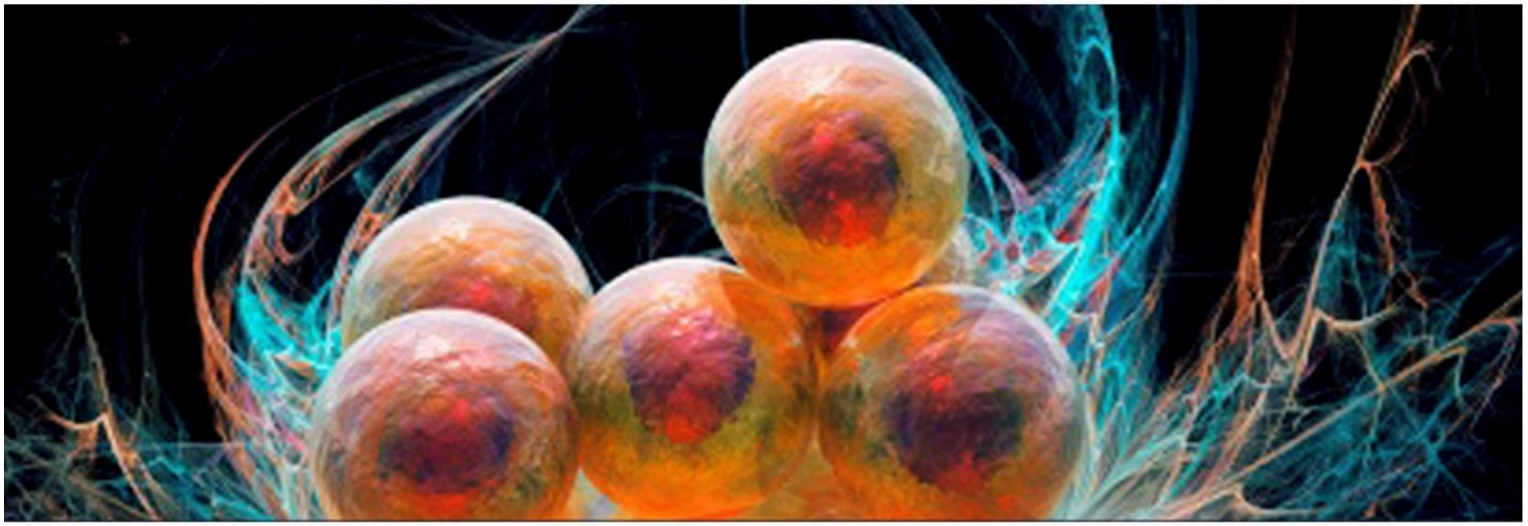
Free Writing Prospectus
Filed pursuant to Rule 433
Registration No.: 333-220843



biorestorative therapies

***Fall 2017***

**OTCQB: BRTX ◆ biorestorative.com**

# Forward Looking Statements

The issuer has filed a registration statement (including a prospectus) with the SEC for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement and other documents the issuer has filed with the SEC for more complete information about the issuer and this offering. You may get these documents for free by visiting EDGAR on the SEC Website at www.sec.gov. Alternatively, the issuer, any placement agent or any dealer participating in the offering will arrange to send you the prospectus if you request it by calling (347) 429-8361.

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 initiate and complete our clinical trials, implement our business plan, satisfy our debt obligations and fund our operations; (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; and (xvi) compliance with applicable federal, state, local, and international requirements. See also "Factors That May Affect Future Results and Financial Condition" listed in the Company's most recent registration statement filed 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.

# Company Overview

***BioRestorative Therapies, Inc. develops therapeutic products using cell and tissue protocols, involving adult stem cells. Core programs address disc/spine disease and metabolic disorders.***

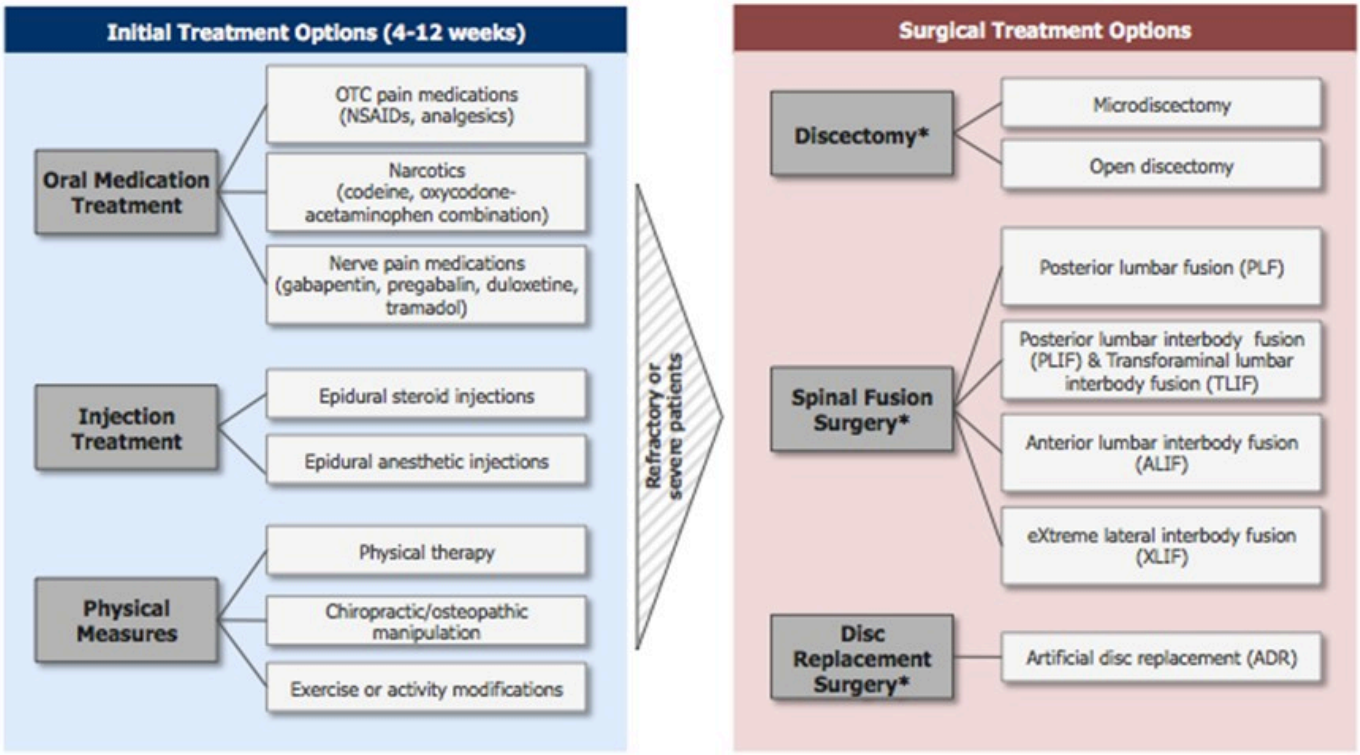
## MULTIPLE CELL THERAPY PROGRAMS

- **DISC/SPINE PROGRAM (*brtxDISC™*):**
  - **FDA Clearance to Commence Phase 2 Clinical Trials**
  - Advanced cell therapy, chronic lumbar disc disease by protruding or bulging discs
  - ***BRTX-100*** - autologous product promoting healing in damaged intervertebral discs

- **METABOLIC PROGRAM (*ThermoStem®*):**
  - Cell-based therapy targeting diabetes, obesity and metabolic disorders using brown adipose (fat) cells and tissue
  - Finalize clinical indication and delivery mechanism and drive to IND filing

# Disc Treatment Options

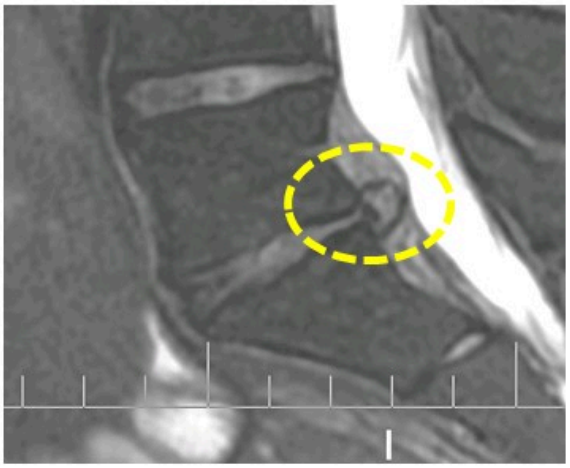
***Current treatment options for the BRTX-100-addressable population range from conservative methods such as medication or physical measures, to more invasive surgical procedures***



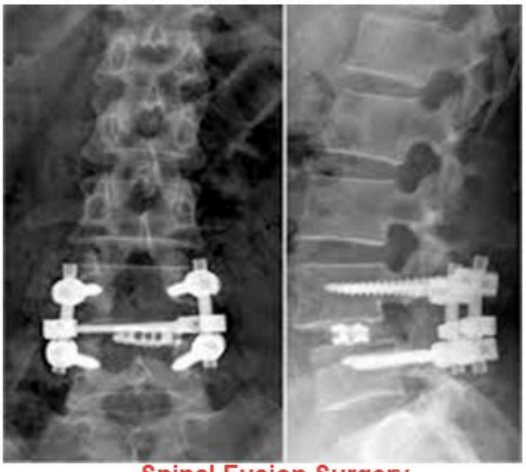

*__Discectomy__: surgery to remove part of the herniated disc material that presses on a nerve root or the spinal cord
*__Spinal Fusion Surgery__: surgery designed to stop the motion at a painful vertebral segment by joining, or fusing, two or more vertebrae
*__Disc Replacement Surgery__: surgery involving replacing a painful disc with an artificial disc (PRODISC®-L currently approved)

# Lower Back Pain Disc Disease

***Lower Back Pain is the Most Common, the Most Disabling, and the Most Costly Musculoskeletal Problem Treated***



Protruding / Bulging Disc



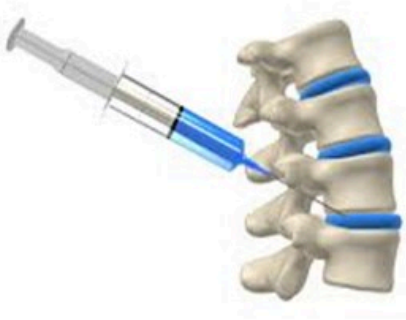
Spinal Fusion Surgery

***INTRODUCING A NEW STANDARD OF CARE TO TREAT CHRONIC LUMBAR DISC DISEASE***

# Cell-Based Lumbar Disc Therapeutic

## *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 Hypoxic Cultured Mesenchymal Stem Cells (or MSCs) Collected from the Patient's Bone Marrow and Co-Administered with Autologous Biomaterial Carrier
- **Treatment** is Intended for Patients Whose Pain Has Not Been Alleviated by Non-Invasive Procedures and Who Potentially Face the Prospect of Surgery
- **Phase 2 Clinical Trial Cleared To Proceed**
- **HUMAN DATA** from Treatments Performed in the US

# *BRTX-100* Product Benefits

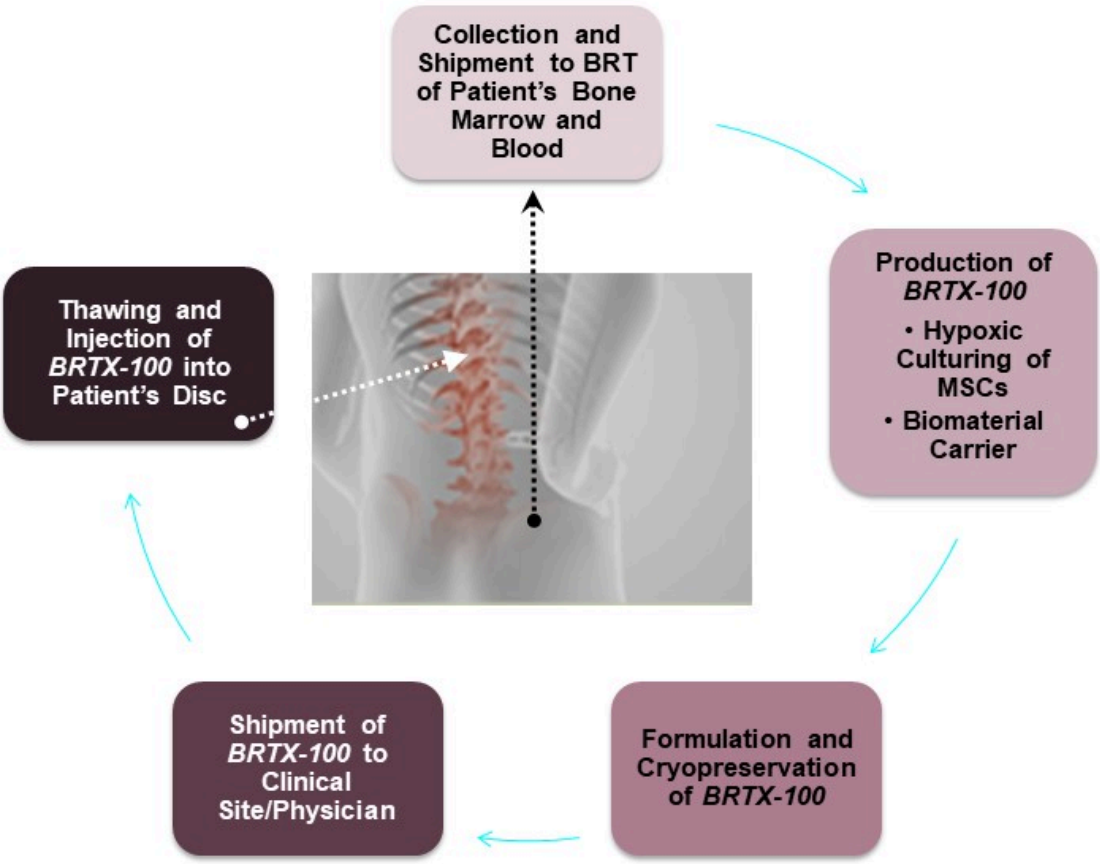
## *Hypoxic Culture Conditions – A Solution for Mesenchymal Stem Cell Based Regenerative Medicine*

| Hypoxic Culture Benefits |
|---|
| Increased Cell Proliferation |
| Greater Plasticity |
| Increased Paracrine Effect |
| Increased Cell Survival |

## *BRTX-100 - A Safer and More Potent Product*

| *BRTX-100* | Mesoblast |
|---|---|
| Autologous | Allogeneic |
| Bone Marrow MSC | Bone Marrow MSC |
| 100% Xeno-Free | FBS Culture |
| Hypoxic Cultured | Normoxic Cultured |
| Platelet Lysate/Carrier | Hyaluronic Acid/Carrier |

# *BRTX-100*: Production Process - 5 Weeks



HUMAN CLINICAL EXPERIENCE SAFETY STUDY

Elabd et al. J Transl Med (2016) 14:253
DOI 10.1186/s12967-016-1015-5

Journal of Translational Medicine

RESEARCH Open Access

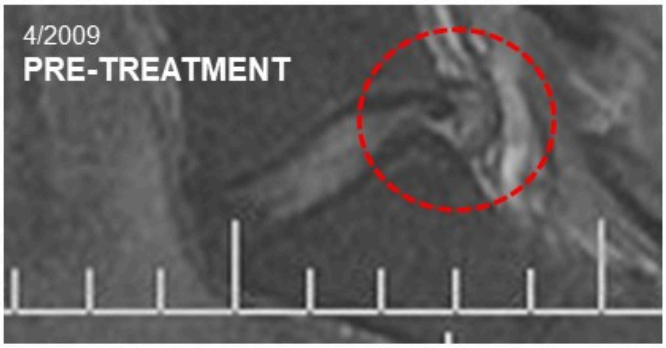
# Intra-discal injection of autologous, hypoxic cultured bone marrow-derived mesenchymal stem cells in five patients with chronic lower back pain: a long-term safety and feasibility study

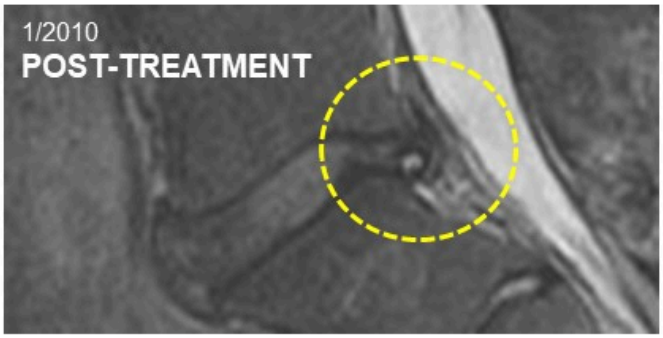
Christian Elabd[1], Christopher J. Centeno[2], John R. Schultz[2], Gregory Lutz[3], Thomas Ichim[4] and Francisco J. Silva[1*]

# Disc Morphologic Changes

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

- 42 yr. old 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

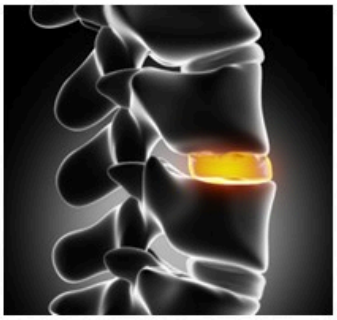


# *BRTX-100*: Clinical Trial Design

## Trial Design:

**A Phase 2 Prospective, Double-Blinded, Placebo Controlled, Randomized Study, n=72**



- Evaluate Safety and Efficacy of a Single Dose of *BRTX-100*
- 15+ Clinical Trial Sites
- Primary Efficacy Endpoint – 6 months
- Patient Follow Up – 12 months, 24 months

## Primary Endpoint

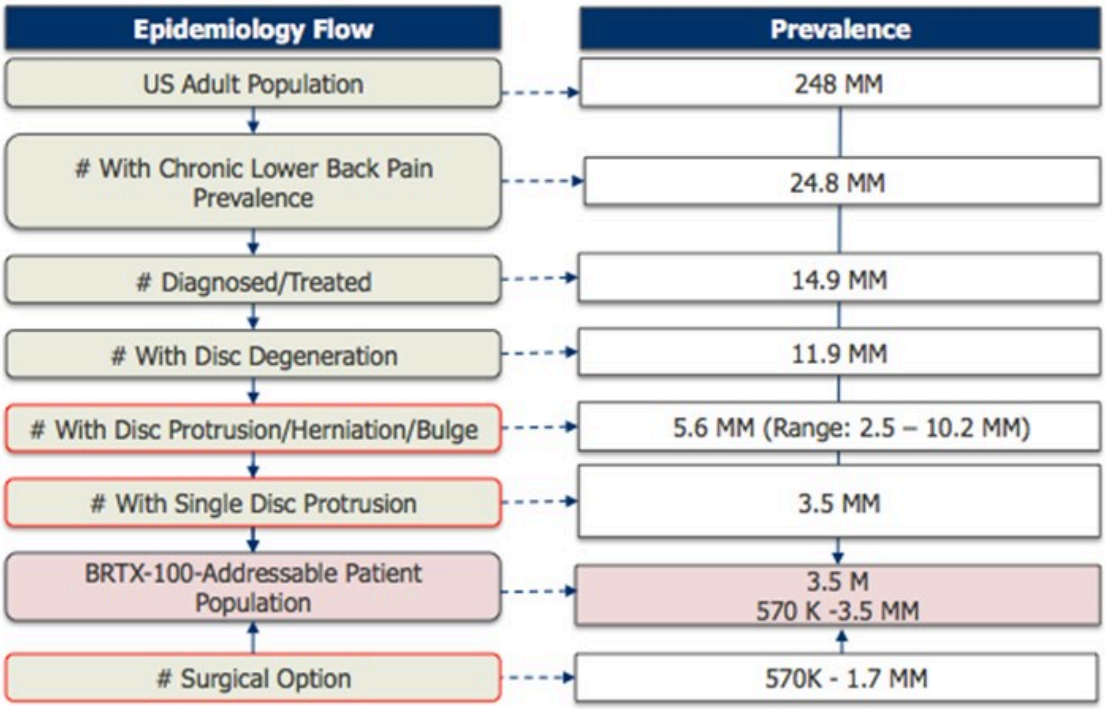
- **Improvement in Function** defined as at least a 30% increase in function based on the Oswestry questionnaires (ODI)
- **Reduction of Pain** defined as at least a 30% decrease in pain as measured using the Visual Analogue Scale (VAS)

## Additional or Secondary Endpoints

- Quality of Life Assessment
- Evolution of Affected Disc(s) by Magnetic Resonance Imaging (MRI)

# Market (Prevalence Summary)

***Trinity Partners used a multi-pronged approach to determine the prevalence of the BRTX-100-addressable patient population***



# Key Highlights - Value Proposition

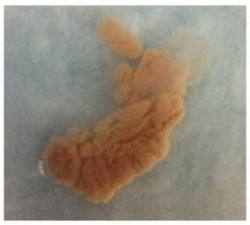
- **Unique Product Engineered to Address the Challenges of the Targeted Application**
  - Autologous Hypoxic-Cultured Cell Product
  - ***BRTX-100*** is Formulated and Co-Administered with Biomaterial Carrier
- **Pending Clinical Trial**
  - FDA Clearance of Phase 2 Clinical Trials
  - Short Duration – Efficacy Endpoint 6 Mo.; Patient Follow Up – 12/24 Mo.
  - **Target Patient Enrollment Expected in Q2 2018**
- **Previous Human Experience**
  - Demonstrates Long Term Safety
  - Suggests Sustainable Therapeutic Benefits
- ***BRTX-100* Addressable U.S. Patient Population**
  - 570 K – 3.5 MM Potential US Patients with Target Indication
  - Revenue Potential: >$1 Billion; $15,000+ for product

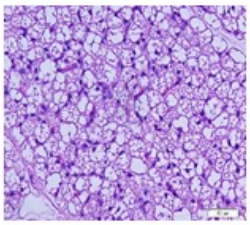
## Potential Treatments for Metabolic Diseases

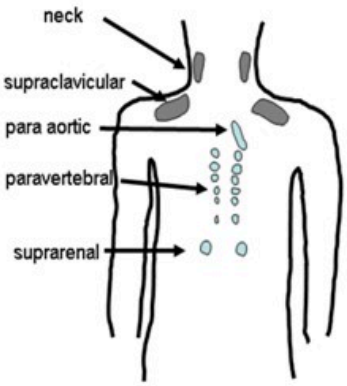

- Pre-clinical allogeneic cell-based therapy to target obesity, diabetes and metabolic disorders using brown adipose (fat) derived stem cells (BADSC) to generate brown adipose tissue (BAT)
- BAT is a specialized adipose tissue found in the human body that plays a key role in the evolutionarily conserved 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.
- Research Collaboration with University of Pennsylvania – Division of Endocrinology, Diabetes and Metabolism on Brown Adipose Stem Cell Program

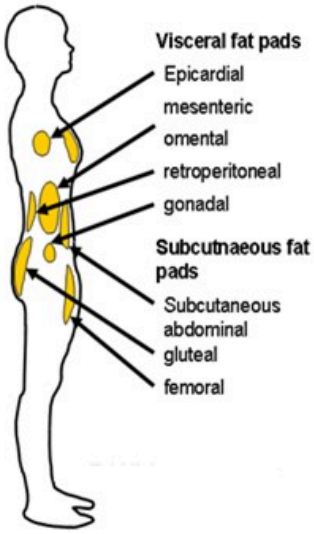
# Potential Treatments for Metabolic Diseases

**BAT**

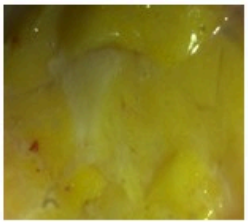


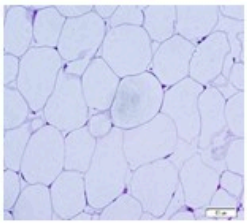





**WAT**





## Brown Adipose Tissue (BAT)

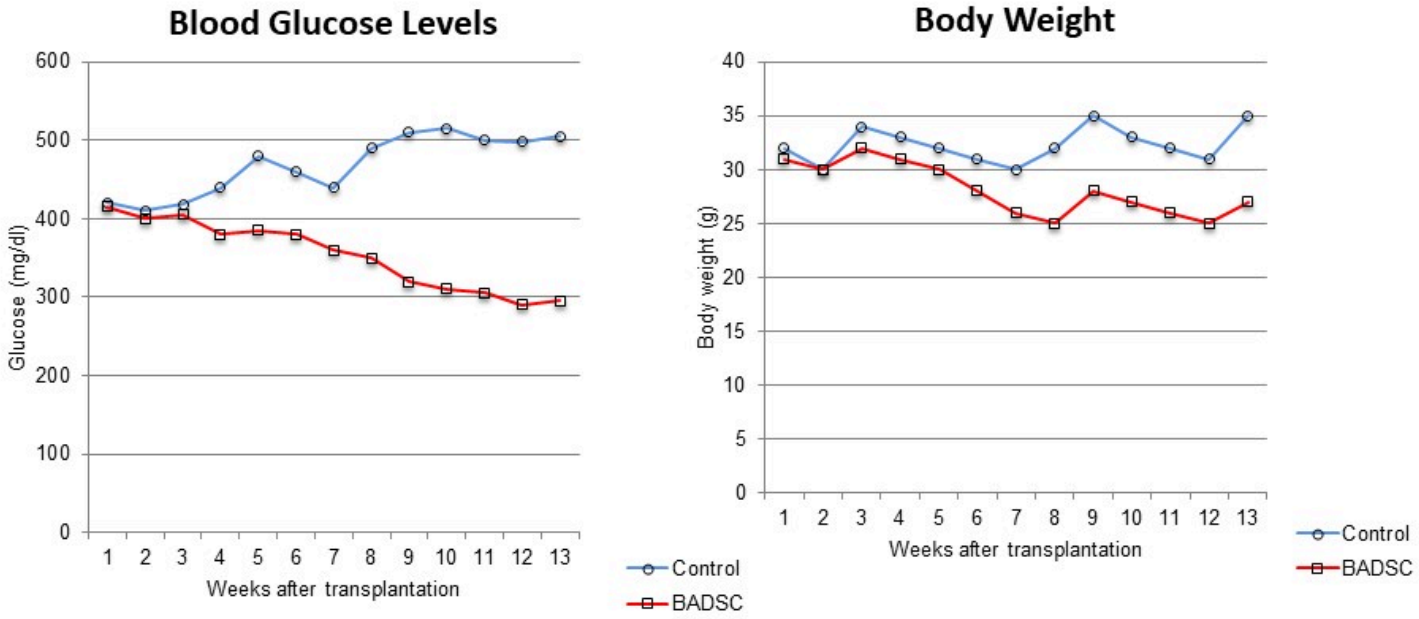
- Metabolism
- Energy wasting

## White Adipose Tissue (WAT)

- Metabolism
- Energy Storage

# Preclinical Metabolic Results

## Glucose and Body Weight

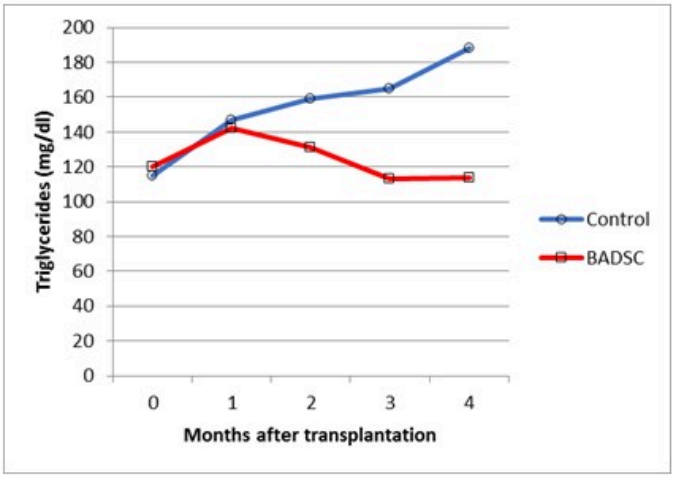



Mice fed high chow diet throughout experiment and transplanted with brown adipose derived stem cells (BADSC)/scaffolds and controls

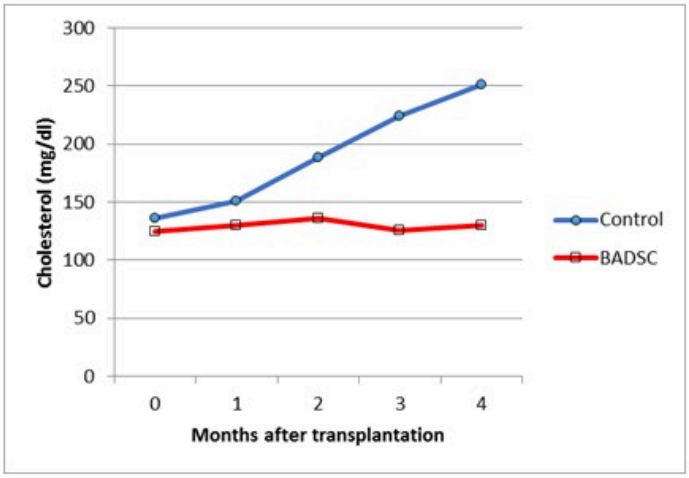
# Preclinical Metabolic Results

## Triglycerides and Cholesterol Levels

### Triglycerides Level




### Cholesterol Level



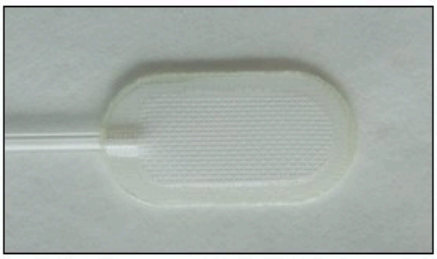

Mice fed high chow diet throughout experiment and transplanted with brown adipose derived stem cells (BADSC)/scaffolds and controls

# Brown Fat Delivery Device

## Benefit of *ThermoStem*™ Generation 2

| | Generation 1 | Generation 2 |
|---|---|---|
| Encapsulation | No | Yes |
| Drug Master File registered with FDA | No | Yes |
| Protect Cells from Immune System | No | Yes |
| Safe for Host | ? | Yes |
| Long-term Biocompatibility | ? | Yes |
| Retrievable | No | Yes |
| Support Brown Adipocyte Differentiation | Yes | Yes |
| Allows Molecule Exchange | Yes | Yes |

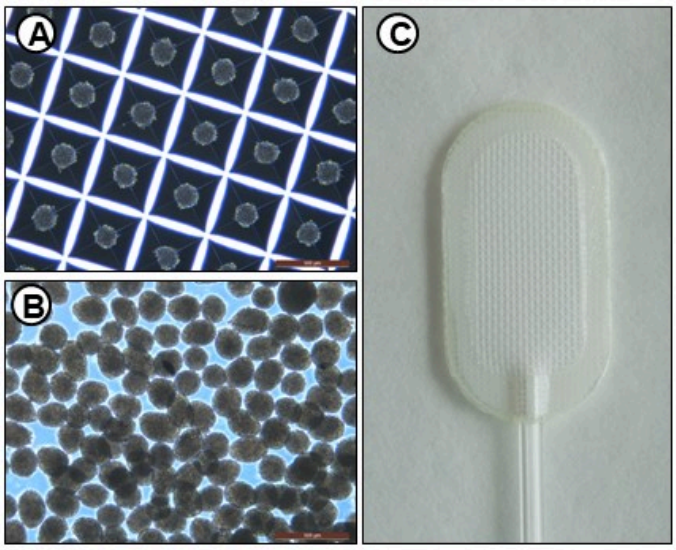
Generation 1



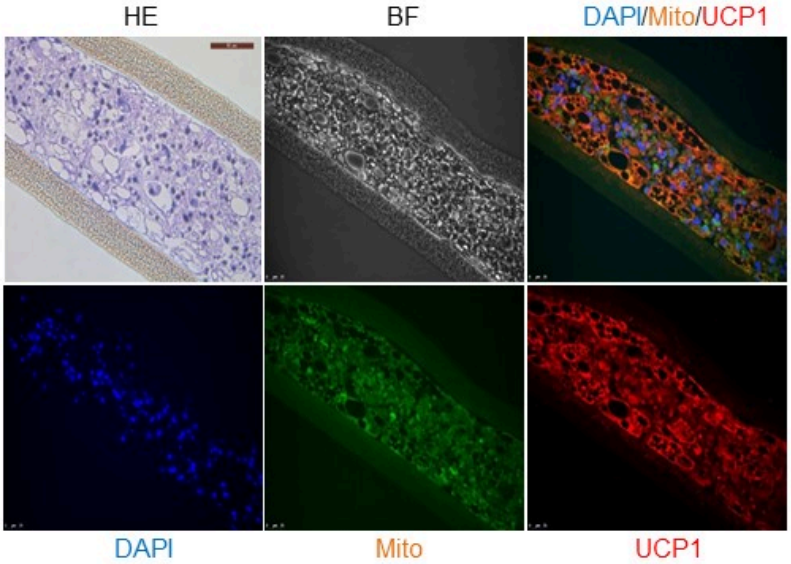
Generation 2

# Brown Fat Delivery Device

## Encapsulation Device/BADSCs




Encapsulation Device containing BADSC that have been differentiated into brown fat. (A) BADSC inside encapsulation device. (B) BASDC prior to loading (C) Encapsulation Device.




Immunohistochemical analysis of a cross section of an encapsulation device containing cells. UCP1 confirms the differentiation and identity of the brown adipose stem cells. DAPI stains nuclei, Mito stains mitochondria.

# Management and Advisory Team

| | |
|---|---|
| **Mark Weinreb, President and CEO** | • Pioneer in regenerative and cellular medicine / science<br>• Former President of NeoStem,Inc. (now Caladrius Biosciences)<br>• Owner BioHealth Labs (now Enzo BioChem Labs) |
| **Francisco Silva, Vice President of Research and Development** | • Former CEO, DV Biologics LLC, President of DaVinci Biosciences LLC<br>• Extensive experience in cell based therapies<br>• Inventor of patents/author of manuscripts in regenerative medicine |
| **Gregory E. Lutz, M.D., Chief Medical Advisor For Spine Medicine** | • Physiatrist-in-Chief Emeritus for Hospital for Special Surgery (HSS)<br>• Member of HSS Board of Trustees<br>• Founded Physiatry Dept. at HSS/Physical Med & Rehab at Mayo Clinic |
| **Wayne Marasco, MD, Ph.D., Chairman, Scientific Advisory Board** | • Principal Faculty Member of Harvard Stem Cell Institute<br>• Professor, Department of Cancer Immunology & AIDS at Dana-Farber Cancer Institute<br>• Professor of Medicine at Harvard Medical School. |
| **Joy Cavagnaro, Ph.D., Regulatory Advisor, Scientific Advisory Board** | • Former Director of Quality Assurance, CBER, FDA<br>• Former V.P., Regulatory Affairs, Human Genome Sciences<br>• President and Founder of Access BIO |

# In Summary

**Opportunity for Meaningful Value Enhancement**

- ***BRTX-100* – FDA cleared, Phase 2 ready**
  - Short duration – 6 month efficacy endpoint
  - Established human data
- **Brown fat cell metabolic platform**
  - Obesity, diabetes and metabolic disorders
- **"Off-the-shelf" cell therapies in development**
  - Broad prospective musculoskeletal applications
- **Short and intermediate value inflection points**
- **Favorable market conditions; <u>the time is now</u>**
  - Recent FDA directives fostering regenerative cell therapies
  - Novartis CAR-T – initial FDA approved gene therapy

# Thank You

biorestorative therapies

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