

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

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FORM 8-K

CURRENT REPORT

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

Date of Report: May 27, 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, 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 May 27, 2015 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 27, 2015 and May 28, 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 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](http://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.

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## **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.

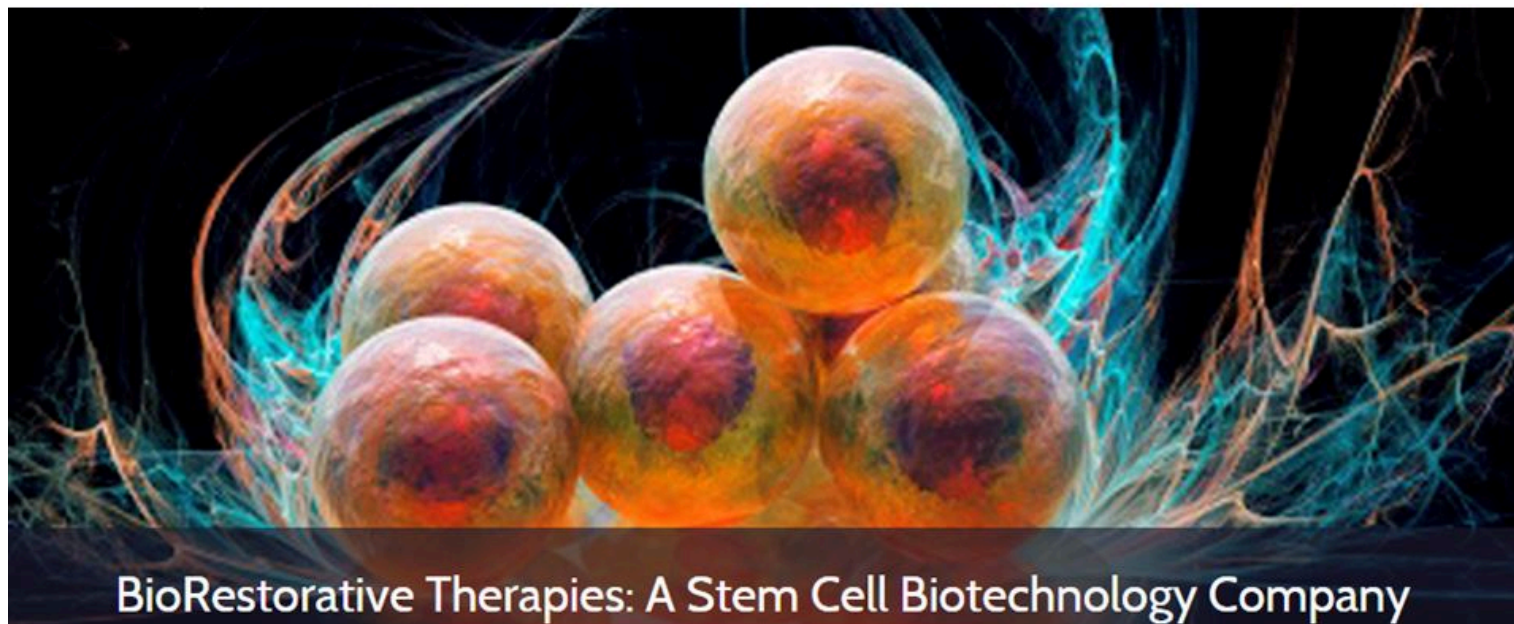
### **BIORESTORATIVE THERAPIES, INC.**

Dated: May 27, 2015

By: /s/ Mark Weinreb

Name: Mark Weinreb

Title: Chief Executive Officer



BioRestorative Therapies: A Stem Cell Biotechnology Company

## MARCUM MICROCAP CONFERENCE

Mark Weinreb, CEO

May 2015

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## 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 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](http://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. This presentation is not an offer to sell securities or a solicitation of an offer to buy securities.

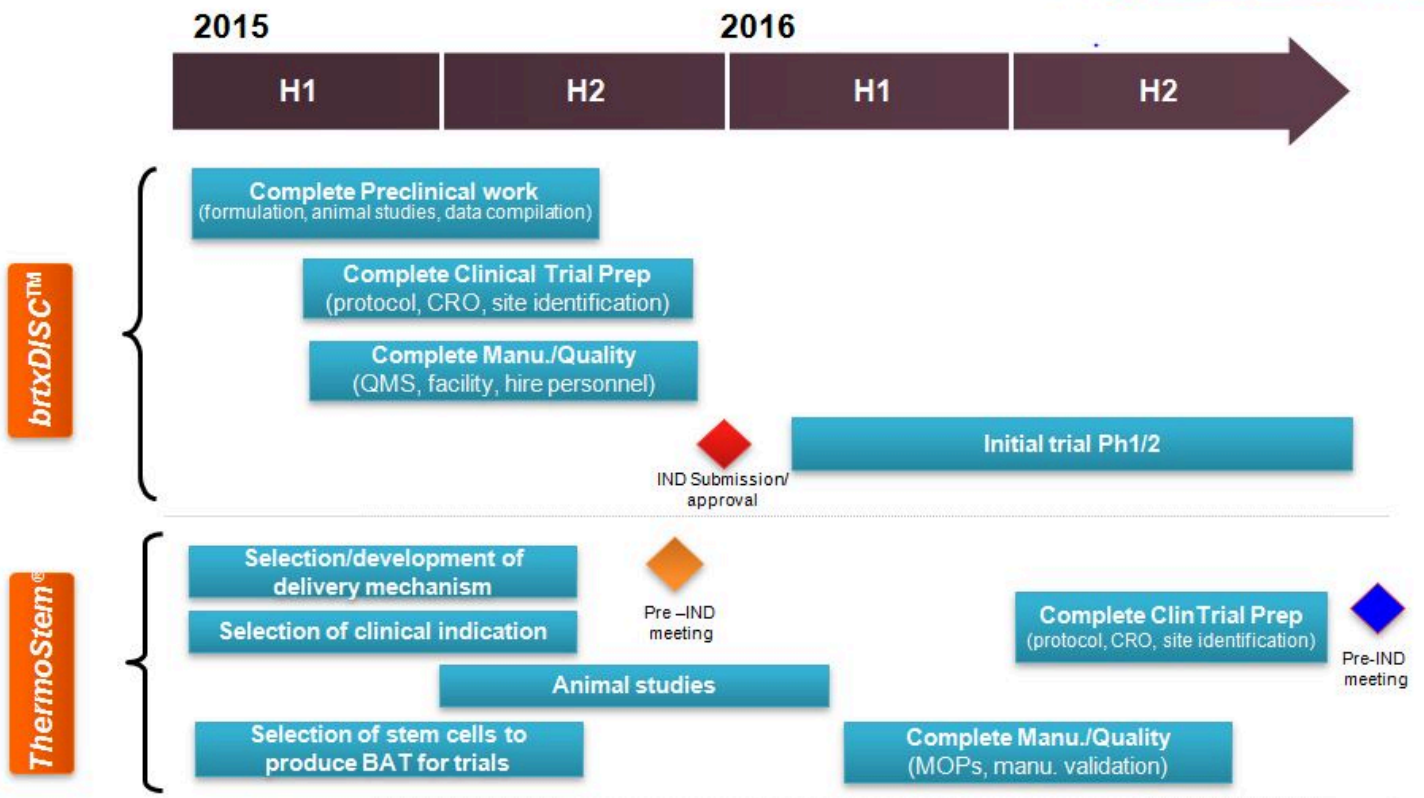




### ***Stem Cell-Driven Innovation in Disc/Spine and Metabolic Disease***

- BioRestorative Therapies, Inc. (“BRT”) develops therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells
- Expertise in cell biology and cell culturing
- Research and development focused on cell-based therapies:
  - ◆ Disc/Spine (*brtxDISC™*)
  - ◆ Metabolic Disease (*ThermoStem®*)

# Program Timing



## BRT's Lead Therapeutic Product: *brtxDISC™*



### *Addressing the Pathophysiology and Symptoms of Intervertebral Disc Disease*



- Autologous mesenchymal stem cells for the treatment of chronic Lumbar Disc Disease (cLDD)
- Successful pre-IND meeting with FDA
- Expected advancement of program into clinical trials by Q1 2016



## The Problem: No Effective Treatments for Lower Back Pain



### Today's Treatments Do Not Address Disease Pathology

#### 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)
- An unmet need requiring a radical change in treatment paradigm

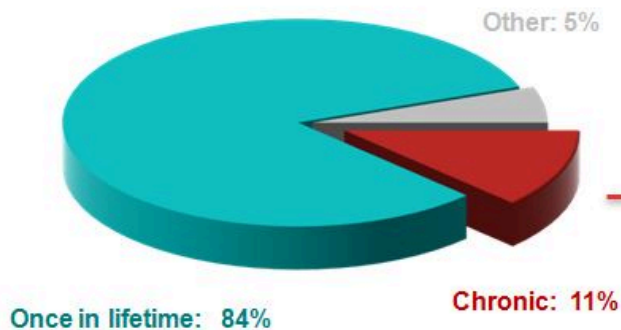
*Current therapy for discogenic back pain largely empirical and aimed at relieving symptoms rather than addressing the underlying disease mechanism*

# Market Opportunity: Disc/Spine Program



## Lower Back Pain Market Opportunity

### US Market Size > \$90B



### Cost Comparison

Current surgical options may be >\$100,000

Office-based BRT procedure \$15,000

- At \$15,000 price per procedure (*private pay*)
  - ♦ \$7,500 of revenue to BRT
  - ♦ \$5,000 of revenue to physician
  - ♦ \$2,500 of diagnostic-related costs
- Manufacturing cost of ~\$2,500 implying a >65% gross margin

# Disc/Spine Program



## Program objective

- Advance lead cell therapy candidate, *brtxDISC*<sup>™</sup>, our anchor product for the Disc/Spine program
- Expect to enter clinical trials by Q1 2016

## Background and Progress To Date

- History of human clinical use lends high degree of confidence of ultimate achievement
  - ◆ Multiple use cases in the US associated with high success rates and no adverse events
- Several actions taken to enhance Disc/Spine Program:
  - ◆ Recruitment of expert Medical Director from Hospital for Special Surgery
  - ◆ FDA consultants engaged
  - ◆ Recruited President to oversee program (cell therapy and regulatory experience)
  - ◆ Held successful pre-IND meeting with FDA

## Near-Term Priorities

- Pre-clinical process finalization
- Clinical trial preparation
- Product manufacturing and Quality Management System (QMS)
- Clinical protocol development and site identification and initiation

## ***brtxDISC*<sup>™</sup>: Treatment Process**



Patient bone marrow collected - shipped to BRT facility



Preparation of mononuclear bone marrow cells



Hypoxic culturing of bone marrow-derived stem cells



Cryopreserve cultured stem cells to create *brtxDISC*<sup>™</sup>



Ship *brtxDISC*<sup>™</sup> product to physician



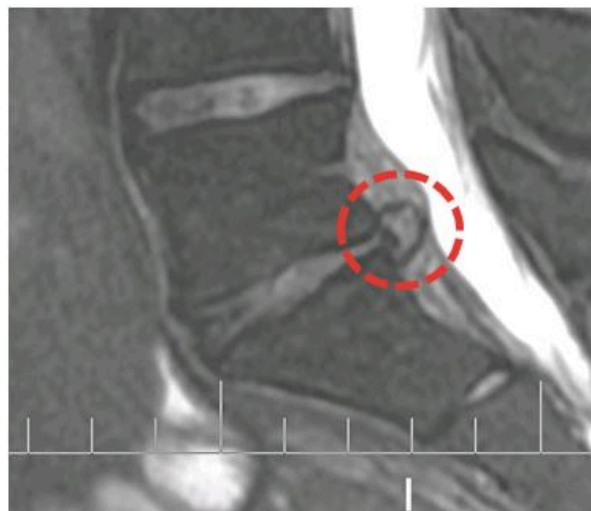
Injection of *brtxDISC*<sup>™</sup> into patient's disc



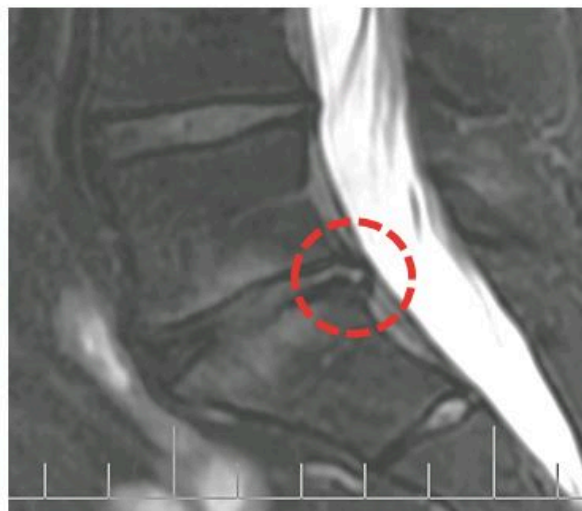
# Impact of Stem Cells on Disc Morphology



## Spine MRIs of Patient Treated with *brtxDISC*™



BEFORE

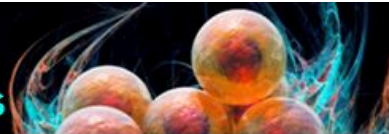


AFTER

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



## Target Physicians Likely to Treat Discs with Stem Cells



*Target physicians are those trained and skilled in performing spinal injections*



- Interventional physiatrists  
(physical medicine physicians)
- Pain management – anesthesiologists
- Interventional radiologists
- Neurosurgeons

*Greater than 10,000 total target physicians estimated in the US*

# ***brtxDISC™*: Clinical Trial Principal Investigator**



**Gregory E. Lutz, M.D.**

**BRT Chief Medical Advisor for Spine Medicine**

- Physiatrist-in-Chief Emeritus for Hospital for Special Surgery (HSS) and 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

# Anticipated Milestones - Disc/Spine Program



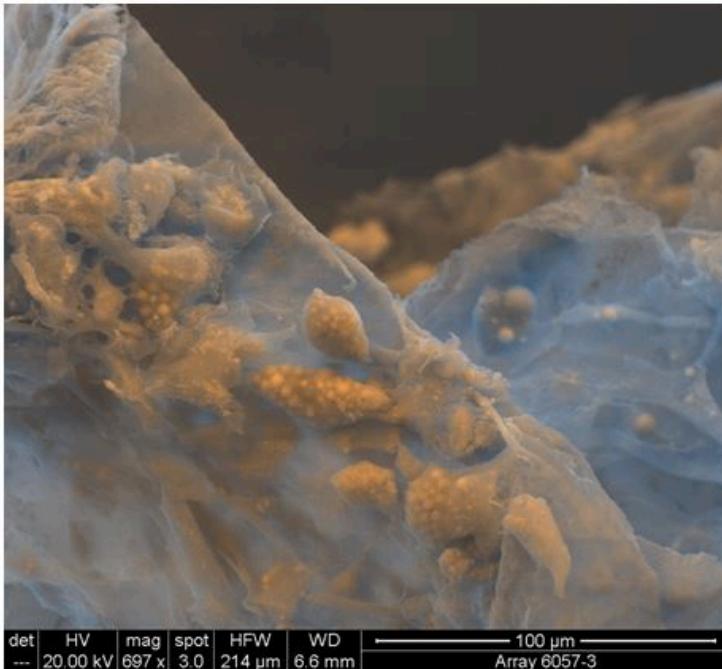
## TARGET TIMEFRAMES

Pre-Clinical	Q4 2015	<ul style="list-style-type: none"><li>Finalize product formulation</li><li>Complete required animal studies</li><li>Compile all required data for IND filing</li></ul>
Clinical Trial Preparation	Q3-Q4 2015	<ul style="list-style-type: none"><li>Finalize protocol and procedures</li><li>Engage Contract Research Organization (CRO)</li><li>Hire Director, Clinical Trial Ops</li><li>Identify and engage potential trial sites and investigators</li></ul>
Manufacturing/ Quality	Q3 2015	<ul style="list-style-type: none"><li>Complete installation of cGMP facility in existing lab</li><li>Conduct facility certification and process validation, QMS development</li><li>Hire key personnel (cell therapy manufacturing, QA, lab personnel)</li></ul>
Clinical Trial	Q1 2016	<ul style="list-style-type: none"><li>FDA clearance of IND</li><li>Trial Commencement</li><li>Recruiting and enrollment</li></ul>

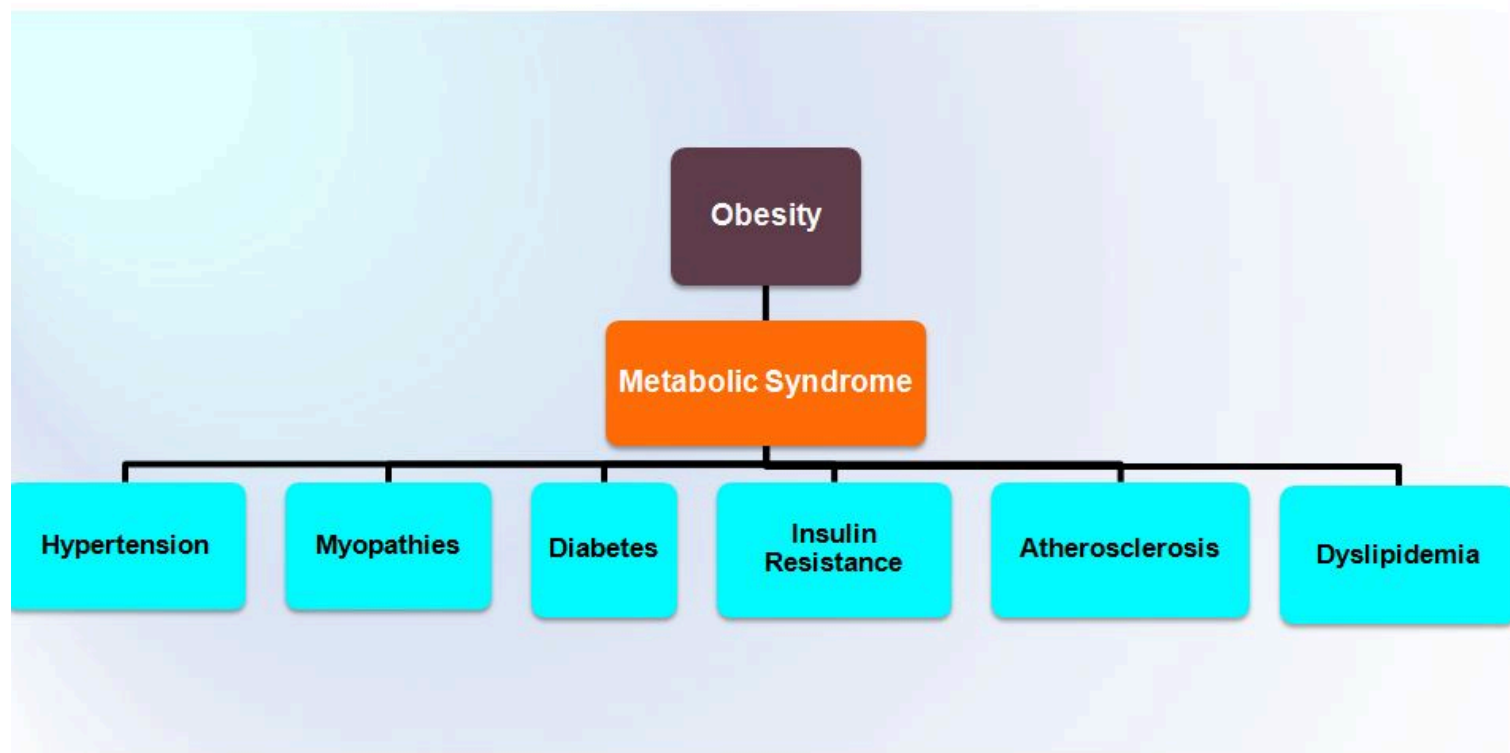
- 
- **Key Strategic Imperative:** Complete steps required for IND submission / initiate trials



## Potential Treatments for Metabolic Diseases



- Brown adipose tissue preclinical program for the treatment of metabolic disorders
- Pfizer collaboration on development of human brown adipose cells
- Cell-based approach – brown adipose-derived stem cells
- Target indications: obesity and type 2 diabetes
- Potential biologic discovery program

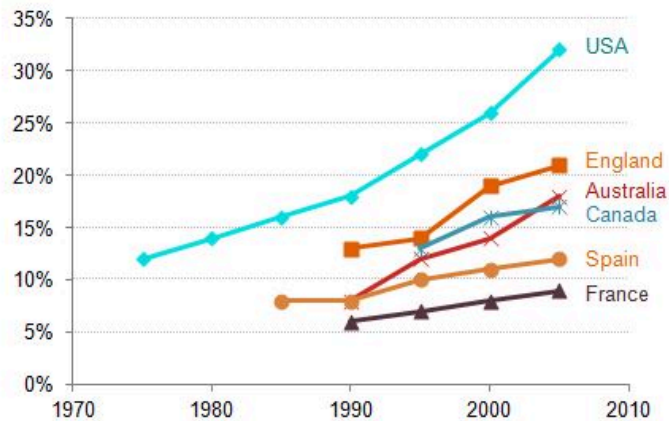




# Market Opportunity: Obesity and Metabolic Disorders Market

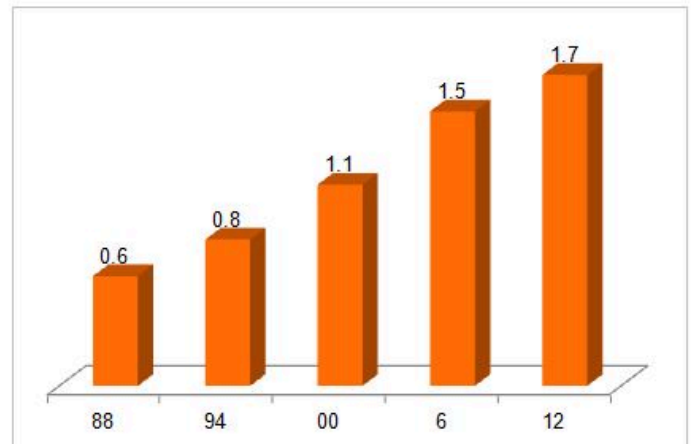


Obesity Rates In Selected Countries



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*

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

# ThermoStem® Program



## Program Objective

- Advance pre-clinical development leading to filing of IND
  - ◆ Demonstrate that brown adipose tissue (BAT) derived from differentiated human stem cells can be used to treat or prevent metabolic disorders and restore metabolic homeostasis

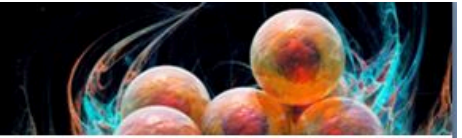
## Progress To Date

- Established unique human brown fat library
- Initial pre-clinical studies
  - ◆ Created a 3D tissue engineered brown adipose construct and successfully implanted into mice
  - ◆ At 6 month observation period, scaffold still intact, metabolic impact observed (weight loss, reduced glucose levels)
- Generated publications around initial results
- Established Pfizer relationship

## Near-Term Priorities

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

# 2014 Publication in *STEM CELLS* Journal

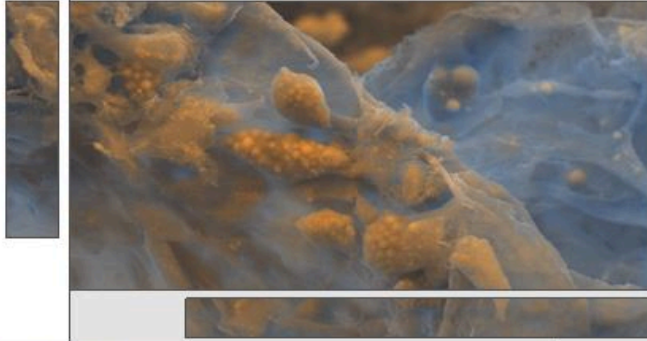


Volume 32, Number 2, February 2014



## STEM CELLS

The International Journal of Cell  
Differentiation and Proliferation



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

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

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biorestorative<sup>®</sup>  
therapies



- 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® Program: Key Considerations



## Options for Delivery Mechanism

- Use existing encapsulation technology already deployed in FDA trials
- Alternative existing encapsulation technology
- Creation of in-house developed device

## Clinical Indication

- Orphan disease option
  - ♦ Accelerated clinical development path
  - ♦ Collection of data relevant to metabolic syndrome (glucose, lipid levels, etc)
- Larger traditional indications
  - ♦ Dyslipidemia
  - ♦ Obesity
  - ♦ Type 2 diabetes

## Strengthen Program

- Creation of brown adipose Strategic Advisory Board
- Partnerships with subject-matter experts
- IP generation
- Research potential biologics application

- 
- **Key Strategic Imperative: Finalize lead indication and delivery mechanism to support IND filing**

- **Target Timeframe - Q4 2016**





## CORE PROGRAMS

- **DISC/SPINE PROGRAM (*brtxDISC*<sup>TM</sup>):**
  - ◆ Complete requirements to submit IND and commence trials
  - ◆ Develop additional *brtxDISC*<sup>TM</sup> indications
  
- **METABOLIC PLATFORM PROGRAM (*ThermoStem*<sup>®</sup>):**
  - ◆ Finalize clinical indication and delivery mechanism and drive to IND filing
  - ◆ Develop biologics program

Thank You



OTCQB: BRTX ♦ [biorestorative.com](http://biorestorative.com)

