

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: February 9, 2015
(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, Suite 1, Melville, New York	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 February 9, 2015 in presentations about the Company’s business. The Company intends to use the Presentation Materials, possibly with modification, at the TBG Innovations Conference being held on February 9, 2015 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 or 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: February 9, 2015

By: /s/ Mark Weinreb

Mark Weinreb

Chief Executive Officer



BioRestorative Therapies

A Stem Cell Biotechnology Company

Innovations Conference | February 9, 2015

Forward Looking Statements

This presentation contains "forward-looking statements" within the meaning of the federal securities laws, including statements concerning the ability of BioRestorative Therapies, Inc. (the "Company") to develop its adult stem cell business, the future of regenerative medicine and the role of adult stem cells in that future, and the potential revenue growth of the Company's business. Such forward-looking statements, including revenue assumptions, involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: (1) the Company's limited operating history, lack of significant revenues, substantial losses since inception, and substantial working capital deficiency and stockholders' deficiency, (2) the Company's ability to obtain sufficient financing to satisfy its debt obligations and fund its operations, (3) the ability of the Company to obtain reimbursement for its therapies from private and governmental insurers, (4) the Company's ability to build management, human resources and infrastructure necessary to support the growth of its business, (5) competitive factors beyond the Company's control, (6) scientific and medical developments beyond the Company's control, (7) the Company's ability to comply with applicable federal, state, local, and international governmental requirements, (8) the Company's ability to protect its proprietary rights both within and outside the United States, and (9) other factors discussed in the Company's periodic documents filed with the Securities and Exchange Commission (which are available for review at www.sec.gov). Given these uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. We assume no obligation to update these forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements.



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BioRestorative Therapies (BRT)

Research and Development focus cell based therapies

brtxDISC™ Mesenchymal stem cells for the treatment of chronic Lumbar Disc Disease (cLDD)

Lead therapeutic product – successful pre-IND meeting

ThermoStem® Brown adipose tissue preclinical program for the treatment of metabolic disorders

Cell based approach - brown adipose derived stem cells

Pre-clinical therapy for obesity and type 2 diabetes

Potential small molecule application and biologic discovery program

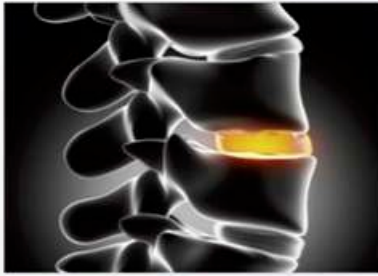
BRT develops products and medical therapies using cell and tissue protocols, primarily involving adult stem cells



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BRT's Lead Therapeutic Product: *brtxDISC*TM



Addressing the pathophysiology and symptoms of intervertebral disc disease



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*brtxDISC*TM Treatment for Lumbar Disc Disease

*brtxDISC*TM is BioRestorative Therapies' lead product candidate

*brtxDISC*TM is an autologous hypoxic cultured Mesenchymal Stem Cell (MSC) product derived from adult human bone marrow formulated with a proprietary carrier
13/132,840 Methods and Compositions to Facilitate Repair of Avascular Tissue

Therapeutic application of *brtxDISC*TM is a sterile cellular product to be provided in vials for injection into damaged lumbar discs in a 30 minute outpatient procedure



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The Market Opportunity: Lower Back Pain (LBP)

LBP is the most common, disabling and costly musculoskeletal problem

Global population prevalence of LBP

84% of populace with an occurrence during lifetime

23% with pain recurrence within 6 months

11% with chronic LBP

Out of 291 medical conditions evaluated in the Global Burden of Disease 2010 Study, LBP ranked as the number one cause of disability

Quality of life deteriorates with lower back pain

Annual direct healthcare costs of LBP in the United States is approaching \$100 billion



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The Problem: No Good Treatments for Lower Back Pain

Today's treatments do not address the pathophysiology of the disease

Non-Surgical treatments

- Physical therapy and weight loss
- Non-steroidal anti-inflammatory drugs
- Spinal manipulation (chiropractic care)
- Epidural steroid injections

Surgical treatments

- Surgery (percutaneous, minimally invasive, fusion/disc replacement)

Clinical and economic outcomes point to the need for a radical change in treatment

At the present time, therapy for discogenic back pain is largely empirical and aimed at relieving symptoms rather than addressing the underlying disease mechanism.



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PROBLEM

The Solution: *brtxDISC*™ to treat Lumbar Disc Disease

The clinical benefit of mesenchymal stem cells (MSCs) is due to a number of mechanisms that act upon the site of pathology in the disc

Replacement: MSCs differentiation into chondrocytes

Repair/Regeneration: Activation of certain beneficial signal transduction pathways for the recruitment of endogenous cells to the vasculature

Repair/Regeneration: Inducement of the immune system to inhibit the chronic inflammation associated with the damaged disc

Repair/Regeneration: Restoration of system that removes lactic acid waste from the disc

Replacement, regeneration and repair of cells promotes healing of the disc



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SOLUTION

brtxDISC™ Treatment Process

brtxDISC™ production begins with the physician collecting (1) bone marrow and (2) blood plasma from the patient

- Bone marrow harvested from the patient's iliac crest under a local anesthesia

- Peripheral blood collected from the patient

Physician sends patient bone marrow and blood samples to BioRestorative for lab culturing and proprietary carrier preparation

Process takes approximately 3 weeks

BRT sends therapeutic stem cell cryopreserved in a vial back to physician where it is thawed prior to the procedure

Patient receives cells via a 25 gauge needle device in the physician office in a 30 minute outpatient procedure



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PROCESS

Clinical Results from a Physician Sponsored Study

Patients received injection of autologous Mesenchymal Stem Cells to the intervertebral disc

Autologous mesenchymal stems cells are safe

No adverse events observed

Maximum dose of 40 million stem cells well tolerated

Mesenchymal stems cells are effective

Patients experienced pain relief, healing

Benefits in mobility and decreases in disability

Beneficial disc morphology changes observed

Study suggests that autologous mesenchymal stem cells administered for lower back pain are safe and effective

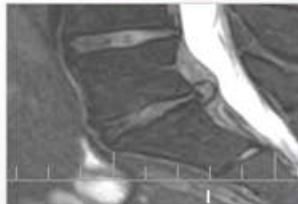


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Impact of Stem Cells on Disc Morphology

MRIs of patient treated with BioRestorative Stem Cell Technology



Before stem cell treatment



After stem cell treatment

Stem cells may have a significant impact on the morphology of the disc and bring relief of symptoms



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Clinical Development Plans

brtxDISC™ is an autologous MSC product injected into the intervertebral disc. MSCs will be formulated with a proprietary carrier.

Therapeutic application of *brtxDISC™* in treatment of cLDD delivered by a standard 20G 3.5 inch introducer needle and a 25G 6 inch needle to enter the disc

Company envisions conducting Phase 1/2a, Phase 2b, Phase 3 clinical trials under the regulation of the FDA's Center for Biologics Evaluation and Research (CBER)

Phase 1/2a will investigate safety and determine maximum tolerated dose

Phase 2b will investigate safety and efficacy of selected dose

Phase 3 will further investigate safety and efficacy of selected dose

BioRestorative Therapies has a deep and rich pipeline of additional regenerative medicine therapies



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brtxDISC™ Clinical Trial Principal Investigators

Gregory E. Lutz, M.D.; BRT Chief Medical Advisor for Spine Medicine

Physiatrist-in-Chief Emeritus for Hospital for Special Surgery (HSS) and is a member of the Board of Trustees

Regenerative Medicine clinical trial experience

Associate Professor of Clinical Rehabilitation Medicine, Weill Medical College of Cornell

Consulting physician to the National Hockey League Players' Association

Wayne Olan, M.D.; Member of BRT Scientific Advisory Board

Associate Professor at The George Washington University School of Medicine & Health Sciences

Director of Interventional and Endovascular Neurosurgery

Published extensively on minimally invasive spinal interventions

Experience in medical devices for the spine

U.S. 2014

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Target Physicians Likely To Treat Discs with Stem Cells

Large pool of physicians in the United States that will use brtxDISC™

Physicians currently trained and skilled in performing spinal injections are the target physicians for injections of brtxDISC™

Interventional physiatrists (physical medicine physicians)

Pain management - anesthesiologists

Interventional radiologists

Neurosurgeons

Greater than 10,000 total target physicians estimated in the United States

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brtxDISC™ Revenue Assumptions

brtxDISC™ effective in a wide spectrum of lumbar disc disease (from IDD to protrusions to moderate/severe disc degeneration)

Non-steep learning curve for physicians

Up to 10% market penetration in the first year

Maximum market penetration of 80% by year 5

\$15,000 price per procedure (acceptable to out-of-pocket early adopters)

\$7,500 of revenue to BioRestorative

\$5,000 of revenue to the physician

\$2,500 of revenue for MRI's, needles, additional tests, shipping

Compared to cost of surgery that can be as high as \$100,000 (disc fusion) without favorable outcomes and significant additional cost and time for physical therapy

Manufacturing cost of brtxDISC™—\$600 implying a >90% gross margin

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Pipeline Overview and Anticipated Progress in 2015

Program	Preclinical	Phase 1	Phase 2	Phase 3
Autologous <i>brtxDISC</i> TM	Begin Phase 1/2a 2015			
Allogeneic <i>brtxDISC</i> TM				
Proprietary Development Project				



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Market Adoption Strategy

Phase 3 study showing a clinically meaningful effect of MSCs treating disc protrusions will help drive market adoption

- Long term follow-up data confirming the safety and efficacy of the therapy
- Company plans to conduct other supportive studies
- Promotional activities at spine/orthopedic physician conferences
- Physician education materials and marketing via a sales force
- Economic incentives to the caregiver
- Insurance reimbursement strategy based on clinical and economic data

*Positive Phase 3 results could make *brtxDISC*TM an accepted standard of care for chronic lower back pain*



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Strategic Partnerships for Distribution

Strategic partner will be sought for the marketing and distribution of *brtxDISC*TM

Partner characteristics include

- Sales force with presence in the spine/orthopedic care setting
- Expertise and vision for the growth of the regenerative medicine market

BioRestorative product pipeline presents an attractive fit for companies with presence in the spine/orthopedic and regenerative medicine markets

Ample partnership opportunities exist for all global markets



North America

Europe

Japan

Rest of world



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ThermoStem® Program (Brown Fat Stem Cells)

Potential Treatments for Metabolic Diseases



Magnification of brown adipose derived stem cells cultured and differentiated into brown adipocytes on porous extracellular matrix scaffolds



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Metabolic Platform Program



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ThermoStem® Brown Fat Program

"One of the most powerful organs in the body... Since it consumes both glucose and fatty acids, it is possible we could utilize brown fat to treat obesity and metabolic dysfunction seen in diabetes and hyperlipidemia."

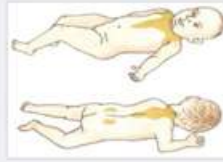
Aaron M. Cypress, M.D., Ph.D., Joslin Diabetes Center and Harvard Medical School

Infants have a larger population of brown fat that is responsible for generating body heat and creating metabolic homeostasis

Potential Cellular Product as allogeneic "off the shelf" product using brown fat stem cells to treat type 2 diabetes and obesity

Developing a novel cellular therapy that transplants brown fat stem cells

BRT has identified a stem cell populations isolated from brown adipose depots in humans



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BRT February
2014 Publication
in *STEM CELLS*
Journal

Volume 32, Number 2, February 2014

STEM CELLS®
The International Journal of Cell
Differentiation and Proliferation

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BioRestorative Therapies/Pfizer Collaboration



Jointly conducting a study entitled "Development and Validation of a Human Brown Adipose Cell Model"

BRT has a collection of human brown adipose tissue samples, pre-adipocyte cell lines and immortalized cell lines

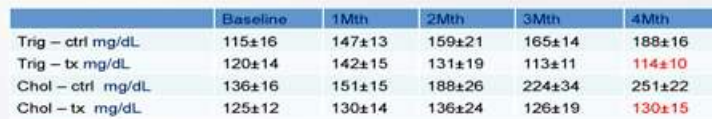
Characterization of identity and metabolic function of cell lines



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In Summary

brtxDISC™

Successful pre-IND meeting with FDA
Expect to commence clinical trial by year end

ThermoStem®

Maintenance and regulation of metabolism
Metabolic Platform (Brown Fat) Program addresses large markets
Pfizer collaboration

Deep expertise in stem cell biology and public management



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Thank You



OTCBB: BRTX



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