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)

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

40 Marcus Drive, Suite One

Melville, New York 11747

(631) 760-8100

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mark Weinreb, President and Chief Executive Officer

BioRestorative Therapies, Inc.

40 Marcus Drive, Suite One

Melville, New York 11747

(631) 760-8100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Fred Skolnik, Esq.	**Barry I. Grossman, Esq.**
Daniel R. Palmadesso, Esq.	**Sarah E. Williams, Esq.**
Certilman Balin Adler & Hyman, LLP	**Ellenoff Grossman & Schole LLP**
90 Merrick Avenue	**1345 Avenue of the Americas**
East Meadow, New York 11554	**New York, New York 10105**
(516) 296-7048	**(212) 370-1300**

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act (check one):

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

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

Calculation of Registration Fee

Title of Each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price** [(1)]	Amount of Registration Fee
Units consisting of shares of Common Stock, par value $0.001 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)	$	$
TOTAL REGISTRATION FEE	$19,550,000	$ 2,369.46

(1)

Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes Units which may be issued upon exercise of a 45-day option granted to the underwriters to cover over-allotments, if any.

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

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

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

(6) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The warrants are exercisable at a per share exercise price equal to 125% of the public offering price. As estimated solely for the purpose of recalculating the registration fee pursuant to Rule 457(g) under the Securities Act, the proposed maximum aggregate offering price of the Underwriter 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.

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

(1) Does not reflect additional compensation to the underwriters in the form of warrants to purchase up to 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.

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

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

TABLE OF CONTENTS

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.

6

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. The information on our website is not (and should not be considered) part of this prospectus and is not incorporated into this prospectus by reference.

Summary of the Offering

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

Common Stock to be Outstanding after the Offering:	shares, excluding the possible sale of over-allotment Units, if any. The number of shares of our common stock to be outstanding after the completion of this offering is based on 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.

15

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.

17

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;

21

- 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.

29

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;

30

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/Steven 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	%	$	

46

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