

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: May 29, 2014
(Date of earliest event reported)

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

Nevada	000-54402	91-1835664
(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification Number)
555 Heritage Drive, Jupiter, Florida	33458	
(Address of Principal Executive Offices)	(Zip Code)	

Registrant's telephone number, including area code: (561) 904-6070

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 May 29, 2014 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 May 29, 2014 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: May 29, 2014

By: /s/ Mark Weinreb

Mark Weinreb

Chief Executive Officer



BioRestorative Therapies: A Stem Cell Biotechnology Company

May 2014 • OTC/BB: BRTX • biorestorative.com

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 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 funds 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.

Corporate Overview

Second-Generation Stem Cell Regenerative Medicine Company

BioRestorative Therapies (“BRT”) is a life sciences company focused on adult stem cell-based cellular therapies for various personal medical applications. BRT develops products and medical procedures using cell and tissue protocols.

LEAD THERAPEUTIC PROGRAM

- **brtxDISC™** Treatment for Bulging and Protruding Disc Disease

METABOLIC PLATFORM PROGRAM

- **ThermoStem®** Pre-clinical treatment for Type 2 Diabetes and Obesity

Lead Therapeutic Program

The logo graphic for BRT Disc X, featuring a stylized human figure in a dynamic pose with arms and legs extended, surrounded by three concentric circular motion lines.
**b
rt
disc^x**

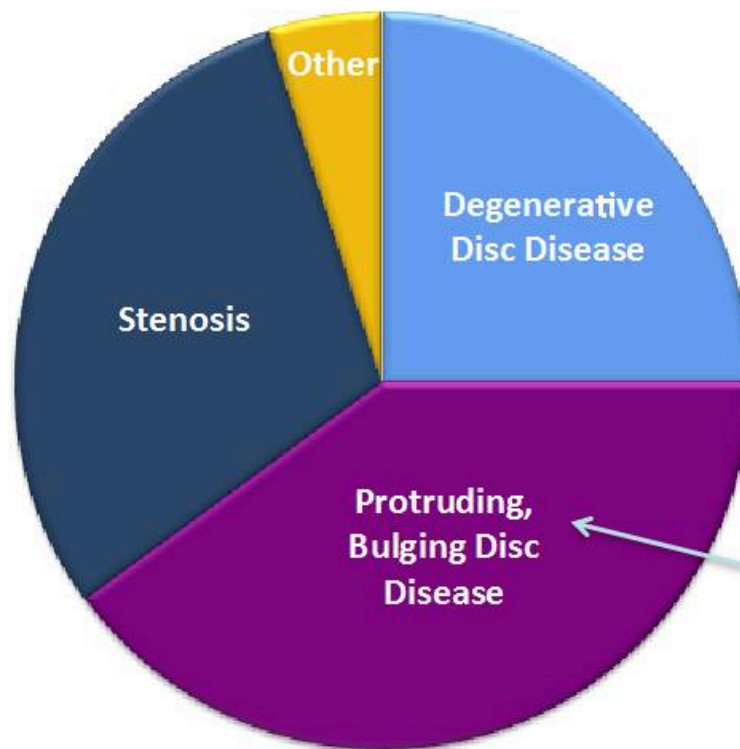


brtxDISC™ Overview

brtxDISC™ (Disc Implanted Stem Cells) Program

- Non-surgical autologous stem cell treatment for bulging and protruding disc disease
- Outpatient procedure performed in a physician's office is intended for patients who have failed all non-surgical disc treatments and face surgery
- Addresses unmet medical need between non-invasive and surgical procedures, representing a large market opportunity
- *Estimated 1 million patients per year in the U.S. require back surgery for bulging/protruding disc disease*
- ~38 patients have been treated in the U.S. using this procedure
- Company performing retrospective safety study for FDA submission
- Program is expected to initiate Clinical Trials in 2015

brtxDISC™ Target Markets



brtxDISC™ Market Size & Costs

Procedure	Annual Incidence (U.S.)	Surgical Cost	brtxDISC™ (Estimated Cost)	Savings Per Patient
Spinal Fusion	300,000	\$75-100K	\$18K	\$57-82K
Disc Replacement	200,000	\$35-50K	\$18K	\$17-32K
Discectomy	200,000	\$20-50K	\$18K	\$2-32K

Surgical procedures are typically followed by additional rehabilitation and related costs that may equal or exceed the current cost of the surgery

Essential Proprietary Procedure

Cell Culturing

- Utilizes patient's own stem cells to repair damaged tissue
- Disc procedure requires the selection of mesenchymal stem cells that can survive in low oxygen (hypoxic) and avascular (lack of blood supply) environment

Therapeutic Delivery Device

- Essential to the success of the treatment
- Enables physician to deliver cells at precise location within damaged disc

brtxDISC™ Cell Delivery Device



Delivery Device Animation



Short Physician Learning Curve

Certain physicians already trained and skilled in performing disc injections

5 Groups

Physiatrists

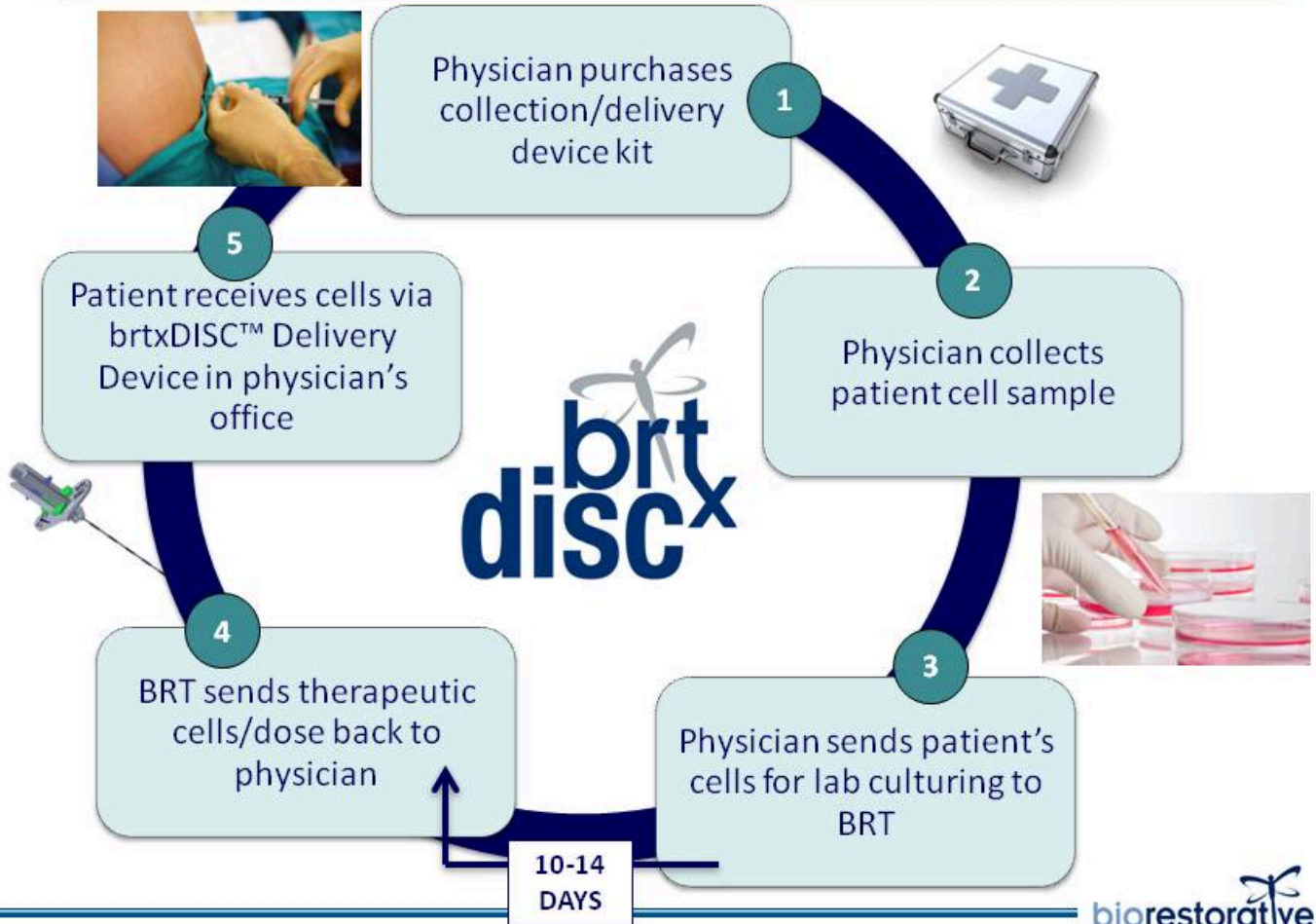
Pain Management Physicians

Interventional Radiologists

Orthopedic Spine Physicians

Neurosurgeons

brtxDISC™ Process Overview

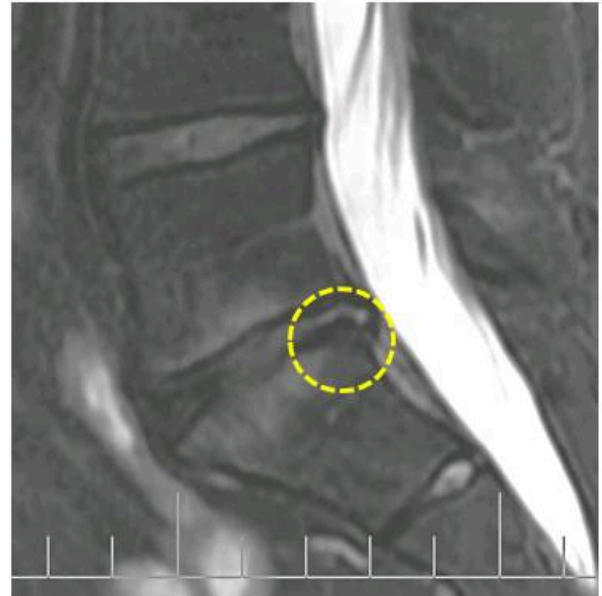


brtxDISC™ MRI Results

- **42 y/o Male:** Annular tear at L5-S1 noted on 2003 MRI and radiculopathy diagnosed. 2007 MRI showed a mild L5-S1 disc bulge.
- **Treated in Physician's Office:** 5-month follow-up MRI showed complete resolution of the L5-S1 disc bulge on both sagittal and axial slices with some concurrent advancement of mild DDD.



MRI Before Treatment



MRI 5 Months After Treatment

brtxDISC™ Clinical Trial PI's

- **Gregory E. Lutz, M.D**
 - Physiatrist-in-Chief Emeritus for Hospital for Special Surgery (HSS) and is a member of the Board of Trustees
 - Regenerative Medicine clinical trial experience
 - Spine Device Company, principal
 - Associate Professor of Clinical Rehabilitation Medicine, Weill Medical College of Cornell
 - Consulting physician to the National Hockey League Players' Assoc.
- **Wayne Olan, M.D**
 - Director of Interventional and Endovascular Neurosurgery
 - Associate Professor at The George Washington University School of Medicine & Health Sciences
 - Published extensively on minimally invasive spinal interventions
 - Experience in medical devices for the spine

brtxDISC™ Clinical Trial

- Safety and Preliminary Efficacy Study of Hypoxic Cultured Mesenchymal Stem Cells in Subjects with Lumbar Back Pain
- Phase 2 – Prospective, Controlled, Randomized, Double Blind Clinical Trial
- 100 Patients – Multicenter; 24-36 Month Study
- Cost -- ~\$35,000/patient
- Primary Endpoints – Safety
 - Physical Examinations
 - Clinical Lab Tests
- Secondary Endpoints – Efficacy of Single injection of low dose (10 million) and high dose (20 million) autologous MSCs
 - MRI Changes
 - Pain VAS Score
 - ODI Changes
- Patients will be monitored every 3 months with full follow-up
- Interim results will be available & reported 6 months post injection

brtxDISC™ Near Term Goals

- Finalize retrospective safety study of treated patients; submit results for publication (3Q 2014)
- Complete FDA-related work pertaining to the therapeutic delivery device (3Q 2014)
- Hold pre-trial meeting with FDA (4Q 2014)
- Finalize trial preparation and file IND/IDE with FDA (1Q 2015)
- Initiate Clinical Trials (2015)

Brown Fat - Metabolic Program



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

ThermoStem® Program (Brown Fat Stem Cells)

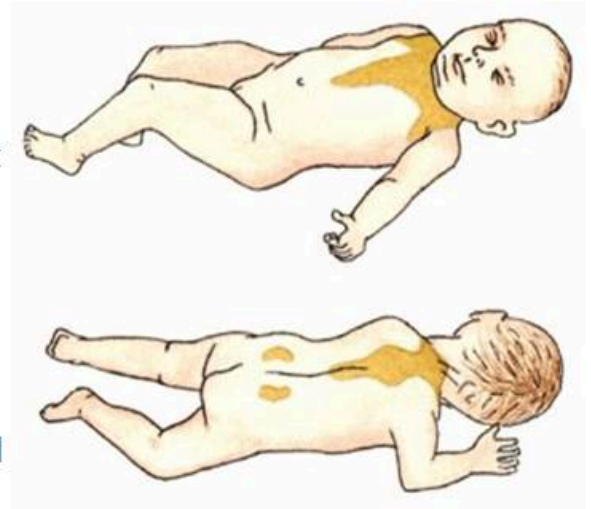
Potential Treatments for Type 2 Diabetes and Obesity

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

- **Potential Pharma Product** – allogeneic “off the shelf” product using brown fat stem cells to treat type 2 diabetes and obesity
- Infants have a larger population of brown fat that is responsible for generating body heat and creating metabolic homeostasis
- BRT has identified a stem cell population isolated from brown adipose depots in humans
- Developing a novel cellular therapy that transplants brown fat stem cells into large white fat areas using a biodegradable biological scaffold method for cell delivery



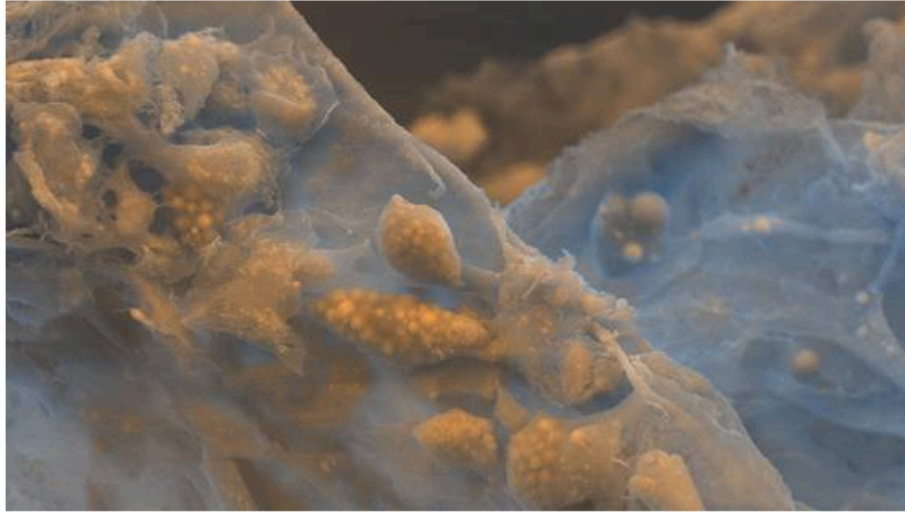
Pfizer – BRT Collaboration



- BRT and Pfizer will jointly conduct a study entitled *"Development and Validation of a Human Brown Adipose Cell Model"*
- Further characterize the identity and metabolic function of these cell lines
- Advances Each Company's Programs

ThermoStem[®] Scaffold


Brown Fat Cells Implanted in a Biological Scaffold



Cell delivery method incorporates subcutaneous implant of decellularized scaffold containing brown fat

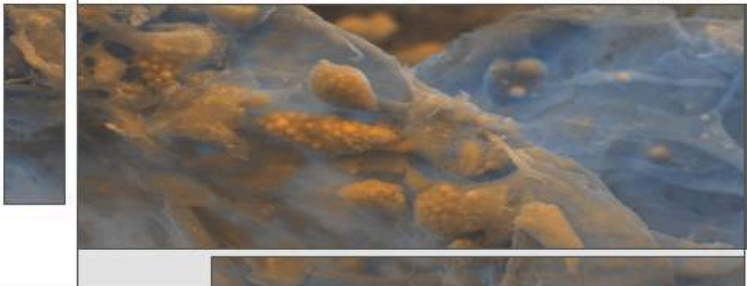
Publication in STEM CELLS

Volume 32, Number 2, February 2014





STEM CELLS[®]

The International Journal of Cell Differentiation and Proliferation



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Sister Journal of  **STEM CELLS**
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Preclinical – Glucose/Weight

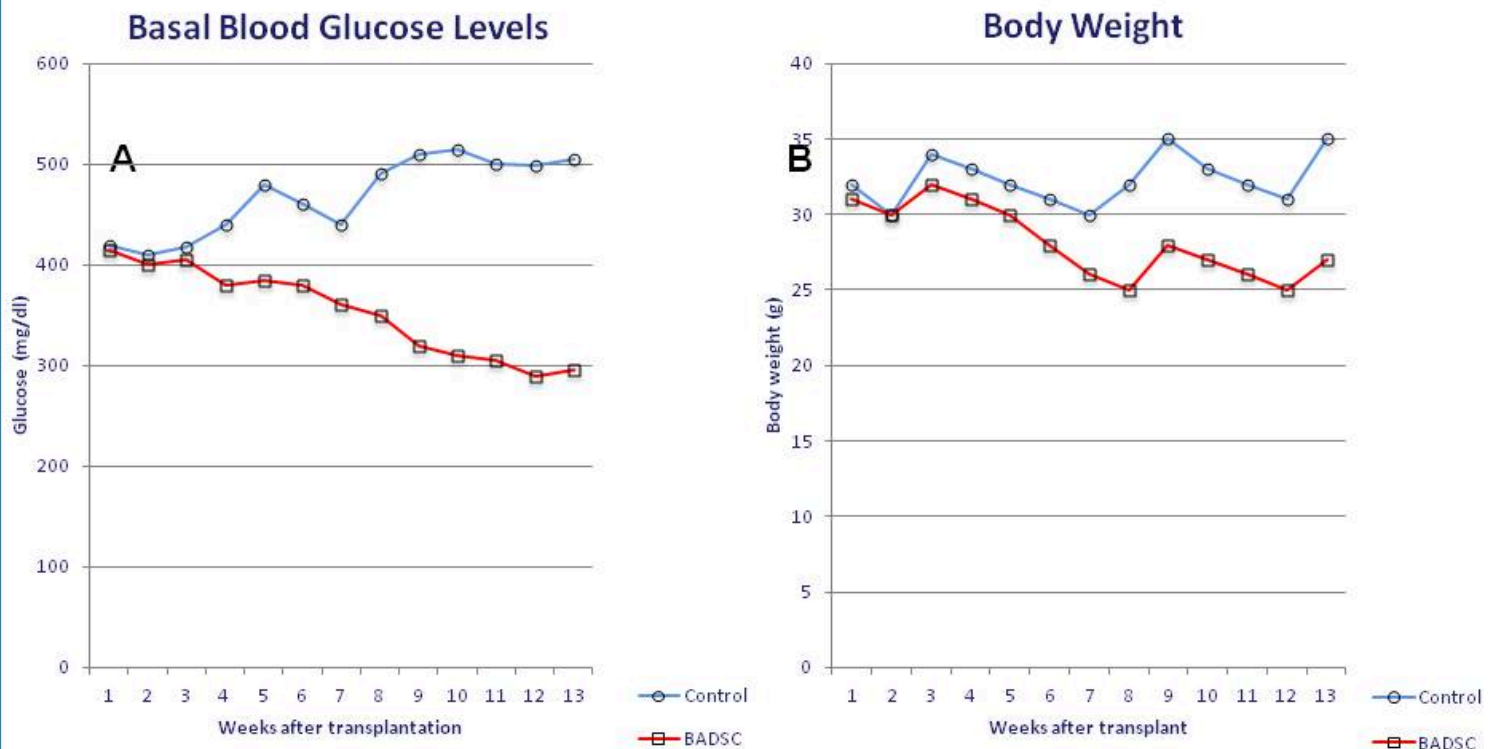
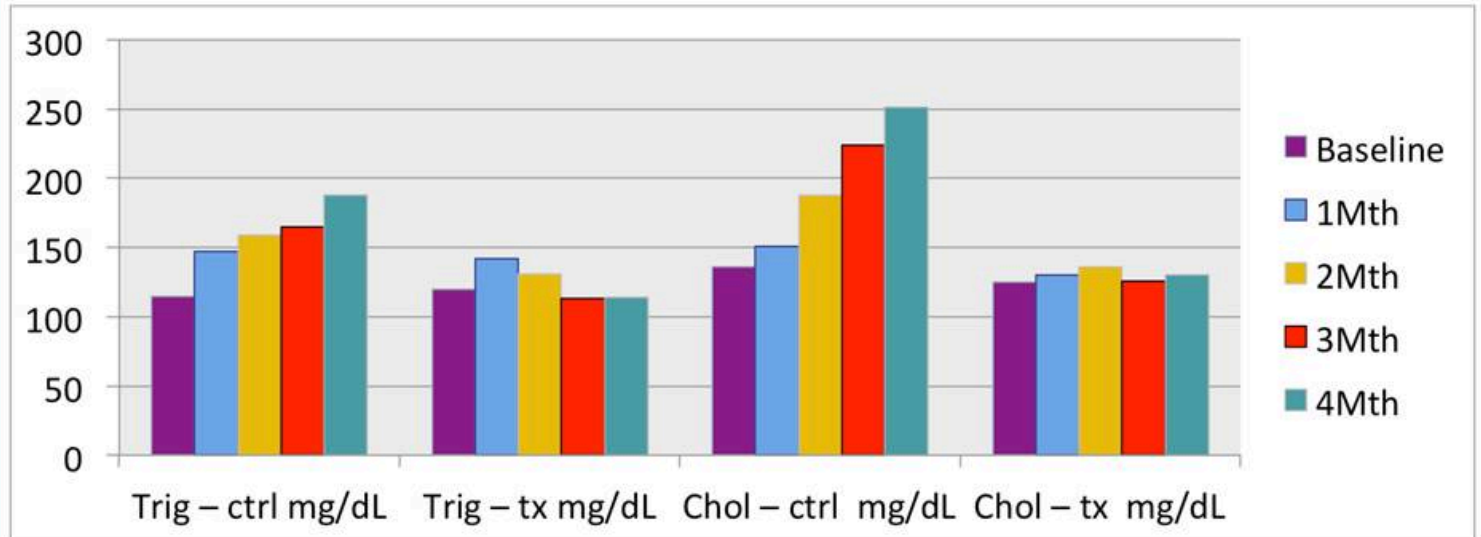


Fig. 7. (A) Glucose levels of mice transplanted with BADSC/scaffolds and controls. (B) Weights of mice transplanted with BADSC/scaffolds and controls.

Preclinical – Trig/Chol Levels



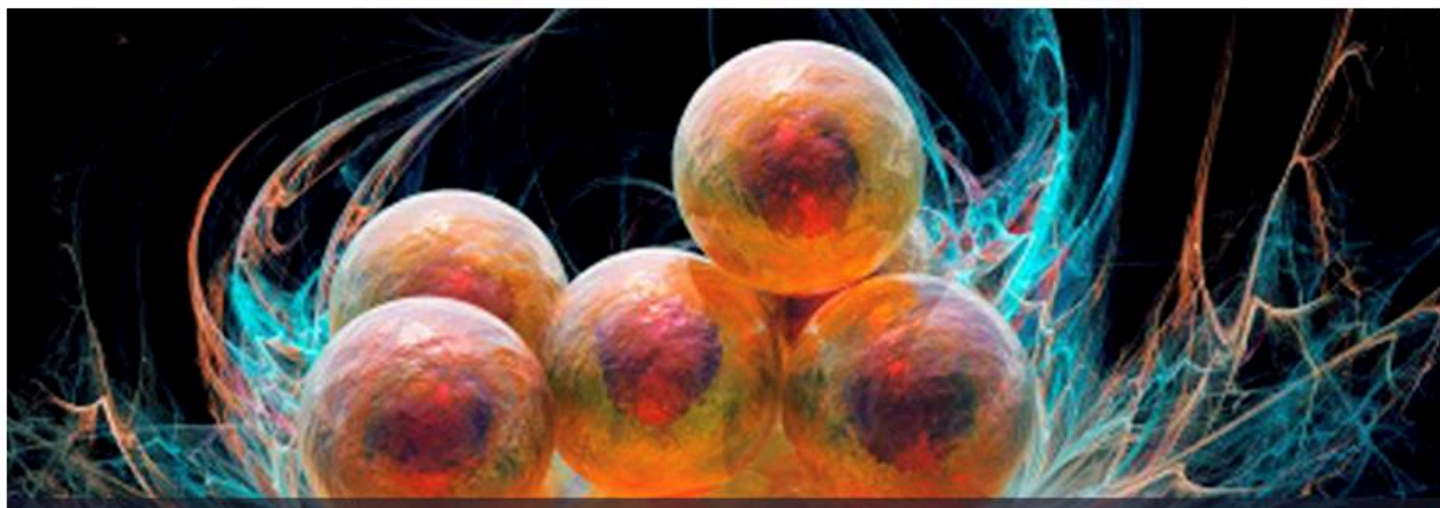
	Baseline	1Mth	2Mth	3Mth	4Mth
Trig – ctrl mg/dL	115 ± 16	147 ± 13	159 ± 21	165 ± 14	188 ± 16
Trig – tx mg/dL	120 ± 14	142 ± 15	131 ± 19	113 ± 11	114 ± 10
Chol – ctrl mg/dL	136 ± 16	151 ± 15	188 ± 26	224 ± 34	251 ± 22
Chol – tx mg/dL	125 ± 12	130 ± 14	136 ± 24	126 ± 19	130 ± 15

Highlights of Brown Fat Program

- Treatment design is an allogeneic cell based therapy – faster to market with limited competition
- Well conceived delivery method – subcutaneous injection of a biodegradable, biological scaffold to allow brown fat tissue to remain where transplanted and to continue increasing in volume
- Fat (brown) in Fat (white) procedure – homologous transplant – potential commencement of human trials within 2.5 years -- very safe and faster regulatory approval process
- PFIZER'S CVMED Program utilizing BRT's extensive brown fat cell and tissue library
- BRT receives funding and research support from Pfizer

In Summary

- Spinal disc program is poised to enter Clinical Trials
 - IRB approval secured
 - Retrospective human safety/feasibility study underway
- Proprietary therapeutic disc delivery device offers additional opportunities for value creation
- Metabolic Platform (Brown Fat) Program addresses large markets
 - Developing cellular treatment for type 2 diabetes and obesity
- ThermoStem® Program collaboration with Pfizer
- Strong expertise in cellular biology/experienced stem cell company and public management



Thank You

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