

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: January 15, 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))
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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 January 15, 2016 in presentations about the Company’s business. The Company intends to use the Presentation Materials, possibly with modification, in presentations to current and potential investors, brokers, 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.

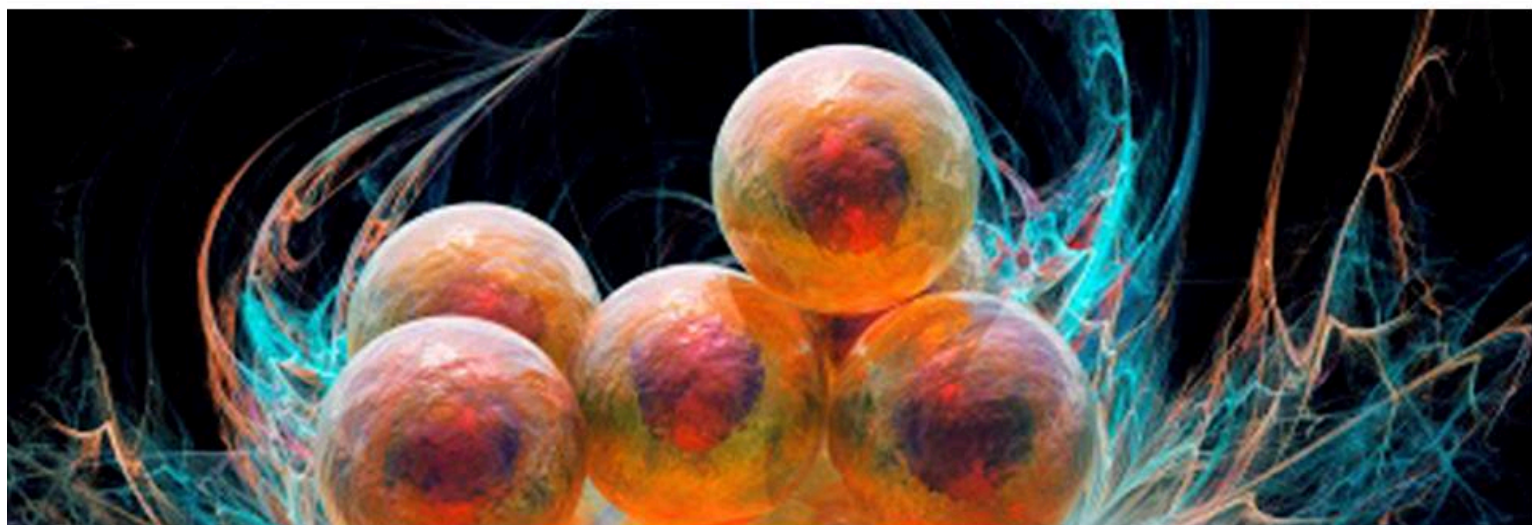
BIORESTORATIVE THERAPIES, INC.

Dated: January 15, 2016

By: /s/ Mark Weinreb

Mark Weinreb

Chief Executive Officer



CORPORATE PRESENTATION

January 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 satisfy our debt obligations and fund our operations; (iii) our ability to timely and successfully develop and commercialize *brfxDISC*, 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 "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: Company Overview



Cell-Based Therapies

- Focused on cell therapies to treat disc / spine and metabolic diseases
- High level of expertise in developing proprietary biologics
- Strong skills in cell biology and cell culturing

Disc/Spine Program Lead Product: *brtxDISC*™

- Novel autologous biologic 30 minute outpatient procedure for the treatment of chronic lumbar disc disease
- \$10B (US market) chronic lower back pain with unmet medical need
- Successful FDA meeting - Initiation of clinical trial anticipated by 4Q 2016
- Initial promising data from investigational human treatment in US

Metabolic Program *ThermoStem*®

- Brown adipose tissue (brown fat) pre-clinical program for the treatment of metabolic disorders (obesity, diabetes, hyperlipidemia, etc.)
- Allogeneic cell-based treatment using brown adipose-derived stem cells

Validating Collaborations

- Pfizer on Brown Adipose Stem Cell Program
- University of Pennsylvania - Division of Endocrinology, Diabetes, and Metabolism on Brown Adipose Stem Cell Program
- Hospital for Special Surgery on Lumbar Disc Program

Strong Management Team



Mark Weinreb President and CEO

- Pioneer in regenerative and cellular medicine / science
- Former President of NeoStem (now Caladrius Biosciences); Owner, BioHealth Labs (now Enzo BioChem Labs)
- Bachelor of Arts, Northwestern University
- Master of Science in Medical Biology, C. W. Post (LIU)

Edward Field President, Disc / Spine Division

- Advanced 8 cell therapies into clinical trials
- Established commercial scale cell manufacturing facility
- Former President/ COO of Aldagen/Cytomedix
- Bachelor of Arts, Duke University
- MBA, Darden School at University of Virginia

Francisco Silva Vice President of Research and Development and Chief Scientist

- Former CEO, DV Biologics, President of DaVinci Biosciences
- Extensive experience in cell based therapies
- Inventor of patents/author of manuscripts in regenerative medicine
- California State Polytechnic Univ. Degree in Biology, Graduate Presidential Fellowship and MBRS Fellowship

Advisory Board



Gregory E. Lutz, M.D., Chief Medical Advisor For Spine Medicine

- Physiatrist-in-Chief Emeritus for Hospital for Special Surgery (HSS)
- Member of HSS Board of Trustees
- Founded Physiatry Dept. at HSS/Physical Med & Rehab at Mayo Clinic

Joy Cavagnaro, Ph.D., Regulatory Advisor

- Former Director, CBER, FDA
- Former V.P., Regulatory Affairs, Human Genome Sciences
- President and Founder of Access BIO

Wayne Marasco, MD, Ph.D. Chairman, Scientific Advisory Board

- Principal Faculty Member of Harvard Stem Cell Institute
- Professor, Department of Cancer Immunology & AIDS at Dana-Farber Cancer Institute
- Professor of Medicine at Harvard Medical School.

brtxDISC[™]: Target Product Profile

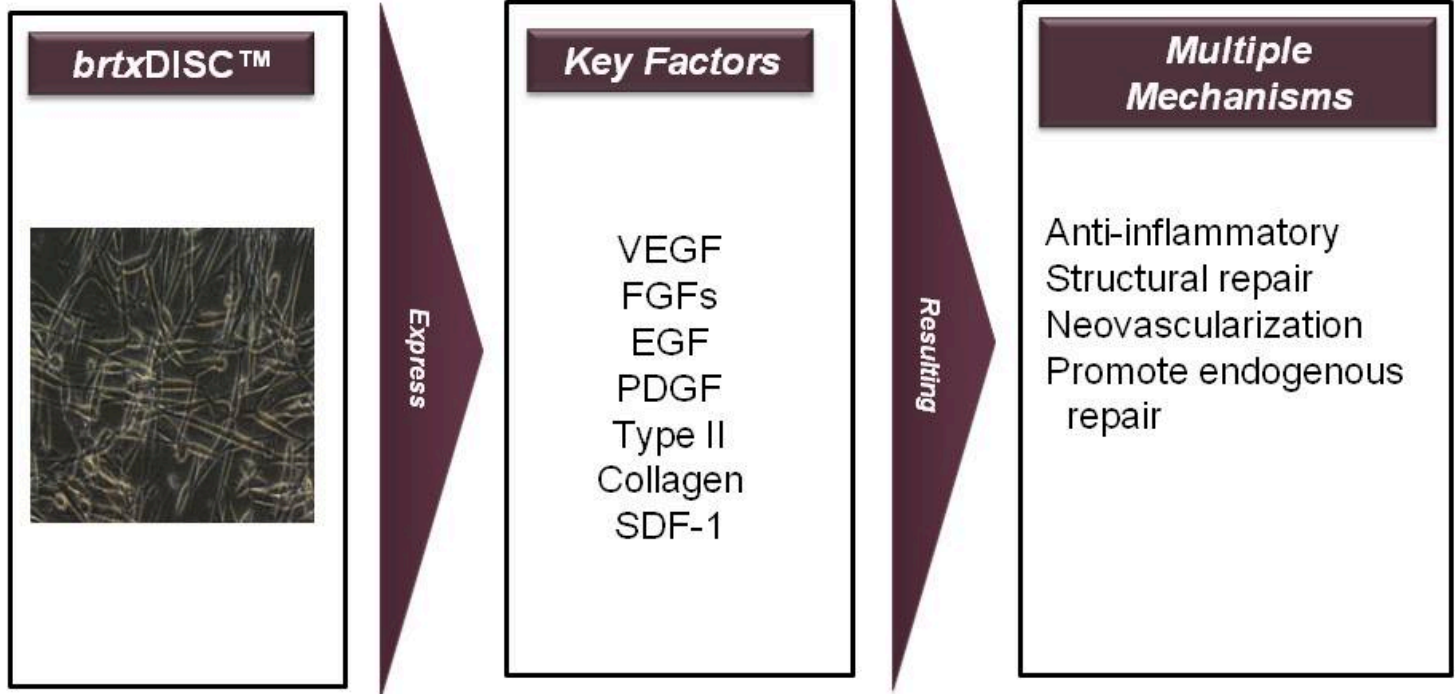


- *brtxDISC*[™] is a cryopreserved autologous cell therapy consisting of hypoxic cultured mesenchymal stem cells (MSCs) and a proprietary carrier.
- *brtxDISC*[™] is intended for patients who have chronic lower lumbar disease caused by protruding/bulging discs.
- *brtxDISC*[™] will be injected into damaged lumbar discs using a standard needle in a 30 minute outpatient procedure.
- Primary Indication:
brtxDISC[™] is indicated to both improve function and decrease pain in patients with chronic lower lumbar disease.
- Targeted Physician Population:
Physical medicine and rehabilitation physicians, interventional physiatrists, pain management physicians, interventional radiologists

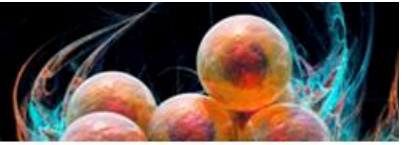
brtxDISC™: Mechanism of Action



Aim is to change disease pathology and improve disc morphology.



***brtx*DISC™: Previous Human Data**

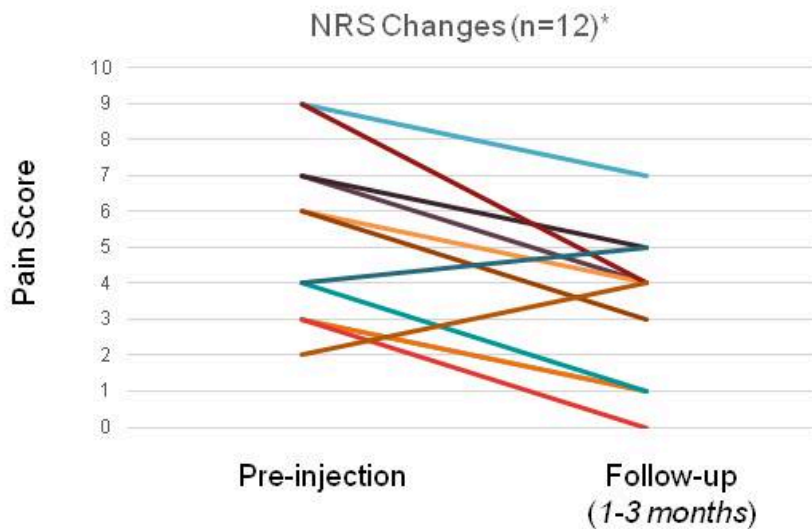


- A physician-sponsored, IRB-approved study investigated the effect of hypoxic cultured MSCs on disc protrusions (from 2008-2010)
- Safety observations:
 - ◆ No adverse events observed
 - ◆ Maximum dose of 40 million cells well tolerated
 - ◆ MRI results interpreted by an independent radiologist in a subset of 5 patients demonstrated no long term adverse events
- Efficacy observations:
 - ◆ Reduction in pain
 - ◆ Improved function
 - ◆ Improved self-reported Quality Of Life
- Beneficial disc morphology changes observed

brtxDISC™: Pain Improvements



67% (8 of 12) of Subjects Had $\geq 30\%$ Improvement in Pain Score



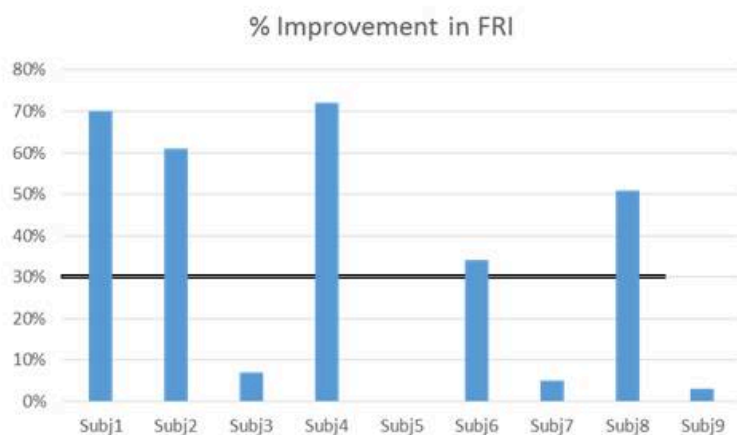
- Numerical Rating Scale (NRS) is a standardized patient reported measure of pain score from 1 -10
- Minimally clinical important difference (MCID) in NRS is defined as $\geq 30\%$ improvement ¹

* Two patients had similar NRS changes

¹ Ostelo et al Spine Vol 33,no1.pp90-94



56% (5 of 9) of Subjects Had $\geq 30\%$ Improvement in FRI

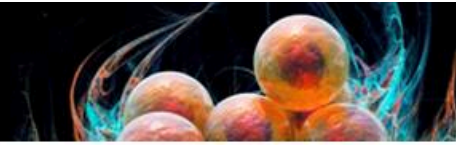


- Functional Rating Index (FRI) is a standardized measure of measuring subjects' ability to do everyday activities
- Minimally clinical important difference (MCID) in functional rating scales is defined as $\geq 30\%$ improvement ¹

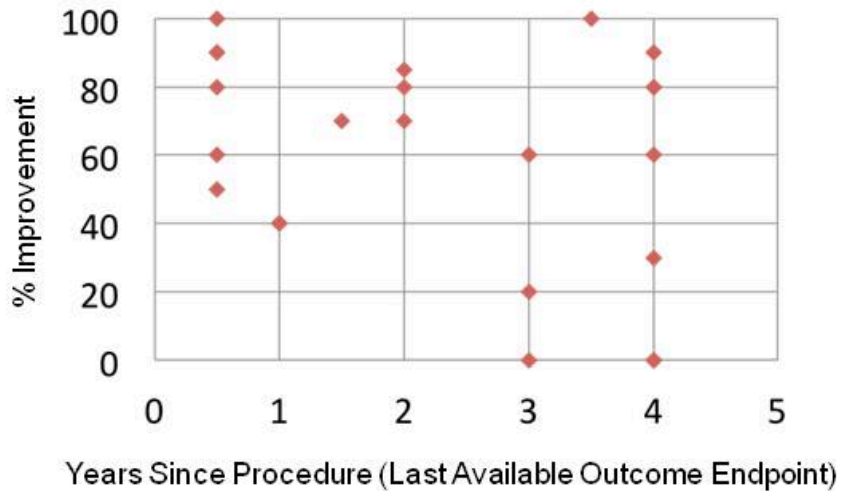
- 63% (5 of 8) of subjects had both $\geq 30\%$ Reduction in NRS Score and Improvement in FRI

¹ Ostelo et al Spine Vol 33,no1.pp90-94

brtxDISC™: QOL Improvements



Mean Improvement of ~60% in patient Quality of Life,
Mean time since treatment 2.3 yrs.*

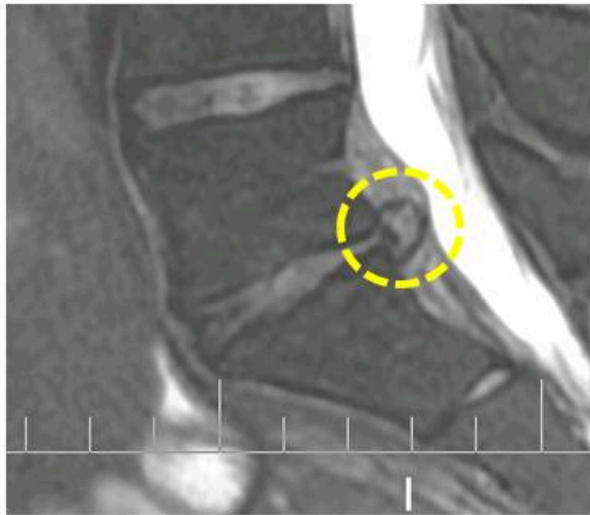


- Quality of Life (QOL) is a standardized questionnaire measuring subjects' functional and mental wellness

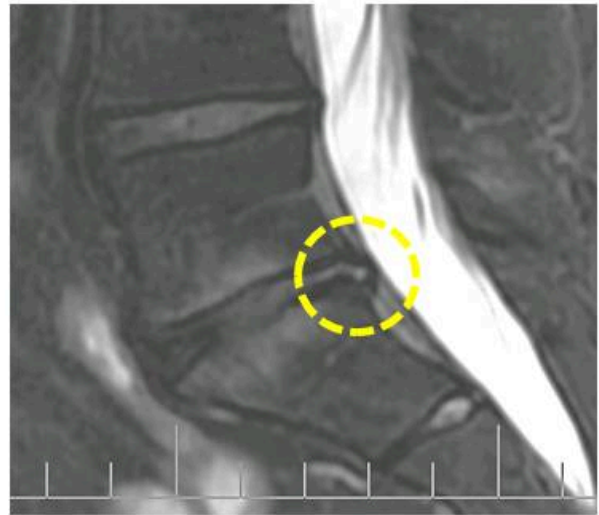
* Patient reported improvement



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



BEFORE



AFTER

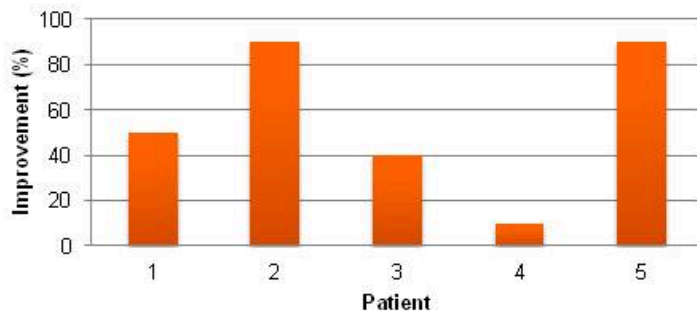
- 56% (9 of 16) of Subjects had $\geq 50\%$ Reduction in Disc Bulge Size

brtxDISC™: Summary of Retrospective Analysis

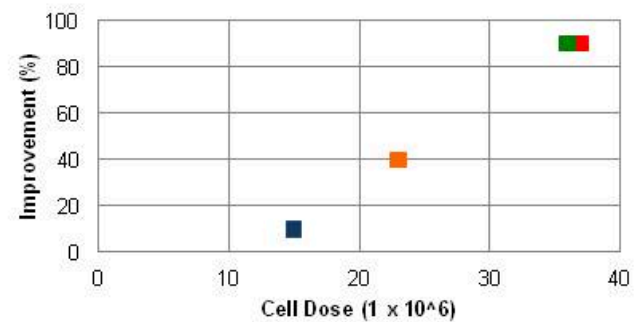


80% Reported Improvement in Range of Motion and 100% Reported Improvement in Strength Post-Treatment

% QOL Improvement Post-Treatment



% Improvement vs Cell Dose



- We believe there is a correlation between the QOL improvement percentage and dosage based on our finding in our 5 patient retrospective analysis.



- A Phase 2 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 *brtxDISC*[™] 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)

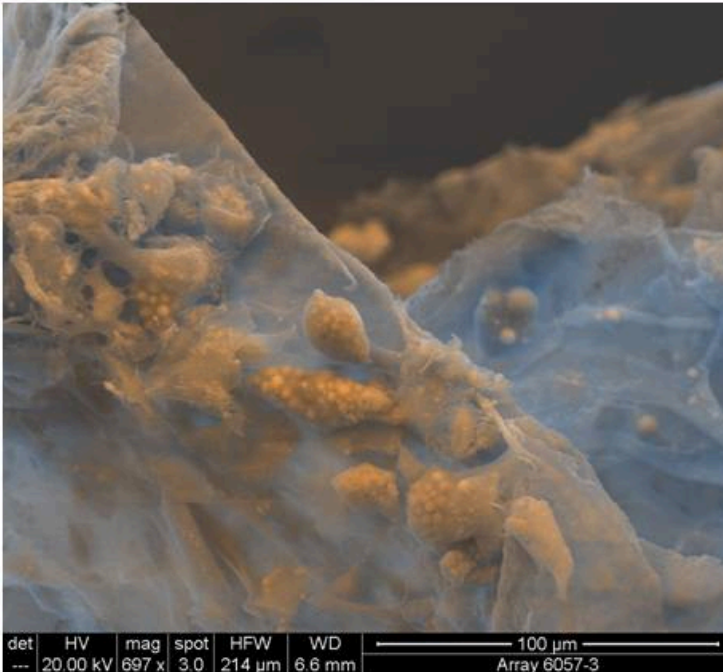


***brtxDISC™*: Key 2016 Targeted Milestones**



Milestones	Target Timeline
Animal study data	March/April
Select CRO, clinical study start-up (sites, data)	April - August
cGMP facility certification/qualification	April/May
Manufacturing qualification runs	June/July
Submit IND	August
IND Clearance	September/October
First Patient Enrolled	October/November

Potential Treatments for Metabolic Diseases



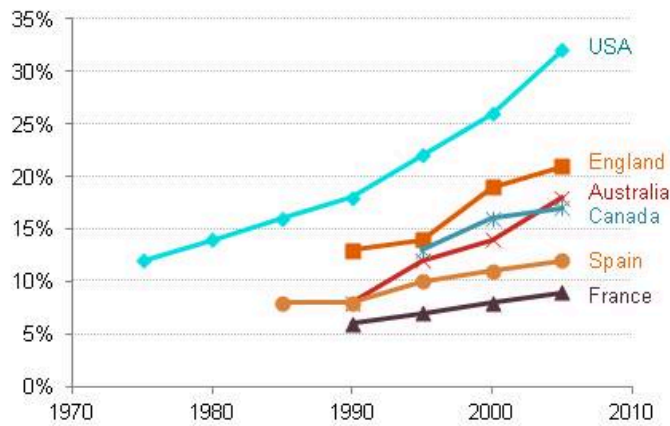
- Pre-clinical allogeneic cell-based therapy to target obesity, diabetes and metabolic disorders using brown adipose (fat) derived stem cells (BADSC) to generate brown adipose tissue (BAT)
- BAT is a specialized adipose tissue found in the human body that plays a key role in the evolutionarily conserved 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.
- Pfizer collaboration on development of human brown adipose cells
- Potential biologic discovery program

Market Opportunity: Obesity and Metabolic Disorders Market



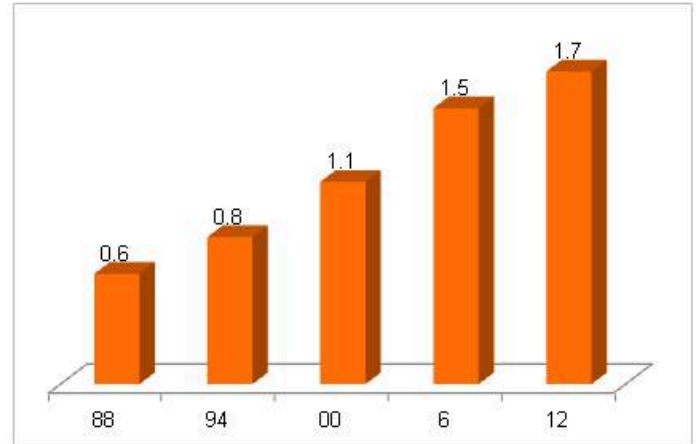
The pandemic of obesity and metabolic disorders is widespread and continues to grow worldwide, despite efforts to curb its progress

Obesity Rates In Selected Countries



Source: OECD. *The obesity epidemic: Analysis of past and projected future trends in selected OECD countries*

New Diabetes US cases annually (MM)



Source: CDC. *Diabetes. Successes and Opportunities for Population-Based Prevention and Control At A Glance; National Diabetes Statistics Report, 2014*



Program Objective

- Advance pre-clinical development, leading to IND filing
 - Demonstrate that BAT derived from differentiated human stem cells can be used to treat or prevent metabolic disorders and restore homeostasis

Progress To-date

- Established unique human brown fat library
- Initial pre-clinical studies
 - Created 3D tissue engineered BAT construct; successfully implanted into mice
 - At 6-month observation, scaffold still intact; metabolic impact observed
- Generated publications around initial results
- Established Pfizer and University of Pennsylvania relationships

Near-term Priorities

- Develop delivery mechanism for introducing brown fat tissue to humans
- Finalize target disease and clinical indication

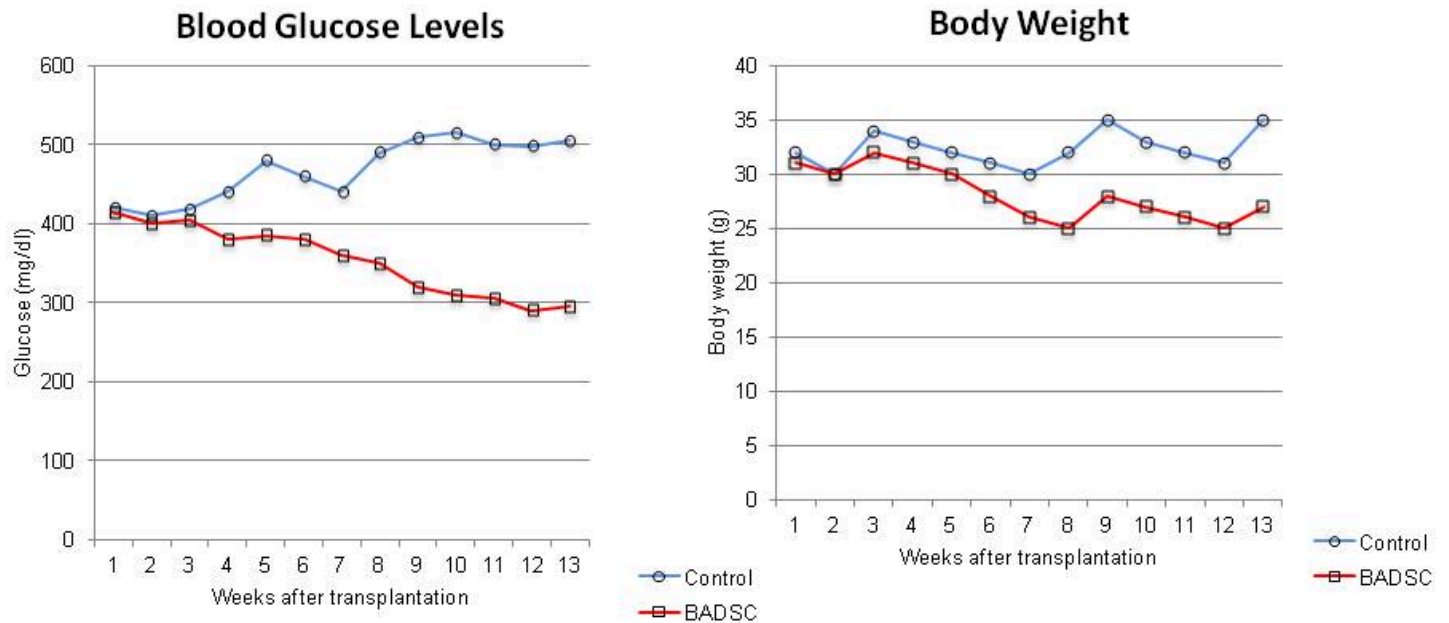


572. Metabolically Active Human Brown Adipose Tissue-Derived Stem Cells

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

Preclinical Metabolic Results

Glucose and Body Weight



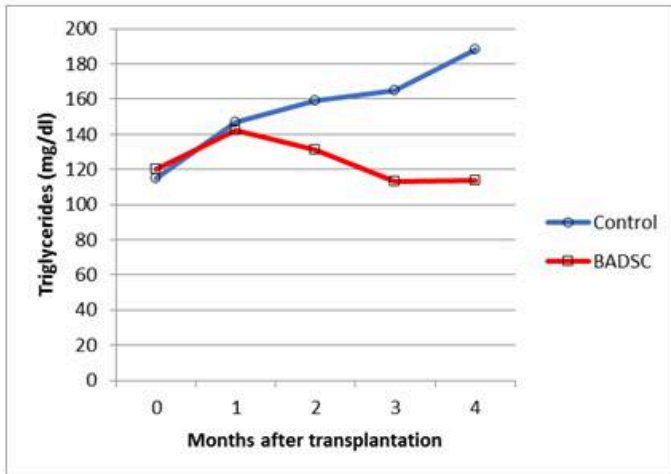
Mice fed high chow diet throughout experiment and transplanted with brown adipose derived stem cells (BADSC)/scaffolds and controls

Preclinical Metabolic Results

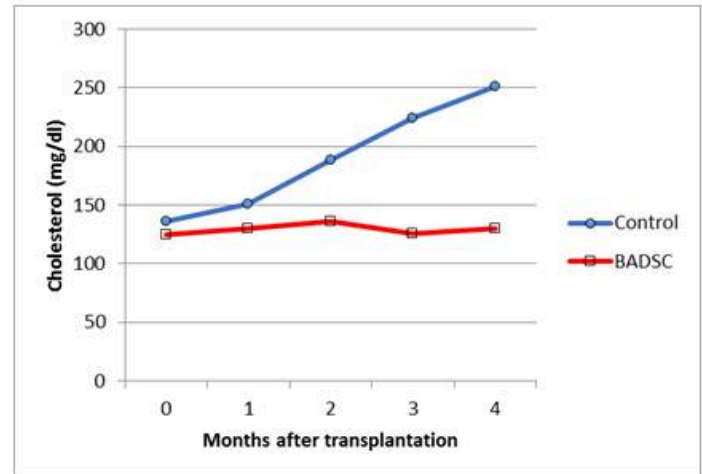


Triglycerides and Cholesterol Levels

Triglycerides Level



Cholesterol Level



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

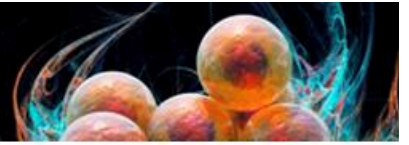


- Jointly conducting a study entitled “*Development and Validation of a Human Brown Adipose Cell Model*”
- BRT will leverage its human brown adipose tissue sample collection, pre-adipocyte cell lines and immortalized cell lines
- Characterization of identity and metabolic function of cell lines

ThermoStem®: Key 2016/17 Targeted Milestones



Milestones	Target Timeline
Identify Key Cell Line for Pre-Clinical Testing	Jan-March
Develop Delivery System for BAT	April - July
Initiate Pre-Clinical Testing in Animals	April/May
Identify Target Indication	June/July
Complete Pre-Clinical Testing in Animals	December
Pre-IND filing with FDA	January/February 2017



MULTIPLE CELL THERAPY PROGRAMS

- **DISC/SPINE PROGRAM (*brtxDISC*TM):**
 - ◆ Complete requirements to submit IND and commence trials
 - ◆ Develop additional *brtxDISC*TM indications

- **METABOLIC PROGRAM (*ThermoStem*[®]):**
 - ◆ Finalize clinical indication and delivery mechanism and drive to IND filing
 - ◆ Develop biologics program

STRONG MANAGEMENT & ADVISORY TEAMS

POTENTIAL FOR ADDITIONAL INDICATIONS OF THERAPY

Thank You



OTCQB: BRTX ♦ biorestorative.com