

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 1, 2016
(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))
-

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 1, 2016 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 1, 2016 and June 2, 2016 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.

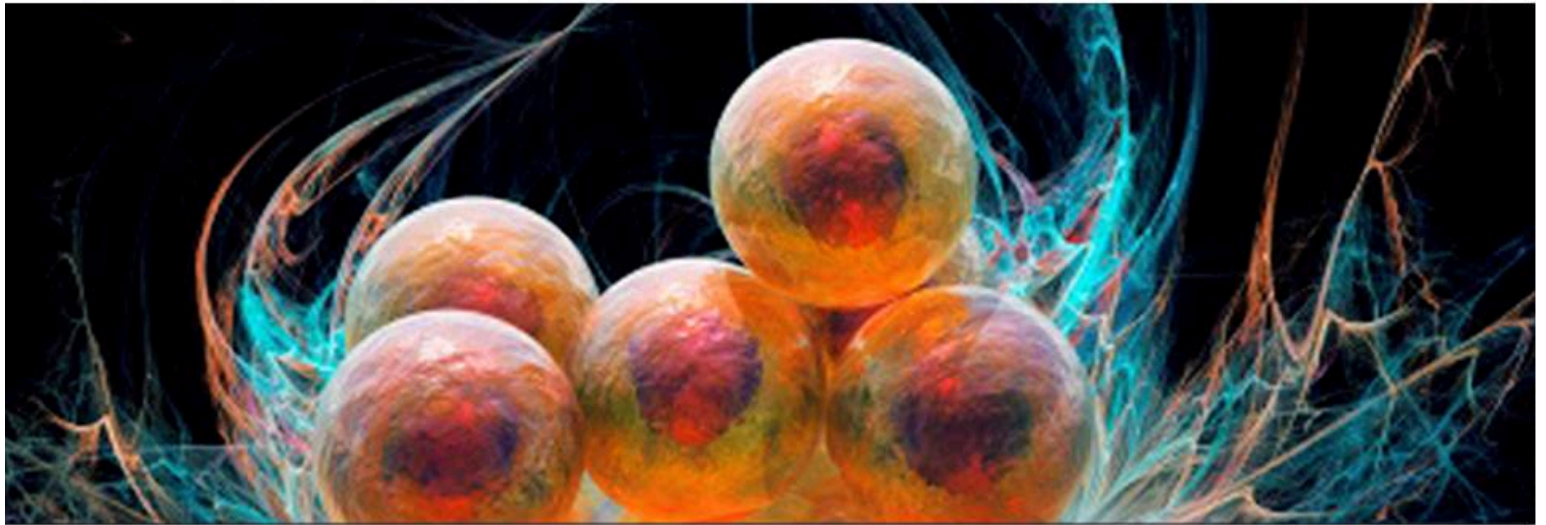
BIORESTORATIVE THERAPIES, INC.

Dated: June 1, 2016

By: /s/ Mark Weinreb

Mark Weinreb

Chief Executive Officer



PRESENTATION

2016

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 complete our clinical trials, implement our business plan and satisfy our debt obligations; (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; (xvi) compliance with applicable federal, state, local, and international requirements; (xvii) dependence upon our executive officers and need to attract additional qualified personnel; and (xviii) vulnerability to competition and technological changes. See also "Risk Factors" listed in the Company's most recent filings 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™*):

- ◆ 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
- ◆ IND submission targeted 4Q 2016 with clinical trial commencement 1Q 2017

■ METABOLIC PROGRAM (*ThermoStem®*):

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

STRONG MANAGEMENT & ADVISORY TEAMS

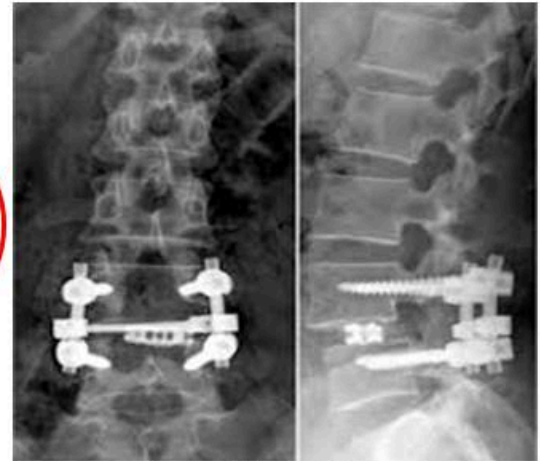
Lower Back Pain Disc Therapy Program



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)

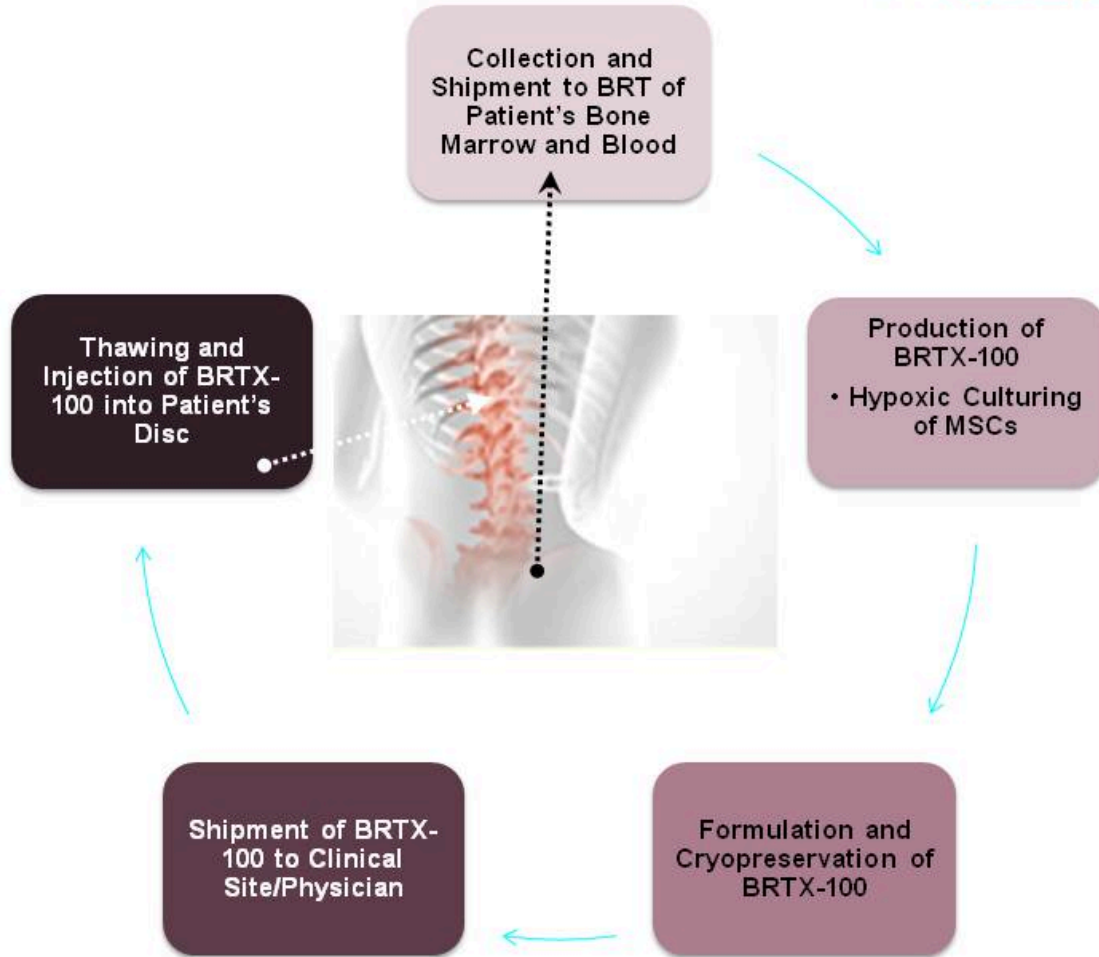


Single Injection Procedure

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 Cultured Mesenchymal Stem Cells (or MSCs) Collected from the Patient's Bone Marrow
- **Treatment** is Intended for Patients Whose Pain Has Not Been Alleviated by Non-Invasive Procedures and Who Potentially Face the Prospect of Surgery
- **Clinical Trial** recruitment expected to commence 1Q 2017
Initial Successful Pre-IND Meeting with FDA
- **Promising HUMAN Data** from Treatments Performed in the US

BRTX-100: Production Process



BRTX-100: Engineered for the Disc



■ BRTX-100 Key Attributes:

- ◆ Autologous
- ◆ Contains Hypoxic (Low Oxygen) Cultured Mesenchymal Stem Cells
- ◆ High Cell Viability for Disc
- ◆ Cryopreserved



■ BRTX-100 Cell Based Therapy (2 step mechanism):

- ◆ Structural (Bio-Mechanical Properties)
 - Supply disc tissue-specific cells that replace lost or damaged resident cells of disc
 - ↪ ↑ Extracellular matrix integrity
 - Secretion of growth factors to enhance cell structure
- ◆ Immuno-Modulate the Inflammatory Response
 - ↪ ↓ Inflammatory cascade

■ BRTX-100 Primary Endpoint:

- ◆ Improve Function and Decrease Pain in Patients with Chronic Lower Lumbar Disease

Previous Human Data



- A physician-sponsored, IRB-approved study investigated the effect of hypoxic cultured MSCs on disc protrusions (from 2008-2010)
- Safety observations:
 - ◆ No adverse events observed
- Efficacy observations:
 - ◆ Reduction in pain – 67% of subjects (n=12) had $\geq 30\%$ improvement in pain score
 - ◆ Improved function – 56% of subjects (n=9) had $\geq 30\%$ improvement in FRI
 - ◆ Improved self-reported Quality Of Life – mean improvement of $\sim 60\%$ in patient QoL (*mean time since treatment = 2.3 yrs*)
- Beneficial disc morphology changes observed

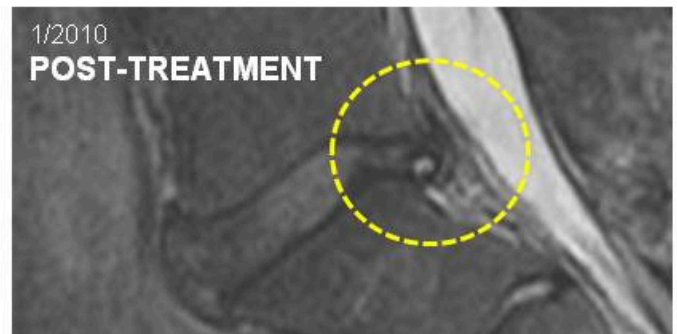
63% of subjects had $\geq 30\%$ Reduction in Pain Score and $\geq 30\%$ Improvement in Function

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



56% of Subjects (n=16) had $\geq 50\%$ Reduction in Disc Bulge Size



- A prospective, double-blinded, placebo controlled, randomized study, n=62
 - ◆ 12 patient dose escalation cohort with 10mm, 20mm and 40mm cell dose cohorts
 - ◆ 50 patient safety and efficacy cohort with maximum dose
 - Evaluate safety and preliminary efficacy of a single dose intradiscal injection of BRTX-100 in patients with chronic lumbar disc disease
 - ◆ 5-10 clinical trial sites

- Endpoints

- ◆ Pain assessment using Visual Analogue Scales (VAS)
- ◆ Oswestry questionnaires (ODI)
- ◆ Quality of life assessment
- ◆ Evolution of affected disc(s) by Magnetic Resonance Imaging (MRI)

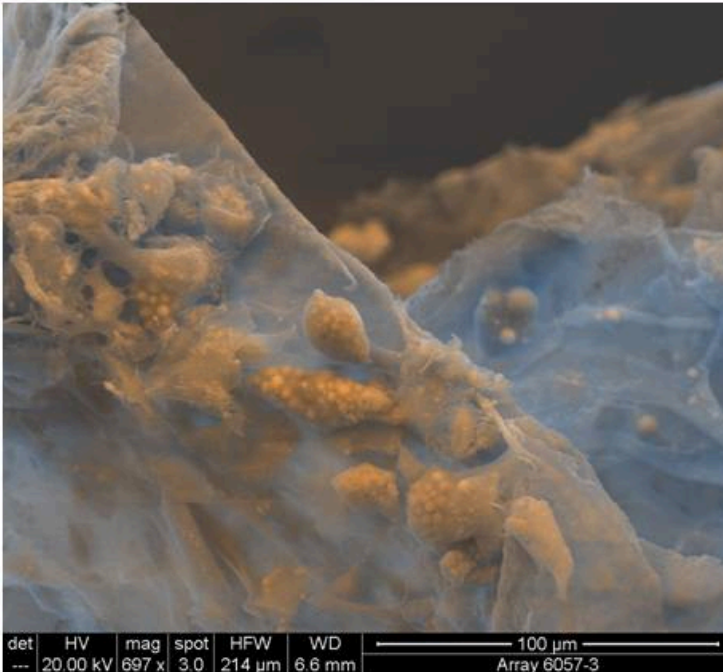


Key Milestones



| Milestones | Target Timeline |
|---------------------------------|-----------------|
| Animal Study Data | 2Q 2016 |
| Publish Animal Study Data | 4Q 2016 |
| Submit IND/IND Clearance | 4Q 2016 |
| Patient Enrollment | 1Q 2017 |
| Dose Escalation Cohort Data | 3Q 2017 |
| Primary End Point Efficacy Data | 3Q 2018 |

Potential Treatments for Metabolic Diseases



- Pre-clinical allogeneic cell-based therapy to target obesity, diabetes and other 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.
- University of Pennsylvania – Division of Endocrinology, Diabetes and Metabolism on Brown Adipose Stem Cell Program



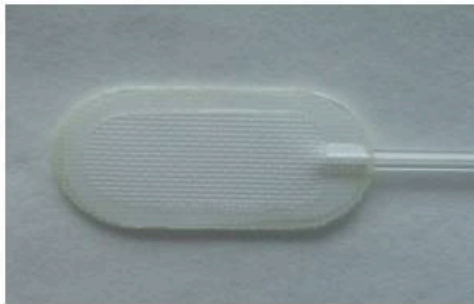
572. Metabolically Active Human Brown Adipose Tissue-Derived Stem Cells

Francisco J Silva, Dolly J Holt, Vanessa Vargas et al.

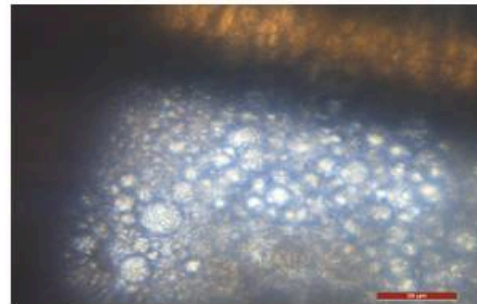
Brown Fat Delivery Device



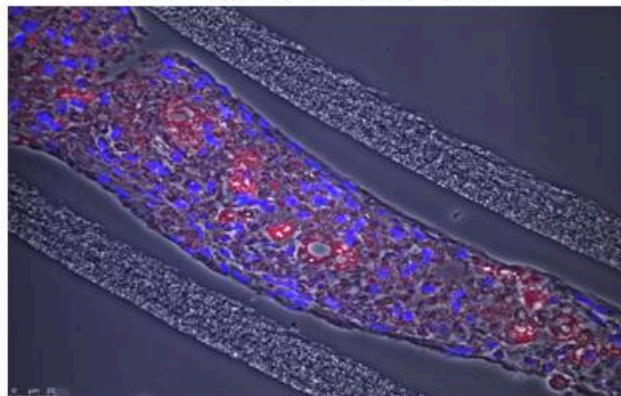
Encapsulation Device



Brown Adipose Cells (live)



UCP1 (red) Positive Cells



Metabolic Key 2016/17 Targeted Milestones



| Milestones | Target Timeline |
|-------------------------------------------------|-----------------|
| Identify Key Cell Line for Pre-Clinical Testing | 3Q 2016 |
| Develop Delivery System for BAT | 3Q 2016 |
| Initiate Pre-Clinical Testing in Animals | 4Q 2016 |
| Identify Target Indication | 4Q 2016 |
| Complete Pre-Clinical Testing in Animals | 2Q 2017 |
| Pre-IND filing with FDA | 3Q 2017 |



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Thank You



OTCQB: BRTX ♦ biorestorative.com