

BioRestorative Therapies, Inc.  
Form S-1  
April 26, 2019

**As filed with the Securities and Exchange Commission on April 26, 2019**

**Registration No. 333-**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM S-1**

**REGISTRATION STATEMENT**

***UNDER***

***THE SECURITIES ACT OF 1933***

**BIORESTORATIVE THERAPIES, INC.**

**(Exact name of registrant as specified in its charter)**

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

**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)**

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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. [ ]

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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 ☒ Smaller reporting company ☒  
Emerging growth company ☒

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

## Calculation of Registration Fee

Title of Each Class of Securities to be Registered	<b>Proposed Maximum Aggregate Offering Price</b> <sup>(1)</sup>	Amount of Registration Fee
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)	\$ 19,550,000	\$ 2,369.46
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 Warrants to purchase Common Stock (3)	\$ -	\$ -
Shares of Common Stock issuable upon exercise of the Warrants (4)(5)	\$	\$
Shares of Common Stock issuable upon exercise of Underwriter Warrants (5)(6)	\$	\$
<b>TOTAL REGISTRATION FEE</b>	<b>\$ 19,550,000</b>	<b>\$ 2,369.46</b>

(1)

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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.

- In accordance with Rule 457(g) under the Securities Act, because the shares of the registrant's common stock  
(3) underlying the Warrants and Underwriter Warrants are registered hereby, no separate registration fee is required with respect to the warrants registered hereby.

- There will be issued                warrants to purchase                share[s] of common stock for every                share[s] of  
(4) common stock offered. The warrants are exercisable at a per share price of % of the common stock public offering price.

- (5) Includes shares of common stock which may be issued upon exercise of additional warrants which may be issued upon exercise of 45-day option granted to the underwriters to cover over-allotment, if any.

- 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  
(6) 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 Warrants is \$ , which is equal to 125% of \$ ( % of \$ ).

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

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

*The information in this 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 \_\_\_\_\_, 2019**

Units

Each Unit Consisting of

One Share of Common Stock (par value \$0.001)

and

One Warrant to Purchase      Share of Common Stock

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

Our common stock is presently traded on the 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. No assurance can be given that our application will be approved. On April 19, 2019, the last reported sales price for our common stock as quoted on the OTCQB market was \$0.65 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 or before this offering.

**IN REVIEWING THIS PROSPECTUS, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DESCRIBED IN THE SECTION TITLED “RISK FACTORS” BEGINNING ON PAGE 10 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.**

	<b>Per Unit</b>	<b>Total</b>
Public offering price	\$	\$
Underwriting discounts (1)	\$	\$
Proceeds to us before offering expenses (2)	\$	\$

Does not reflect additional compensation to the underwriters in the form of warrants to purchase up to \_\_\_\_\_ shares of common stock (assuming the underwriters’ over-allotment 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. See “Underwriting” on page 115 of this prospectus for a description of these arrangements.

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

We have granted the underwriters a 45-day option to purchase up to \_\_\_\_\_ additional Units at the initial public offering price less applicable underwriting discounts. See “Underwriting” on page 115 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**



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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 ™ 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 10 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 reflect 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 or before this offering.*

## What We Do

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

***Disc/Spine Program (brtxDisc).*** Our lead cell therapy candidate, *BRTX-100*, is a product formulated from autologous (or a person’s own) cultured mesenchymal stem cells, or MSCs, collected from the patient’s bone marrow. We intend that the product will be used for the non-surgical treatment of painful lumbosacral disc disorders. 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, or 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 third 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, or BADSC, to generate brown adipose tissue, or BAT. We refer to this as our *ThermoStem Program*. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning, as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. 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 \$39,000,000 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, or IRB, approved human studies were undertaken with regard to our licensed culturing technology with success rates and no known adverse results.

We have assembled a management team with significant 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.

In February 2017, we obtained authorization from the FDA to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease.

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

#### ***Metabolic Program (ThermoStem)***

We established a relationship with Pfizer with regard to a joint study of the development and validation of a human brown adipose (fat) cell model.



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 10 of this prospectus.

## Listing on the Nasdaq Capital Market

We have applied to list our common stock and warrants on The NASDAQ Capital Market, or NASDAQ, under the symbols “BRTX” and “BRTXW,” respectively. If our listing application is approved, we expect to list our common stock and warrants on NASDAQ upon consummation of this offering, at which point our common stock will cease to be traded on the OTCQB market, or 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.

## Corporate Information

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

## Summary of the Offering

Securities Offered:	Units, each Unit consisting of one share of our common stock and one warrant to purchase share of our common stock. Each warrant will have an exercise price of \$ per share (            % of the public offering price of each Unit), will be exercisable immediately and will expire        years from the date of issuance.
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Common Stock Outstanding prior to the Offering:	15,192,967 shares
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Number of Shares:

Number of Warrants:

Warrant Exercise Price:	\$            per share (        % of the public offering price of each Unit)
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Common Stock to be Outstanding after the Offering: shares, excluding the possible sale of over-allotment Units, if any. The number of shares of our common stock to be outstanding after the completion of this offering is based on 15,192,967 shares of our common stock outstanding as of April 15, 2019, and excludes the following:

4,750,868 shares of common stock (net of cancellations) issuable upon the exercise of outstanding options granted under our 2010 Equity Participation Plan, or the Plan, as of April 15, 2019, with a weighted average exercise price per share of \$1.04;

5,204,132 shares of common stock that are available for future issuance under the Plan as of April 15, 2019;

4,601,841 shares of common stock issuable upon the exercise of outstanding warrants as of April 15, 2019, with a weighted average exercise price per share of \$2.92;

9,338,617 shares of common stock issuable upon the conversion of outstanding convertible promissory notes as of April 15, 2019, with a weighted average conversion price per share of \$1.04, plus an indeterminate number of shares of common stock issuable upon the conversion of outstanding convertible promissory notes that provide for conversion prices based upon the market value of our common stock at the time of conversion;

shares of common stock issuable upon the exercise of the warrants issued pursuant to this offering; and

a contemplated reverse split of our common stock at a ratio of not less than 1-for-2 and not more than 1-for-20 to be effective concurrently with or before this offering.

Underwriters'  
Over-Allotment  
Option:

The underwriting agreement provides that we will grant to the underwriters an option, exercisable within 45 days after the 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 \$ from our sale of Units in this offering, after deducting underwriting discounts and estimated offering expenses payable by us. We intend to use the net proceeds of this offering as follows: undertaking of clinical trials with respect to *BRTX-100* and its related collection and delivery procedure; pre-clinical research and development with respect to our *ThermoStem Program*; 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: \$ per Unit.

Trading Symbol: Our common stock is presently quoted on the OTCQB 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 10 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. See “Underwriting” on page 115.

## Summary Financial Data

The following table sets forth summary consolidated financial data of BioRestorative Therapies, Inc. 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 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)
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

December 31,  
2018                      2017

Balance Sheet Data:

Cash	\$ 117,523	\$ 451,680
Working capital deficiency	\$(9,073,901)	\$(7,833,592)
Total assets	\$ 1,192,381	\$ 1,758,607
Total liabilities	\$ 9,833,419	\$ 8,595,175
Total stockholders' deficiency	\$(8,641,038)	\$(6,836,568)

## 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 December 31, 2018, we had a working capital deficiency of \$9,073,901 and stockholders' deficiency of \$8,641,038. 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 \$23,000,000). 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 December 31, 2018, our outstanding debt of \$5,161,916, together with interest at rates ranging up to 15% per annum, are due on various dates through December 2019. Subsequent to December 31, 2018, we have received aggregate equity financing and debt financing of \$656,000 and \$3,802,198, respectively, debt (inclusive of accrued interest) of \$1,081,128 has been exchanged for common stock, \$2,149,205 of debt (inclusive of accrued interest and prepayment premiums) has been repaid, and the due date for the repayment of \$155,000 of debt has been extended to December 2019. Giving effect to the above actions, we currently have notes payable in the aggregate principal amount of \$143,528 which are past due. As of the date of this prospectus, the outstanding balance of our debt of \$6,316,542, together with accrued interest, was due and payable either on demand or on various dates through March 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, we will not be able to repay such 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 May 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 \$143,528 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 develop expertise as needed would have a substantial negative effect on our results of operations and financial condition.

**Risks Related to Our Cell Therapy Product Development Efforts**

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

We are dependent upon the successful development, approval and commercialization of our product candidates. Before we are able to seek regulatory approval of our product candidates, we must conduct and complete extensive clinical trials to demonstrate their safety and efficacy in humans. Our lead product candidate, *BRTX-100*, is in early stages of development and we only recently received Food and Drug Administration, or 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, or IRB, approval at each clinical study site;

imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors or approved products post-market for related technology that raise FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

difficulty collaborating with patient groups and investigators;

failure by our CROs, other third parties, or us to adhere to clinical study requirements;

failure to perform in accordance with the FDA's current Good Clinical Practices, or GCP, requirements, or applicable regulatory guidelines in other countries;



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

patients dropping out of a study;

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

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

transfer of manufacturing processes from any academic collaborators to larger-scale facilities operated by either a contract manufacturing organization, or CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;

delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing;

the FDA may not accept clinical data from trials that are conducted at clinical sites in countries where the standard of care is potentially different from the United States; and  
failure to raise sufficient funds to complete our clinical trials.

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

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

obtain approval for indications that are not as broad as the indications we sought;

have the product removed from the market after obtaining marketing approval;

encounter issues with respect to the manufacturing of commercial supplies;

be subject to additional post-marketing testing requirements; and/or

be subject to restrictions on how the product is distributed or used.

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

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

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

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

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

We have not commenced the clinical trials necessary to obtain FDA approval to market our product candidate, *BRTX-100*, or any of our other product candidates in development. Since 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 regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, contraindications or a Risk Evaluation and Mitigation Strategy, or REMS. These regulatory authorities may require warnings or precautions with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims or allow the promotional claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations and prospects.



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

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

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

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

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



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

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

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

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

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

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

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

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

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

Pursuant to our license agreement with Regenerative Sciences, LLC, we must complete our Phase 2 clinical trial by a certain date (which we believe to be February 2022) in order to maintain our exclusive rights with regard to the disc/spine technology. 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 similar to ours or which perform similar functions or which are marketed before ours.

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

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

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

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

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

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

collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their

strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;

collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;

a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;

collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and

collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

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

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



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

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

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

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

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

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

significantly impaired.

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

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

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

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

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

We intend to market our products and services both domestically and in foreign markets. A number of risks are inherent in international transactions. In order for us to market our products and services in non-U.S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances in these countries and must comply with the country specific regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International

operations and sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our services and products by increasing the price of our products and services in the currency of the countries in which the products and services are offered.

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

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

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

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

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

**Risks Related to Our Intellectual Property**

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

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

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

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

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

services, which could adversely affect our business and results of operations.

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

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

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

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

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



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

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

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

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

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



**Risks Related to Government Regulation**

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

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

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

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

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

seize or detain the product or otherwise demand or require the withdrawal or recall of the product from the market;

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

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

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

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

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

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

issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert the attention of our management from operating our business.

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

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

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

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

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

laws and regulations enforced by the FDA, the EU and comparable foreign authorities for all of our product candidates in clinical development.



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

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

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

To date, we have not received regulatory approval to market any of our product candidates in any jurisdiction. If we seek approval of any of our cell therapy product candidates, we will be required to submit to the FDA and potentially other regulatory authorities extensive pre-clinical and clinical data supporting its safety and efficacy, as well as information about the manufacturing process and to undergo inspection of our manufacturing facility or other contract manufacturing facilities, 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. 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 European Union, or 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 maintain a continuous two-sided market, are required to honor firm quotations for only a limited number of securities, and are free to withdraw firm quotations at any time. Even with a market maker, factors such as our past losses from operations and the small size of our company mean that there can be no assurance of an active and liquid market for our securities developing in the foreseeable future. Even if 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, or Rule 144, and, as such, sales of our securities pursuant to Rule 144 cannot be made unless, among other things, we continue to remain subject to Section 13 or 15(d) of the Exchange Act, and we file all of our required periodic reports with the SEC under the Exchange Act. Because our unregistered securities cannot be sold pursuant to Rule 144 unless we continue to meet such requirements, any unregistered securities we sell in the future or issue to consultants or employees, in consideration for services rendered or for any other purpose, will have no liquidity unless we continue to comply with such requirements. As a result, it may be more difficult for us to obtain financing to fund our operations and pay our consultants and employees with our securities instead of cash.

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

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

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

The market price of our common stock and warrants may be subject to significant fluctuations and be highly volatile, which may make it difficult for a securityholder to resell our securities at the volume, prices and times the securityholder finds attractive. There are many factors that will impact our stock and warrant prices and trading volume, including, but not limited to, the factors listed above under “Risks Related to Our Business Generally,” “Risks Related to Our Cell Therapy Product Development Efforts,” “Risks Related to Our Intellectual Property,” “Risks Related to Government Regulation,” “Risks Related to this Offering and Our Common Stock and Warrants” and “Risks Associated with Our Contemplated Reverse Stock Split and NASDAQ listing.”

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



securities.

***There may be 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 10,000,000 shares of our common stock issuable under our 2010 Equity Participation Plan, or the Plan. As of April 15, 2019, options to purchase 4,750,868 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 5,204,132 shares were reserved for future grants under the Plan. Our Board of Directors has approved an increase in the number of shares of our common stock issuable pursuant to the Plan to 20,000,000, subject to stockholder approval. In the event of stockholder approval, we intend to register the additional shares of common stock authorized to be issued pursuant to the Plan on a registration statement on Form S-8. 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 equity-related securities that are senior to our common stock in the future for a number of reasons, including, without limitation, to support operations and growth, and to comply with any future changes in regulatory standards.

***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 April 15, 2019, Dale Broadrick beneficially owned 3,161,452 shares of our common stock (including 1,000,000 shares of our common stock issuable pursuant to a currently exercisable warrant), representing 19.5% of the outstanding shares of our common stock. In addition, as of April 15, 2019, John M. Desmarais, one of our directors, beneficially owned 2,029,574 shares of our common stock (including 1,536,176 shares of our common stock issuable

pursuant to currently exercisable options and warrants), representing 12.1% of the outstanding shares of our common stock. Further, as of April 15, 2019, SCG Capital, LLC, or SCG, and Steven Geduld beneficially owned 1,600,798 shares of common stock (including 831,041 shares of our common stock issuable pursuant to currently exercisable warrants and a currently convertible note), representing 9.99% of the outstanding shares of our common stock. Moreover, as of April 15, 2019, Westbury (Bermuda), Ltd., or 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 7.5% of the outstanding shares of our common stock.

Mr. Broadrick, Mr. Desmarais, SCG/Mr. Geduld and Westbury, through their beneficial ownership of our common stock, 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/Mr. Geduld and Westbury 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 \$6,316,542. 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, or 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 \$ per share, based on the assumed public offering price of \$ per Unit. Investors in this offering will pay a price per share that substantially exceeds the book value of our assets after subtracting our liabilities. See “Dilution” for a more complete description of how the value of your investment will be diluted upon the completion of this offering.

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

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

***Warrants are speculative in nature.***

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

***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 scheduled to be held on May 30, 2019, in addition to seeking stockholder approval of a reverse stock split at a ratio of not less than 1-for-2 and not more than 1-for-20, we will be proposing, among other things, that the stockholders approve 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. In addition, we will be seeking stockholder approval (in the event the reverse stock split proposal is approved) 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, we will, in effect, have additional shares of common stock available for issuance. Any such issuance of shares would result in a dilution of the percentage ownership of existing stockholders.

## **USE OF PROCEEDS**

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

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

undertaking of clinical trials with respect to *BRTX-100* and its related collection and delivery procedure;  
pre-clinical research and development with respect to our *ThermoStem Program*;

repayment of indebtedness (as of the date of this prospectus, our outstanding debt was \$[       ], and such debt is repayable, with interest at rates ranging up to 15% per annum, on various dates through March 2020); and general corporate and working capital purposes.

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

**CAPITALIZATION**

The following table sets forth our consolidated capitalization as of December 31, 2018 (i) on an actual basis, and (ii) as adjusted to give effect to the offering at the assumed public offering price of \$        per Unit, for total net proceeds of approximately \$        (assuming no exercise of the underwriters' over-allotment option).

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

	At December 31, 2018	
	Actual	As Adjusted
Non-Current Liabilities	\$578,531	\$
Stockholders' (Deficiency) Equity		
Preferred stock, \$0.01 par value; 20,000,000 shares authorized, -0- shares issued and outstanding before the offering and on an as adjusted basis	\$-	\$ -
Common stock, \$0.001 par value; 75,000,000 shares authorized; 11,728,394 shares issued and outstanding before the offering; shares issued and outstanding, as adjusted	11,728	
Additional paid-in capital	55,269,490	
Accumulated deficit	(63,922,256)	
Total stockholders' deficiency	(8,641,038 )	
Total capitalization	\$(8,062,507 )	\$

**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 December 31, 2018, we had a net tangible book value of (\$9,455,097), or (\$0.81) per share. 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 on the date the book value is determined. 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 on the date the tangible book value is determined. After giving effect to the sale of Units offered by us in this offering at an assumed offering price of \$ per Unit and the application of the estimated net proceeds from this offering, our pro forma as adjusted net tangible book value as of December 31, 2018 would have been \$ or \$ per share. This represents an immediate increase in net tangible book value to existing stockholders of \$ per share and an immediate dilution to new investors of \$ per share. The following table illustrates this per share dilution to new investors purchasing Units in this offering.

Assumed offering price per Unit	\$
Net tangible book value per share as of December 31, 2018	(0.81)
Increase per share attributable to new investors	
Pro forma, as adjusted, net tangible book value per share after the offering	
Dilution per share to new investors	\$

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

The following table sets forth on an unaudited pro forma as adjusted basis, as of December 31, 2018, the difference between the total consideration paid and the average price per share paid by existing stockholders and by the new investors purchasing Units in this offering, before deducting underwriting discounts and estimated offering expenses payable by us:

Shares Purchased	Total Consideration	Average
---------------------	------------------------	---------

	Number	Percent	Amount (in thousands)	Percent	Price Per Share
Existing stockholders		%	\$	%	\$
New investors		%	\$	%	\$
Totals		100 %	\$	100 %	\$

The above discussion and table is based on 11,728,394 shares of common stock outstanding as of December 31, 2018, does not reflect the potential sale of up to additional shares of our common stock which may be purchased in this offering at the discretion of the underwriters pursuant to their over-allotment option, and excludes:

2,952,460 shares of common stock issuable upon the exercise of stock options that were exercisable as of December 31, 2018 at a weighted-average exercise price of \$4.03 per share;

3,483,403 shares of common stock issuable upon the exercise of warrants to purchase common stock that were exercisable as of December 31, 2018 at a weighted average exercise price of \$3.63 per share;

5,251,215 shares available for future issuance as of December 31, 2018 under the Plan; and

9,200,062 shares of common stock issuable upon the conversion of convertible notes that were convertible as of December 31, 2018 at a weighted average conversion price of \$0.89 per share.

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

## **SELECTED FINANCIAL DATA**

The following table sets forth selected consolidated financial data of BioRestorative Therapies, Inc. The financial data as of 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 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)
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

December 31,  
2018      **2017**

Balance Sheet Data:

Cash	\$117,523	\$451,680
Working capital deficiency	\$(9,073,901)	\$(7,833,592)
Total assets	\$1,192,381	\$1,758,607
Total liabilities	\$9,833,419	\$8,595,175
Total stockholders' deficiency	\$(8,641,038)	\$(6,836,568)

**DETERMINATION OF OFFERING PRICE**

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;
- 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 April 15, 2019, there were 304 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 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 Analysis of Financial Condition and Results of Operations" may not occur. Generally, these statements relate to business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions to be made by us, or projections involving anticipated revenues, earnings or other aspects of our operating results. The words "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 10 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 third 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 April 2017, and a Japanese patent related to the *ThermoStem Program* was issued in December 2017.

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

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

As of December 31, 2018, our accumulated deficit was \$63,922,256, our stockholders' deficiency was \$8,641,038 and our working capital deficiency was \$9,073,901. 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 December 31, 2018, and our forecast for continued operating losses, we require equity and/or debt financing to continue our operations. As of December 31, 2018, our outstanding debt of \$5,161,916 together with interest at rates ranging up to 15% per annum, was due on various dates through December 2019. Subsequent to December 31, 2018, we have received aggregate equity financing and debt financing of \$656,000 and \$3,802,198, respectively, debt (inclusive of accrued interest) of \$1,081,128 has been exchanged for common stock, \$2,149,205 of debt (inclusive of accrued interest and prepayment premiums) has been repaid, and the due date for the repayment of an aggregate of \$155,000 of debt has been extended to December 2019. Giving effect to the above actions, we currently have notes payable in the aggregate principal amount of \$143,528 which are past due. Based upon our working capital deficiency and outstanding debt, prior to the receipt of any proceeds of this offering, we expect to be able to fund our operations through May 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* (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*. 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.

**Consolidated Results of Operations*****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,	
	2018	2017
Cash	\$ 117,523	\$ 451,680

Working Capital Deficiency \$(9,073,901) \$(7,833,592)

Notes Payable (Gross) \$5,161,916 \$3,999,335

***Availability of Additional Funds***

Based upon our working capital and stockholders' deficiencies of \$9,073,901 and \$8,641,038, respectively, as of December 31, 2018, 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 one year after the issuance date of our audited financial statements as of December 31, 2018 and 2017 and for the years then ended, which are included elsewhere in this prospectus under "Index to Financial Statements."

As of December 31, 2018, our outstanding debt of \$5,161,916, together with interest at rates ranging up to 15% per annum, was due on various dates through December 2019. Subsequent to December 31, 2018, we have received aggregate equity financing and debt financing of \$656,000 and \$3,802,198 respectively, debt (inclusive of accrued interest) of \$1,081,128 has been exchanged for common stock, \$2,149,205 of debt (inclusive of accrued interest and prepayment premiums) has been repaid, and the due date for the repayment of an aggregate of \$155,000 of debt has been extended to December 2019. Giving effect to the above actions, we currently have notes payable in the aggregate principal amount of \$143,528 which are past due. As of the date of this prospectus, our outstanding debt was as follows:

Maturity Date	Principal Amount
Past Due	\$143,528
QE 6/30/19	450,000
QE 9/30/19	1,865,000
QE 12/31/19	2,365,000
QE 3/31/20	1,493,014
	\$6,316,542

Based upon our working capital deficiency, outstanding debt and forecast for continued operating losses, prior to the receipt of the proceeds of this offering, we expect that the cash we currently have available will fund our operations through May 2019 while we continue to apply efforts to raise additional capital. 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 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 year ended December 31, 2018, our sources and uses of cash were as follows:

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

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, primarily as a result of increases in accrued interest, expenses and other current 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 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 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 consolidated financial statements for the year ended December 31, 2018.

## 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 10 provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Readers should be aware that the occurrence of any of the events described in these risk factors could have a material adverse effect on our business, results of operations and financial condition. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events, or otherwise.

## BUSINESS

### General

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

***Disc/Spine Program (brtxDisc).*** Our lead cell therapy candidate, *BRTX-100*, is a product formulated from autologous (or a person’s own) cultured mesenchymal stem cells, or MSCs, collected from the patient’s bone marrow. We intend that the product will be used for the non-surgical treatment of painful

lumbosacral disc disorders. 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, or 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 third 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, or BADSC, to generate brown adipose tissue, or BAT. We refer to this as our *ThermoStem Program*. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning, as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. 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 two 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, or 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 (\$5,161,916 as of December 31, 2018) (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 funding are correct or that we will be able to accomplish our goals within the timeframes projected. In addition, no assurance can be given that we will be able to obtain any required financing on commercially reasonable terms or otherwise. We may also seek to have our debtholders convert all or a portion of their debt into equity. No assurance can be given that we will be able to convert

such debt into equity on commercially reasonable terms or otherwise. If we are unable to obtain adequate funding, we may be required to significantly curtail or discontinue our proposed operations. 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 obligations.”

## *Disc/Spine Program*

### *General*

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

Lower back pain is the most common, most disabling, and most costly musculoskeletal ailment faced worldwide. According to a recent market report, there are nearly 25 million people in the United States with chronic lower back pain of which approximately 5 million have pain caused by a protruding or injured disc. We believe that between 500,000 and 1 million of these back pain sufferers will have an invasive surgical procedure to try to alleviate the pain associated with these lower back conditions. 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 and costly (often altering the spine’s biomechanics unfavorably and predisposing it to further disc degeneration) and are associated with unacceptably low success rates.

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 third 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 carrier. We have designed the cryopreserved sterile cellular product candidate to be provided in vials for injection into painful lumbar discs. We anticipate the product candidate will be delivered using a standard 20 gauge 3.5 inch introducer needle and a 25 gauge 6 inch needle that will extend into the disc center upon delivery. Upon regulatory approval, we plan to provide training to medical practitioners with regard to the approved injection procedure. It is anticipated that the delivery of the product candidate will be a 30 minute procedure.

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

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



### *Production and Delivery*

The production of our product candidate, *BRTX-100*, begins with the physician collecting bone marrow from the patient under local anesthesia. Peripheral blood is also collected from the patient. The physician will then send the patient's bone marrow and blood samples to our laboratory (or a contract laboratory) for culturing and formulation. The hypoxic culturing process 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, or Regenerative, that became effective in April 2012 or the Regenerative License Agreement, we have obtained, among other things, a worldwide (excluding Asia and Argentina), exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain method for culturing cells for use in our developmental program involving disc and spine conditions, including protruding or painful discs. 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.

### *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 third 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

72 patients; randomized 2:1, *BRTX-100* to control  
10-20 clinical trial sites  
Primary efficacy endpoint at 12 months  
Patient safety and efficacy follow up at 24 months

##### 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

Quality of life assessment  
Evolution of affected disc(s) by magnetic resonance imaging (MRI)

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, or KOLs (i.e., orthopedic surgeons specializing in back and spine surgery with experience in stem cell therapy), who, upon studying applicable clinical material, could offer opinions regarding the future therapeutic potential of *BRTX-100*.

As noted in the Defined Health report, the KOLs 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.

### **Metabolic Brown Adipose (Fat) Program**

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

Brown fat is a specialized adipose (fat) tissue found in the human body that plays a key role in the evolutionarily conserved mechanisms underlying thermogenesis (generation of non-shivering body heat) and energy homeostasis in mammals - long known to be present at high levels in hibernating mammals and human newborns. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of healthy metabolism, thus potentially being involved in caloric regulation. The pre-clinical *ThermoStem Program* involves the use of a cell-based (brown adipose tissue construct) treatment for metabolic disease, such as type 2 diabetes, obesity, hypertension and other metabolic disorders, as well as cardiac deficiencies. We have had initial success in transplanting the brown adipose tissue construct in animals, and we are currently exploring ways to deliver into humans. Even though present, BAT mass is very low in healthy adults and even lower in obese populations. Therefore, it may not be sufficient to either naturally impact whole body metabolism, or to be targeted by drugs intended to increase its activity in the majority of the population. Increasing BAT mass is crucial in order to benefit from its metabolic activity and this is what our *ThermoStem Program* seeks to accomplish. We may also

identify other naturally occurring biologics and chemically engineered molecules that may enhance brown adipose tissue performance and activity.

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

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

In order to deliver these differentiated cells into target locations *in vivo*, we seeded BADSCs onto 3-dimensional biological scaffolds. Pre-clinical animal models of diet-induced obesity, that were transplanted with differentiated BADSCs supported by a biological scaffold, presented significant reductions in weight and blood glucose levels compared to 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 treatment of obesity and related metabolic disorders.

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

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

In March 2014, we entered into a Research Agreement with Pfizer Inc., a global pharmaceutical company, or 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 second 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, or CND, that is a needle system with a curved inner cannula to allow access to difficult-to-locate regions for the delivery or removal of fluids and other substances. The investigational CND is intended to deliver stem cells and/or other therapeutic products or material to the interior of a human intervertebral disc, the spine region, or potentially other areas of the body. The device is designed to rely on the use of pre-curved nested cannulae that allow the cells or material to be deposited in the posterior and lateral aspects of the disc to which direct access is not possible due to outlying structures such as vertebra, spinal cord and spinal nerves. We anticipate that the use of the investigational CND will facilitate the delivery of substances, including living cells, to specific locations within the body and minimize the potential for damage to nearby structures. The investigational device may also have more general use applications. In August 2015, a United States patent for the CND was issued to the licensor, Regenerative. We anticipate that FDA approval or clearance will be necessary for the investigational CND prior to commercialization. We do not intend to utilize the CND in connection with our contemplated Phase 2 clinical trial with regard to *BRTX-100*. 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*, three 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 two applications remain pending.

In our *ThermoStem Program*, we have three pending United States patent applications within two patent families. We have been issued a United States patent in each of the two patent families. Patent applications with regard to the first patent family in the *ThermoStem Program* have been filed in five foreign jurisdictions (of which two applications have granted as foreign patents and one application has lapsed). Patent applications with regard to the second patent family in the *ThermoStem Program* have been filed in four foreign jurisdictions.

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

Program	I.D.	Jurisdiction	Title
<i>Disc/Spine</i> <i>(brtxDisc)</i>	13/132,840*	US	Methods and compositions to facilitate repair of avascular tissue
	15/891,852	US	Surgical methods and compositions to facilitate repair of avascular tissue
	U.S. Patent No. 9,113,950 B2**	US	Therapeutic delivery device
<i>Metabolic</i> <i>(ThermoStem)</i>	U.S. Patent No. 9,133,438	US	Brown fat cell compositions and methods
	13/932,468	US	
	15/910,625	US	

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AU Patent No. 2012275335	Australia	
12743811.7	Europe	
230237	Israel	
JP Patent No. 6243839	Japan	
U.S. Patent No. 10,167,449	US	Human brown adipose derived stem cells and uses
16/183,370	US	
2014253920	Australia	
14729769.1	Europe	
242150	Israel	
2016-509105	Japan	

\*Patent application filed by licensor, Regenerative Sciences, LLC

\*\*Patent issued to licensor, Regenerative Sciences, LLC

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

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. We conduct prior rights searches before launching any new product or service to put us in the best position to avoid claims of infringement.

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, Sanofi, Merck, Eli Lilly, Roche, Pfizer and Regeneron.

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

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



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

## **Customers**

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

## **Governmental Regulation**

### ***U.S. Government Regulation***

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

### ***FDA Regulation of Stem Cell Treatment and Products***

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

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

Under Section 361 of the PHSA, the FDA issued specific regulations governing the use of HCT/Ps in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations, or CFR, 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' use of cultured stem cells without FDA approval is in violation of the FDCA, claiming that the defendants' product is a drug. The defendants asserted that their procedure is part of the practice of medicine and therefore beyond the FDA's regulatory authority. The District Court ruled in favor of the FDA, and in February 2014 the Circuit Court affirmed the District Court's holding.

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

registration and listing of HCT/Ps with the FDA;

donor eligibility determinations, including donor screening and donor testing requirements;

current good tissue practices, specifically including requirements for the facilities, environmental controls, equipment, supplies and reagents, recovery of HCT/Ps from the patient, processing, storage, labeling and document controls, and distribution and shipment of the HCT/Ps to the laboratory, storage, or other facility;

tracking and traceability of HCT/Ps and equipment, supplies, and reagents used in the manufacture of HCT/Ps;

adverse event reporting;

FDA inspection; and

abiding by any FDA order of retention, recall, destruction, and cessation of manufacturing of HCT/Ps.

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

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

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

#### *Drug and Biological Product Regulation*

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

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

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

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

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

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

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

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

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

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

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

established quality control standards.

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

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

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

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

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

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





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

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

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

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

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production,

withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

### *FDA Expedited Review Programs*

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

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

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

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

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

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

approval pre-approval of promotional materials.

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

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

#### *Medical Device Regulation*

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

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

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



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

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

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

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

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

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

We may establish, or license technology to third parties in connection with their establishment of, adult stem cell therapy facilities outside the United States. We also intend to work with hospitals and physicians to make the stem



cell-based therapies available for patients who travel outside the United States for treatment. “Medical tourism” is defined as the practice of traveling across international borders to obtain health care.

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

### ***Federal Regulation of Clinical Laboratories***

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

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

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

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

effect, thus complicating compliance efforts. Further, we may need to also comply with additional federal or state privacy laws and regulations that may apply to certain diagnoses, such as HIV/AIDS, to the extent that they apply to us.

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

***Other Applicable U.S. Laws***

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

state and local licensure, registration, and regulation of the development of pharmaceuticals and biologics;

state and local licensure of medical professionals;

state statutes and regulations related to the corporate practice of medicine;

laws and regulations administered by U.S. Customs and Border Protection related to the importation of biological material into the United States;

other laws and regulations administered by the FDA;

other laws and regulations administered by HHS;

state and local laws and regulations governing human subject research and clinical trials;

the federal physician self-referral prohibition, also known as Stark Law, and any state equivalents to Stark Law;

the federal False Claims Act, or FCA;

the federal Anti-Kickback Statute, or AKS, and any state equivalent statutes and regulations;

federal and state coverage and reimbursement laws and regulations;

state and local laws and regulations for the disposal and handling of medical waste and biohazardous material;

Occupational Safety and Health Administration, or OSHA, regulations and requirements;

the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to “excess benefit transactions” with tax-exempt organizations;

the Physician Payments Sunshine Act (in the event that our products are classified as drugs, biologics, devices or medical supplies and are reimbursed by Medicare, Medicaid or the Children’s Health Insurance Program);

state and other federal laws addressing the privacy of health information; and

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

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

### ***Foreign Government Regulation***

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



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

## Offices

Our principal executive offices are located at 40 Marcus Drive, Melville, New York, and our telephone number is (631) 760-8100. Our website is [www.biorestorative.com](http://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	47	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	54	Director
Paul Jude Tonna	60	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 among 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 University of Pennsylvania and holds a Bachelor of Arts degree from Cornell University. We believe that Mr. Radov's executive-level management experience and his extensive experience in the finance industry give him the qualifications and skills to serve as one of our directors.

**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 Neurotrophe 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 as a forensic foundation in creating unique security solutions addressing the challenges of modern commerce. Dr. Ryan earned a doctorate in Oral Biology and Pathology 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 Chapter. Mr. Tonna is a founding director of Empire National Bank and 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.	Professor, Department of Cancer Immunology & AIDS, Dana-Farber Cancer Institute; Professor of Medicine, Harvard Medical School;
Chairman	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;

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Associate Professor, Neurosurgery and Radiology, George Washington University Medical Center;

Consulting Physician, Department of Radiology, National Institutes of Health



Joy Cavagnaro, Ph.D., DABT, RAC	President and Founder, Access BIO, L.C.; Fellow, Academy of Toxicological Sciences and the Regulatory Professional Society;  Formerly Senior Pharmacologist and Director of Quality Assurance, Food and Drug Administration's Center for Biologics Evaluation and Research
Jason Lipetz, M.D.	Founder, Long Island Spine Rehabilitation Medicine;
Chairman, Disc Advisory Committee	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 Plataras, M.D.	Clinical Director of Musculoskeletal Spine and Sports Rehabilitation Medicine and Physiatrist, MossRehab;  Formerly Director of The Penn Spine and Rehabilitation Center;  Formerly Director of Spine, Sports and Musculoskeletal Medicine Fellowship, University of Pennsylvania  Founder, Partner and Physiatrist, New Jersey Sports Medicine, LLC and New Jersey Regenerative Institute;
Gerard A. Malanga, M.D.	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	I	2021
John M. Desmarais	II	2019
A. Jeffrey Radov	III	2020
Charles S. Ryan	I	2021
Paul Jude Tonna	II	2019

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 Position	Year	Salary	Bonus (1)	Option Awards	All Other	Total
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				<b>Earned (2)</b>		<b>Compensation</b>	
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	2017	\$-	\$-	\$-	\$ -	\$-	
Development (8)							
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	\$-	\$-	\$-	\$ -	\$-	

- (1) Represents bonus amounts earned pursuant to the achievement of certain performance goals.

(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.

**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:

Name	Option Awards			Stock Awards			Equity incentive plan awards:		
	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options	Option exercise Price(1)	Option expiration date	Number of shares or units that have not vested	Market value of shares or 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	-	\$ -	-	\$ -

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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	-	\$ -	-	\$ -



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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 is 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.
- 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.
- (5)
  - (6) Option is exercisable on June 10, 2019.
  - (7) Option is exercisable to the extent of 26,667 shares on July 12, 2019 and 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 is exercisable on June 10, 2019.
  - (10) Option is exercisable to the extent of 13,333 shares on each of July 12, 2019 and 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	Fees Earned or Paid in Cash	Stock Awards	Option Awards (1)	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	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, or 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, or 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.

## Others

In August 2016, we borrowed \$100,000 from Robert B. Catell, one of our non-employee directors. The promissory note evidencing the loan, or 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 five-year 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 five-year 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. On February 8, 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 the event that, prior to the maturity date of the Catell 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. Catell has the right to require that we prepay the amount due under the Catell Note (subject to the consent of the party that provided the particular financing).

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 9.0% of our outstanding common stock as of April 15, 2019 (based on 15,192,967 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 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 April 15, 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).

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 15,192,967 shares of common stock outstanding as of April 15, 2019, and 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 additional shares of our common stock which may be issued in the event the underwriters exercise their over-allotment option).

Beneficial Owner	Number of Shares  Beneficially Owned	Approximate Percent of Class	
		Prior to the Offering	After the Offering <sup>(12)</sup>
Dale Broadrick 3003 Brick Church Pike Nashville, Tennessee	3,161,452 (1)	19.5 %	
John M. Desmarais 230 Park Avenue New York, New York	2,029,574 (2)	12.1 %	
SCG Capital, LLC Steven Geduld 21200 NE 38th Avenue Aventura, Florida	1,600,798 (3)	9.99 %	
Westbury (Bermuda) Ltd. Westbury Trust Victoria Hall 11 Victoria Street Hamilton, HMEX Bermuda	1,151,661 (4)	7.5 %	
Mark Weinreb 40 Marcus Drive, Suite One Melville, New York	1,124,501 (5)	6.9 %	
A. Jeffrey Radov	486,834 (6)	3.1 %	
Paul Jude Tonna	339,834 (7)	2.2 %	
Robert B. Catell	305,399 (8)	2.0 %	
Charles S. Ryan	251,001 (9)	1.6 %	
Francisco Silva	188,562 (10)	1.2 %	
Robert Paccasassi	33,334 (11)	*	
Adam Bergstein	2	*	
All directors and executive officers as a group (10 persons)	4,969,756 (11)	25.6 %	

(1) Based upon Schedule 13D filed with the SEC. Includes 1,000,000 shares of common stock issuable upon the exercise of currently exercisable warrants.

(2) Based upon Schedule 13D filed with the SEC and other information known to us. Includes 1,536,176 shares of common stock issuable upon the exercise of currently exercisable options and warrants (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).

Based upon Schedule 13G filed with the SEC and other information known to us. Includes 831,041 shares of common stock issuable upon the conversion of a currently convertible note and the exercise of currently exercisable warrants. The shares, convertible note and warrants are owned directly by SCG Capital, LLC, or SCG. Steven Geduld as President of SCG has an indirect beneficial ownership in the securities held by SCG. SCG has rights, under a convertible promissory note, to own an aggregate number of shares of our common stock

- (3) 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 15,192,967 shares of common stock outstanding as of April 15, 2019 (16,024,008 shares of common stock outstanding giving effect to the shares issuable pursuant to the warrants and the convertible note, subject to the cap), the number of shares of our common stock beneficially owned by SCG as of April 15, 2019 was 1,600,798 shares of common stock.

Based upon Schedule 13D filed with the SEC and other information known to us. Includes 199,182 shares of

- (4) 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.

- (5) Includes 1,044,501 shares of common stock issuable upon the exercise of currently exercisable options.

- (6) Includes 474,334 shares of common stock issuable upon the exercise of currently exercisable options.

- (7) Represents (i) 1,500 shares of common stock held jointly with Mr. Tonna's wife and (ii) 303,834 shares of common stock issuable upon the exercise of currently exercisable options and warrants.

- (8) Includes 224,533 shares of common stock issuable upon the exercise of currently exercisable options and warrants.

- (9) Includes 208,084 shares of common stock issuable upon the exercise of currently exercisable options and warrants.

- (10) Includes (i) 170 shares of common stock held in an individual retirement account for the benefit of Mr. Silva and (ii) 184,317 shares of common stock issuable upon the exercise of currently exercisable options.

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

- (12) Includes 4,219,830 shares of common stock issuable upon the exercise of options and warrants that are exercisable currently or within 60 days.

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

The following table sets forth information as of December 31, 2018 with respect to compensation plans (including individual compensation arrangements) under which our shares of common stock are authorized for issuance, aggregated as follows:

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

**Equity Compensation Plan Information**

	<b>Number of securities to be issued upon exercise of outstanding options</b>  <b>(a)</b>	<b>Weighted-average exercise price of outstanding options</b>  <b>(b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</b>
Equity compensation plans approved by security holders	4,703,785	\$ 3.21	5,251,215
Total	4,703,785	\$ 3.21	5,251,215

**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 95,000,000 shares of capital stock. We are authorized to issue 75,000,000 shares of common stock, par value \$0.001 per share, and 20,000,000 shares of preferred stock, par value \$0.01 per share. Our Board of Directors has proposed, and we are submitting to our stockholders for approval, an amendment to our charter pursuant to which the number of shares of common stock that we will be authorized to issue will be increased to 150,000,000. The number of shares of common stock authorized to be issued may be decreased in connection with contemplated reverse split of our outstanding common stock. See “Contemplated Reverse Stock Split” below.

As of April 15, 2019, there were 15,192,967 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding.

## **Common Stock**

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

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

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

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

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

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

## **Preferred Stock**

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



**2010 Equity Participation Plan; Options**

Pursuant to the Plan, as of December 31, 2018, we were authorized to issue up to 10,000,000 shares of common stock pursuant to the grant of stock options and stock appreciation rights, restricted stock grants and stock bonus grants. Our Board of Directors has proposed, and we are submitting to our stockholders for approval, an amendment to the Plan pursuant to which the number of shares of common stock authorized to be issued pursuant to the Plan will be increased to 20,000,000.

As of December 31, 2018, we had outstanding options under the Plan to purchase an aggregate of 4,703,785 shares of common stock, of which options for the purchase of 2,952,460 shares were then exercisable.

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

Options Outstanding		Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life	Weighted Average Remaining Life
		In Years	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

Subsequent to December 31, 2018 and through April 15, 2019, we issued a ten-year option to a Scientific Advisory Board member to purchase 70,000 shares of common stock at an exercise price of \$1.00 per share. The option vests to the extent of one-third on the date of grant and one-third on each of the first and second anniversaries of the date of grant. In addition, subsequent to December 31, 2018, our Board of Directors reduced the exercise price of all outstanding options held by employees, non-employee directors and Scientific Advisory Board members to \$0.75 per share.

## **Warrants**

As of December 31, 2018, we had outstanding warrants to purchase an aggregate of 3,483,403 shares of common stock, all of which were then exercisable.

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

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life	Exercisable Number of Warrants
		In Years	
\$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

Subsequent to December 31, 2018 and through April 15, 2019, we issued immediately vested five-year warrants for the purchase of an aggregate of 640,000 shares of common stock at exercise prices ranging from \$0.85 to \$1.00 per share and an immediately vested one-year warrant for the purchase of 500,000 shares of common stock at an exercise price of \$0.70 per share.

### 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, or Warrant, to purchase        share of our common stock.

*Public Warrants.* This offering of Units includes shares of our common stock and Warrants to purchase additional shares of our common stock. Accordingly, upon completion of this offering we expect to have an additional        common stock purchase Warrants outstanding (        if the Units issuable upon exercise of the underwriters' over-allotment option are sold). Each Warrant is exercisable for the purchase of        share of common stock at an exercise price of \$        per share (        % of the price of each Unit sold in the offering) and is exercisable for a period of        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, that would have been issued or conveyed to the Warrant holder had the holder exercised the Warrant immediately preceding the closing of the Fundamental Transaction. In lieu of receiving such common stock and additional consideration in the Fundamental Transaction, the Warrant holder may elect to have us or the successor entity purchase the Warrant holder’s Warrant for its fair market value measured by the Black Scholes method.

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

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

*Underwriter Warrants.* We also expect to have up to an additional            common stock purchase warrants outstanding (        if the Units issuable upon exercise of the underwriters' over-allotment option are sold), issuable to the underwriters of this offering, or Underwriter Warrants. Each Underwriter 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 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 Warrants will not be redeemable. The Underwriter Warrants may not be transferred, assigned or hypothecated for six months following the closing of this offering, except that the underwriters may assign the Underwriter 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 Warrants will contain provisions for one demand registration of the shares underlying the Underwriter 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 Warrants outstanding and the exercise price of the Underwriter Warrants will be adjusted proportionately, as permitted by Financial Industry Regulatory Authority, or 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 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 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 Warrant holder will have the right to receive, for each share of common stock issuable upon the exercise of the Underwriter Warrant, at the option of the holder, the number of shares of common stock of the successor or acquiring corporation or of us (if we are the surviving corporation), and any additional consideration payable as a result of the Fundamental Transaction that would have been issued or conveyed to the Underwriter Warrant holder had the holder exercised the Underwriter Warrant immediately preceding the closing of the Fundamental Transaction. In lieu of receiving such common stock and additional consideration in the Fundamental Transaction, the Underwriter Warrant holder may elect to have us or the successor entity purchase the Underwriter Warrant for its fair market value measured by the Black Scholes method.

We will promptly notify the holders of the Underwriter Warrants in writing of any adjustment to the exercise price or to the number of the outstanding Underwriter 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 1,395,750 shares of our common stock and warrants for the purchase of 1,040,000 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, outstanding convertible promissory notes in the aggregate principal amount of \$1,893,750 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 right can be reduced (to zero if necessary). In addition, 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 is entitled to based on any increase or decrease in the value of our capital stock or any derivative instruments; (ix) any other information relating to each such party that would be required to be disclosed in a proxy statement; and (x) a statement as to whether or not each such party will deliver a proxy statement and form of proxy to holders of at least that percentage of voting power of all of the shares of our capital stock reasonably believed to be sufficient to elect the nominee or nominees proposed to be nominated; and

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

#### *Stockholder Proposals.*

In order for a stockholder to make a proposal at an annual meeting of stockholders, under our bylaws, timely notice must be received by us in advance of the meeting. To be timely, a stockholder's notice must be delivered to or mailed and received by our Secretary at our principal executive offices not less than 45 days nor more than 75 days prior to the one-year anniversary of the date on which we first mailed the proxy materials for the preceding year's annual meeting of stockholders; provided, however, that if the meeting is convened more than 30 days prior to or delayed more than 30 days after the anniversary of the preceding year's annual meeting or if no annual meeting was held in the preceding year, to be timely a stockholder's notice must be received not later than the close of business on the later of (i) the 90<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 is entitled to based on any increase or decrease in the value of our capital stock or any derivative instruments; (ix) any other information relating to each such party that would be required to be disclosed in a proxy statement; and (x) a statement as to whether or not each such party will deliver a proxy statement and form of proxy to holders of at least that percentage of voting power of all of our shares of capital stock required under applicable law to carry the proposal.

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

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

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

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

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

### **Limitations on Director Liability**

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

### **Indemnification of Directors and Officers**

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

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

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

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

### **Contemplated Reverse Stock Split**

At our annual meeting of stockholders scheduled to be held on May 30, 2019, we intend to propose that the stockholders approve 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, we intend to propose to our stockholders that they authorize our Board of Directors, in the event the reverse stock split proposal is approved, 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 stock split.

### **Transfer Agent**

The transfer agent for our common stock is Transshare Corporation.

### **UNDERWRITING**

We have entered into an underwriting agreement with Maxim Group LLC, or 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:

<b>Name of Underwriter</b>	<b>Number of Shares</b>	<b>Number of Warrants</b>
Maxim Group LLC		

Total

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

### **Over-Allotment Option**

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

### **Underwriter Warrants**

We have agreed to issue Underwriter 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 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 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 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 Warrants will not be redeemable. The Underwriter Warrants (a) may not be sold, transferred, assigned or hypothecated for six months following the closing of this offering, except that the underwriters may assign the Underwriter 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 and (b) shall not 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. The Underwriter Warrants will contain provisions for one demand registration of the shares underlying the Underwriter Warrants at our expense and unlimited piggyback registration rights for a period of five (5) years after the effective date of the registration statement for this offering at our expense.

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

## Underwriting Discounts

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.

	<b>Per Unit(1)</b>	<b>Total Without Over-Allotment</b>	<b>Total With Over-Allotment(2)</b>
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 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 Warrant as described above under "Underwriter 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 \$      .

(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.



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 involved is greater than the number of shares of common stock or Warrants in the over-allotment option. To close out a short position, the underwriters may elect to exercise all or part of the over-allotment option. The underwriters may also elect to stabilize the price of our common stock and Warrants or reduce any short position by bidding for, and purchasing, common stock and Warrants in the open market.

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

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

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

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

a passive market maker may not effect transactions or display bids for our common stock in excess of the highest independent bid price by persons who are not passive market makers;

net purchases by a passive market maker on each day are generally limited to 30% of the passive market maker's average daily trading volume in our common stock during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and

passive market making bids must be identified as such.