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## FORWARD LOOKING STATEMENT



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 THE U.S. FEDERAL AND STATE 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, BUSINESS PLAN 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, AND SUBSTANTIAL LOSSES SINCE INCEPTION;(II) OUR ABILITY TO OBTAIN SUFFICIENT FINANCING TO INITIATE AND COMPLETE OUR CLINICAL TRIALS 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 THE COMPANY IS 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 AND LACK OF AN ALTERNATIVE MANUFACTURING SUPPLY; (VIII) A 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 TO WHICH THE COMPANY MAY BE SUBJECT, 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 "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS - FACTORS THAT MAY AFFECT FUTURE RESULTS AND FINANCIAL CONDITION" SET FORTH IN THE COMPANY'S MOST RECENT ANNUAL REPORT 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. YOU ARE CAUTIONED THAT FORWARD LOOKING STATEMENTS ARE NOT GUARANTEES OF FUTURE PERFORMANCE, AND YOU SHOULD NOT PLACE 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 AND THE ECONOMY GENERALLY WILL CONTINUE SUBSTANTIALLY IN THE ORDINARY COURSE. THESE ASSUMPTIONS, ALTHOUGH CONSIDERED REASONABLE AT THE TIME OF PREPARATION, MAY PROVE TO BE INCORRECT.

THE DESCRIPTION OF THE COMPANY AND ITS BUSINESS IN THIS PRESENTATION DOES NOT PURPORT TO BE COMPLETE AND IS SUBJECT TO THE MORE DETAILED DESCRIPTION OF THE COMPANY AND ITS BUSINESS IN THE COMPANY'S ANNUAL, QUARTERLY AND CURRENT REPORTS FILED WITH THE SEC.

## LEADERSHIP





LANCE ALSTODT Chairman & CEO

Lance leads BRTX's mission to improve the lives of patients through using Regenerative Medicine. Lance spent over 30 years leading, advising and operating companies within the Healthcare sector.

Lance is the founder of MedVest Capital, a Healthcare fund created in 2013 and prior to that led the Medical Technology Investment banking group at Bank of America Merrill Lynch and Leerink Partners.



**ROBERT KRISTAL** *Chief Financial Officer* 

Robert has a versatile background of over 25 years on Bay Street and Wall Street

Robert most recently was the DOR for a Healthcare focused Investment Bank. His career has spanned Trading, Sales, Investment Banking and Research.



**FRANCISCO SILVA** Vice President of R&D

Francisco has over 20 years of experience in the Research & development of cell based and off the shelf therapeutics. As a Vice President R&D he has established high throughput Stem Cell Research Program in Biorestorative Therapies based on his academic and industrial research experience.

Francisco has obtained several patents in cell therapy, and has manuscripts published with regards to translational stem cell research.



**BOB PACCASASSI** Vice President of Quality

Robert has over 25 years of biotech operations and combined experience in Quality Assurance, Regulatory, and Manufacturing.

Robert is responsible for Quality Control and Regulatory and has held positions at Regeneron, Millennium, and Merck Pharmaceutical companies

## FULLY INTEGRATED REGENERATIVE MEDICINE COMPANY





![](_page_4_Picture_0.jpeg)

#### **BIORESTORATIVE THERAPIES INC-COMMERCIAL COSMETIC PRODUCTS**

## **Key Features of Cosmetics and Hair Growth Biologics Products**

![](_page_4_Picture_3.jpeg)

- Global Cosmetic market \$63 billion and growing
- Global injectable market 12% CAGR 2021-2026 est @ 11.9 billion
- Derms need differentiated product
- Bundle with current procedures

![](_page_4_Picture_8.jpeg)

- cGMP ISO 7 Certified Facility
- Molecular Biology Expertise
- Multi use facility highlights versatility

![](_page_4_Picture_12.jpeg)

- Umbilical cord derived
- Highly enriched & potent
- cytokines, chemokines, growth factors
- Medical and aesthetic benefits

# Clinical / Preclinical Programs

![](_page_5_Picture_1.jpeg)

![](_page_5_Picture_2.jpeg)

#### <u>Spine</u>

- Lumbar
- Cervical
- Thoracic

Autologous

Allogeneic

#### **Musculoskeletal System**

- Hips/Knees
- Extremities
- Avascular Zones

#### **Metabolic**

- Type 2 Diabetes
- Obesity
- PCOS

#### **Brown Adipose Stem Cells**

- ARDS
- Long Hauler Covid

#### **Gene Modification**

• BRTX 200 Polymer/Crispr

![](_page_6_Picture_0.jpeg)

# **CHRONIC LUMBAR DISC DISEASE PROGRAM – PHASE 2**

- Lead investigational therapeutic product
- Autologous (patient's own) cell-based biologic
- Hypoxic (low oxygen) cultured, bone marrow-derived
- Single intradiscal injection anticipated 30 minute in-office procedure
- Prior human data provides insight into the potential safety and efficacy of BRTX-100
- FDA authorized commencement of Phase 2 clinical trial
- Large growing market with few comparable autologous therapies

![](_page_6_Picture_9.jpeg)

# **MARKET OPPORTUNITY – BRTX 100**

![](_page_7_Picture_1.jpeg)

![](_page_7_Figure_2.jpeg)

1. Trinity Partners Report, "Degenerative Disc Disease US Market Assessment (Phase I)," Feb. 2016, Slide 9 of report.

![](_page_8_Picture_0.jpeg)

# **STANDARD OF CARE: CLINICAL AND ECONOMIC PROBLEM**

![](_page_8_Figure_2.jpeg)

![](_page_9_Picture_0.jpeg)

# LOGISTICAL/CLINICAL PROCESS

![](_page_9_Figure_2.jpeg)

![](_page_10_Picture_0.jpeg)

# **CLEARED DSMB June 2023**

- Unanimous approval by the DSMB to continue trial without changes
- BRTX-100 is safe and well tolerated
- All 4 subjects successfully dosed with either 40 mil hMSCs or placebo
- First time 40 million cells injected in a human subject
- 3:1 randomization
- No Significant Adverse Events
- VAS, ODI, SF-12, RMDQ, and FRI scores to measure pain and function were collected
- Opportunity to leverage this data and clinical package

![](_page_10_Picture_10.jpeg)

# **POSITIVE HUMAN DATA**

![](_page_11_Picture_1.jpeg)

Human data from studies of therapies similar to brtx-100 show reduced pain, increased function, and an absence of significant safety issues with a durable response.

![](_page_11_Picture_3.jpeg)

![](_page_12_Picture_0.jpeg)

![](_page_12_Picture_1.jpeg)

## FDA Cleared IND 17275: Phase 2 Randomized, Controlled Study Design in Patients with CLDD

## **Study Design and Patient Population**

- Study includes 99 subjects (2:1 product to placebo)
- 40.000.000 cells/dose
- Included subjects will have only one symptomatic diseased disc
- Primary efficacy endpoint at 12 m, F/U at 24 m
  - Improvement in function: at least 30% increase in function based on Oswestry Disability Index questionnaires (ODI)
  - Reduction of pain: at least 30% decreased in pain as measured using a Visual Analogue Scale (VAS)
- Subjects must have current diagnosis of cLDD, typical pain with degeneration of a single disc confirmed by history, exam, radiography, or other acceptable means
- Subjects will have exhausted previous conservative non-operative therapies

![](_page_13_Picture_0.jpeg)

# **COMPETITIVE LANDSCAPE KEY DIFFERENTIATING FACTORS**

![](_page_13_Figure_2.jpeg)

## **BIORESTORATIVE THERAPY PROGRAMS**

![](_page_14_Picture_1.jpeg)

#### **Metabolic Program**

![](_page_14_Figure_3.jpeg)

### **ThermoStem Program**

- "Off the shelf" allogeneic cell-based therapy targeted to treat obesity, Type 2 diabetes and metabolic disorders using brown fat
   stem cells
- Brown fat has been shown to regulate metabolic homeostasis in the body
- Large library of human brown adipose tissue (BAT), white adipose tissue (WAT) and brown adipose-derived stem cells (BADSC)
- Initial proof of concept completed in small animal model
- Related BAT patent portfolio, including issued patents in the U.S., Australia and Japan
- Platform program for the development of cell and small molecule therapies

# **METABOLIC PROGRAM HIGHLIGHTS**

![](_page_15_Picture_1.jpeg)

![](_page_15_Figure_2.jpeg)

- First human stem cell derived BAT transfer
- Creation of first human 3D engineered artificial brown adipose tissue construct (aBAT)
- Successful delivery of 3D aBAT construct in mouse model
- Transplantation of aBAT lowered blood glucose levels
- Transplantation of aBAT decreased weight in obese mice
- Published initial proof of concept completed

## **METABOLIC PROGRAM CLINICAL PATHWAY**

![](_page_16_Picture_1.jpeg)

![](_page_16_Figure_2.jpeg)

# **INTELLECTUAL PROPERTY**

![](_page_17_Picture_1.jpeg)

![](_page_17_Picture_2.jpeg)

#### PATENT TITLES

- Methods and Compositions to facilitate repair
   of avascular tissue
- Surgical Methods and Compositions to facilitate repair of avascular tissue
- Therapeutic Delivery Device

#### No. of APPLICATIONS

• 12

#### STATUS

2 ISSUED | 10 PENDING

![](_page_17_Picture_11.jpeg)

#### PATENT TITLES

- Brown Fat Compositions and Methods
- Human Brown Adipose Derived Stem Cells and Uses
- Non-naturally occurring three-dimensional (3D)
   Brown Adipose-Derived Stem Cell aggregates and methods of generating and using the same

#### No. of APPLICATIONS

• 25

STATUS

17 ISSUED | 9 PENDING

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## **2023 ACCOMPLISHMENTS**

- ✓ Expanded Thermostem patent portfolio in US and Japan
- ✓ Two Notice of Allowances
- ✓ Completed 4 patient Safety Run-in component for Phase 2
- ✓ Announced a filing and execution of an ATM
- ✓ Announced Northwell Healthcare Partnership Largest Healthcare System in the Northeast
- ✓ Cleared the DSMB and will continue our Phase 2 trial
- ✓ Closed a \$2.1 Million Registered Direct financing
- Enhanced shareholder profile with small institutions and family offices
- Leveraged our expertise in Regenerative Medicine in our FDA company, ISO-7 cGMP certified to manufacture advanced logistic products of maximum potency and efficacy

![](_page_18_Picture_11.jpeg)

**BRTX cGMP Clean Room** 

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## **SCIENTIFIC ADVISORY BOARD**

<b>WAYNE MARASCO, MD, PhD</b> Chairman of SAB	<b>Dr. Marasco,</b> is a principal faculty member of Harvard Stem Cell Institute as well as a Professor in the Department of Cancer Immunology & AIDS at the Dana-Farber Cancer Institute and a Professor of Medicine at Harvard Medical School.	
<b>JASON LIPETZ, MD</b> Chairman of SAB Sub Committee Disc Advisory Board	<b>Dr. Lipetz</b> is chief of Spine Medicine for the Northwell Health Spine Center and the founder of Long Island Spine Rehabilitation Medicine.	
HARVINDER SANDHU, MD Member Disc Advisory Board	<b>Dr. Sandhu</b> is an orthopedic spine surgeon at the Hospital for Special Surgery, specializing in minimally invasive spine surgery, endoscopic spine surgery, microsurgery, computer-assisted surgery, and the study and use of spinal biologics	
WAYNE OLAN, MD Clinical Director of Regenerative Disc / Spine Program	<b>Dr. Olan</b> is a board-certified Interventional Neuroradiologist and the director of Endovascular and Minimally Invasive Neurosurgery in Washington, D.C. at The George Washington University Medical Center.	
<b>CHRISTOPHER PLASTARAS, MD</b> Member Disc Advisory Board	Dr. Plastaras is MossRehabs' Clinical Director of Musculoskeletal Spine & Sports Rehabilitation Medicine.	

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# **COMPANY HIGHLIGHTS**

- CGMP ISO-7 Certified Clean room
- Disruptive Platform Technologies in Cellular Therapy
- Strong Preliminary Data Indicative of Positive Trial Outcomes
- ✓ Active Phase 2 Trial in Spine
- ✓ Addressing Multi-Billion Dollar Markets with Unmet Needs
- Opportunity for Key Strategic Partnerships in Cosmetic Space
- ✓ Strong Intellectual Property Protection
- Experienced Management Team & Scientific Advisory Board

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![](_page_21_Picture_0.jpeg)

# **FINANCIAL SUMMARY**

<b>Current Capitalization</b>	Shares
Basic Shares Outstanding	4,706,000
Cash	12.2 MILLION
Debt	\$0

Data as Q3 filing

# **BIORESTORATIVE UPCOMING MILESTONES**

![](_page_22_Picture_1.jpeg)

Platform	Stage	Situation Overview
Tissue derived Exosome product	Skin regeneration, facial application /hair growth	<ul> <li>Regenerative Cosmetic &amp; Aesthetic treatment to rejuvenate skin and grow hair</li> </ul>
BRTX-100	Degenerative Disc Disease (DDD)	<ul> <li>Anticipate providing updates on sites and enrollment</li> </ul>
Brown Fat Derived Adipose Tissues	Obesity, PCOS and Metabolic Disorders	<ul> <li>Advance this technology through DMF and IND</li> </ul>
PATENTED PATENTED	Expand Patent Portfolio	<ul> <li>Additional patents announcements - Brown Fat</li> <li>Provisional Patent around BRTX 200 (next generation)</li> </ul>

#### **Biorestorative Therapies Inc.**

- Address: 40 Markus Drive, Melville, NY 11747
   Suite 1
- Phone: 631-760-8100
- Website: www.biorestorative.com

# biorestorative therapies

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