in the principal amount of \$65,000, 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 10.67
- 10.66
   Letter agreement, dated December 14, 2016, between BioRestorative Therapies, Inc. and John M. Desmarais, 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 10.68
- 10.67 Form of Warrant, dated March 1, 2017, issued by BioRestorative Therapies, Inc. to each of Robert B. Catell, John M. Desmarais, Charles S. Ryan and Paul Jude Tonna, 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 10.70

- 10.68 Convertible Promissory Note, with an original issue date of August 4, 2016, issued by BioRestorative Therapies, Inc. to St. George Investments LLC in the principal amount of \$215,250 ("St. George August 2016 Note"), incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.63
- 10.69
   Amendment to Convertible Promissory Note, dated January 15, 2018, with regard to St. George August 2016 Note, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.65
- 10.70 Convertible Promissory Note, with an original issue date of January 3, 2017, issued by BioRestorative Therapies, Inc. to St. George Investments LLC in the principal amount of \$242,000 ("St. George January 2017 Note"), incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.70
- 10.71 Amendment to Convertible Promissory Note, dated January 15, 2018, with regard to St. George January 2017 Note, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.67
- 10.72 Convertible Promissory Note, with an original issue date of May 10, 2017, issued by BioRestorative Therapies, Inc. to St. George Investments LLC in the principal amount of \$180,000 ("St. George May 2017 Note"), incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.72
- 10.73 Amendment to Convertible Promissory Note, dated February 15, 2018, with regard to St. George May 2017 Note, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.69
- 10.74 <u>Stock Option Agreement, dated as of June 23, 2017, between BioRestorative Therapies, Inc. and Mark Weinreb, incorporated by reference to the registrant's</u> Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.73
- 10.75 Form of Stock Option Agreement, dated as of June 23, 2017, between BioRestorative Therapies, Inc. and each of Robert B. Catell, John M. Desmarais, A. Jeffrey Radov, Charles S. Ryan and Paul Jude Tonna, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.74
- 10.76
   Letter agreement, dated as of July 5, 2017, between BioRestorative Therapies, Inc. and Tuxis Trust, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.75
- 10.77 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
- 10.78 Stock Option Agreement, dated as of July 12, 2017, between BioRestorative Therapies, Inc. and Robert Paccasassi, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.77

10.79	Promissory Note, dated as of July 13, 2017, issued by BioRestorative Therapies, Inc. to John M. Desmarais in the principal amount of \$175,000 ("Desmarais
	Note"), incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as
	Exhibit 10.77

 
 10.80
 Security Agreement, dated as of July 13, 2017, by and among BioRestorative Therapies, Inc., Tuxis Trust and John M. Desmarais, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.78

10.81 Letter agreement, dated November 17, 2017, with regard to Desmarais Note incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.76

- 10.82 Warrant, dated as of August 11, 2017, issued by BioRestorative Therapies, Inc. to Robert B. Catell for the purchase of 5,000 shares of common stock, incorporated by reference to the registrant's Form S-1 Registration Statement (Registration No. 333-220843), wherein such document is identified as Exhibit 10.79
- 10.83 Convertible Promissory Note, dated October 25, 2017, issued by BioRestorative Therapies, Inc. to Tangiers Global, LLC, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated October 27, 2017, wherein such document is identified as Exhibit 10.1
- 10.84 Executive Employment Agreement, dated as of September 2, 2015, between BioRestorative Therapies, Inc. and Robert Paccasassi ("Paccasassi Employment Agreement"), 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 10.83
- 10.85 Amendment to Paccasassi Employment Agreement, dated March 24, 2016, 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 10.84
- 10.86 Amendment to Paccasassi Employment Agreement, dated March 1, 2017, 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 10.85
- 10.87 Amendment to Paccasassi Employment Agreement, dated May 30, 2018, 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 10.86
- 10.88 Executive Employment Agreement, dated as of January 16, 2018, between BioRestorative Therapies, Inc. and Adam D. Bergstein, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated January 16, 2018, wherein such document is identified as Exhibit 10.1
- 10.89 Stock Option Agreement, dated as of January 19, 2018, between BioRestorative Therapies, Inc. and Adam D. Bergstein, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated January 16, 2018, wherein such document is identified as Exhibit 10.2
- 10.90 Convertible Promissory Note, dated March 27, 2018, issued by BioRestorative Therapies, Inc. to Auctus Fund, LLC incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, wherein such document is identified as Exhibit 10.83
- 10.91 Convertible Promissory Note, dated August 31, 2018, issued by BioRestorative Therapies, Inc. to Tangiers Global, LLC, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated September 6, 2018, wherein such document is identified as Exhibit 10.1

- 10.92 Executive Employment Agreement, dated as of October 15, 2018, 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 15, 2018, wherein such document is identified as Exhibit 10.1
- 10.93 Stock Option Agreement, dated as of October 15, 2018, 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 15, 2018, wherein such document is identified as Exhibit 10.2
- 10.94
   Convertible Promissory Note, dated October 19, 2018, issued by BioRestorative Therapies, Inc. to Labrys Fund, L.P., 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 10.93
- 10.95 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
- 10.96
   Form of Stock Option Agreement, dated as of October 29, 2018, between BioRestorative Therapies, Inc. and each of Robert B. Catell, John M Desmarais, A. Jeffrey Radov, Charles S. Ryan and Paul Jude Tonna, 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 10.95
- 10.97 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
- 10.98 Stock Option Agreement, dated as of October 29, 2018, between BioRestorative Therapies, Inc., and Robert Paccasassi, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.97
- 10.99 <u>Convertible Promissory Note, dated November 12, 2018, issued by BioRestorative Therapies, Inc. to SCG Capital, LLC, 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 10.98</u>
- 10.100 Letter agreement, dated November 20, 2018, with regard to Desmarais Note, 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 10.99
- 10.101 12% Convertible Redeemable Note, dated November 28, 2018, issued by BioRestorative Therapies, Inc to Eagle Equities, LLC, 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 10.100
- 10.102 Form of Convertible Promissory Note issued by BioRestorative Therapies, Inc. in connection with \$675,000 debt financing, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated January 4, 2019, wherein such document is identified as Exhibit 10.1

- 10.103 Convertible Promissory Note, dated January 18, 2019, issued by BioRestorative Therapies, Inc. to Auctus Fund, LLC, incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2018, wherein such document is identified as Exhibit 10.102
- 10.104 Convertible Promissory Note, dated February 6, 2019, issued by BioRestorative Therapies, Inc. to Harvey P. Alstodt and Melody Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 6, 2019, wherein such document is identified as Exhibit 10.1
- 10.105 Amendment to Convertible Promissory Note, dated February 6, 2019, between BioRestorative Therapies, Inc. and Harvey P. Alstodt and Melody Alstodt, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 6, 2019, wherein such document is identified as Exhibit 10.2
- 10.106 Warrant, dated February 19, 2019, issued by BioRestorative Therapies, Inc. to Dale Broadrick, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 19, 2019, wherein such document is identified as Exhibit 10.1
- 10.107 Warrant, dated February 19, 2019, issued by BioRestorative Therapies, Inc. to Dale Broadrick, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated February 19, 2019, wherein such document is identified as Exhibit 10.2
- 10.108 Warrant, dated May 7, 2019, issued by BioRestorative Therapies, Inc. to Dale Broadrick, incorporated by reference to Amendment No. 1 to Schedule 13D filed by Mr. Broadrick with the Securities and Exchange Commission on May 9, 2019, wherein such document is identified as Exhibit A
- 10.109
   Warrant, dated May 7, 2019, issued by BioRestorative Therapies, Inc. to Dale Broadrick, incorporated by reference to Amendment No. 1 to Schedule 13D filed by Mr. Broadrick with the Securities and Exchange Commission on May 9, 2019, wherein such document is identified as Exhibit B
- 10.110 Convertible Promissory Note, dated June 13, 2019, issued by BioRestorative Therapies, Inc. to Auctus Fund, LLC, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated June 18, 2019, wherein such document is identified as Exhibit 10.2
- 10.111 Amended and Restated Exchange Agreement, dated as of July 26, 2019, between BioRestorative Therapies, Inc. and John M. Desmarais, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 26, 2019, wherein such document is identified as Exhibit 10.2
- 10.112 Amended and Restated Exchange Agreement, dated as of July 26, 2019, between BioRestorative Therapies, Inc. and Tuxis Trust, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 26, 2019, wherein such document is identified as Exhibit 10.3
- 10.113 Securities Purchase Agreement, dated as of July 26, 2019, between BioRestorative Therapies, Inc. and Arena Investors, LP, including exhibits thereto, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 26, 2019, wherein such document is identified as Exhibit 10.1
- 10.114 Form of Exchange Agreement between BioRestorative Therapies, Inc. and the holders of \$675,000 principal amount of indebtedness, incorporated by reference to the registrant's Current Report on Form 8-K for an event dated July 26, 2019, wherein such document is identified as Exhibit 10.4
- 10.115 Exchange Agreement, dated as of August 8, 2019, between BioRestorative Therapies, Inc. and Harvey P. Alstodt and Merry Alstodt\*\*
- 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 <u>Power of Attorney (included on signature page)</u>
- 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

#### **EXCHANGE AGREEMENT**

EXCHANGE AGREEMENT, dated as of August 8, 2019 (the "Agreement"), by and between BIORESTORATIVE THERAPIES, INC., a Delaware corporation (the "Company"), and HARVEY P. ALSTODT AND MELODY ALSTODT (the "Holder").

WHEREAS, the Holder is the holder of a Promissory Note, dated February 6, 2019, issued by the Company to the Holder in the principal amount of \$450,000 (as amended, the "Note").

WHEREAS, the maturity date for the payment of the principal amount of the Note, together with accrued interest thereon, was August 6, 2019.

WHEREAS, the Note provides for the right of the Holder to convert the principal amount of the Note, together with accrued interest, into shares of Common Stock of the Company ("Common Stock") and a warrant for the purchase of Common Stock in, or substantially in, the form attached to the Note as Exhibit 1 (the "Current Warrant") at a conversion price of sixty cents (\$0.60) per share of Common Stock (subject to adjustment for reverse stock splits and the like) (the "Note Conversion Price").

WHEREAS, the Company has requested that the Holder extend the maturity date of the Note to September 30, 2019 (the "New Maturity Date") and, in connection therewith to provide for an automatic conversion of the Note into shares of Common Stock and a modification to the terms of the Current Warrant as hereinafter provided (the "Exchange Warrant"), in exchange for the amounts payable pursuant to the Note (the "Exchange Offer").

WHEREAS, the Holder desires to exchange the amounts payable pursuant to the Note for Common Stock and the Exchange Warrant pursuant to the Exchange Offer, subject to the terms and conditions hereof.

WHEREAS, the Holder is willing to extend the maturity date of the Note to September 30, 2019 and modify the terms of the Note and the Current Warrant as hereinafter provided.

NOW, THEREFORE, the parties agree as follows:

#### 1. Exchange; Extension of Maturity Date.

1.1 In the event, on or prior to the New Maturity Date, the Company enters into an underwriting agreement for a public offering of its securities pursuant to which, after giving effect to such offering, the Common Stock will be listed on the Nasdaq Stock Market (the "Public Offering"), then, thereupon, the outstanding principal amount of the Note, together with accrued interest thereon, shall be automatically deemed to have been exchanged for Common Stock (the "Exchange Shares" and together with the Exchange Warrant, the "Exchange Securities") and the Exchange Warrant at an exchange price (the "Exchange Price") equal to the lesser of (i) seventy-five percent (75%) of the offering price for the Common Stock or units of Common Stock and warrants, as the case may be, pursuant to the Public Offering (the "Public Offering Price") and (ii) the Note Conversion Price (the "Exchange"). The number of shares of Common Stock issuable pursuant to the Exchange Warrant shall be equal to the lesser of (a) the exercise price set forth in the Current Warrant or (b) one hundred twenty-five percent (125%) of the Exchange Price.

1.2 The certificates evidencing the Exchange Shares and the Exchange Warrant issuable to the Holder pursuant to the Exchange Offer will be delivered by the Company to the Holder within five (5) days of closing of the Public Offering.

1.3 The Holder agrees that, in connection with the Public Offering, it shall enter into a lock-up agreement with the managing underwriter of the Public Offering, upon terms reasonably acceptable to such managing underwriter and the Holder, which lock-up agreement shall provide for, among other things, a one hundred thirty-five (135) day lock-up period and a termination of such lock-up period in the event the closing price for the Common Stock equals or exceeds one hundred fifty percent (150%) of the Public Offering Price for a period of five (5) consecutive trading days.

1.4 The parties agree that the maturity date for the payment of the principal amount of the Note, together with accrued interest thereon, is the New Maturity

# Date.

## 2. Representations by Holder.

The Holder understands and agrees that the Company is relying and may rely upon the following representations, warranties, acknowledgements, consents, confirmations and covenants made by the Holder in entering into this Agreement:

2.1 The Holder recognizes that the acquisition of the Exchange Securities and, in the event of the exercise of the Exchange Warrant, the shares of Common Stock issuable pursuant thereto (the "Warrant Shares") involves a high degree of risk and is suitable only for persons of adequate financial means who have no need for liquidity with respect to the Exchange Securities in that (a) the Holder may not be able to liquidate the Exchange Securities in the event of emergency; (b) transferability is extremely limited; and (c) the Holder could sustain a complete loss of its investment.

2.2 The Holder represents and warrants that it (a) is competent to understand and does understand the nature of the Exchange Offer; and (b) is able to bear the economic risk of an acquisition of the Exchange Securities.

2.3 The Holder represents and warrants that it is an "accredited investor," as such term is defined in Rule 501 of Regulation D promulgated under the Securities Act of 1933, as amended (the "Act"). The Holder meets the requirements of at least one of the suitability standards for an "accredited investor" as set forth on the Accredited Investor Certification contained herein.

2.4 The Holder represents and warrants that it has significant prior investment experience, including investment in restricted securities, and that it has read this Agreement and the Current Warrant in order to evaluate the merits and risks of the Exchange Offer.

2.5 The Holder represents and warrants that it has reviewed all reports, statements and other documents filed by the Company with the Securities and Exchange Commission (collectively, the "SEC Reports"), including, the risk factors set forth therein. The Holder also represents and warrants that it has been furnished by the Company with all information regarding the Company which it had requested or desired to know; that all documents which could be reasonably provided have been made available for its inspection and review; that it has been afforded the opportunity to ask questions of and receive answers from duly authorized representatives of the Company concerning the terms and conditions of the Exchange Offer, and any additional information which it had requested; and that it has had the opportunity to consult with its own tax or financial advisor concerning an acquisition of the Exchange Securities. The Holder confirms that no oral representations have been made or oral information furnished to the Holder or its advisers in connection with the Exchange Offer that are inconsistent in any respect with the SEC Reports, this Agreement or the Current Warrant.

2.6 The Holder acknowledges that the Exchange Offer has not been reviewed by the Securities and Exchange Commission (the "SEC") because it is intended to be either (a) a non-public offering pursuant to Section 4(a)(2) of the Act and Rule 506 of Regulation D promulgated thereunder or (b) exempt from the registration requirements of the Act pursuant to Section 3(a)(9) thereof. The Holder represents that the Exchange Securities are and will be being acquired for its own account, for investment and not for distribution to others. The Holder agrees that it will not sell, transfer or otherwise dispose of the Exchange Securities, or any portion thereof, unless they are registered under the Act or unless an exemption from such registration is available.

2.7 The Holder consents that the Company may, if it desires, permit the transfer of the Exchange Securities by the Holder out of its name only when its request for transfer is accompanied by an opinion of counsel satisfactory to the Company that neither the sale nor the proposed transfer results in a violation of the Act or any applicable state "blue sky" laws (collectively, "Securities Laws"). The Holder agrees to be bound by any requirements of such Securities Laws.

2.8 The Holder acknowledges and agrees that the Company is relying on the Holder's representations and warranties contained in this Agreement in determining whether to enter into this Agreement.

2.9 The Holder consents to the placement of a legend on the Exchange Securities stating that they have not been registered under the Act and setting forth or referring to the restrictions on transferability and sale thereof. The Holder is aware that the Company will make a notation in its appropriate records with respect to the restrictions on the transferability of the Exchange Securities.

2.10 The Holder represents and warrants that the address set forth on the signature page is the Holder's true and correct address.

2.11 The Holder represents and warrants that it is unaware of, is in no way relying on, and did not become aware of, the Exchange Offer through, or as a result of, any form of general solicitation or advertising, including, without limitation, articles, notices, advertisements or other communications published in any newspaper, magazine or other similar media or broadcast over television or radio or any seminar or meeting where the attendees have been invited by any such means of general solicitation or advertising.

2.12 The Holder represents and warrants as follows:

(i) if a natural person, the Holder has reached the age of 21 and has full power and authority to execute and deliver this Agreement and all other related agreements or certificates and to carry out the provisions hereof and thereof;

(ii) if a corporation, partnership, limited liability company or partnership, association, joint stock company, trust, unincorporated organization or other entity, the Holder was not formed for the specific purpose of acquiring the Exchange Securities, it is duly organized, validly existing and in good standing under the laws of the state of its organization, the consummation of the transactions contemplated hereby is authorized by, and will not result in a violation of, its charter or other organizational documents, it has full power and authority to execute and deliver this Agreement and all other related agreements or certificates and to carry out the provisions hereof and thereof and to acquire and hold the Exchange Securities, the execution and delivery of this Agreement has been duly authorized by all necessary action, this Agreement has been duly executed and delivered on behalf of the Holder and this Agreement a legal, valid and binding obligation of the Holder; and

(iii) if executing this Agreement in a representative or fiduciary capacity, the Holder has full power and authority to execute and deliver this Agreement in such capacity and on behalf of the individual, ward, partnership, trust, estate, corporation, limited liability company or partnership, or other entity for whom the Holder is executing this Agreement, and such individual, ward, partnership, trust, estate, corporation, limited liability company or partnership, or other entity has full right and power to perform pursuant to this Agreement and acquire the Exchange Securities, and that this Agreement constitutes a legal, valid and binding obligation of such entity.

2.13 The Holder represents and warrants that the execution and delivery of this Agreement will not violate or be in conflict with any order, judgment, injunction, agreement or other document to which the Holder is a party or by which it is bound.

2.14 NEITHER THE EXCHANGE SHARES, NOR THE WARRANT NOR THE WARRANT SHARES OFFERED HEREBY HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE AND ARE BEING OFFERED AND SOLD IN RELIANCE ON EXEMPTIONS FROM THE REGISTRATION REQUIREMENTS OF SAID ACT AND SUCH LAWS. THE EXCHANGE SHARES, THE WARRANT AND THE WARRANT SHARES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER SAID ACT AND SUCH LAWS PURSUANT TO REGISTRATION OR EXEMPTION THEREFROM. NEITHER THE EXCHANGE SHARES, NOR THE WARRANT NOR THE WARRANT SHARES HAVE BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION, ANY STATE SECURITIES COMMISSION OR ANY OTHER REGULATORY AUTHORITY, NOR HAVE ANY OF THE FOREGOING AUTHORITIES PASSED UPON OR ENDORSED THE MERITS OF THIS OFFERING OR THE ACCURACY OR ADEQUACY OF THE SEC REPORTS. ANY REPRESENTATION TO THE CONTRARY IS UNLAWFUL.

2.15 The Holder represents and warrants that no commission or other remuneration has been or will be given, directly or indirectly, by the Holder in connection with the Exchange Offer.

2.16 The Holder represents and warrants that the officers, directors, trustees, managers and other controlling parties of the Holder, if any, have not adopted any resolutions relative to the distribution of any of the Exchange Securities to its shareholders, members or beneficiaries and they have no present intention to do so.

2.17 The Holder represents and warrants that any information which the Holder has heretofore furnished or furnishes herewith to the Company is complete and accurate and may be relied upon by the Company.

2.18 The Holder represents and warrant that it does not control, and it is not controlled by, any officer, director, employee or consultant of the Company and that it has determined to accept the Exchange Offer knowingly and voluntarily and without any coercion or direction on the part of any person.

#### 3. Representations by the Company.

The Company represents and warrants to the Holder as follows:

3.1 The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware with full power and authority to carry on its business as now conducted.

3.2 The Company has the power and authority to execute and deliver this Agreement and to carry out its obligations hereunder. The execution, delivery and performance by the Company of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all necessary action on the part of the Company and this Agreement constitutes the valid and legally binding obligation of the Company enforceable against the Company in accordance with its terms, except as the same may be limited by bankruptcy, insolvency, reorganization or other laws affecting the enforcement of creditors' rights generally now or hereafter in effect and subject to the application of equitable principles and the availability of equitable remedies.

3.3 The execution, delivery and performance of this Agreement do not and will not, with the giving of notice or the passage of time or both, violate or result in a breach or termination of any provision of, or constitute a default under, the certificate of incorporation or by-laws of the Company or any order, judgment, decree, statute, regulation, contract, agreement or any other restriction of any kind or description to which the Company or its assets may be bound or subject.

#### 4. Miscellaneous.

4.1 Any notice or other communication given hereunder shall be deemed sufficient if in writing and hand delivered or sent by certified mail (return receipt requested, postage prepaid), or overnight mail or courier, addressed as follows:

To the Company:

40 Marcus Drive, Suite One Melville, New York 11747 Attn: Chief Executive Officer

With a copy to:

Certilman Balin Adler & Hyman, LLP 90 Merrick Avenue East Meadow, New York 11554 Attn: Fred Skolnik, Esq.

To the Holder: at its address indicated on the signature page of this Agreement

or to such other address as to which either party shall notify the other in accordance with the provisions hereof. Notices shall be deemed to have been given on the date of mailing, except notices of change of address, which shall be deemed to have been given when received.

4.2 This Agreement shall not be charged, modified or amended except by a writing signed by the party to be charged, and this Agreement may not be discharged except by performance in accordance with its terms or by a writing signed by the party to be charged.

4.3 This Agreement shall be binding upon and inure to the benefit of the parties hereto and to their respective successors, assigns and legal representatives. This Agreement sets forth the entire agreement and understanding between the parties as to the subject matter thereof and merges and supersedes all prior discussions, agreements and understandings of any and every nature between them.

4.4 This Agreement and its validity, construction and performance shall be governed in all respects by the laws of the State of New York, applicable to agreements to be performed wholly within the State of New York. The Company and the Holder hereby irrevocably consent and submit to the exclusive jurisdiction of any federal or state court located within Nassau County or Suffolk County, New York over any dispute arising out of or relating to this Agreement and each party hereby irrevocably agrees that all claims in respect of such dispute or any legal action related thereto may be heard and determined in such courts. Each of the Company and the Holder hereby irrevocably waives, to the fullest extent permitted by applicable law, any objection that it may now or hereafter have to the laying of venue of any such dispute brought in such court or any defense of inconvenient forum for the maintenance of such dispute.

4.5 The headings in this Agreement are inserted only as a matter of convenience, and in no way define, limit, extend or interpret the scope of this Agreement or of any particular section.

4.6 All references to the neuter gender herein shall likewise apply to the masculine or feminine gender as and where applicable, and vice-versa.

4.7 This Agreement may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall constitute one instrument. Signatures transmitted herein via facsimile or other electronic image shall be deemed original signatures. Upon the execution and delivery of this Agreement by the Holder, this Agreement shall become the binding obligation of the Holder with respect to the acquisition of the Exchange Securities as herein provided.

4.8 Only upon written approval and acceptance of this Agreement by the Company shall the Company be obligated hereunder.

4.9 The Holder acknowledges that it has been represented by counsel, or afforded the opportunity to be represented by counsel, in connection with this Agreement. Accordingly, any rule of law or any legal decision that would require the interpretation of any claimed ambiguities in this Agreement against the party that drafted it has no application and is expressly waived by the Holder. The provisions of this Agreement shall be interpreted in a reasonable manner to give effect to the intent of the parties hereto.

[Remainder of page intentionally left blank. Signature page follows.]

#### **BIORESTORATIVE THERAPIES, INC.**

## EXCHANGE AGREEMENT

#### <u>Accredited Investor Certification</u> (Initial the appropriate box(es))

The Holder represents and warrants that it, he or she is an "accredited investor" based upon the satisfaction of one or more of the following criteria:

- (1) he or she is a natural person who has a net worth or joint net worth with his or her spouse in excess of \$1,000,000 at the date hereof<sup>1</sup>; or
- (2) he or she is a natural person who had an individual income in excess of \$200,000 in each of the two most recent years or a joint income with his or her spouse in excess of \$300,000 in each of those years and has a reasonable expectation of reaching the same income level in the current year; or
- (3) he or she is a director or executive officer of the Company; or

(4) it is either (a) a bank as defined in Section 3(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), or a savings and loan association or other institution as defined in Section 3(a)(5)(A) of the Securities Act, whether acting in its individual or fiduciary capacity, (b) a broker or dealer registered pursuant to Section 15 of the Securities Exchange Act of 1934, (c) an insurance company as defined in Section 2(13) of the Securities Act, (d) an investment company registered under the Investment Company Act of 1940 or a business development company as defined in Section 2(a)(48) of such act, (e) a small business investment company licensed by the United States Small Business Administration under Section 301(c) or (d) of the Small Business Investment Act of 1958, (f) a plan established and maintained by a state or its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of \$5,000,000 or (g) an employee benefit plan within the meaning of Title I of the Employee Retirement Income Security Act of 1974, if the determination to accept the Exchange Offer is made by a plan fiduciary, as defined in Section 3(21) of such act, which plan fiduciary is a bank, savings and loan association, an insurance company or a registered investment advisor, or if the employee benefit plan has total assets in excess of \$5,000,000 or, if a self-directed plan, with the determination to accept the Exchange Offer made solely by persons who otherwise meet these suitability standards; or

(ii) Indebtedness that is secured by the Holder's primary residence, up to the estimated fair market value of the primary residence at the date hereof, shall not be included as a liability (except that if the amount of such indebtedness outstanding at the date hereof exceeds the amount outstanding 60 days before the date hereof, other than as a result of the acquisition of the primary residence, the amount of such excess shall be included as a liability); and

(iii) Indebtedness that is secured by the Holder's primary residence in excess of the estimated fair market value of the primary residence at the date hereof shall be included as a liability.

<sup>&</sup>lt;sup>1</sup> For purposes of calculating net worth:

<sup>(</sup>i) The Holder's primary residence shall not be included as an asset;

- (5) it is a private business development company as defined in Section 202(a)(22) of the Investment Advisers Act of 1940; or
- (6) it is an organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, a corporation, a Massachusetts or similar business trust or a partnership not formed for the specific purpose of acquiring the Exchange Securities offered hereby, with total assets in excess of \$5,000,000; or
- (7) it is a trust, with total assets in excess of \$5,000,000, not formed for the specific purpose of acquiring the Exchange Securities, whose determination to accept the Exchange Offer is directed by a sophisticated person who has such knowledge and experience in financial and business matters that he or she is capable of evaluating the merits and risks of the acquisition of the Exchange Securities; or
- (8) it is a corporation, partnership or other entity, and each and every equity owner of such entity initials a separate Accredited Investor Certification pursuant to which it, he or she certifies that it, he or she meets the qualifications set forth in either (1), (2), (3), (4), (5), (6) or (7) above.

#### If the Holder is an INDIVIDUAL, or if the Exchange Securities are being acquired as JOINT TENANTS, as TENANTS IN COMMON, or as COMMUNITY PROPERTY:

# If the Holder is a PARTNERSHIP, CORPORATION, LIMITED LIABILITY COMPANY or TRUST:

Harvey P. Alstodt and Melody Alstodt	
Name(s) of Holder	Name of Holder
	By:
Signature of Holder	Signature of Authorized Representative
Signature, if jointly held	Name and Title of Authorized Representative
August 8, 2019	
Date	Date

## **BIORESTORATIVE THERAPIES, INC.**

By:

Mark Weinreb President and Chief Executive Officer

If the Holder is an INDIVIDUAL, or if the Exchange Securities are being acquired as JOINT TENANTS, as TENANTS IN COMMON, or as COMMUNITY PROPERTY:

Harvey P. Alstodt and Melody Alstodt	###-##-##### / ###-##-#####	
Print Name(s)	Social Security Number	
	224 Grande Pointe Drive	
	Palm Beach Gardens, FL 33418	
Signature(s)	Address(es)	
	August 8, 2019	
	Date	

## If the Holder is a PARTNERSHIP, CORPORATION, LIMITED LIABILITY COMPANY or TRUST:

Name of Partnership, Corporation Limited Liability Company or Trust	Type of Entity
By: Name: Title:	Federal Taxpayer Identification Number
	Address
	State of Organization
	Date

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of BioRestorative Therapies, Inc. (the "Company") on Amendment No. 1 to Form S-1 (File No. 333-231079) of our report, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, dated March 29, 2019 with respect to our audits of the consolidated financial statements of BioRestorative Therapies, Inc. and Subsidiary as of December 31, 2018 and 2017 and for each of the two years in the period ended December 31, 2018, which report appears in the Prospectus, which is part of this Registration Statement. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus.

/s/ Marcum LLP

Marcum LLP New York, NY September 6, 2019