BioRestorative Therapies, Inc.
Form S-1/A
September 25, 2015

As filed with the Securities and Exchange Commission on September 25, 2015

Registration No. 333-204672

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

BIORESTORATIVE THERAPIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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.	**Lawrence G. Nusbaum, Esq.**
Nicholas Venditto, Esq.	**Andrew Russell, Esq.**
Certilman Balin Adler & Hyman, LLP	**Bryan S. Dixon, Esq.**
90 Merrick Avenue	**Gusrae Kaplan Nusbaum PLLC**
East Meadow, New York 11554	**120 Wall Street**
(516) 296-7048	**New York, New York 10005**
	(212) 269-1400

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. ¨

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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer ¨ Accelerated Filer ¨ Non-Accelerated Filer ¨ Smaller reporting company x

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 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED SEPTEMBER 25, 2015

1,550,388 Shares of Common Stock

Warrants to Purchase 1,550,388 Shares of Common Stock

We are offering for sale 1,550,388 shares of our common stock, together with warrants to purchase 1,550,388 shares of our common stock (and the shares issuable from time to time upon exercise of the warrants), pursuant to this prospectus. The shares and warrants will be separately issued and sold to purchasers in equal proportion. Each warrant will have an exercise price of $ per share (125% of the public offering price per share in this offering), will be exercisable upon issuance and will expire five years from the date of issuance.

Our common stock is quoted on the OTCQB market under the symbol “BRTX.” We have applied to list our common stock and the warrants being sold in this offering on The NASDAQ Capital Market under the symbols “BRTX” and “BRTXW”, respectively. No assurance can be given that our application will be approved. On September 15, 2015, the last reported sale price of our common stock on the OTCQB market was $6.45 per share.

All references in this prospectus to numbers of shares of common stock and per share information give retroactive effect to the 1-for-20 reverse split of our shares of common stock effected as of July 7, 2015.

Investing in the offered securities involves a high degree of risk. See “Risk Factors” beginning on page 8 of this prospectus for a discussion of information that you should consider before investing in our securities.

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.

	Combined Per Share and Warrant	Total
Public offering price	$	$
Underwriting discount [(1)]	$	$
Net proceeds, before expenses, to us	$	$

(1) Does not include a non-accountable expense allowance equal to 1% of the gross proceeds of this offering payable to the underwriter. See "Underwriting" beginning on page 111 of this prospectus for a description of the compensation payable to the underwriter. The registration statement of which this prospectus is a part also covers the underwriter's warrant and the shares of common stock issuable from time to time upon the exercise of the underwriter's warrant.

We have granted a 45-day option to the underwriter to purchase from us up to an additional 232,558 shares of common stock at a public purchase price of $ per share and/or warrants to purchase from us up to an additional 232,558 shares of common stock at a public purchase price of $0.01 per warrant, solely to cover over-allotments, if any. The shares and warrants issuable upon exercise of the underwriter option are identical to those offered by this prospectus and have been registered under the registration statement of which this prospectus forms a part.

The underwriter expects to deliver our shares of common stock and warrants on or about , 2015.

Aegis Capital Corp

TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY	1
RISK FACTORS	8
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	39
USE OF PROCEEDS	40
DIVIDEND POLICY	41
CAPITALIZATION	41
DILUTION	42
SELECTED FINANCIAL DATA	43
MARKET FOR COMMON STOCK AND RELATED STOCKHOLDER MATTERS	44
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	45
BUSINESS	60
MANAGEMENT	83
EXECUTIVE COMPENSATION	88
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	92
PRINCIPAL STOCKHOLDERS	94
DESCRIPTION OF SECURITIES	96
MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF COMMON STOCK	107
UNDERWRITING	111
LEGAL MATTERS	121
EXPERTS	121
WHERE YOU CAN FIND ADDITIONAL INFORMATION	122
INDEX TO FINANCIAL STATEMENTS	123

We have not, and the underwriter has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell the securities offered hereby, but only under the circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: we have not, and the underwriter has not, taken any action that would permit this offering, or the possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside the United States.

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.

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 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 over-allotment option granted to the underwriter or any exercise of the warrant to be issued to the underwriter.

All references in this prospectus to numbers of shares of common stock and per share information give retroactive effect to the 1-for-20 reverse split of our shares of common stock effected as of July 7, 2015.

What We Do

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

· ***Disc/Spine Program.*** Our lead cell therapy candidate, *brtxDISC* (**D**isc **I**mplanted **S**tem **C**ells), is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells collected from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of protruding and bulging lumbar discs in patients suffering from chronic lumbar disc disease. The treatment involves collecting a patient's own stem cells, culturing and cryopreserving the cells, and then having a physician inject *brtxDISC* into the patient's damaged disc in a contemplated 30 minute outpatient office procedure. The treatment is intended for patients whose pain has not been alleviated by non-invasive procedures and who potentially face the prospect of surgery. We expect to file an investigational new device, or IND, application with the Food and Drug Administration, or the FDA, with regard to

brtxDISC during the first quarter of 2016 and anticipate that we will commence clinical trials using *brtxDISC* and its related collection and delivery procedure by the middle of 2016.

1

· ***Metabolic Program (ThermoStem).*** We are developing an allogeneic cell-based therapy to target obesity and metabolic disorders using brown adipose (fat) derived stem cells 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 the body 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. In March 2014, we entered into a Research Agreement with Pfizer, Inc., a global pharmaceutical company, pursuant to which we have been engaged to provide research and development services with regard to a joint study of the development and validation of a human brown adipose (fat) cell model. A United States patent related to the *ThermoStem Program* issued in September 2015.

We have also licensed a curved needle device designed to deliver cells and/or other therapeutic products or material to the spine and discs. In August 2015, a United States patent for this device was issued to the licensor, Regenerative Sciences, LLC.

In addition, we have developed a human cellular extract that has been demonstrated in *in vitro* skin studies to increase the production of collagen and fibronectin, which are proteins that are essential to combating the aging of skin. We also offer plant stem cell-based facial creams and beauty products under the *Stem Pearls* brand.

Significant Accomplishments

We have made significant 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 $15,000,000 in equity and debt financings over the past five years, 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, *brtxDISC*.

- We had a successful pre-IND application meeting with the FDA, with regard to *brtxDISC* and are preparing for an IND submission to the FDA.

- 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, including the President of our Disc/Spine Division who additionally has cell therapy and regulatory experience.

- We have a five member Scientific Advisory Board, including a Professor of Medicine at the Harvard Medical School and the Dana-Faber Cancer Institute, the Director of Endovascular and Minimally Invasive Image Guided Neurosurgery at George Washington University Medical Center and the former Director of Quality Assurance for the FDA's Center for Biologics Evaluation and Research.

- We have engaged a Chief Medical Advisor for Spine Medicine who is an Assistant Professor at Weill Medical College of Cornell and established the Physiatry Department at the Hospital for Special Surgery.

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

- We have established a new laboratory in Melville, New York to be used for research purposes and the possible development of cellular-based treatment protocols.

- We are seeking clean room certification with regard to a newly fabricated portion of our laboratory.

- We have licensed a curved needle device, patented in August 2015, designed to deliver cells and/or other therapeutic products or material to, among other possible difficult-to- locate regions of the body, the spine and discs.

Metabolic Program (ThermoStem)

- We have 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.

- A United States patent related to the *ThermoStem Program* issued in September 2015.

3

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; and we have a substantial working capital deficiency and a stockholders' deficiency.

- Following the offering, we will need to obtain a significant amount of additional financing to complete our clinical trial 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 *brtxDISC*, 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.

- We are required to pay certain minimum amounts to maintain our exclusive license rights with regard to our disc/spine technology; the loss of such exclusive rights would have a material adverse effect upon us.

.

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.

- 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 8 of this prospectus.

Reverse Stock Split and Recapitalization

All references in this prospectus to numbers of shares of common stock and per share information give retroactive effect to the 1-for-20 reverse split of our shares of common stock effected as of July 7, 2015. In connection with the reverse split, we reduced the number of our authorized shares of common stock from 200,000,000 to 30,000,000.

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. Our subsidiary, Stem Pearls, LLC, also has a website at www.stempearls.com. The information on those websites is not (and should not be considered) part of this prospectus and is not incorporated into this prospectus by reference.

The Offering

Securities offered by us	1,550,388 shares of our common stock and warrants to purchase 1,550,388 shares of our common stock (or 1,782,946 shares and 1,782,946 warrants if the underwriter exercises its over-allotment option in full).
Description of warrants	The shares and warrants will be separately transferable immediately upon issuance, but the shares and warrants will be issued and sold to purchasers in equal proportion. Each warrant will have an exercise price of $ per share (125% of the public offering price per share in this offering), will be exercisable upon issuance and will expire five years from the date of issuance.
Common stock outstanding before this offering	2,854,268 shares.
Common stock to be outstanding after this offering(1)	4,404,656 shares (or 4,637,214 shares if the underwriter exercises its over-allotment option in full).
Use of proceeds	We intend to use the net proceeds of this offering as follows: (i) submission of investigational new device, or IND, application to the United States Food and Drug Administration, or FDA, with respect to *brtxDISC* and its related collection and delivery procedure, and commencement of associated clinical trials; (ii) pre-clinical research and development with respect to *ThermoStem Program*; (iii) repayment of indebtedness; and (iv) for general corporate and working capital purposes. For a more complete description of our anticipated use of proceeds from this offering, see “Use of Proceeds.”
Risk factors	An investment in our securities involves a high degree of risk. You should carefully read and consider the risks discussed under the caption “Risk Factors” beginning on page 8 and all other information included in this prospectus before making a decision to invest in our securities in this offering.
OTCQB symbol for our common stock	BRTX
Listing	We have filed an application to list our common stock and the warrants offered pursuant to this prospectus on The NASDAQ Capital Market under the symbols “BRTX” and “BRTXW”, respectively. No assurance can be given that our application will be accepted.

(1) The number of shares of our common stock to be outstanding after this offering is based on 2,854,268 shares outstanding as of September 15, 2015. The number of shares of common stock to be outstanding after this offering includes 1,550,388 shares of our common stock sold in this offering. Unless otherwise indicated, the number of outstanding shares of common stock presented in this prospectus excludes:

- 1,782,946 shares of our common stock issuable upon the exercise of the warrants sold in this offering, including pursuant to and assuming the full exercise of the underwriter's over-allotment option;

- 1,315,450 shares of our common stock issuable upon the exercise of outstanding options granted under our 2010 Equity Participation Plan as of September 15, 2015 (including 505,250 options which are subject to stockholder approval of an increase in the number of shares of common stock authorized to be issued under our 2010 Equity Participation Plan from 1,000,000 to 2,000,000, or such greater number of shares as the Compensation Committee of our Board of Directors shall determine to propose for stockholder approval, as discussed herein);

- 639,550 shares of our common stock that are available for future issuance under our 2010 Equity Participation Plan as of September 15, 2015 (assuming stockholder approval of an increase in the number of shares of common stock authorized to be issued under our 2010 Equity Participation Plan from 1,000,000 to 2,000,000, as discussed herein);

- 792,334 shares of our common stock issuable upon the exercise of outstanding warrants as of September 15, 2015;

- 232,558 shares of our common stock issuable pursuant to the exercise of the underwriter's over-allotment option; and

- 46,512 shares of our common stock issuable upon the exercise of the warrant issued to the underwriter in connection with this offering.

Summary Selected Financial Data

The following table sets forth summary consolidated financial data of BioRestorative Therapies, Inc. The financial data as of June 30, 2015 and for the six months ended June 30, 2015 and 2014 have been derived from our unaudited condensed consolidated financial statements included in this prospectus under "Index to Financial Statements". The financial data as of December 31, 2014 and 2013 and for the years then ended have been derived from our audited consolidated financial statements included in this prospectus under "Index to Financial Statements". The summary consolidated financial results in the table below are not necessarily indicative of our expected future operating results. The following summary historical financial information should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the historical financial statements and notes thereto appearing in this prospectus under "Index to Financial Statements".

	For The Six Months Ended June 30,		For The Years Ended December 31,	
	2015 (unaudited)	2014	2014	2013
Selected Statement of Operations Data:				
Revenues	$ 333,666	$ 176,316	$ 415,996	$ 1,680
Cost of sales	151,077	42,426	213,834	208
Gross profit	182,589	133,890	202,162	1,472

Operating expenses				
Marketing and promotion	94,028	47,329	125,626	114,951
Consulting	504,060	824,763	1,310,121	779,462
Research and development	859,344	787,071	1,430,614	1,594,054
General and administrative	1,613,927	1,184,632	2,258,307	2,265,275
Total operating expenses	3,071,359	2,843,795	5,124,668	4,753,742
Other expense	(291,649)	(292,910)	(665,106)	(998,924)
Net loss	$ (3,180,419)	$ (3,002,815)	$ (5,587,612)	$ (5,751,194)
Net loss per share - basic and diluted	$ (1.60)	$ (2.79)	$ (4.38)	$ (6.96)
Weighted average number of common shares outstanding - basic and diluted	1,993,544	1,077,606	1,276,904	826,340

	June 30, 2015 (unaudited)	December 31, 2014	2013
Selected Balance Sheet Data:			
Cash	$ 6,445	$ 91,798	$ 201,098
Working capital deficit	(4,673,421)	(8,410,686)	(7,262,748)
Total assets	2,070,578	1,691,801	1,382,915
Total liabilities	4,951,101	8,580,194	8,067,984
Total stockholders' deficiency	(2,880,523)	(6,888,393)	(6,685,069)

RISK FACTORS

In addition to the other information included in this prospectus and any free writing prospectus we authorize for use in connection with this offering, 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 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; 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 very limited operating history. Since our inception in December 2008, we have incurred net losses. As of June 30, 2015, we had notes payable with an aggregate principal balance of $275,000 which were past due. We are currently in the process of negotiating extensions or discussing conversions to equity with respect to these notes. However, there can be no assurance that we will be successful in extending or converting these notes. As of June 30, 2015, we had a working capital deficiency of $4,673,421 and stockholders' deficiency of $2,880,523. The report of our independent registered public accounting firm with respect to our financial statements as of December 31, 2014 and 2013 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, 2014 and 2013 and for the years then ended (see “Index to Financial Statements”). 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 additional financing to complete our clinical trials and implement our business plan.

Since our inception, we have not generated any significant revenues from our operations and have funded our operations through the sale of our equity securities (approximately $8,000,000) and debt securities (approximately $10,000,000). The implementation of our business plan, as discussed in "Business", will require the receipt of sufficient equity and/or debt financing to purchase necessary equipment, technology and materials, fund our research and development efforts, retire our outstanding debt and otherwise fund our operations. If we are able to complete this offering, we anticipate that the estimated net proceeds of $8,800,000 from this offering will fund our operations until September 2016 (assuming that the underwriter does not exercise its over-allotment option to purchase additional shares and/or warrants, we do not receive any revenues from operations, we do not receive any additional financing and our remaining debt is not converted into equity) and should permit us to conduct a significant portion of our initial clinical trial with regard to our *Disc/Spine Program*, as further discussed in "Business". We anticipate that we will require between $20,000,000 and $30,000,000 in additional funding to complete our clinical trials with regard to our *Disc/Spine Program.* 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 discussed in "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.

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 stock an unsuitable investment for many investors.

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

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

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

Our performance is substantially dependent on the performance of 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 in December 2017. We are also dependent on the performance of Edward Field, President of our Disc/Spine Division, and Francisco Silva, our Vice President of Research and Development, in establishing and developing our products and operations. Mr. Field and Mr. 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. Field 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.

Continued turmoil in the economy could harm our business.

Negative trends in the general economy, including, but not limited to, trends resulting from an actual or perceived recession, tightening credit markets, increased cost of commodities, actual or threatened military action by the United States and threats of terrorist attacks in the United States and abroad, could cause a reduction of investment in and available funding for companies in certain industries, including ours. Our ability to raise capital has been and may in the future be adversely affected by downturns in current credit conditions, financial markets and the global economy.

Risks Related to Our Cell Therapy Product Development Efforts

Our future success is significantly dependent on the timely and successful development and commercialization of brtxDISC, 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, *brtxDISC,* is in early stages of development and we must first complete pre-clinical work to submit an investigational new drug, or IND, application for FDA clearance to commence clinical trials.

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; 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 raises 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 cGCP, 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 our 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; and

· 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.

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 to, 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 *brtxDISC* product 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 *brtxDISC* or any of our other products in development. Our management lacks significant experience in completing clinical trials and bringing a drug through commercialization. Clinical trials for *brtxDISC* and other products 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 or our failure, or the failure of our contract manufacturers, to comply with current Good Manufacturing Practices, or 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;

- inability to continue to fund clinical trials or to find a partner to fund the clinical trials;

- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and

- delays in completing data collection and analysis for clinical trials.

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

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

When manufacturing an autologous cell therapy, the number and the 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.

14

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 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.

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.

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 to exclusively provide the cell processing services necessary for clinical production of *brtxDISC* 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 *brtxDISC* 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 *brtxDISC* 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.

16

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

Our research agreement with the University of Utah (which expired in June 2015) provided an opportunity for us to obtain brown adipose (fat) tissue that we use 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 relationships that we may establish with other potential sources of brown adipose tissue. The loss of brown tissue procurement would have a material adverse effect upon our ability to advance the *ThermoStem Program.*

We are required to pay certain minimum amounts 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, or Regenerative, unless certain milestones are satisfied, we will be required to pay to Regenerative minimum amounts of between $225,000 and $475,000 during the period from April 2017 to April 2019 in order to maintain our exclusive rights with regard to the disc/spine technology. No assurances can be given that we will have sufficient funds to pay such minimum amounts if the milestones are not satisfied. Any loss of such exclusive rights would have a material adverse effect upon our business, results of operations and financial condition.

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.

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

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

· collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;

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

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

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

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

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

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

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

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our

existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

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

Over the past four 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, 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, *brtxDISC* 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 *brtxDISC*, 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.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. 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 one biosimilar product, 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 permit biosimilar applicants to reference approved biologics other than our therapeutic candidates, thus circumventing our exclusivity and potentially creating the opportunity for competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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, once we commence human clinical trials, 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 increase our insurance coverage when we begin clinical trials and commercializing product candidates, if ever. At that time, 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.

21

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.

22

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

Successful sales of health care products and services generally depends, in part, upon the availability and amounts of reimbursement from third party healthcare payor organizations, including government agencies, private healthcare insurers and other healthcare payors, such as health maintenance organizations and self-insured employee plans. Uncertainty exists as to the availability of reimbursement for such new therapies as stem cell-based therapies. There can be no assurance that such reimbursement will be available in the future at all or without substantial delay or, if such reimbursement is provided, that the approved reimbursement amounts will be sufficient to support demand for our products and services at a level that will be profitable.

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 to us 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 intend to also 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 intend to 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, and any lower court decisions have not been reviewed by either the Federal Circuit Court of Appeals or the Supreme Court, a process that will take years. The first major change is that AIA switches the United States patent system from a “first to invent” system to a “first to file” system. Now that the first to file system is in effect, there is a risk that another company may independently develop identical or similar patents at approximately the same time, and be awarded the patents instead of us. Further, for the second major change, AIA abolished interference proceedings, and establishes derivation proceedings to replace interference proceedings in all cases in which the time period for instituting an interference proceeding has not lapsed where an inventor named in an earlier application derived the claimed invention from a named inventor. Now that the derivation proceedings are in effect, there is a risk that the inventorship of any pending patent application can be challenged for reasons of derivation. The third major change is that AIA established post-grant opposition proceedings that will apply only to patent applications filed after “first to file” became effective. Post-grant opposition will enable a person who is not the patent owner to initiate proceedings in the Patent Office within nine months after the grant of a patent that can result in cancellation of a patent as invalid. In addition to AIA, recent court decisions have created uncertainty with regard to our ability to obtain and maintain patents. Therefore there is a risk that any of our patents once granted may be subject to post-grant opposition, which will increase uncertainty on the validity of any newly granted patent or may ultimately result in cancellation of the patent.

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

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

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

Risks Related to Government Regulation

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.

We intend to develop stem cell based therapeutic products and related device accessories. These products and operations are subject to regulation in the United States by the FDA, the Federal Trade Commission, or FTC, the Centers for Medicare and Medicaid Services, or CMS, state authorities and comparable authorities in foreign jurisdictions. Government regulation is a significant factor affecting the research, development, formulation, manufacture, and marketing of our products. If we fail to comply with applicable regulations, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, operating restrictions and criminal prosecution.

The FDA requires facilities that are engaged in the recovery, processing, storage, labeling, packaging, or distribution of human cells, tissues, cellular and tissue-based products, or HCT/Ps, or in the screening or testing of donors of HCT/Ps to register and list the HCT/Ps that it manufactures, comply with current Good Tissue Practices, or cGTPs, and other procedures to prevent the introduction, transmission, and spread of communicable diseases. Our New York-based laboratory and any treatment centers we may open in the United States may be required to comply with the HCT/P regulations. In addition, any third party retained by us that engages in the manufacture of an HCT/P on our behalf must also comply with the HCT/P regulations. If we or our third-party contractors fail to register, update registration information, or comply with any HCT/P regulation, we will be out of compliance with FDA regulations, which could adversely affect our business. Furthermore, adverse events in the field of stem cell therapy may result in greater governmental regulation, which could create increased expenses, potential delays, or otherwise affect our business.

We believe that some of our products and services may be regulated solely as HCT/Ps; however, it is possible that some or all of our products may be regulated as drugs, medical devices, and/or biological products and therefore will likely require FDA regulatory approval or clearance prior to being marketed in the United States. The FDA approval process can be lengthy, expensive, and uncertain and there is no guarantee of ultimate approval or clearance. Even if our products are approved, FDA regulation of promotional and manufacturing activities can affect our ability to market a drug, biologic or medical device. These products must comply with the applicable current Good Manufacturing Practices (for drug products), Quality System Regulations (for medical devices), or General Biological Product Standards (for biological products) as set forth in Title 21 of the Code of Federal Regulations. These regulations govern the manufacture, processing, packaging, and holding of the products. The FDA conducts inspections to enforce compliance with these regulations. We and any third-party contractor that manufactures these products on our behalf must comply with the applicable regulations. If we or any third party retained by us that engages in the manufacture of a drug, medical device, or biological product fails to comply with the applicable regulations, we will be out of compliance with FDA regulations, which could adversely affect our business. Discovery after FDA approval of previously unknown problems with a product, manufacturer or manufacturing process, or a failure to comply with regulatory requirements, may result in actions such as:

- warning letters or untitled letters or other actions requiring changes in product manufacturing processes or restrictions on product marketing or distribution;

- product recalls or seizures or the temporary or permanent withdrawal of a product from the market; and

- fines, restitution or disgorgement of profits or revenue, the imposition of civil penalties or criminal prosecution.

In addition, the FDA regulates and prescribes good laboratory practices, or GLPs, for conducting nonclinical laboratory studies that support applications for research or marketing permits for products regulated by the FDA. GLPs provide requirements for organization, personnel, facilities, equipment, testing, facilities operation, test and control articles, protocol for nonclinical laboratory study, records, reports, and disqualification by the FDA to ensure the quality and integrity of the safety data filed in research and marketing permits. Failure to comply with the GLPs could adversely affect our business.

Although cosmetic products are subject to fewer regulatory requirements than drugs or medical devices, in the United States cosmetic products are subject to FDA and FTC requirements as well as applicable state and local requirements. It is also possible that some of the skin care products developed and marketed by our *Stem Pearls* cosmetic skincare company and pursuant to our *brtx-C Cosmetic Program* may be regulated as both cosmetics and drugs under the Federal Food, Drug and Cosmetic Act, or FDCA. If they are, these products must satisfy the regulatory requirements of both drugs and cosmetics. Failure to comply with the appropriate regulations could result in a restraining order, seizure, or criminal action, which could have an adverse effect on our business.

The FTC regulates and polices advertising in the United States of medical treatments, procedures, and regimens that take place inside and outside of the United States. FTC regulations are designed to prevent unfair and deceptive practices and false advertising. The FTC requires advertisers and promoters to have a reasonable basis to substantiate and support claims. Failure to sufficiently substantiate and support claims can lead to enforcement action by the FTC, such as a disgorgement order of any profits made from the promoted business or an injunction from further violative promotion. Such enforcement actions could have an adverse effect on our business.

State and local governments impose additional licensing and other requirements for clinical laboratories and facilities that collect, process, and administer stem cells. Our laboratory and any future treatment facilities that we may operate in the United States must comply with these additional licensing and other requirements. The licensing regulations require personnel with specific education, experience, training, and other credentials. There can be no assurance that these individuals can be retained or will remain retained or that the cost of retaining such individuals will not materially and adversely affect our ability to operate our business profitably. There can be no assurance that we can obtain the necessary licensure required to conduct business in any state or that the cost of compliance will not adversely affect our ability to operate our business profitably.

CMS has authority to implement the Clinical Laboratories Improvement Amendments, or CLIA, program. When we begin laboratory operations in the United States, we will need to comply with the CLIA program standards. CLIA is designed to establish quality laboratory testing by ensuring the accuracy, reliability, and timeliness of patient test results. Laboratories that handle stem cells and other biologic matter are included under the CLIA program. Under the CLIA program, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections, and pay fees. The failure to comply with CLIA standards could result in suspension, revocation, or limitation of a laboratory's CLIA certificate. In addition, fines or criminal penalties could also be levied. To the extent that our business activities require CLIA certification, we intend to obtain and maintain such certification. There is no guarantee that we will be able to gain CLIA certification. Failure to gain CLIA certification or comply with the CLIA requirements will adversely affect our business.

The Department of Health and Human Services, or HHS, published the *Standards for Privacy of Individually Identifiable Health Information,* or the Privacy Rule, and the *Security Standards for the Protection of Electronic Protected Health Information*, or the Security Rule, pursuant to the Health Insurance Portability and Accountability Act, or HIPAA. The Privacy Rule specifies the required, permitted and prohibited uses and disclosures of an individual's protected health information by health plans, health care clearinghouses, and any health care provider that transmits health information in electronic format (referred to as covered entities). The Security Rule establishes a national security standard for safeguarding protected health information that is held or transferred in electronic form (referred to as electronic protected health information). The Security Rule addresses the technical and non-technical safeguards that covered entities must implement to secure individuals' electronic protected health information.

In addition to covered entities, the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, made certain provisions of the Security Rule, as well as the additional requirements the HITECH Act imposed that relate to security and privacy and that are imposed on covered entities, directly applicable as a matter of law to individuals and entities that perform permitted functions on behalf of covered entities when those functions involve the use or disclosure of protected health information. These individuals and entities are referred to as business associates. Covered entities are required to enter into a contract with business associates, called a business associate agreement, that also imposes many of the Privacy Rule requirements on business associates as a matter of contract.

28

Regulations implementing the majority of the requirements created by the HITECH Act were issued in January 2013 (we refer to these regulations as the Final Rule). Among other things, the Final Rule broadened the definition of business associate to include subcontractors. As a result, a subcontractor who performs tasks involving the use or disclosure of protected health information on behalf of a business associate must likewise comply with the same obligations as the business associate.

The HITECH Act also established notification requirements in the event that a breach of the protected health information occurs at a covered entity or business associate. These notification obligations mandate that each affected individual whose protected health information was impermissibly accessed receive written notification mailed to his residence of record and that the Secretary of HHS and potentially the media also be notified. HHS, through its Office for Civil Rights, investigates breach reports and determines whether administrative or technical modifications are required and whether civil or criminal sanctions should be imposed. Companies failing to comply with HIPAA and the implementing regulations may also be subject to civil money penalties or in the case of knowing violations, potential criminal penalties, including monetary fines, imprisonment, or both. In some cases, the State Attorneys General may seek enforcement and appropriate sanctions in federal court.

To the extent that our business requires compliance with HIPAA, we intend to fully comply with all requirements as well as to other additional federal or state privacy laws and regulations that may apply to us. As HIPAA is amended and changed, we will incur additional compliance burdens. We may be required to spend substantial time and money to ensure compliance with ever-changing federal and state standards as electronic and other means of transmitting protected health information evolve.

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

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

· state and local licensure of medical professionals;

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

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

- other laws and regulations administered by the FDA;

- other laws and regulations administered by HHS;

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

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

- the federal Anti-Kickback Law and any state equivalent statutes and regulations;

- federal and state coverage and reimbursement laws and regulations;

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

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

- the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to "Excess Benefit Transactions" with tax-exempt organizations;

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

- state and other federal laws governing the privacy of health information.

Any violation of these laws could result in a material adverse effect on our business.

In the event we determine to operate in foreign jurisdictions, we will need to comply with the government 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 cell therapy and cell banking 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, government regulations can change with little to no notice and may result in up-regulation of our products, thereby creating a greater regulatory burden for our

cell processing technology products. We have not yet thoroughly explored the applicable laws and regulations that we will need to comply with in foreign jurisdictions. It is possible that we may not be permitted to expand our business into one or more foreign jurisdictions.

We intend to conduct our business in full compliance with all applicable federal, state and local, and foreign laws and regulations. However, the laws and regulations affecting our business are complex, often are not contemplated by existing legal régimes, and are subject to change without notice. As a result, the laws and regulations affecting our business are uncertain and have not been the subject of judicial or regulatory interpretation. Furthermore, stem cells and cell therapy are topics of interest in the government and public arenas. 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.

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 False Claims Act, or FFCA, 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 FFCA 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 anti-kickback law, Stark Law or other healthcare-related laws, including laws enforced by the FDA, may be considered a violation of the FFCA. 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 material 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 and Medicaid 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 receive a portion of our revenues from services rendered to patients enrolled in federal health care programs, such as Medicare, and we may also directly or indirectly receive revenues from federal health care programs. 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 and Medicaid. 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 legislation 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, comprehensive programs are under consideration that seek to, among other things, increase access to healthcare for the uninsured and control the escalation of healthcare expenditures within the economy. In 2010, healthcare reform legislation was signed into law. While we do not believe this legislation will have a direct impact on our business, the legislation requires the adoption of implementing regulations, which may have unintended consequences or indirectly impact our business. For instance, the scope and implications of the amendments pursuant to the Fraud Enforcement and Recovery Act of 2009, or FERA, have yet to be fully determined or adjudicated and as a result it is difficult to predict how future enforcement initiatives may impact our business. If the legislation causes such unintended consequences or indirect impact, it could have a material adverse effect on our business, financial condition and results of operations.

Competitor companies or hospitals may be able to take advantage of European Union, or 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 and there is no assurance that an active trading market for our common stock will develop.

Although our common stock is quoted on the OTCQB market 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 The NASDAQ Capital Market. 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 securities, 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 stockholders will be able to resell their securities at any price.

If, following this offering, our common stock is classified 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. For any transactions involving a penny stock, 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 the offering, the market price for shares of our common stock is 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 common stock.

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 of 1933, as amended, 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 Securities Exchange Act of 1934, or 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 require a significant amount of time and attention from our management.

Our stock price may fluctuate significantly and be highly volatile and this may make it difficult for you to resell shares of our common stock at the volume, prices and times you find attractive.

The market price of our common stock could be subject to significant fluctuations and be highly volatile, which may make it difficult for you to resell shares of our common stock at the volume, prices and times you find attractive. There are many factors that will impact our stock price and trading volume, including, but not limited to, the factors listed above under “Risks Related to Our Business Generally”, “Risks Related to Our Cell Therapy Product Development Efforts”, “Risks Related to Our Intellectual Property”, “Risks Related to Government Regulation”, and “Risks Related to This Offering and Our Common Stock and Warrants.”

Stock markets, in general, experience significant price and volume volatility, and the market price of our common stock 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 common stock.

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 common stock.

Except as described under “Underwriting,” 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 1,000,000 shares of our common stock issuable under our 2010 Equity Participation Plan. In September 2015, the Compensation Committee of our Board of Directors approved an increase in the number of shares issuable pursuant to our 2010 Equity Participation Plan to 2,000,000, subject to stockholder approval. In the event our stockholders approve such increase, we intend to register the additional 1,000,000 shares on Form S-8. Options to purchase 1,315,450 shares of our common stock are outstanding under this plan, including options to purchase 505,250 shares of our common stock granted to certain officers, directors, employees and Scientific Advisory Board members. The exercisability of such 505,250 options is subject to stockholder approval of an increase in the number of shares of common stock authorized to be issued under the plan from 1,000,000 to 2,000,000, or such greater number of shares as the Compensation Committee of the Board of Directors shall determine to propose for stockholder approval. 639,550 shares are reserved for future grants under the plan (assuming stockholder approval of an increase in the number of shares issuable pursuant to the plan to 2,000,000). 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 this offering or 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 common stock 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 stockholder currently owns a substantial number of shares of our common stock and has, and following the offering will continue to have, the power to significantly influence the vote on all matters submitted to a vote of our stockholders.

As of September 15, 2015, Westbury (Bermuda), Ltd., or Westbury, beneficially owned 1,191,661 shares of our common stock (including 239,182 shares of our common stock issuable pursuant to currently exercisable warrants), representing 38.5% of the outstanding shares of our common stock. Westbury will beneficially own 25.7% of the outstanding shares of our common stock following the offering (assuming that the underwriter does not exercise its over-allotment option).

Westbury, through its beneficial ownership of our common stock, has, and following the offering will continue to 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 Westbury may not coincide with the interests of our other stockholders, and it could take actions that advance its own interests to the detriment of our other stockholders.

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.

We intend to use the net proceeds of this offering for the following purposes: (i) the submission of an IND application to the FDA with respect to *brtxDISC* and its related collection and delivery procedure, and the commencement of

associated clinical trials; (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. See "Use of Proceeds."

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 stockholders.

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 stockholders from receiving a premium for their shares of common stock. Our certificate of incorporation provides that our Board of Directors may issue up to 5,000,000 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, the influence of Westbury over the election of our directors, and other factors may hinder or prevent a change in control, even if the change in control would be beneficial to, or sought by, our stockholders. See "Description of Securities — Certain Provisions Having Potential Anti-Takeover Effects."

The warrants are speculative in nature.

The warrants being offered pursuant to this prospectus do not confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of 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 $ per share (125% of the public offering price per share in this offering), prior to five 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.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Since the price per share of our common stock being offered is higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the assumed public offering price of $6.45 per share, which is the last reported sale price of our common stock on the OTCQB market on September 15, 2015, after deducting the underwriting discount and estimated offering expenses payable by us, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $5.33 per share in the net tangible book value of the common stock. See "Dilution" for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

38

To the extent that outstanding options or warrants or awards are exercised, you will experience further dilution. As of September 15, 2015, there were options outstanding to purchase 1,315,450 shares of common stock at a weighted average exercise price of $10.18 per share, and warrants outstanding to purchase 792,334 shares of common stock at a weighted average exercise price of $15.86 per share.

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 could result in further dilution to our stockholders.

In this offering we will sell 1,550,388 shares (exclusive of any shares that we may sell pursuant to an exercise by the underwriter of its over-allotment option), or approximately 54.3 % of our outstanding common stock as of September 15, 2015, and warrants to purchase up to 1,550,388 shares (exclusive of any warrants that we may sell pursuant to an exercise by the underwriter of its over-allotment option). This sale and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this prospectus under the captions “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Risk Factors,” and elsewhere are “forward-looking statements” within the meaning of the protections of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act. These forward-looking statements are covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and we are including this statement for purposes of invoking these safe harbor provisions.

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” 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.

39

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 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 8 in 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.

USE OF PROCEEDS

We anticipate that the net proceeds to us from the sale of our securities will be approximately $8,800,000, after deducting offering expenses and the underwriting discount (or $10,195,000, if the underwriter exercises its over-allotment option in full).

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

- submission of an IND application to the FDA with respect to *brtxDISC* and its related collection and delivery procedure, and the commencement of associated clinical trials, including costs related to pre-clinical services, clinical development, manufacturing and quality control development and administrative services;

- pre-clinical research and development with respect to our *ThermoStem Program*, including labor costs, equipment, manufacturing and third party development costs, and costs related to animal studies*;*
- repayment of indebtedness;
- general corporate and working capital purposes.

Before we apply any of the proceeds for any uses, they likely will be temporarily invested in short-term investment securities. The precise amounts and timing of the application of proceeds has yet to be determined by our management.

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 funds legally available.

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.

CAPITALIZATION

The following table sets forth our consolidated capitalization as of June 30, 2015 (i) on an actual basis and (ii) as adjusted, on a pro forma basis, to give effect to the sale of our shares of common stock and warrants at the assumed public offering price of $6.45 per share and warrant (which is the last reported sale price of our common stock on the OTCQB market on September 15, 2015), for total net proceeds of approximately $8,800,000.

This information should be read together with our consolidated financial statements and other financial information set forth in our financial statements included in this prospectus under “Index to Financial Statements.”

	At June 30, 2015	
	Actual	**Pro Forma As Adjusted[2]**
Non-Current Liabilities	$ 31,539	$ 31,539
Stockholders' (Deficiency) Equity		
Preferred stock, $0.01 par value; 5,000,000 shares authorized; -0- shares issued and outstanding	$ -	$ -
Common stock, $0.001 par value; 30,000,000 shares authorized[1]; 2,818,363 shares issued before the offering [1] (4,368,751 shares pro forma, as adjusted)[2]; 2,790,431 shares outstanding before the offering[1] (4,340,819 shares pro forma, as adjusted)[2]	2,818	4,368
Additional paid-in capital	25,729,104	34,527,554
Accumulated deficit	(28,580,445)	(28,580,445)
Treasury stock, at cost, 27,932 shares	(32,000)	(32,000)
Total stockholders' (deficiency) equity	(2,880,523)	5,919,477
Total capitalization	$ (2,848,984)	$ 5,951,016

(1) Gives retroactive effect to a decrease, effective July 7, 2015, in the number of authorized, issued and outstanding shares of common stock that occurred as a result of a reverse split of our common stock of 1-for-20 and a concurrent decrease in our authorized shares of common stock to 30,000,000.

(2) Assumes that the over-allotment option has not been exercised.

DILUTION

If you invest in our securities in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the net tangible book value per share of our common stock immediately after this offering.

The net tangible book value (deficit) is determined by dividing our total tangible assets less our total liabilities by the number of shares of common stock outstanding. Our historical net tangible book value (deficit) as of June 30, 2015 was $(3,956,712), or $(1.42) per share. After giving effect to the sale of shares of common stock and warrants by us at an assumed public offering price of $6.45 per share, which is the last reported sale price of our common stock on the OTCQB market on September 15, 2015, less the estimated offering expenses payable by us and underwriting discounts (estimated to be an aggregate of $1,200,000), our pro forma net tangible book value at June 30, 2015 would have been approximately $4,843,000, or $1.12 per share. This would represent an immediate increase in the net tangible book value of $2.54 per share to existing stockholders and an immediate dilution of $5.33 per share to investors in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share		$ 6.45
Historical net tangible book value (deficit) per share as of June 30, 2015	$ (1.42)	
Increase in historical net tangible book value per share attributable to existing investors in this offering	2.54	
Pro forma, as adjusted, net tangible book value per share as of June 30, 2015 after giving effect to this offering		$ 1.12
Dilution per share to investors in this offering		$ 5.33

If the underwriter exercises its over-allotment option to purchase additional shares and warrants in full, pro forma, as adjusted, net tangible book value as of June 30, 2015 would increase to approximately $6,238,000, or $1.36 per share, representing an increase to existing stockholders of $2.78 per share, and the dilution to investors in this offering would be $5.09 per share.

The following table summarizes, as of June 30, 2015, the differences between the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders and by investors participating in this offering, before deducting underwriting discounts and estimated offering expenses, at an assumed public offering price of $6.45 per share, which is the last reported sale price of our common stock on the OTCQB market on September 15, 2015.

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Average Price per Share
Existing stockholders	2,790,431	64 %	$ 19,397,669	66 %	$ 6.95
New investors	1,550,388	36 %	10,000,000	34 %	$ 6.45
Totals	4,340,819	100 %	$ 29,397,669	100 %	$ 6.77

The above discussion and table is based on 2,790,431 shares of common stock outstanding as of June 30, 2015 and excludes:

- 232,558 shares of common stock, and 232,558 shares of common stock issuable upon the exercise of warrants to purchase common stock, issuable in the event the underwriter elects to exercise its over-allotment option in full;
- 789,200 shares of common stock issuable upon the exercise of stock options as of June 30, 2015 at a weighted-average exercise price of $12.25 per share;
- 728,850 shares of common stock issuable upon the exercise of warrants to purchase common stock that were outstanding as of June 30, 2015, with a weighted average exercise price of $16.17 per share; and
- 165,800 shares available for future issuance as of June 30, 2015 under our 2010 Equity Participation Plan.

To the extent that outstanding options and warrants are exercised, 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 summary consolidated financial data of BioRestorative Therapies, Inc. The financial data as of June 30, 2015 and for the six months ended June 30, 2015 and 2014 have been derived from our unaudited condensed consolidated financial statements included in this prospectus under “Index to Financial Statements”. The financial data as of December 31, 2014 and 2013 and for the years then ended have been derived from our audited consolidated financial statements included in this prospectus under “Index to Financial Statements”. The summary

consolidated financial results in the table below are not necessarily indicative of our expected future operating results. The following summary historical financial information should be read together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the historical financial statements and notes thereto appearing in this prospectus under “Index to Financial Statements”.

	For The Six Months Ended June 30,		For The Years Ended December 31,	
	2015 (unaudited)	2014	2014	2013
Selected Statement of Operations Data:				
Revenues	$ 333,666	$ 176,316	$ 415,996	$ 1,680
Cost of sales	151,077	42,426	213,834	208
Gross profit	182,589	133,890	202,162	1,472
Operating expenses				
Marketing and promotion	94,028	47,329	125,626	114,951
Consulting	504,060	824,763	1,310,121	779,462
Research and development	859,344	787,071	1,430,614	1,594,054
General and administrative	1,613,927	1,184,632	2,258,307	2,265,275
Total operating expenses	3,071,359	2,843,795	5,124,668	4,753,742
Other expense	(291,649)	(292,910)	(665,106)	(998,924)
Net loss	$ (3,180,419)	$ (3,002,815)	$ (5,587,612)	$ (5,751,194)
Net loss per share - basic and diluted	$ (1.60)	$ (2.79)	$ (4.38)	$ (6.96)
Weighted average number of common shares outstanding - basic and diluted	1,993,544	1,077,606	1,276,904	826,340

	June 30, 2015 (unaudited)	December 31, 2014	2013
Selected Balance Sheet Data:			
Cash	$ 6,445	$ 91,798	$ 201,098
Working capital deficit	(4,673,421)	(8,410,686)	(7,262,748)
Total assets	2,070,578	1,691,801	1,382,915
Total liabilities	4,951,101	8,580,194	8,067,984
Total stockholders' deficiency	(2,880,523)	(6,888,393)	(6,685,069)

MARKET FOR COMMON STOCK AND

RELATED STOCKHOLDER MATTERS

Our common stock is currently listed for trading on the OTCQB market under the symbol “BRTX”. At September 15, 2015, there were 2,854,268 shares of common stock outstanding. At September 15, 2015, there were 256 holders of record of our common stock.

The last reported sales price of our common stock on September 15, 2015 was $6.45 per share. The following table shows the high and low bid prices per share for our common stock by calendar quarter for the periods indicated. On April 15, 2013, we effected a 1-for-50 reverse split of our common stock. On July 7, 2015, we effected a 1-for-20 reverse split of our common stock. The prices shown have been retroactively adjusted to give effect to the reverse splits. The quotations set forth below reflect inter-dealer quotations that do not include retail markups, markdowns or commissions and may not represent actual transactions.

	High	Low
2013		
First Quarter	$ 39.00	$ 23.00
Second Quarter	$ 33.00	$ 14.00
Third Quarter	$ 19.80	$ 6.60
Fourth Quarter	$ 14.00	$ 8.00
2014		
First Quarter	$ 18.00	$ 5.60
Second Quarter	$ 12.00	$ 4.80
Third Quarter	$ 8.00	$ 5.00
Fourth Quarter	$ 10.40	$ 5.20
2015		
First Quarter	$ 10.00	$ 7.00
Second Quarter	$ 9.80	$ 6.00
Third Quarter (through September 15, 2015)	$ 12.25	$ 5.72

MANAGEMENT'S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the results of operations and financial condition of BioRestorative Therapies, Inc. as of June 30, 2015 and for the six months ended June 30, 2015 and 2014 and as of December 31, 2014 and 2013 and for the years then ended 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 8 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 therapeutic product being called *brtxDISC* (**D**isc **I**mplanted **S**tem **C**ells). We have obtained a license to use technology for 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 legs and feet. We are also developing our *ThermoStem Program*. This pre-clinical program involves the use of brown fat in connection with the cell-based treatment of type 2 diabetes and obesity as well as hypertension, other metabolic disorders and cardiac deficiencies. A United States patent related to the *ThermoStem Program* issued in September 2015.

We are developing a patented curved needle device, or CND, that is a needle system to allow access to difficult to locate regions for the delivery or removal of fluids and other substances. We also offer stem cell derived cosmetic and skin care products.

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

As of June 30, 2015, our accumulated deficit was $28,580,445, our stockholders' deficiency was $2,880,523 and our working capital deficiency was $4,673,421. While we have recently begun to generate a modest amount of revenue, our losses have principally been operating expenses incurred in research and development, marketing and promotional activities in order to commercialize our products and services, plus costs associated with meeting the requirements of being a public company. We expect to continue to incur substantial costs for these activities over at least the next year.

Based upon our working capital deficiency as of June 30, 2015 and our forecast for continued operating losses, we require equity and/or debt financing to continue our operations. As of June 30, 2015, our outstanding debt of $1,226,685, together with interest at rates ranging between 10% and 15% per annum, was due on various dates through February 2016. Subsequent to June 30, 2015 and through September 15, 2015, we have received aggregate equity financing and debt financing of $310,000 and $370,015, respectively, and $30,000 and $1,736 of debt and accrued interest, respectively, has been exchanged for or converted into common stock and warrants. If we are able to complete this offering, we anticipate that the net proceeds of the offering will fund our operations until September 2016 (assuming that the underwriter does not exercise its over-allotment option to purchase additional shares and/or warrants, we do not receive any revenues from operations, we do not receive any additional financing and our remaining debt is not converted into equity) and should permit us to conduct a significant portion of our initial clinical trial with regard to our *Disc/Spine Program.* We anticipate that we will require between $20,000,000 and $30,000,000

in additional funding to complete our clinical trials with regard to our *Disc/Spine Program.* 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 discussed in "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 considering 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 and, notwithstanding any request we may make, our debt holders 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.

Recent Developments

Westbury Debt Conversion

On May 27, 2015, we entered into an exchange agreement with Westbury (Bermuda), Ltd., our principal stockholder and then principal debtholder, pursuant to which Westbury exchanged $4,480,374 of indebtedness for 746,729 shares of our common stock and a five year warrant to purchase 186,682 shares of our common stock at an exercise price of $15.00 per share.

Consolidated Results of Operations

Six Months Ended June 30, 2015 Compared with Six Months Ended June 30, 2014

The following table presents selected items in our unaudited condensed consolidated statements of operations for the six months ended June 30, 2015 and 2014, respectively:

	For The Six Months Ended June 30,	
	2015	2014
Revenues	$ 333,666	$ 176,316
Cost of sales	151,077	42,426
Gross Profit	182,589	133,890

Operating Expenses		
Marketing and promotion	94,028	47,329
Consulting	504,060	824,763
Research and development	859,344	787,071
General and administrative	1,613,927	1,184,632
Total Operating Expenses	3,071,359	2,843,795
Loss From Operations	(2,888,770)	(2,709,905)
Other (Expense) Income		
Interest expense	(124,736)	(145,521)
Amortization of debt discount	(140,884)	(244,435)
Loss on extinguishment of notes payable, net	(26,029)	(49,094)
Warrant modification expense	-	(30,128)
Gain on settlement of payables	-	176,268
Total Other Expense	(291,649)	(292,910)
Net Loss	$ (3,180,419)	$ (3,002,815)

47

Revenues

For the six months ended June 30, 2015, we generated $327,466 of revenues through the services provided pursuant to our research and development agreements, $6,000 from royalty revenue and $200 from sales of Stem Pearls® skincare products. For the six months ended June 30, 2014, we generated $175,025 of revenues through the services provided pursuant to our research and development agreements and $1,291 from sales of Stem Pearls® skincare products.

Cost of sales

For the six months ended June 30, 2015, cost of sales was $151,077 as compared to $42,426 for the comparable 2014 period. For the six months ended June 30, 2015, cost of sales consisted almost entirely of costs related to our research and development agreements. For the six months ended June 30, 2014, cost of sales consisted primarily of costs related to our research and development agreements.

Gross profit

For the six months ended June 30, 2015, gross profit was $182,589 (55% of revenues) as compared to $133,890 (76% of revenues) for the comparable 2014 period, primarily due to increased research and development costs related to our research and development agreements. We incurred additional costs in the current period relating to our research agreements as a result of the increased usage of a third-party laboratory.

Marketing and promotion

Marketing and promotion expenses include advertising and promotion, marketing and seminars, meals, and entertainment and travel expenses. For the six months ended June 30, 2015, marketing and promotion expenses increased by $46,699, or 99%, to $94,028 from $47,329 in the comparable 2014 period. The increase is primarily due to increased travel expenses of approximately $14,000 and increased hotel expenses of approximately $12,000.

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

Consulting

Consulting expenses consist of consulting fees and stock-based compensation to consultants. For the six months ended June 30, 2015, consulting expenses decreased $320,703, or 39%, to $504,060 from $824,763 in the comparable 2014 period. The decrease is primarily due to an approximate $445,000 decrease in non-cash stock-based compensation to directors, consultants and advisors, partially offset by an increase in cash compensation to consultants of approximately $124,000.

Research and development

Research and development expenses include cash and non-cash compensation of our Chief Executive Officer (in part) along with employee, consultant and other costs related to our brown fat and disc/spine initiatives. Research and development expenses are expensed as they are incurred. For the six months ended June 30, 2015, research and development expenses increased by $72,273, or 9%, to $859,344 from $787,071 in the comparable 2014 period. The increase is primarily attributable to an increase in payroll of approximately $165,000 due to hiring of new staff, the costs incurred related to operating our Melville laboratory of approximately $88,000, an increase in stock-based compensation to directors, consultants and advisors in the amount of approximately $82,000, all partially offset by a decrease in cash compensation to consultants of approximately $118,000, the amendment of our University of Utah Research Agreement resulting in a reduction of expense related to our brown fat and disc/spine initiatives as compared to the prior period of approximately $90,000 and the reduction of our Chief Executive Officer’s salary which resulted in approximately $53,000 less expense.

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

General and administrative

General and administrative expenses consist primarily of salaries, bonuses, payroll taxes, severance costs and stock-based compensation to employees (excluding any cash or non-cash compensation of our Chief Executive Officer or employees attributable to research and development) as well as corporate support expenses such as legal

and professional fees, investor relations and occupancy related expenses. For the six months ended June 30, 2015, general and administrative expenses increased by $429,295, or 36%, to $1,613,927 from $1,184,632 in the comparable 2014 period. The increase is primarily due to increased professional fees of approximately $314,000 primarily due to a legal settlement, an increase in salary and payroll expenses associated with hiring additional personnel of approximately $63,000, an increase in expenses related to furnishing and operating our Melville offices of approximately $37,000 and an increase in stock-based compensation to employees in the amount of approximately $28,000 due to awards granted during the second half of 2014.

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

Interest expense

For the six months ended June 30, 2015, interest expense decreased $20,785, or 14%, to $124,736 from $145,521 in the comparable 2014 period. The decrease was due to a lower average debt balance as compared to the comparable 2014 period.

Amortization of debt discount

For the six months ended June 30, 2015, amortization of debt discount decreased by $103,551, or 42%, to $140,884 from $244,435 in the comparable 2014 period. The decrease was primarily due to the decrease in note issuances and timing.

Loss on extinguishment of notes payable, net

For the six months ended June 30, 2015, we recorded a loss on extinguishment of notes payable of $26,029, as compared to a net loss on extinguishment of notes payable of $49,094 for the comparable 2014 period, which is associated with investors' exchange of debt into equity securities.

Warrant modification expense

For the six months ended June 30, 2015, we recorded warrant modification expense of $0. For the six months ended June 30, 2014, we recorded expense of $30,128 related to the modification of outstanding investor warrants.

Gain on settlement of note and payables, net

For the six months ended June 30, 2015, we recognized a gain on settlement of payables of $0. For the six months ended June 30, 2014, we recorded a $176,268 gain primarily related to the settlement amendment of our University of Utah Research Agreement regarding our brown fat and disc/spine initiatives whereby a portion of the fees payable to the University of Utah were cancelled.

50

Year Ended December 31, 2014 Compared with Year Ended December 31, 2013

The following table presents selected items in our consolidated statements of operations for the years ended December 31, 2014 and 2013, respectively:

	For The Years Ended December 31,	
	2014	2013
Revenues	$415,996	$1,680
Cost of sales	213,834	208
Gross Profit	202,162	1,472
Operating Expenses		
Marketing and promotion	125,626	114,951
Consulting	1,310,121	779,462
Research and development	1,430,614	1,594,054
General and administrative	2,258,307	2,265,275
Total Operating Expenses	5,124,668	4,753,742
Loss From Operations	(4,922,506)	(4,752,270)
Other (Expense) Income		
Interest expense	(285,275)	(371,281)
Amortization of debt discount	(464,470)	(405,531)
Loss on extinguishment of note and payables, net	(49,094)	(7,200)
Warrant modification expense	(50,035)	(214,912)
Gain on settlement of notes and payables	183,768	-
Total Other Expense	(665,106)	(998,924)
Net Loss	$(5,587,612)	$(5,751,194)

Revenues

For the year ended December 31, 2014, we generated $413,777 of revenues through the services provided pursuant to our research and development agreements and $2,219 of sales of *Stem Pearls* skincare products. For the year ended

December 31, 2013, revenues consisted only of $1,680 of sales of *Stem Pearls* skincare products.

Cost of sales

For the year ended December 31, 2014, cost of sales was $213,834 as compared to $208 for 2013. For the year ended December 31, 2014, cost of sales consisted primarily of $198,162 of costs related to our research and development agreements. For the year ended December 31, 2013, cost of sales consisted of the costs of the underlying *Stem Pearls* skincare products.

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, 2014, marketing and promotion expenses increased by $10,675, or 9%, from $114,951 to $125,626, as compared to the year ended December 31, 2013.

We expect that marketing and promotion expenses will continue to increase in the future as we increase our marketing activities in connection with our clinical trials and 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, 2014, consulting expenses increased $530,659, or 68%, from $779,462 to $1,310,121, as compared to the year ended December 31, 2013. The increase is primarily due to an approximate $525,000 increase in non-cash stock-based compensation to directors, consultants and advisors and an approximate $40,000 increase in directors fees related to the resignation of one of the members of our Board of Directors, whereby we agreed to pay the director for the remainder of his 2014 compensation, and the increase of our Board of Directors by one member, partially offset by an approximate $34,000 reduction of cash consulting fees.

Research and development

Research and development expenses include cash and non-cash compensation of (a) our Chief Executive Officer (in part); (b) our Vice President of Research and Development; and (c) our Scientific Advisory Board members, 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, 2014, research and development expenses decreased by $163,440 from $1,594,054 to $1,430,614, or 10%, as compared to the year ended December 31, 2013. The decrease is primarily related to the amendment of our University of Utah Research Agreement resulting in a reduction of expense related to our brown fat and disc/spine initiatives as compared to the prior period of approximately $135,000, the reclassification of a portion of our Vice President of Research and Development's salary of approximately $128,000 to cost of sales for services related to our research and development agreements and a reduction of our Chief Executive Officer's salary during 2014 which resulted in approximately $88,000 less expense in 2014 as compared to 2013, partially offset by an increase in non-cash stock-based compensation to our Vice President of Research and Development of approximately $96,000, cash compensation to our Chief Medical Advisor for Spine Medicine of $95,000 and a one-time bonus of $25,000 earned by our Vice President of Research and Development.

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 Chief Executive Officer attributable to research and development and (b) our Vice President of Research and Development) as well as corporate support expenses such as legal and professional fees, investor relations and occupancy related expenses. For

the year ended December 31, 2014, general and administrative expenses decreased by $6,968, or less than 1%, from $2,265,275 to $2,258,307, as compared to the year ended December 31, 2013.

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

Interest expense

For the year ended December 31, 2014, interest expense decreased $86,006, or 23%, as compared to the year ended December 31, 2013. The decrease was due to a reduction in interest-bearing short-term borrowings as compared to the year ended December 31, 2013 including the restructuring of our largest note payable.

Amortization of debt discount

For the year ended December 31, 2014, amortization of debt discount increased $58,939, or 15%, as compared to the year ended December 31, 2013. The increase was primarily due to the recognition of expense related to the beneficial conversion features of convertible notes and the timing of the recognition of the debt discount expense.

Loss on extinguishment of notes payable

For the year ended December 31, 2014, we recorded a loss on extinguishment of notes payable of $49,094, which is associated with investors' conversion of debt into equity securities, as compared to a loss on extinguishment of notes payable of $7,200 for the year ended December 31, 2013.

Warrant modification expense

During the year ended December 31, 2014, we recorded expense related to the modification of outstanding warrants of $50,035, as compared to expense related to the modification of outstanding warrants of $214,912 for the year ended December 31, 2013.

Gain on settlement of notes and payables, net

During the year ended December 31, 2014, we recorded a gain on settlement of notes and payables, net, of $183,768 related to a $166,668 gain on the amendment of our University of Utah Research Agreement regarding our brown fat and disc/spine initiatives whereby a portion of the fees payable to the University of Utah were cancelled, a $9,600

gain on the settlement of accrued expenses to consultants and a $7,500 gain on the settlement of a convertible note. There were no gains on settlement of notes or payables recorded during the year ended December 31, 2013.

Liquidity and Capital Resources

Liquidity

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

	June 30, 2015 (unaudited)	December 31, 2014	2013
Cash	$ 6,445	$ 91,798	$ 201,098
Working Capital Deficiency	$ (4,673,421)	$ (8,410,686)	$ (7,262,748)
Notes Payable (Gross)	$ 1,226,685	$ 5,851,496	$ 5,754,500

Availability of Additional Funds

Based upon our working capital and stockholders' deficiency of $4,673,421 and $2,880,523, respectively, as of June 30, 2015, we require additional equity and/or debt financing to continue our operations. These conditions raise substantial doubt about our ability to continue as a going concern.

As of June 30, 2015, our outstanding debt of $1,226,685, together with interest at rates ranging between 10% and 15% per annum, was due on various dates through February 2016. Subsequent to June 30, 2015 and through September 15, 2015, we have received aggregate equity and debt financing of $310,000 and $370,015, respectively, and $30,000 and $1,736 of debt and accrued interest, respectively, has been exchanged for or converted into common stock and warrants. As of September 15, 2015, our outstanding debt was as follows:

Maturity Date	Principal Amount
Past Due	$ 275,000
QE 12/31/15	1,005,703
QE 3/31/16	310,000
	$ 1,590,703

Since our inception, we have not generated any significant revenues from our operations and have funded our operations through the sale of our equity securities (approximately $8,000,000) and debt securities (approximately $10,000,000). The implementation of our business plan, as discussed in "Business", will require the receipt of sufficient equity and/or debt financing to purchase necessary equipment, technology and materials, fund our research and development efforts, retire our outstanding debt and otherwise fund our operations. If we are able to complete this offering, we anticipate that the estimated net proceeds of $8,800,000 from this offering will fund our operations until September 2016 (assuming that the underwriter does not exercise its over-allotment option to purchase additional shares and/or warrants, we do not receive any revenues from operations, we do not receive any additional financing and our remaining debt is not converted into equity) and should permit us to conduct a significant portion of our initial clinical trial with regard to our *Disc/Spine Program.* We anticipate that we will require between $20,000,000 and $30,000,000 in additional funding to complete our clinical trials with regard to our *Disc/Spine Program.* 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 discussed in "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.

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

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

During the six months ended June 30, 2015 and 2014 and the years ended December 31, 2014 and 2013, our sources and uses of cash were as follows:

Net Cash Used in Operating Activities

We experienced negative cash flow from operating activities for the six months ended June 30, 2015 and 2014 in the amounts of $1,484,389 and $1,759,925, respectively. The net cash used in operating activities for the six months ended June 30, 2015 was primarily due to cash used to fund a net loss of $3,180,419, adjusted for net non-cash expenses in the aggregate amount of $856,050 partially offset by $839,980 of net cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in accrued interest, expenses and other current liabilities and deferred revenues. The net cash used in operating activities for the six months ended June 30, 2014 was primarily due to cash used to fund a net loss of $3,002,815, adjusted for non-cash expenses in the aggregate amount of $1,116,329 partially offset by $126,561 of net cash provided primarily as a result of increases in accounts payable plus accrued expenses and other current liabilities, due to cash constraints during the period.

We experienced negative cash flows from operating activities for the years ended December 31, 2014 and 2013 in the amounts of $3,227,851 and $2,672,404, respectively. The net cash used in operating activities for the year ended December 31, 2014 was primarily due to cash used to fund a net loss of $5,587,612, adjusted for non-cash expenses in the aggregate amount of $1,878,162, partially offset by $481,599 of cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in accounts payable plus accrued expenses and other liabilities, due to cash constraints during the period. The net cash used in operating activities for the year ended December 31, 2013 was primarily due to cash used to fund a net loss of $5,751,194, adjusted for non-cash expenses in the aggregate amount of $1,559,567, partially offset by $1,519,223 of cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in accounts payable plus accrued expenses and other liabilities, due to cash constraints during the period.

Net Cash Used in Investing Activities

During the six months ended June 30, 2015, $151,914 of cash was used to purchase fixed assets and $75,000 was used to retain exclusivity of our disc/spine license. During the six months ended June 30, 2014, $980 was provided by investing activities from the sale of fixed assets.

During the year ended December 31, 2014, net cash used in investing activities was $167,396, primarily due to cash used for the purchase of furniture, computer equipment and medical equipment. During the year ended December 31, 2013, net cash used in investing activities was $11,160, primarily due to cash used for the purchase of medical equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the six months ended June 30, 2015 and 2014 was $1,625,950 and $1,617,010, respectively. During the six months ended June 30, 2015, $583,000 of net proceeds were from debt financings and $1,051,000 of proceeds were from equity financings. During the six months ended June 30, 2014, $592,010 of proceeds were from debt financings and $1,025,000 of proceeds were from equity financings (including proceeds received in connection with the exercise of common stock purchase warrants).

Net cash provided by financing activities during the years ended December 31, 2014 and 2013 was $3,285,947 and $2,884,299, respectively. During the year ended December 31, 2014, $567,947 of net proceeds were from debt financings and $2,718,000 of proceeds were from equity financings (including proceeds received in connection with the exercise of common stock purchase warrants). During the year ended December 31, 2013, $1,473,490 of net proceeds were from debt financings and $1,410,809 of proceeds were from equity financings (including proceeds received in connection with the exercise of common stock purchase warrants).

Critical Accounting Policies and Estimates

Use of Estimates

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

Intangible Assets

Intangible assets are comprised of trademarks and licenses with original estimated useful lives of 10 and 17.7 years (20 year life of underlying patents being licensed, less 2.3 years elapsed since the application date of the respective patents), respectively. Once placed into service, we amortize the cost of the intangible assets over their estimated useful lives on a straight line basis.

Impairment of Long-lived Assets

We review for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount.

Revenue Recognition

Research and Development Agreements

Our policy relating to research and development agreements is to recognize research and development revenues associated with such agreements either on a straight-line basis over the term of the agreement, or in accordance with the milestone method of revenue recognition, depending on the nature of the contract terms, subject to potential acceleration upon achievement of contractually specified deliverables.

On March 19, 2014, we entered into a one-year agreement with a Japanese pharmaceutical company to perform specified research and development activities related to stem cells. The agreement terminated on June 19, 2015. Payment terms are (1) $150,000 at commencement; (2) $50,000 upon achievement of a specified deliverable; and (3) $50,000 upon achievement of the final specified deliverable. As of June 30, 2015, $200,000 had been received under the agreement, $250,000 had been recognized as revenue and the unpaid $50,000 was recorded as accounts receivable. In August 2015, we received the remaining $50,000.

On March 24, 2014, we entered into a two-year agreement with a U.S. pharmaceutical company to perform specified research and development activities related to brown fat. The agreement may be terminated earlier or extended, as provided for in the agreement. Payment terms are (1) $250,000 at commencement; (2) $356,250 payable in four equal quarterly installments, subject to acceleration upon achieving a specified deliverable; and (3) $168,750 payable in two equal bi-annual installments, subject to acceleration upon achieving a specified deliverable. As of June 30, 2015, $605,359 had been received under the agreement, $491,241 had been recognized as revenue and $114,118 was recorded as deferred revenues on the condensed consolidated balance sheet.

During the six months ended June 30, 2015 and 2014 and the year ended December 31, 2014, we recognized revenue related to research and development agreements of $327,466, $175,025 and $413,776, respectively. We did not recognize any revenue related to research and development agreements during the year ended December 31, 2013.

Other

Our policy is to recognize product sales when the risk of loss and title to the product transfers to the customer, after taking into account potential returns. We recognize sublicensing and royalty revenue when all of the following have occurred: (i) persuasive evidence of an arrangement exists, (ii) the service is completed without further obligation, (iii) the sales price to the customer is fixed or determinable, and (iv) collectability is reasonably assured.

For the six months ended June 30, 2015 and 2014, we recognized revenue related to sales of *Stem Pearls* skincare products of $200 and $1,291, respectively. For the years ended December 31, 2014 and December 31, 2013, we recognized revenue related to sale of *Stem Pearls* skincare products of $2,220 and $1,680, respectively.

In connection with our license agreement with Regenerative Sciences, LLC, as described in "Business – Disc/Spine Program – License", for the six months ended June 30, 2015 and 2014, we recognized royalty revenue of $6,000 and $0, respectively.

Income Taxes

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

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

Stock-Based Compensation

We measure the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. Since the shares underlying our 2010 Equity Participation Plan are not currently registered, the fair value of our restricted equity instruments was estimated by us based on observations of the cash sales prices of both restricted shares and freely tradable shares.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, “Revenue from Contracts with Customers,” or ASU 2014-09. ASU 2014-09 supersedes the revenue recognition requirements in Accounting Standards Codification, or ASC, 605 - Revenue Recognition and most industry-specific guidance throughout the ASC. The standard requires that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective on January 1, 2017 and should be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application. We are currently evaluating the impact of the adoption of ASU 2014-09 on our consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-10, “Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation,” or ASU 2014-10. ASU 2014-10 removes the definition of a development stage entity from the ASC, thereby removing the financial reporting distinction between development stage entities and other reporting entities from GAAP. In addition, ASU 2014-10 eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of operations, cash flows, and stockholders’ equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early adoption is permitted. We elected to adopt ASU 2014-10 effective with the period ended June 30, 2014 and its adoption resulted in the removal of previously required development stage disclosures.

In June 2014, the FASB issued ASU No. 2014-12, "Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period," or ASU 2014-12. The amendments in ASU 2014-12 require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in ASC Topic No. 718, "Compensation - Stock Compensation" as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. We do not anticipate that the adoption of ASU 2014-12 will have a material impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern”, or ASU 2014-15. ASU 2014-15, which is effective for annual reporting periods ending after December 15, 2016, extends the responsibility for performing the going-concern assessment to management and contains guidance on how to perform a going-concern assessment and when going-concern disclosures would be required under U.S. GAAP. We elected to adopt ASU 2014-15 effective with the period ended September 30, 2014. Management’s evaluations regarding the events and conditions that raise substantial doubt regarding our ability to continue as a going concern have been discussed above and also disclosed in the footnotes to the December 31, 2014 consolidated financial statements included elsewhere in this prospectus.

In April 2015, the FASB issued ASU No. 2015-03, “Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs,” or ASU 2015-03. This standard amends the existing guidance to require that debt issuance costs be presented in the balance sheet as a deduction from the carrying amount of the related debt liability instead of as a deferred charge. ASU 2015-03 is effective on a retrospective basis for annual and interim reporting periods beginning after December 15, 2015, but early adoption is permitted. We do not anticipate that the adoption of ASUI 2015-03 will have a material impact on our consolidated financial statements.

Off-Balance Sheet Arrangements

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

BUSINESS

General

We develop therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult (non-embryonic) stem cells. Our two core programs, as discussed below, relate to the treatment of disc/spine disease and metabolic disorders:

- ***Disc/Spine Program.*** Our lead cell therapy candidate, *brtxDISC* (**D**isc **I**mplanted **S**tem **C**ells), 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 protruding and bulging lumbar discs in patients suffering from chronic lumbar disc disease. The treatment involves collecting a patient’s own stem cells, culturing and cryopreserving the cells, and then having a physician inject *brtxDISC* into the patient’s damaged disc in a contemplated 30 minute outpatient office procedure. The treatment is intended for patients whose pain has not been alleviated by non-invasive procedures and who potentially face the prospect of surgery. We intend to file an IND application with the FDA with regard to *brtxDISC* during the first quarter of 2016 and anticipate that we will commence clinical trials using *brtxDISC* and its related collection and delivery procedure by the middle of 2016. See “Disc/Spine Program” below.

.

Metabolic Program (ThermoStem). We are developing an allogeneic cell-based therapy to target obesity and metabolic disorders using brown adipose (fat) derived stem cells 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 the body 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. In order to deliver BAT into target locations *in vivo*, we seeded brown adipose derived stem cells, or BADSC, onto 3 – dimensional biological scaffolds. We are identifying alternative *in vivo* delivery methods, including encapsulation technology, in small animal models. In March 2014, we entered into a Research Agreement with Pfizer, Inc., a global pharmaceutical company, pursuant to which we have been engaged to provide research and development services with regard to a joint study of the development and validation of a human brown adipose (fat) cell model. A United States patent related to the *ThermoStem Program* issued in September 2015. See “Metabolic Brown Adipose (Fat) Program” below.

We have also licensed a patented curved needle device designed to deliver cells and/or other therapeutic products or material to the spine and discs. The patent for this device was issued to the licensor, Regenerative Sciences, LLC, in August 2015. See “Curved Needle Device” below.

In addition, we have developed a human cellular extract that has been demonstrated in *in vitro* skin studies to increase the production of collagen and fibronectin, which are proteins that are essential to combating the aging of skin. We also offer plant stem cell-based facial creams and beauty products under the *Stem Pearls* brand. See “Cosmetic Products” below.

Overview

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

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

We intend to concentrate initially on therapeutic areas in which risk to the patient is low, recovery is relatively easy, results can be demonstrated through sufficient clinical data, and patients and physicians will be comfortable with the procedure. We believe that there will be readily identifiable groups of patients who will benefit from these procedures.

Accordingly, we plan to focus our initial efforts in offering cellular-based therapeutic products and treatment programs in selective areas of medicine for which the treatment protocol is minimally invasive. Such areas include the treatment of the disc and spine and metabolic-related disorders. We will seek to obtain third party reimbursement for our products and procedures; however, patients may be required to pay for our products and procedures out of pocket in full and without the ability to be reimbursed by any governmental and other third party payors.

61

We have obtained a patent and patent and patent pending licenses and have undertaken research and development efforts in connection with the development of therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. See “Disc/Spine Program”, “Metabolic Brown Adipose (Fat) Program” and “Curved Needle Device” below.

We also offer human and plant stem cell derived cosmetic and skin care products. See “Cosmetic Products” below.

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

Disc/Spine Program

General

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

Lower back pain is the most common, most disabling, and most costly musculoskeletal ailment faced worldwide. It is estimated that 84% of the global populace will have an occurrence of lower back pain during their lifetime and that 11% will have chronic lower back pain. Annual direct healthcare costs relating to lower back pain in the United States are estimated to be in excess of $90 billion. Clinical studies have documented that the source of the pain is most frequently damage to the IVD. This can occur when forces, whether a single load or repetitive microtrauma, exceed the IVD’s inherent capacity to cope with those loads. Aging, obesity, smoking, lifestyle, and certain genetic factors may predispose one to an IVD injury.

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

and relieve pain.

We are concentrating on the development of a mesenchymal stem cell product derived from autologous (or a person's own) human bone marrow, cultured and formulated to be delivered into a protruding or bulging disc. We intend to file an IND application with the FDA with regard to *brtxDISC* during the first quarter of 2016 and anticipate that we will commence clinical trials using *brtxDISC* and its related collection and delivery procedure by the middle of 2016.

In addition to developing *brtxDISC*, we may also seek to sublicense the technology to third parties for use in connection with cellular-based treatment programs with regard to disc and spine related conditions.

We have established a laboratory to perform cellular characterization and culturing for the production of cell products for use in our clinical trials. This capability may also enable us to develop our pipeline of future products and expand our stem cell-related IP. See “Laboratory” and “Technology; Research and Development” below.

brtxDISC

Our lead therapeutic product*, brtxDISC,* is an autologous hypoxic (low oxygen) cultured mesenchymal stem cell product derived from an adult patient’s bone marrow and formulated with a proprietary carrier. The cryopreserved sterile cellular product will be provided to the clinician in vials for injection into damaged lumbar discs. The therapeutic application of *brtxDISC*, in treatment of chronic lumbar disc disease, is performed using a standard 20 gauge 3.5 inch introducer needle and a 25 gauge 6 inch needle that extends into the disc region where the product is delivered. Specific medical practitioners will be provided training using the product with regard to the injection procedure. It is anticipated that the treatment and delivery of the product will be a 30 minute outpatient procedure.

MSCs used in *brtxDISC* are similar to other MSCs under development by others; however, in order to enhance the survivability of our bone marrow-derived MSCs in the avascular environment of the damaged disc, *brtxDISC* is expanded under hypoxic conditions for a period of three weeks. This process results in a cell population with enhanced viability and therapeutic potential following injection locally into injured spinal discs. A study has demonstrated that MSCs preconditioned in hypoxic environment show enhanced skeletal muscle regeneration, improved blood flow and vascular formation compared to MSCs cultured under normoxic (normal oxygen) conditions.

Production and Delivery

The production of *brtxDISC* begins with the physician collecting bone marrow from the patient under a local anesthesia. Peripheral blood is also collected from the patient. The physician will then send the patient’s bone marrow and blood samples to our laboratory for culturing and proprietary carrier preparation. The hypoxic culturing process applied is intended to result in the selection of a cell population that is suitable for an improved possibility of survival in the internal disc environment. The cell culturing process and product formulation will take approximately three weeks. We will then send the therapeutic cryopreserved stem cells (*brtxDISC*) in a sterile vial back to the physician’s offices where it will be thawed prior to the procedure. The price structure for the procedure and our services has not been determined and no assurances can be given in this regard. The following chart illustrates the process.

63

License

Pursuant to a license agreement between Regenerative Sciences, LLC, or Regenerative, and us that became effective in April 2012, we have obtained, among other things, a worldwide (excluding Asia and Argentina), exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain method for culturing cells for use in treating, among other things, disc and spine conditions, including protruding and bulging discs. The technology that has been licensed is an advanced stem cell culture and injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the legs and feet. Pursuant to the license agreement, we have also obtained a worldwide, exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain curved needle device for the administration of specific cells and/or cell products to the disc and/or spine (and other parts of the body). We intend to advance the design of this medical device to facilitate the delivery of substances, including living cells, to specific locations within the body and minimize the potential for damage to nearby structures.

The license agreement provides for the requirement that we achieve certain milestones or pay certain minimum royalty amounts in order to maintain the exclusive nature of the licenses. The license agreement also provides for a royalty-bearing sublicense of certain of the technology to Regenerative for use for certain purposes, including in the Cayman Islands. Further, the license agreement requires that Regenerative furnish certain training, assistance and consultation services with regard to the licensed technology.

Clinical Trial

In December 2014, we held a pre-IND meeting with the FDA's Office of Cellular Tissue and Gene Therapies within the FDA's Center for Biologics, Evaluation and Research. At the meeting, representatives of the FDA commented on our plans for an IND submission and a clinical trial with regard to *brtxDISC*. No obstacles were identified at the meeting by the FDA representatives that we believe would materially impact the IND plans for a clinical trial with regard to *brtxDISC* in patients with chronic lumbar disc disease. We intend to file an IND application with the FDA with respect to our proposed treatment protocol and initiate a clinical trial. We expect to file the IND application during the first quarter of 2016 and anticipate that we will begin a clinical trial by the middle of 2016. The principal investigator for our clinical trial is intended to be Dr. Gregory E. Lutz, our Chief Medical Advisor for Spine Medicine. See "Management-Scientific Advisors".

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

Metabolic Brown Adipose (Fat) Program

We are engaging in pre-clinical research efforts with respect to a platform technology utilizing BAT for therapeutic purposes. We have labeled this initiative our *ThermoStem Program*. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of healthy metabolism, thus potentially being involved in caloric regulation. This pre-clinical program involves the use of a cell-based (brown adipose tissue) treatment for metabolic disease, such as type 2 diabetes, obesity, hypertension and other metabolic disorders and cardiac deficiencies. Although we have had initial success in transplanting the tissue in animals, we are currently exploring ways to deliver the brown fat tissue into humans. Even though present, BAT mass is very low in healthy adults and even lower in obese populations. Therefore, it may not be sufficient to either naturally impact whole body metabolism, or to be targeted by drugs intended to increase its activity in the majority of the population. Increasing BAT mass is crucial in order to benefit from its metabolic activity and this is what our *ThermoStem*

Program seeks to accomplish. We may also identify other naturally occurring and chemically engineered molecules that may enhance brown adipose tissue performance.

65

BAT is a specialized adipose tissue found in the human body that plays a key role in the evolutionarily conserved mechanisms underlying thermogenesis (generation of non-shivering body heat) and energy homeostasis in mammals - long known to be present at high levels in hibernating mammals and human newborns. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of healthy metabolism, thus potentially being involved in caloric regulation.

Obesity, the abnormal accumulation of white fat tissue, leads to a number of metabolic disorders and is the driving force behind the rise of type 2 diabetes and cardiovascular diseases worldwide. Pharmacological efforts to alter metabolic homeostasis through modulating central control of appetite and satiety have had limited market penetration due to significant psychological and physiological safety concerns directly attributed to modulating these brain centers. Adipose tissue is one of the largest organs in the human body and plays a key role in central energy balance and lipid homeostasis. Two types of adipose tissues are found in mammals, white and brown adipose tissues. White adipose tissue function is to store energy, whereas BAT specializes in energy expenditure. Recent advancements in unraveling the mechanisms that control the induction, differentiation, proliferation, and thermogenic activity of BAT, along with the application of imaging technologies for human BAT visualization, have generated optimism that these advances may provide novel strategies for targeting BAT activation/thermogenesis, leading to efficacious and safe obesity targeted therapies. It is estimated that by 2030 one billion persons worldwide will suffer from obesity and twice that number will be overweight.

In June 2011, we launched the initial research phase of what we believe will develop into a platform technology that involves the use of brown fat in a cell-based therapeutic program referred to as the *ThermoStem Program*. The *ThermoStem Program* will focus on treatments for metabolic disorders such as type 2 diabetes, obesity, hypertension, and cardiac deficiencies, and will involve the study of BADSC, BAT, a therapeutic delivery system, and potentially molecules that would regulate brown adipose tissue function.

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

In order to deliver these differentiated cells into target locations *in vivo*, we seeded BADSC on