



### **CORPORATE PRESENTATION**

October 2015

### **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 brtxDISC, 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 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.





We have filed a registration statement (including a prospectus) with the United States Securities and Exchange Commission (SEC) for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement and other documents we have filed with the SEC for more complete information about us and this offering. You may get these documents for free by visiting EDGAR on the SEC Website at www.sec.gov. Alternatively, we or any underwriter or dealer participating in the offering will arrange to send you the prospectus if you contact Aegis Capital Corp. by calling 212-813-1010.

### BioRestorative Therapies: Company Overview



Issuer

BioRestorative Therapies, Inc.

Exchange / Ticker

NASDAQ Capital Market\*: BRTX/BRTXW

Offering Size

1,834,862 shares of Common Stock together with Class A Warrants to Purchase 1,834,862 shares of Common Stock and Class B Warrants to Purchase 917,431 shares of Common Stock (100% Primary)

Over-Allotment

15% or 275,229 shares of Common Stock and /or Class A Warrants to purchase 275,229 shares of Common Stock and/or Class B Warrants to purchase 137,615 shares of Common Stock

**Use of Proceeds** 

We intend to use the net proceeds of this offering as follows: (i) submission of investigational new drug, or IND, application to the United States Food and Drug Administration, or FDA, with respect to *brtxDISC* and its related collection and delivery procedure, and commencement of associated clinical trials; (ii) pre-clinical research and development with respect to *ThermoStem Program*; (iii) repayment of indebtedness; and (iv) for general corporate and working capital purposes.

Sole Book-Running Manager

Aegis Capital Corp.

\*We have applied to list our common stock and the Class A warrants being sold in this offering on The NASDAQ Capital Market.

### 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 mid 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
- · 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<sup>™</sup> is a cryopreserved autologous cell therapy consisting of hypoxic cultured mesenchymal stem cells (MSCs) and a proprietary carrier
- brtxDISC<sup>TM</sup> 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:

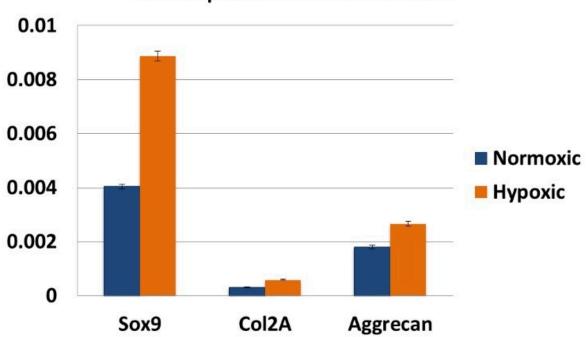
Physical medicine and rehabilitation physicians, interventional physiatrists, pain management physicians, interventional radiologists





### Hypoxic Culture Primes Cells for Chondrocyte Repair

### **Gene Expression Relative to GAPDH**



### brtxDISC™: Mechanism of Action

Express



Aim is to change disease pathology and improve disc morphology.

brtxDISC™



Key Factors

VEGF FGFs EGF PDGF Type II Collagen SDF-1 Multiple Mechanisms

Anti-inflammatory
Structural repair
Neovascularization
Promote endogenous
repair

### brtxDISC™: Previous Human Data

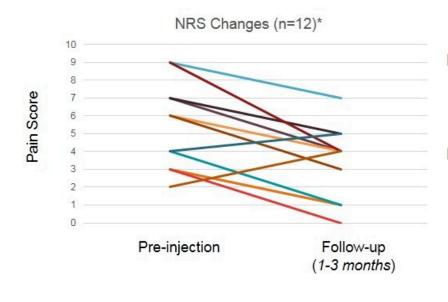


- A physician-sponsored, IRB-approved study investigated the effect of hypoxic cultured MSCs on disc protrusions (from 2008-2010)
- Safety observations:
  - No adverse events observed
  - Maximum dose of 40 million cells well tolerated
  - MRI results interpreted by an independent radiologist in a subset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

### brtxDISC™: Pain Improvements



#### 67% (8 of 12) of Subjects Had ≥ 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 ≥ 30% improvement ¹

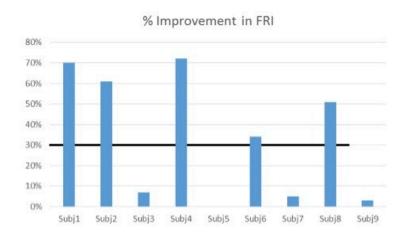
<sup>\*</sup> Two patients had similar NRS changes

<sup>&</sup>lt;sup>1</sup> Ostelo et al Spine Vol 33,no1.pp90-94

### brtxDISC™: FRI Improvements



#### 56% (5 of 9) of Subjects Had ≥ 30% Improvement in FRI



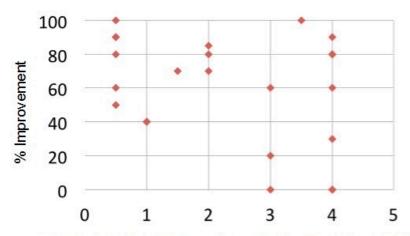
- Functional Rating Index (FRI) is a standardized measure of measuring subjects' ability to do every day activities
- Minimally clinical important difference (MCID) in functional rating scales is defined as ≥ 30% improvement ¹
- 63% (5 of 8) of subjects had both ≥ 30% Reduction in NRS Score and Improvement in FRI

<sup>1</sup> 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

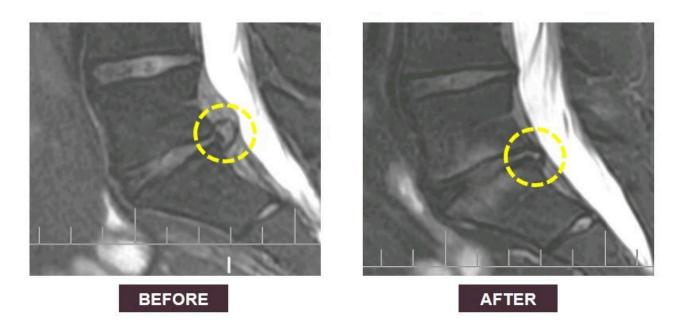
Years Since Procedure (Last Available Outcome Endpoint)

<sup>\*</sup> Patient reported improvement

### brtxDISC™ Treatment: Case Study



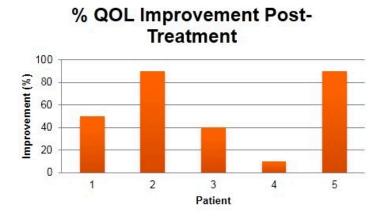
### Therapy May Have a Significant Impact on the Morphology of the Disc

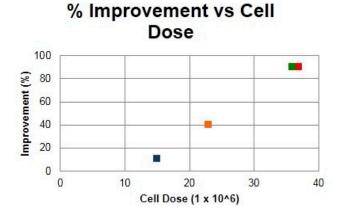


■ 56% (9 of 16) of Subjects had ≥ 50% Reduction in Disc Bulge Size



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





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

### brtxDISC™: Clinical Trial Design

- 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)



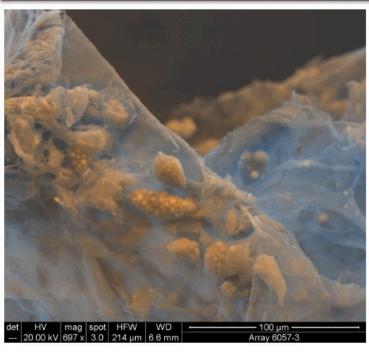
### brtxDISC™: Key Milestones



Milestones	Target Timeline
Pre-IND meeting with FDA	Completed
Finalize product formulation	Completed
Build clean room for product manufacturing	Completed
Required animal studies	In progress
Manufacturing qualification runs	4Q 2015
Submit IND	1Q 2016
IND Clearance	2Q 2016

## ThermoStem® Program (Brown Adipose Stem Cells

### 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, or 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



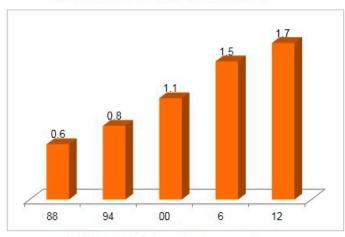
The pandemic of obesity and metabolic disorders is large and continues to grow worldwide, despite efforts to curb its progress

#### **Obesity Rates In Selected Countries**

#### 35% USA 30% 25% England 20% Australia Canada 15% Spain 10% 5% 0% 1970 1980 1990 2000 2010

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

### ThermoStem® Program



### 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 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



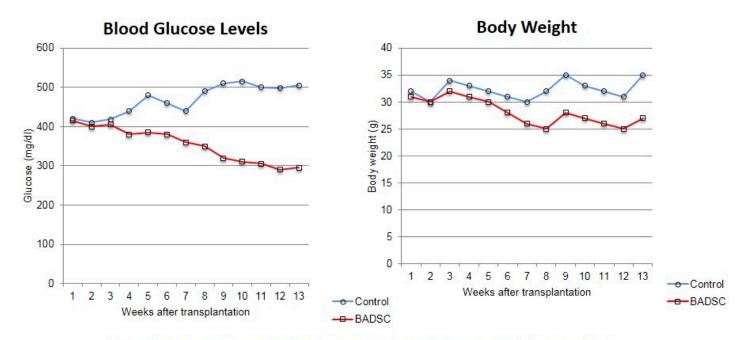


572. Metabolically Active Human Brown Adipose Tissue-Derived Stem Cells

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

### **Preclinical Metabolic Results**

### **Glucose and Body Weight**

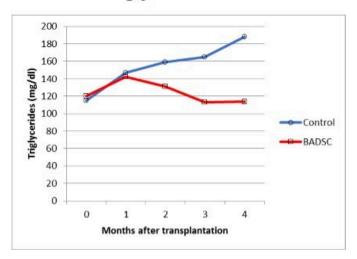


Mice fed high chow diet throughout experiment and transplanted with brown adipose derived stem cells (BADSC)/scaffolds and controls

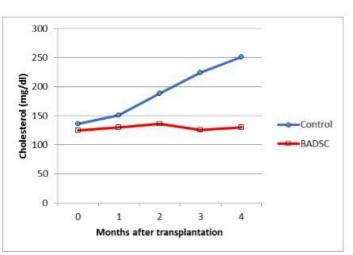
### **Preclinical Metabolic Results**

### **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

### **BioRestorative / Pfizer Collaboration**







- 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

### **Investment Highlights**



#### MULTIPLE CELL THERAPY PROGRAMS

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



#### **CAPITALIZATION AS OF 10/18/15**

#### **Outstanding Shares**

Preferred Stock

 Common Stock
 3,081,950 [1]

 Options
 1,315,450

 Warrants
 1,020,016 [2]

 Convertible Debt
 50,783 [3]

5,468,199

- [1] Gives effect to the issuance of 227,682 shares of Common Stock upon the exchange of certain notes, to be effected immediately preceding the earlier of (a) the effectiveness of the registration statement relating to the offering and (b) the listing of our Common Stock and the Class A Warrants sold in the offering on the NASDAQ Capital Market.
- [2] Gives effect to the issuance of warrants to purchase 227,682 shares of Common Stock upon the note exchange described above.
- [3] Gives effect to the note exchange described above whereby certain convertible debt is exchanged for 117,236 shares of common stock.



OTCQB: BRTX • biorestorative.com

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