

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report: June 15, 2017
(Date of earliest event reported)

BIORESTORATIVE THERAPIES, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	000-54402	91-1835664
(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification Number)
40 Marcus Drive, Melville, NY		11747
(Address of Principal Executive Offices)		(Zip Code)

Registrant's telephone number, including area code: (631) 760-8100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 **Regulation FD Disclosure.**

BioRestorative Therapies, Inc. (the "Company") has prepared presentation materials (the "Presentation Materials") that management intends to use from time to time on and after June 15, 2017 in presentations about the Company's business. The Company intends to use the Presentation Materials, possibly with modification, at the Marcum Microcap Conference being held on June 15, 2017 and June 16, 2017 and may use the Presentation Materials in other presentations to current and potential investors, lenders, creditors, insurers, vendors, customers, employees and others with an interest in the Company and its business.

The information contained in the Presentation Materials is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements that the Company may make by press release or otherwise from time to time. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While the Company may elect to update the Presentation Materials in the future to reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, the Company specifically disclaims any obligation to do so. The Presentation Materials are furnished as Exhibit 99.1 to this Current Report on Form 8-K and are incorporated herein by reference. The presentation materials will also be posted in the Investor Relations section of the Company's website, www.biorestorative.com for 90 days.

The information referenced under Item 7.01 (including Exhibit 99.1 referenced in Item 9.01 below) of this Current Report on Form 8-K is being "furnished" under "Item 7.01. Regulation FD Disclosure" and, as such, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information set forth in this Current Report on Form 8-K (including Exhibit 99.1 referenced in Item 9.01 below) shall not be incorporated by reference into any registration statement, report or other document filed by the Company pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits.

99.1 Presentation Materials.

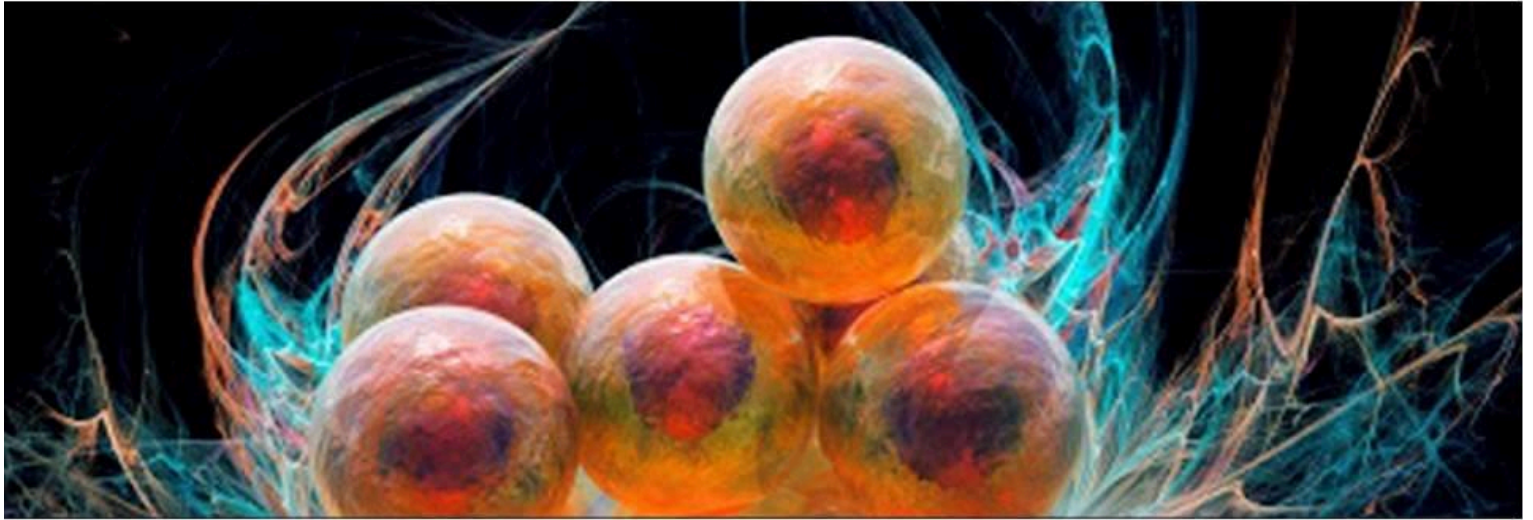
SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIORESTORATIVE THERAPIES, INC.

Dated: June 15, 2017

By: /s/ Mark Weinreb
Mark Weinreb
Chief Executive Officer



PRESENTATION 2017

OTCQB: BRTX ♦ biorestorative.com

Forward Looking Statements



Statements in this presentation, including the information set forth as to the future financial or operating performance of BioRestorative Therapies, Inc. (the "Company"), that are not current or historical factual statements may constitute "forward looking" information within the meaning of securities laws. When used in this presentation, such statements may include, among other terms, such words as "may," "will," "expect," "believe," "plan," "anticipate," "intend," "estimate," "project," "target" and other similar terminology. These statements reflect current expectations, estimates and projections regarding future events and operating performance and speak only as to the date of this presentation. Readers should not place undue importance on forward looking statements and should not rely upon this information as of any other date. 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: (i) our limited operating history, lack of significant revenues, substantial losses since inception, and substantial working capital deficiency and stockholders' deficiency; (ii) our ability to obtain sufficient financing to initiate and complete our clinical trials, implement our business plan, satisfy our debt obligations and fund our operations; (iii) our ability to timely and successfully develop and commercialize *BRTX-100*, our lead product candidate for the treatment of chronic lumbar disc disease; (iv) delays in enrolling patients in our clinical trials; (v) 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; (vi) failure of our clinical trials to demonstrate adequately the safety and efficacy of our product candidates; (vii) our lack of manufacturing capabilities to produce our product candidates at commercial scale quantities; (viii) the loss of our exclusive license rights with regard to our disc/spine technology; (ix) safety problems encountered by us or others developing new stem cell-based therapies; (x) ethical and other concerns surrounding the use of stem cell therapy which negatively impact the public perception of our stem cell products and/or services; (xi) our limited experience in the development and marketing of cell therapies; (xii) our reliance on novel technologies that are inherently expensive and risky; (xiii) significant product liability claims and litigation which we may be subject to, including potential exposure from the use of our product candidates in human subjects; (xiv) our inability to obtain reimbursement for our products and services from private and governmental insurers; (xv) our inability to protect our proprietary rights; and (xvi) compliance with applicable federal, state, local, and international requirements. See also "Factors That May Affect Future Results and Financial Condition" listed in the Company's most recent Annual Report on Form 10-K filed with the SEC. Many of these issues can affect the Company's actual results and could cause the actual results to differ materially from those expressed or implied in any forward looking statements made by, or on behalf of, the Company. Readers are cautioned that forward looking statements are not guarantees of future performance, and should not place undue reliance on them. In formulating the forward looking statements contained in this presentation, it has been assumed that business and economic conditions affecting the Company will continue substantially in the ordinary course. These assumptions, although considered reasonable at the time of preparation, may prove to be incorrect.



BioRestorative Therapies, Inc. develops therapeutic products using cell and tissue protocols, primarily involving adult stem cells. Our two core programs relate to the treatment of disc/spine disease and metabolic disorders.

MULTIPLE CELL THERAPY PROGRAMS

■ DISC/SPINE PROGRAM (*brtxDISC™*):

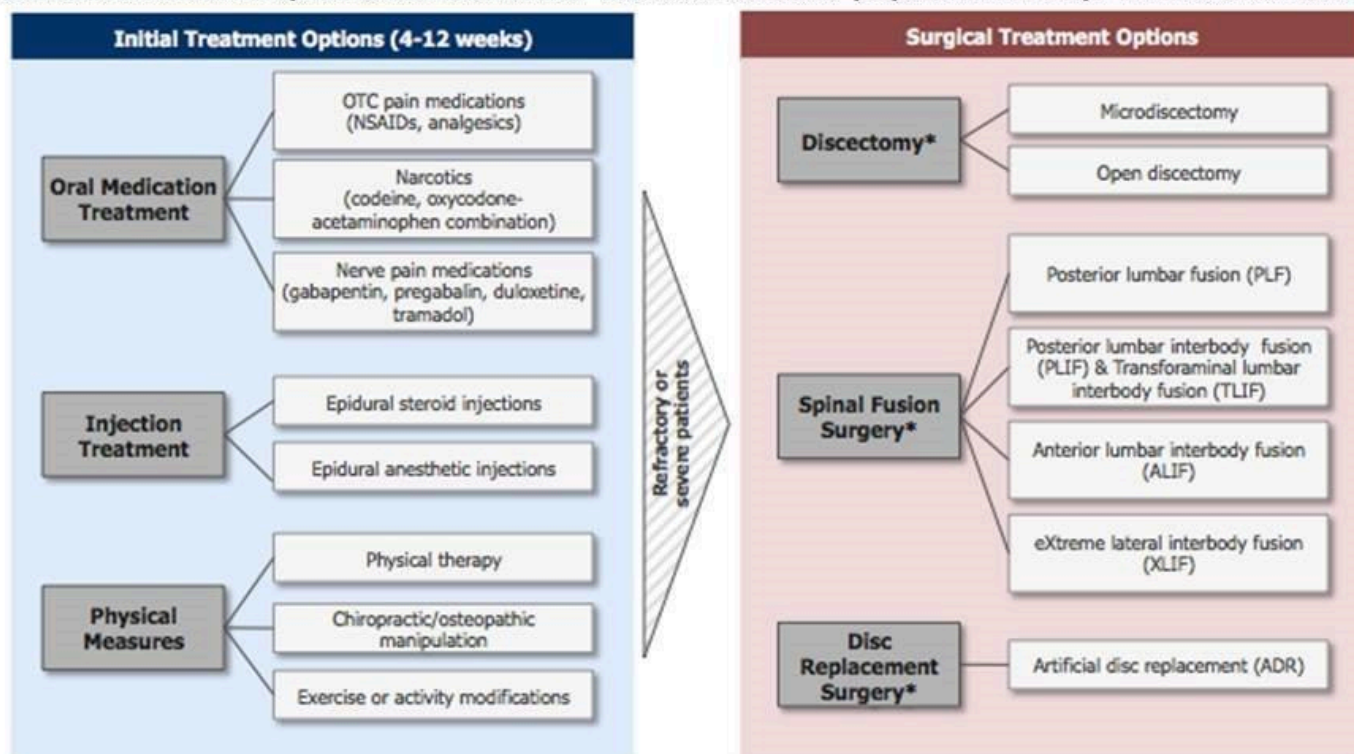
- ♦ **FDA Clearance to Commence Phase 2 Clinical Trials**
- ♦ An advanced cell therapy to treat chronic lumbar disc disease caused by protruding or bulging discs
- ♦ Lead therapeutic product "**BRTX-100**" has been engineered to promote healing in damaged intervertebral discs

■ METABOLIC PROGRAM (*ThermoStem®*):

- ♦ Cell-based therapy to target diabetes, obesity and metabolic disorders using brown adipose (fat) cells and tissue
- ♦ Finalize clinical indication and delivery mechanism and drive to IND filing

Disc Treatment Options

Current treatment options for the BRTX-100-addressable population range from conservative



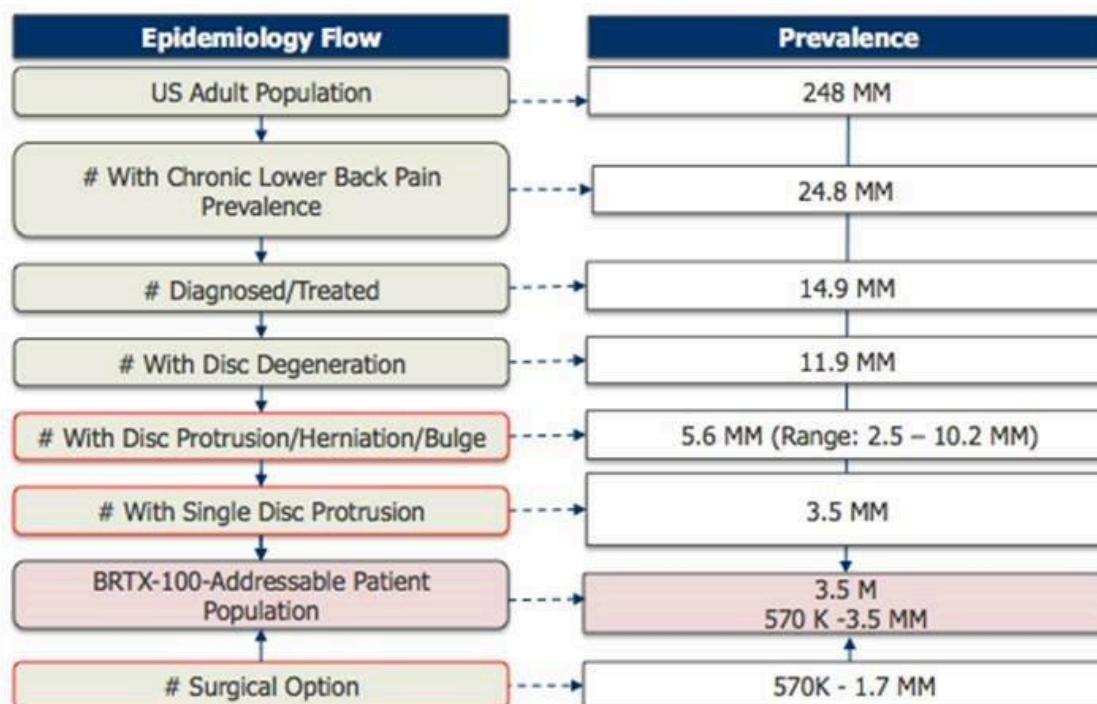
*Discectomy: surgery to remove part of the herniated disc material that presses on a nerve root or the spinal cord

*Spinal Fusion Surgery: surgery designed to stop the motion at a painful vertebral segment by joining, or fusing, two or more vertebrae

*Disc Replacement Surgery: surgery involving replacing a painful disc with an artificial disc (PRODISC®-L currently approved)

Market (Prevalence Summary)

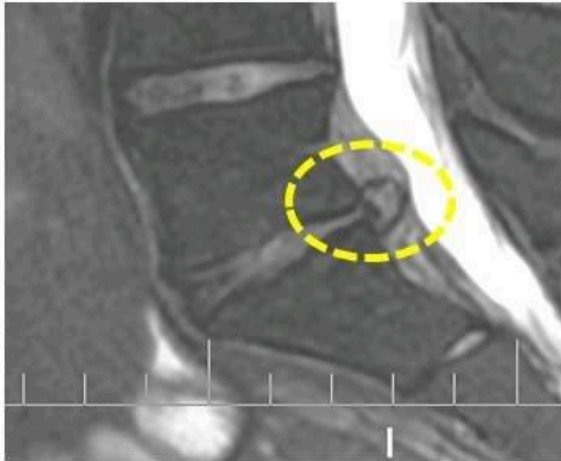
Trinity Partners used a multi-pronged approach to determine the prevalence of the BRTX-100-addressable patient population



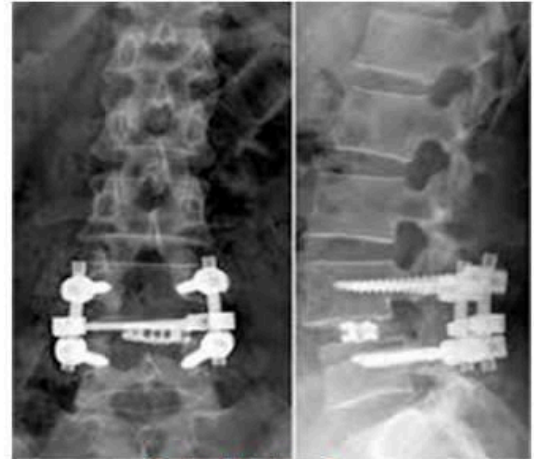
Lower Back Pain Disc Therapy Program



Lower Back Pain is the Most Common, the Most Disabling, and the Most Costly Musculoskeletal Problem Treated



Protruding / Bulging Disc



Spinal Fusion Surgery

***INTRODUCING A NEW STANDARD OF CARE TO TREAT
CHRONIC LUMBAR DISC DISEASE***



Disc Therapy to Treat Chronic Lumbar Disc Disease (Protruding and Bulging Discs)



Single Injection Procedure

Non-Surgical 30 Minute
Outpatient Procedure
Patient's Own Cells
High Patient/Physician
Adoption Expected

■ **BRTX-100 - Lead Cell Therapy Candidate**

Product Formulated from Autologous Hypoxic
Cultured Mesenchymal Stem Cells (or MSCs)
Collected from the Patient's Bone Marrow and Co-
Administered with Autologous Biomaterial Carrier

■ **Treatment** is Intended for Patients Whose Pain
Has Not Been Alleviated by Non-Invasive
Procedures and Who Potentially Face the
Prospect of Surgery

■ **Phase 2 Clinical Trial Cleared To Proceed**

■ **HUMAN DATA** from Treatments Performed in the
US

BRTX-100 Product Benefits



Hypoxic Culture Conditions – A Solution for Mesenchymal Stem Cell Based Regenerative Medicine

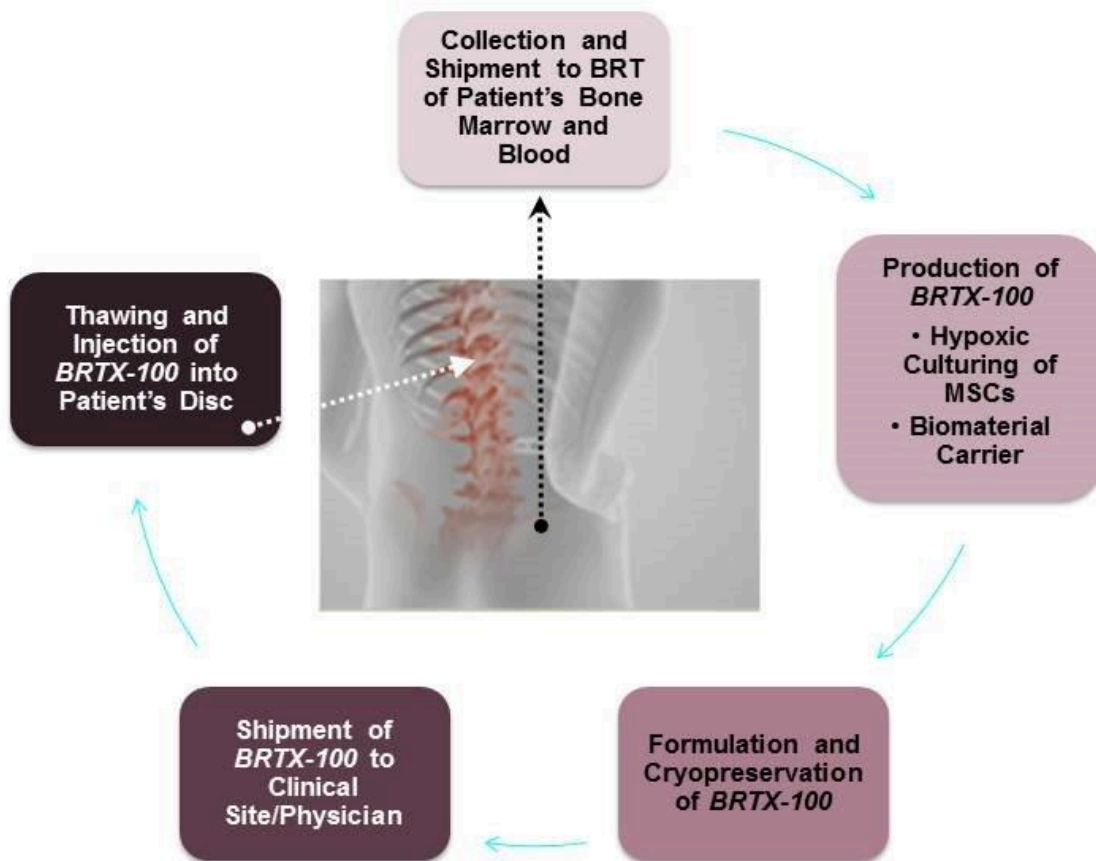
Hypoxic Culture Benefits

- Increased Cell Proliferation
- Greater Plasticity
- Increased Paracrine Effect
- Increased Cell Survival

BRTX-100 - A Safer and More Potent Product

<i>BRTX-100</i>	<i>Mesoblast</i>
Autologous	Allogeneic
Bone Marrow MSC	Bone Marrow MSC
100% Xeno-Free	FBS Culture
Hypoxic Cultured	Normoxic Cultured
Platelet Lysate/Carrier	Hyaluronic Acid/Carrier

BRTX-100: Production Process - 5 Weeks





Elabd et al. *J Transl Med* (2016) 14:253
DOI 10.1186/s12967-016-1015-5

Journal of
Translational Medicine

RESEARCH

Open Access



Intra-discal injection of autologous, hypoxic cultured bone marrow-derived mesenchymal stem cells in five patients with chronic lower back pain: a long-term safety and feasibility study

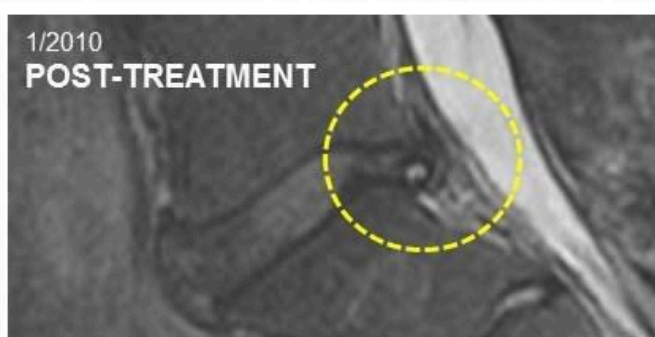
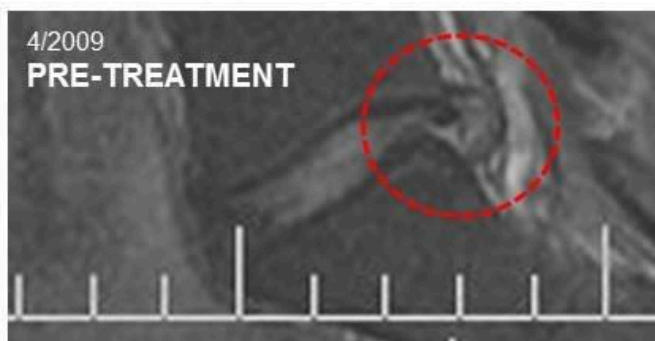
Christian Elabd¹, Christopher J. Centeno², John R. Schultz², Gregory Lutz³, Thomas Ichim⁴ and Francisco J. Silva^{1*}

Disc Morphologic Changes



Therapy May Have a Significant Impact on the Morphology of the Disc

- 42 yo Male needed epidural steroid injections multiple times annually for radiculopathy
- Large central, contained, broad based protrusion (L5-S1)
- 6 Years Conventional treatment
 - ◆ Narcotics
 - ◆ Epidural Steroids
 - ◆ Physical Therapy
- 75% Reduction in disc bulge post treatment
- 70% Reported improvement 2 years post treatment





■ Trial Design:

A Phase 2 Prospective, Double-Blinded, Placebo Controlled, Randomized Study, n=72

- ♦ Evaluate Safety and Efficacy of a Single Dose of *BRTX-100*
- ♦ 15+ Clinical Trial Sites
- ♦ Primary Efficacy Endpoint – 6 months
- ♦ Patient Follow Up – 12 months, 24 months



■ Primary Endpoint

- ♦ **Improvement in Function** defined as at least a 30% increase in function based on the Oswestry questionnaires (ODI)
- ♦ **Reduction of Pain** defined as at least a 30% decrease in pain as measured using the Visual Analogue Scale (VAS)

■ Additional or Secondary Endpoints

- ♦ Quality of Life Assessment
- ♦ Evolution of Affected Disc(s) by Magnetic Resonance Imaging (MRI)

Key Highlights - Value Proposition



- **Unique Product Engineered to Address the Challenges of the Targeted Application**
 - ◆ Autologous Hypoxic-Cultured Cell Product
 - ◆ **BRTX-100** is Formulated and Co-Administered with Biomaterial Carrier
- **Prior Hypoxic-Cultured Cell Therapy Clinical Experience**
 - ◆ BioRestorative Therapies Long Term Safety Study Publication
 - ◆ Promising Human Data from Investigational Study in US
- **Pending Clinical Trial**
 - ◆ FDA Clearance of Phase 2 Clinical Trials
 - ◆ Short Duration – Efficacy Endpoint 6 Mo.; Patient Follow Up – 12/24 Mo.
 - ◆ **Target Patient Enrollment Expected in Q4 2017**
- **BRTX-100 Addressable U.S. Patient Population**
 - ◆ 570 K - 5.6 MM Potential US Patients with Target Indication
 - ◆ \$8.6 Billion Revenue Potential (\$15,000/patient x 570 K Procedures)



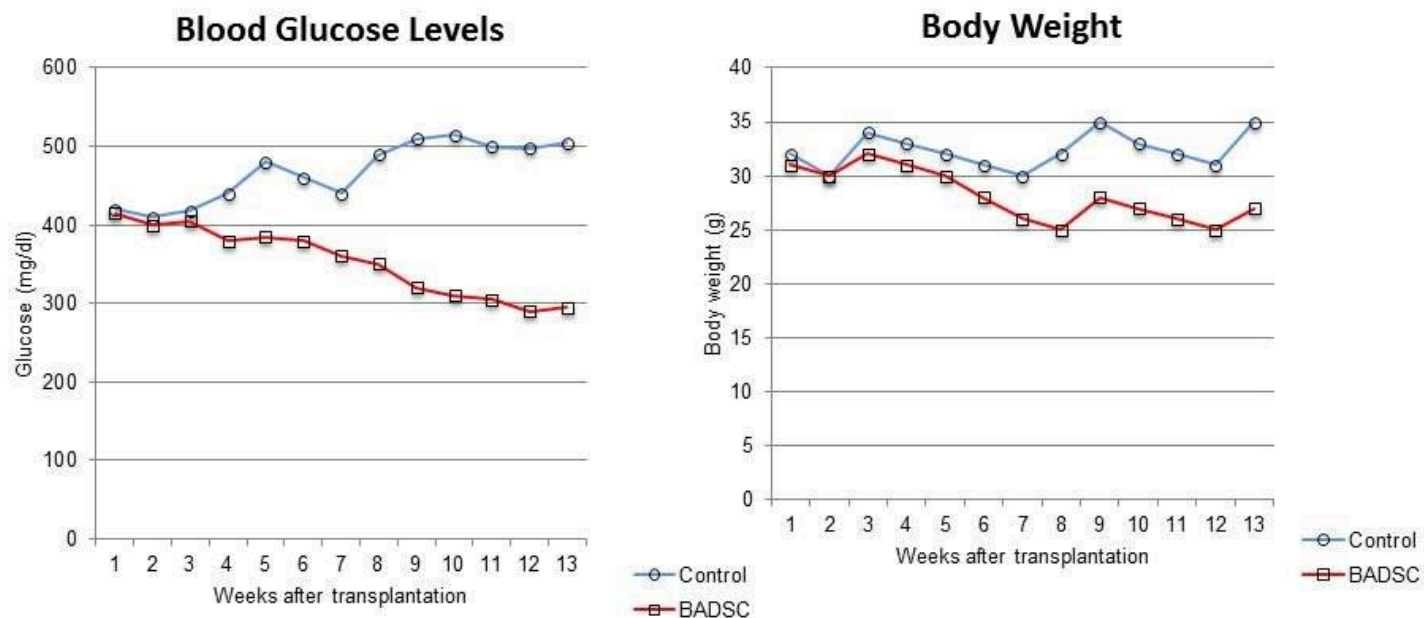
Potential Treatments for Metabolic Diseases



- Pre-clinical allogeneic cell-based therapy to target obesity, diabetes and metabolic disorders using brown adipose (fat) derived stem cells (BADSC) to generate brown adipose tissue (BAT)
- 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.
- Research Collaboration with University of Pennsylvania – Division of Endocrinology, Diabetes and Metabolism on Brown Adipose Stem Cell Program



Glucose and Body Weight



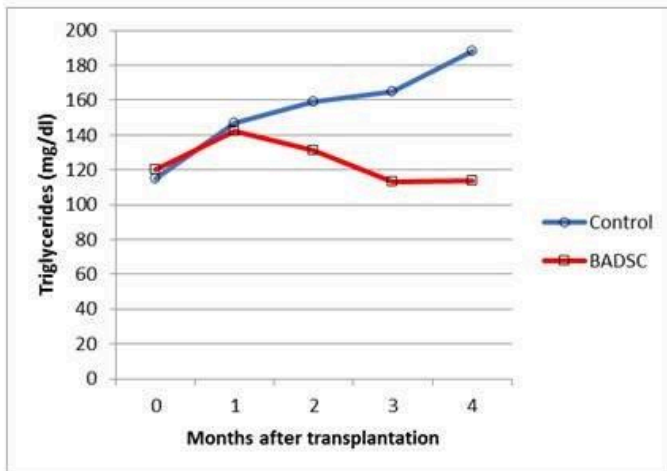
Mice fed high chow diet throughout experiment and transplanted with brown adipose derived stem cells (BADSC)/scaffolds and controls

Preclinical Metabolic Results

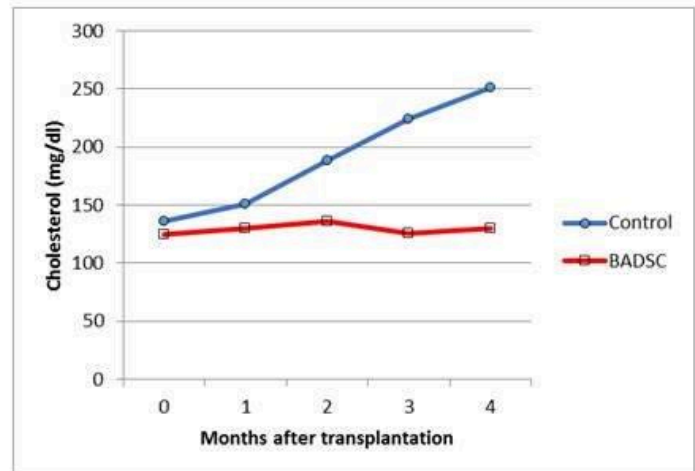


Triglycerides and Cholesterol Levels

Triglycerides Level



Cholesterol Level

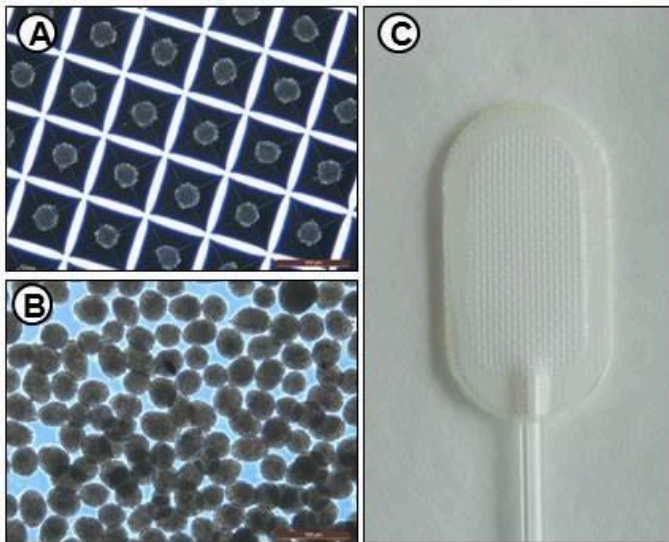


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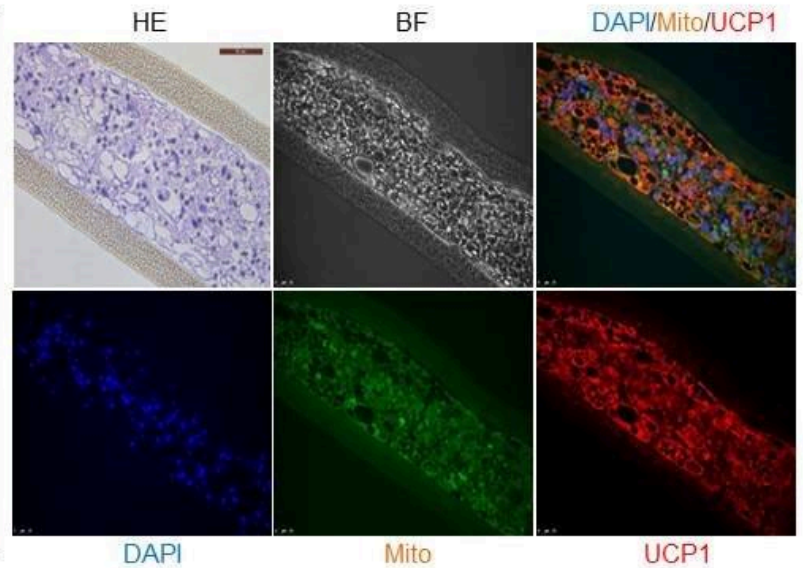
Brown Fat Delivery Device



Encapsulation Device/BADSCs



Encapsulation Device containing BADSC that have been differentiated into brown fat.
(A) BADSC inside encapsulation device.
(B) BASDC prior to loading (C) Encapsulation Device.



Immunohistochemical analysis of a cross section of an encapsulation device containing cells. UCP1 confirms the differentiation and identity of the brown adipose stem cells. DAPI stains nuclei, Mito stains mitochondria.

Thank You



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