

Edgar Filing: BioRestorative Therapies, Inc. - Form FWP

BioRestorative Therapies, Inc.
Form FWP
September 28, 2015

Free Writing Prospectus

Filed pursuant to Rule 433

Registration No. 333-204672

CONFIDENTIAL September 2015 CORPORATE PRESENTATION

- CONFIDENTIAL - 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. Forward Looking Statements 2

- CONFIDENTIAL - Free Writing Prospectus Statement 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 . 3

- CONFIDENTIAL - Issuer Exchange / Ticker Offering Size Over - Allotment Use of Proceeds Sole Book - Running Manager BioRestorative Therapies: Company Overview 4 BioRestorative Therapies, Inc. NASDAQ Capital Market *: BRTX/BRTXW 1,550,388 shares of Common Stock together with Warrants to Purchase 1,550,388 shares of Common Stock (100% Primary) 15% or 232,558 shares of Common Stock and /or Warrants to purchase 232,558 shares of Common Stock We intend to use the net proceeds of this offering as follows: (i) submission of investigational new device, 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. Aegis Capital Corp. *We have applied to list our common stock and the warrants being sold in this offering on The NASDAQ Capital Market.

- CONFIDENTIAL - • 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 Cell - Based Therapies • 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 Disc/Spine Program Lead Product: brtxDISC™ • 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 Metabolic Program ThermoStem® • Pfizer on Brown Adipose Stem Cell Program • Hospital for Special Surgery on Lumbar Disc Program Validating Collaborations BioRestorative Therapies: Company Overview 5

- CONFIDENTIAL - • 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) Mark Weinreb President and CEO • 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 Edward Field President, Disc / Spine Division • 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 Francisco Silva Vice President of Research and Development and Chief Scientist Strong Management Team 6

- CONFIDENTIAL - • Psychiatrist - in - Chief Emeritus for Hospital for Special Surgery (HSS) • Member of HSS Board of Trustees • Founded Psychiatry Dept. at HSS/Physical Med & Rehab at Mayo Clinic Gregory E. Lutz, M.D., Chief Medical Advisor For Spine Medicine • Former Director, CBER, FDA • Former V.P., Regulatory Affairs, Human Genome Sciences • President and Founder of Access BIO Joy Cavagnaro, Ph.D., Regulatory Advisor • 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. Wayne Marasco, MD, Ph.D. Chairman, Scientific Advisory Board Advisory Board 7

- CONFIDENTIAL - 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™ : Target Product Profile 8

- CONFIDENTIAL - brtxDISC™ – Advantage of Hypoxic Culture Hypoxic Culture Primes Cells for Chondrocyte Repair
9

- CONFIDENTIAL - brtxDISC™ : Mechanism of Action brtx DISC™ VEGF FGFs EGF PDGF Type II Collagen SDF -
1 Aim is to change disease pathology and improve disc morphology. Key Factors Anti - inflammatory Structural
repair Neovascularization Promote endogenous repair Multiple Mechanisms Express Resulting 10

- CONFIDENTIAL - brxDISC™ : 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 11

- CONFIDENTIAL - brtxDISC™ : Pain Improvements 67% (8 of 12) of Subjects Had $\geq 30\%$ Improvement in Pain Score
12 Pre - injection Pain Score 0 1 2 3 4 5 6 7 8 9 10 NRS Changes (n=12) Follow - up 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 1 Ostelo et al Spine Vol 33,no1,pp90 - 94

- CONFIDENTIAL - brxDISC™ : FRI Improvements 56% (5 of 9) of Subjects Had ≥ 30% Improvement in FRI 13
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 1 Ostelo et al Spine Vol
33,no1.pp90 - 94

- CONFIDENTIAL - brxDISC™ : QOL Improvements Patient Quality of Life (QOL) Improvements* Graphed by Time Points Mean Improvement of ~ 60% in patient Quality of Life*, Mean time since treatment 2.3 yrs. 14 Years Since Procedure (Last Available Outcome Endpoint) % Improvement * Patient reported improvement Quality of Life (QOL) is a standardized questionnaire measuring subjects' functional and mental wellness

- CONFIDENTIAL - brtxDISC™ Treatment: Case Study Therapy May Have a Significant Impact on the Morphology of the Disc BEFORE AFTER 15 56% (9 of 16) of Subjects had ≥ 50% Reduction in Disc Bulge Size

- CONFIDENTIAL - brtxDISC™ : Summary of Retrospective Analysis 80% Reported Improvement in Range of Motion and 100% Reported Improvement in Strength Post - Treatment 16 We believe there is a correlation between the QOL improvement percentage and dosage based on our finding in our 5 patient retrospective analysis. 0 20 40 60 80 100 1 2 3 4 5 Improvement (%) Patient % QOL Improvement Post - Treatment 0 10 20 30 40 0 20 40 60 80 100 Cell Dose (1 x 10⁶) Improvement (%) % Improvement vs Cell Dose

- CONFIDENTIAL - 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 brtx DISC™ 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) 17

- CONFIDENTIAL - 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 -
CONFIDENTIAL - 18

- CONFIDENTIAL - 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 - CONFIDENTIAL - 19

- CONFIDENTIAL - Market Opportunity: Obesity and Metabolic Disorders Market Obesity Rates In Selected Countries New Diabetes US cases annually (MM) Source: OECD. The obesity epidemic: Analysis of past and projected future trends in selected OECD countries 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 88 94 00 6 12 0.6 0.8 1.1 1.5 1.7 0% 5% 10% 15% 20% 25% 30% 35% 1970 1980 1990 2000 2010 USA England Australia Canada Spain France - CONFIDENTIAL - 20

- CONFIDENTIAL - ThermoStem ® Program • 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 Program Objective • 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 Progress To - date • Delivery mechanism for introducing brown fat tissue to humans • Finalize target disease and clinical indication Near - term Priorities - CONFIDENTIAL - 21

B The International Journal of Cell Differentiation and Proliferation Volume 32, Number 2, February 2014 Inside This Issue See Complete Table of Contents Inside 327 An Osteopontin-Integrin Interaction Plays a Critical Role in Directing Adipogenesis and Osteogenesis by Mesenchymal Stem Cells Qing Chen, Peishun Shou, Liying Zhang et al. 349 Stimulation of Somatic Cell Reprogramming by ERas-Akt-FoxO1 Signaling Axis Yong Yu, Dan Liang, Qing Tian et al. 424 Autophagy Regulates Homeostasis of Pluripotency-Associated Proteins in hESCs Yun-Hee Cho, Kyu-Min Han, Dongkyu Kim et al. 447 MMP-10 Is Required for Efficient Muscle Regeneration in Mouse Models of Injury and Muscular Dystrophy Míriam Bobadilla, Neira Sáinz, José Antonio Rodríguez et al. 500 Transplants of Adult Mesenchymal and Neural Stem Cells Provide Neuroprotection and Behavioral Sparing in a Transgenic Rat Model of Huntington's Disease Julien Rossignol, Kyle Fink, Kendra Davis et al. 572 Metabolically Active Human Brown Adipose Tissue Derived Stem Cells Francisco J Silva, Dolly J Holt, Vanessa Vargas et al. 594 Brief Report: Astroglial Promotes Functional Recovery of Completely Transected Spinal Cord Following Transplantation of hESC-Derived Oligodendrocyte and Motoneuron Progenitors Dunja Lukovic, Lourdes Valdés-Sánchez, Irene Sánchez-Vera et al. www.StemCells.com AlphaMed Press www.StemCellsTM.com Sister Journal of 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. - CONFIDENTIAL - 22

- CONFIDENTIAL - Preclinical Metabolic Results Glucose and Body Weight 0 100 200 300 400 500 600 1 2 3 4 5 6
7 8 9 10 11 12 13 Glucose (mg/dl) Weeks after transplantation Blood Glucose Levels Control BADSC 0 5 10 15 20
25 30 35 40 1 2 3 4 5 6 7 8 9 10 11 12 13 Body weight (g) Weeks after transplantation Body Weight Control BADSC
Mice fed high chow diet throughout experiment and transplanted with brown adipose derived stem cells
(BADSC)/scaffolds and controls - CONFIDENTIAL - 23

- CONFIDENTIAL - 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 - CONFIDENTIAL - 24

- CONFIDENTIAL - 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 BioRestorative / Pfizer Collaboration - CONFIDENTIAL - 25

- CONFIDENTIAL - Investment Highlights 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 MULTIPLE CELL THERAPY PROGRAMS - CONFIDENTIAL - 26 STRONG MANAGEMENT & ADVISORY TEAMS POTENTIAL FOR ADDITIONAL INDICATIONS OF THERAPY

- CONFIDENTIAL - Cap Table 27 Overall Equity Plan Authorized Shares Preferred Stock 5,000,000 Common Stock 30,000,000 Equity Plan 2,000,000 Outstanding Shares Preferred Stock - Common Stock 2,854,268 45,000 Options 1,315,450 1,315,450 Warrants 792,334 - Convertible Debt 139,361 - 5,101,413 1,360,450 CAPITALIZATION AS OF 9/25/15

- CONFIDENTIAL - OTCQB: BRTX biorestorative.com Thank You - CONFIDENTIAL - 28