

BioRestorative Therapies, Inc.  
Form S-1/A  
November 05, 2015

As filed with the Securities and Exchange Commission on November 5, 2015

Registration No. 333-204672

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**AMENDMENT NO. 4**

**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**   **(Primary Standard Industrial**   **(I.R.S. Employer**  
**incorporation or organization)**   **Classification Code Number)**   **Identification Number)**

**40 Marcus Drive, Suite One**

**Melville, New York 11747**

**(631) 760-8100**

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

**Mark Weinreb, President and Chief Executive Officer**

**BioRestorative Therapies, Inc.**

**40 Marcus Drive, Suite One**

**Melville, New York 11747**

**(631) 760-8100**

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

*Copies to:*

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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

**Calculation of Registration Fee**

<b>Title of each class of securities to be registered</b>	<b>Proposed maximum aggregate offering price <sup>(1)</sup></b>	<b>Amount of registration fee <sup>(2)</sup></b>
Common Stock, par value \$.001 per share <sup>(3)</sup>	\$ 4,000,000	\$ 402.80
Common Stock Purchase Warrants <sup>(4)</sup>	\$ -	\$ -
Common Stock Underlying Common Stock Purchase Warrants <sup>(3)</sup>	\$ 5,000,000	\$ 503.50
<b>TOTAL REGISTRATION FEE</b>		<b>\$ 906.30 (5)</b>

(1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933.

- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.  
Pursuant to Rule 416 under the Securities Act of 1933, the shares of common stock registered hereby also include
- (3) an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.
- (4) No registration fee pursuant to Rule 457(g) under the Securities Act of 1933.
- (5) \$906.30 has already been paid.

**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 NOVEMBER 5, 2015

### **842,106 Shares of Common Stock**

### **Warrants to Purchase 842,106 Shares of Common Stock**

We are offering for sale 842,106 shares of our common stock, together with warrants to purchase 842,106 shares of our common stock (and the shares issuable from time to time upon exercise of such warrants), pursuant to this prospectus. The shares and the warrants will be separately issued and sold to purchasers in equal proportion. Each warrant will be exercisable for the purchase of one share of common stock, will have an exercise price of \$        per share (125% of the public offering price per share in this offering), will be exercisable upon issuance, will expire five years from the date of issuance and will be non-transferable.

The offering is being made on a self-underwritten “best efforts” basis with no requirement that any minimum amount be sold. There will be no escrow or impound of funds tendered on subscription, and proceeds from the sale of shares and warrants will be available to us immediately upon acceptance of subscriptions by us. No underwriter has been engaged to facilitate the sale of shares and warrants in this offering. There are no underwriting commissions involved in this offering. See “Plan of Distribution” beginning on page 107 for more information about how the shares and warrants will be sold in this offering.

Our common stock is quoted on the OTCQB market under the symbol “BRTX.” We have not applied, and will not apply, to have the warrants being sold in this offering quoted on the OTCQB market or any other market or exchange. On November 3, 2015, the last reported sale price of our common stock on the OTCQB market was \$4.75 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.**

	<b>Combined</b>	
	<b>Per Share and</b>	<b>Total</b>
	<b>Warrant</b>	
Public offering price	\$	\$
Net proceeds, before expenses, to us <sup>(1)</sup>	\$	\$

(1) Does not give effect to the payment of any commissions to underwriters or brokers in connection with this offering. See “Plan of Distribution”.

**TABLE OF CONTENTS**

	<b>Page</b>
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	8
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	39
<u>USE OF PROCEEDS</u>	40
<u>DIVIDEND POLICY</u>	41
<u>CAPITALIZATION</u>	41
<u>DILUTION</u>	42
<u>SELECTED FINANCIAL DATA</u>	43
<u>MARKET FOR COMMON STOCK AND RELATED STOCKHOLDER MATTERS</u>	44
<u>MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	45
<u>BUSINESS</u>	60
<u>MANAGEMENT</u>	83
<u>EXECUTIVE COMPENSATION</u>	88
<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	92
<u>PRINCIPAL STOCKHOLDERS</u>	94
<u>DESCRIPTION OF SECURITIES</u>	96
<u>PLAN OF DISTRIBUTION</u>	107
<u>LEGAL MATTERS</u>	107
<u>EXPERTS</u>	107
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	108
<u>INDEX TO FINANCIAL STATEMENTS</u>	109

We have 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 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 ®, <sup>SM</sup> or <sup>TM</sup> symbols, and copyrighted content appears without the use of the symbol ©, but the absence of use of these symbols does not reflect upon the validity or enforceability of the intellectual property owned by us or third parties.



## 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.*

*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 plan to file an investigational new drug, or IND, application with the Food and Drug Administration, or the FDA, with regard to *brtxDISC* during the second quarter of 2016 and intend to commence clinical trials using *brtxDISC* and its related collection and delivery procedure by the third quarter of 2016.



· **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*.

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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.



## 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 initiate and 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](http://www.biorestorative.com). Our subsidiary, Stem Pearls, LLC, also has a website at [www.stempearls.com](http://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 842,106 shares of our common stock and warrants to purchase 842,106 shares of our common stock.

Description of warrants The shares and the warrants will be separately issued and sold to purchasers in equal proportion. Each warrant will be exercisable for the purchase of one share of our common stock, will have an exercise price of \$ \_\_\_\_\_ per share (125% of the public offering price per share in this offering), will be exercisable upon issuance, will expire five years from the date of issuance and will be non-transferable.

Common stock outstanding before this offering(1) 2,971,462 shares.

Common stock to be outstanding after this offering(1) 3,813,568 shares.

Use of proceeds We intend to use the net proceeds of this offering as follows: (i) submission of investigational new drug, or IND, application to the United States Food and Drug Administration, or FDA, with respect to *brtxDISC* and its related collection and delivery procedure; (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

(1) The number of shares of our common stock to be outstanding after this offering is based on 2,971,462 shares outstanding as of November 3, 2015. The number of shares of common stock to be outstanding after this offering includes 842,106 shares of our common stock sold in this offering (assuming the sale of all of the shares offered by this prospectus). Unless otherwise indicated, the number of outstanding shares of common stock presented in this

prospectus excludes:

842,106 shares of our common stock issuable upon the exercise of the warrants sold in this offering (assuming the sale of all of the warrants offered by this prospectus);

6

1,315,450 shares of our common stock issuable upon the exercise of outstanding options granted under our 2010 Equity Participation Plan as of November 3, 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 November 3, 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); and

909,528 shares of our common stock issuable upon the exercise of outstanding warrants as of November 3, 2015.

up to 25,264 shares of our common stock issuable upon the exercise of warrants that may be granted to underwriters or brokers in connection with this offering. See “Plan of Distribution”.

### 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, 2015		For The Years Ended December 31, 2014	
	2015	2014	2014	2013
	(unaudited)			
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				

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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 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 initiate and 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. The offering is being made on a “best efforts” basis. Accordingly, we will be able to utilize all subscription proceeds without the requirement that a minimum amount of proceeds be received. If we are able to complete this offering in full, we anticipate that the estimated net proceeds of \$3,600,000 from this offering (assuming that no underwriter or brokerage commissions are paid in connection with this offering) will fund our operations until February 2016 (assuming we do not receive any revenues from operations, we do not receive any additional financing and our remaining debt is not converted into equity). We anticipate that, following this offering (assuming the sale of all of the shares and warrants offered by this prospectus), we will require between \$5,000,000 and \$6,000,000 in additional financing to commence and complete a Phase 2 clinical trial with regard to our *Disc/Spine Program*. We anticipate that we will require between \$20,000,000 and \$30,000,000 in further 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. In the event we do not obtain the financing required for the above purposes, we may have to curtail our development, marketing and promotional activities, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately we could be forced to discontinue our operations and liquidate. See “Risk Factors – Risks Related to This Offering, Our Common Stock and Our Warrants – There is no minimum number of shares and warrants that must be sold and no assurance that the proceeds from the sale of shares and warrants will allow us to meet our goals” and “Use of Proceeds” and “Plan of Distribution”.

***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.