biorestorative therapies

40 Marcus Drive,
Melville, 11747 NY
www.biorestorative.com

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.

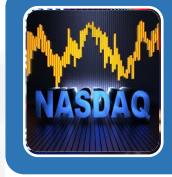
BOB PACCASASSI

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

BRTX COMPANY OVERVIEW



Emerging Growth Publicly Traded Nasdaq Listed Cell Therapy Company

Two platform technologies within multi-billion dollar markets

Each Platform has multiple applications to leverage

Strong Financial Position with a "low float" share structure

Musculoskeletal Health – Active Phase 2 Clinical Trial in lower lumbar disc degeneration

Metabolic Disease – Key Strategic Partnership Opportunities

BRTX -100

- BRTX 100 is a platform technology with multiple applications
- Autologous based Hypoxically Expanded Transition Cell
- First Indication is cLDD currently approved for a Phase 2 Clinical Study
- Near term opportunities to leverage platform across other avascular zones
- In house ISO certified 7 Manufacturing Facility
- Stem Cell processing and management opportunities through banking
- Create an "off the shelf" autologous platform

BROWN FAT

- "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

A Platform Technology

biorestorative therapies

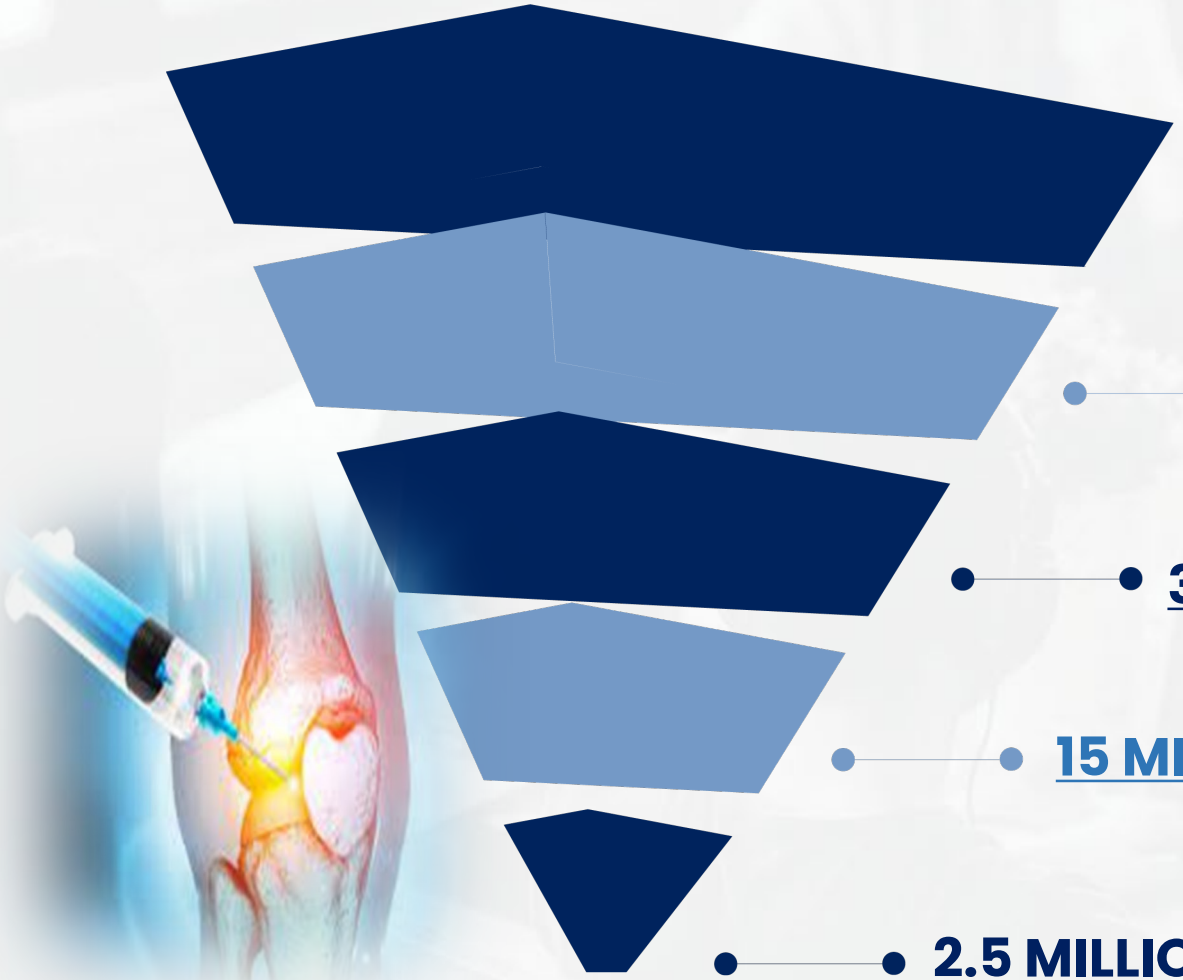
	Preclinical	Phase 1	Phase 2	Phase 3
Autologous				
Spine				
• Lumbar				
• Cervical				
• Thoracic				
Musculoskeletal System				
• Hips/Knees				
• Extremities				
• Avascular Zones				
Allogeneic				
Metabolic				
• Type 2 Diabetes				
• Obesity				
• PCOS				
Brown Adipose Stem Cells				
• ARDS				
• Long Hauler Covid				
Gene Modification				
• BRTX 200 Polymer/Crispr				

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

DISC/SPINE
BRTX-100

MARKET OPPORTUNITY – BRTX 100



258 MILLION American adult population

64.5 MILLION American adults with chronic lower back pain prevalence

32 MILLION American adults with diagnosed and treated disc degeneration

15 MILLION Americans have pain caused by a protruding or injured disc

2.5 MILLION Invasive Surgical Procedures per year $40 billion in surgeries

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

STANDARD OF CARE: CLINICAL AND ECONOMIC PROBLEM

CONSERVATIVE TREATMENTS
OFTEN RECURRENT

ORAL MEDICATION TREATMENT/OPIOIDS
$1,000 - $2,000
Annually

INJECTION TREATMENT
$8,000 [3]
Annually
$2,000 per injection,
2 injections per treatment -semi-annual treatment

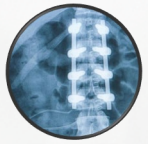
PHYSICAL MEASURES
$20,000 [2]
Annually
$200 per sessions x 2 sessions per week

SIMPLE ELEGANT SOLUTION
INTRODUCE HYPOXIC CULTURED AUTOLOGOUS MSCs

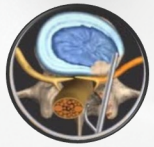
BRTX-100

SINGLE INTRA-DISCAL INJECTION
EXACTLY 40MM CELLS
PROCEDURE TIME ~ 20 minutes

SURGICAL TREATMENTS
WITH RE-OP RATES OFTEN 10-20%



SPINAL FUSION SURGERY
$110,000 [1, 5]



DISCECTOMY
$20,000 - $50,000 [2]

DISC REPLACEMENT SURGERY
$80,000 - $150,000 [1, 5]

NON-INVASIVE TREATMENT | **NON-INVASIVE TREATMENT** | **INVASIVE TREATMENT**

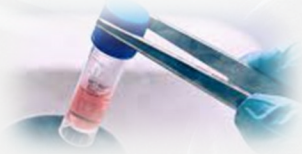
LOGISTICAL/CLINICAL PROCESS

1

Bone marrow and blood collected from subject

Clinical Site

Shipping Cryoport



2

Sample shipped at ambient to BioRestorative Therapies

3

BRTX-100® Manufactured, and QC released

Manufacturing

Shipping Cryoport

BRTX-100® shipped frozen to clinical site

4

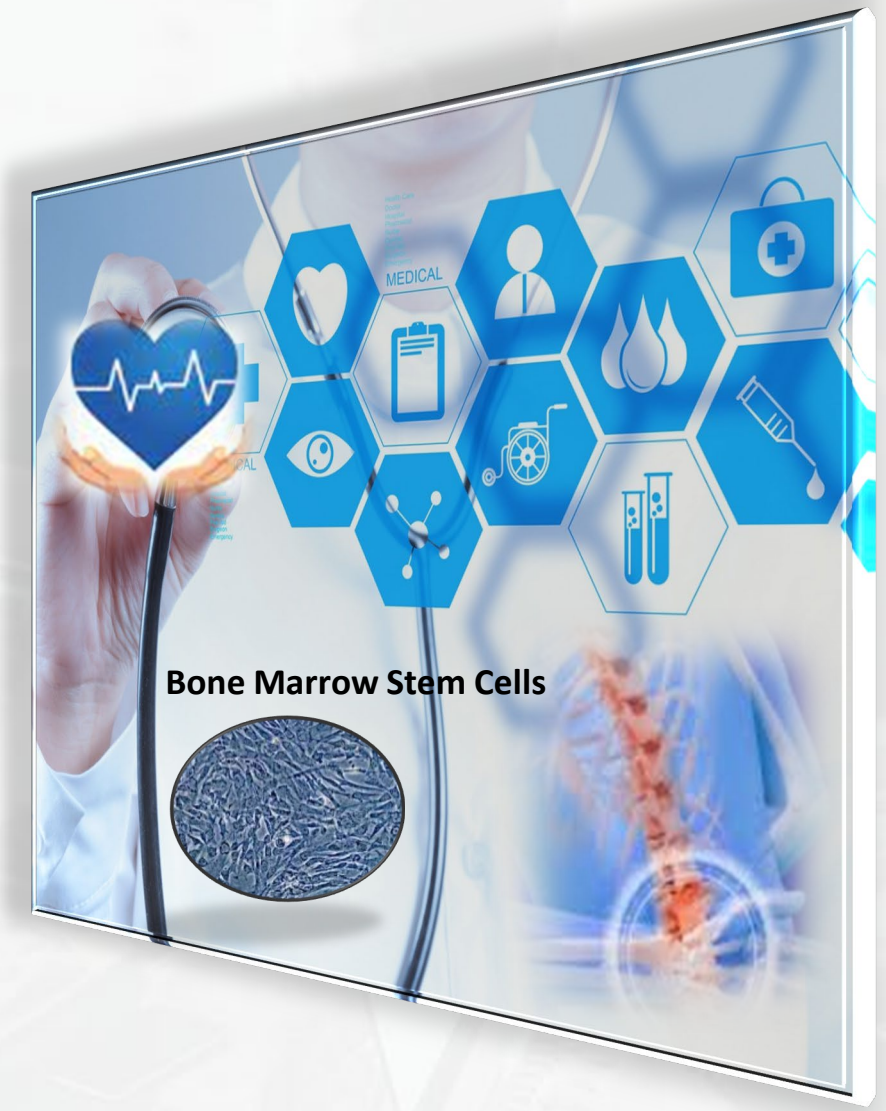
5

Intradiscal delivery of BRTX-100®

Clinical Site

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



POSITIVE HUMAN DATA

biorestorative therapies

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.

Centeno *et al. J Transl Med* (2017) 15:197
DOI 10.1186/s12967-017-1300-y

Journal of Translational Medicine

RESEARCH Open Access

Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy

Christopher Centeno[1,2], Jason Markle[1], Ehren Dodson[2*], Ian Stemper[2], Christopher J. Williams[1], Matthew Hyzy[1], Thomas Ichim[3] and Michael Freeman[4]

Kumar *et al. Stem Cell Research & Therapy* (2017) 8:262
DOI 10.1186/s13287-017-0710-3

Stem Cell Research & Therapy

RESEARCH Open Access

Safety and tolerability of intradiscal implantation of combined autologous adipose-derived mesenchymal stem cells and hyaluronic acid in patients with chronic discogenic low back pain: 1-year follow-up of a phase I study

Hemant Kumar[1†], Doo-Hoe Ha[2†], Eun-Jong Lee[3†], Jun Hee Park[4], Jeong Hyun Shim[4], Tae-Keun Ahn[5], Kyoung-Tae Kim[6], Alexander E. Ropper[7], Seil Sohn[1], Chung-Hun Kim[8], Devang Kashyap Thakor[9], Soo-Hong Lee[10*] and In-Bo Han[1*]

Original Clinical Science—General

Intervertebral Disc Repair by Allogeneic Mesenchymal Bone Marrow Cells: A Randomized Controlled Trial

David C. Noriega, MD, PhD,[1] Francisco Ardura, MD, PhD,[1] Rubén Hernández-Ramajo, MD, PhD,[1] Miguel Ángel Martín-Ferrero, MD, PhD,[1] Israel Sánchez-Lite, MD,[2] Borja Toribio, MD,[2] Mercedes Alberca, PhD,[3] Verónica García, PhD,[3] José M. Moraleda, MD, PhD,[4] Ana Sánchez, MD, PhD,[5] and Javier García-Sancho, MD, PhD[5]

Stem Cells and Development > Vol. 28, No. 17 > Original Research Reports

The Traceability of Mesenchymal Stromal Cells After Injection Into Degenerated Discs in Patients with Low Back Pain

Helena Barreto Henriksson, Nikolaos Papadimitriou, Daphne Hingert, Adad Baranto, Anders Lindahl, and Helena Brisby

Anders Lindahl

Published Online: 23 Aug 2019 | https://doi.org/10.1089/scd.2019.0074

TRIAL DESIGN

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

COMPETITIVE LANDSCAPE KEY DIFFERENTIATING FACTORS

biorestorative therapies	mesoblast
Hypoxic cultured – in low oxygen environment (5%)	Normoxic cultured – with normal oxygen environment (~20%)
Autologous – uses patients own stem cells - 40 million	Allogeneic – uses human derived stem cells (not from patient) - 6 million
Autologous Platelet Lysate Carrier and Ajuvant	Hyaluronic Acid Carrier
100% Animal-Free Manufacturing Process	Animal Products Used in Manufacturing Process

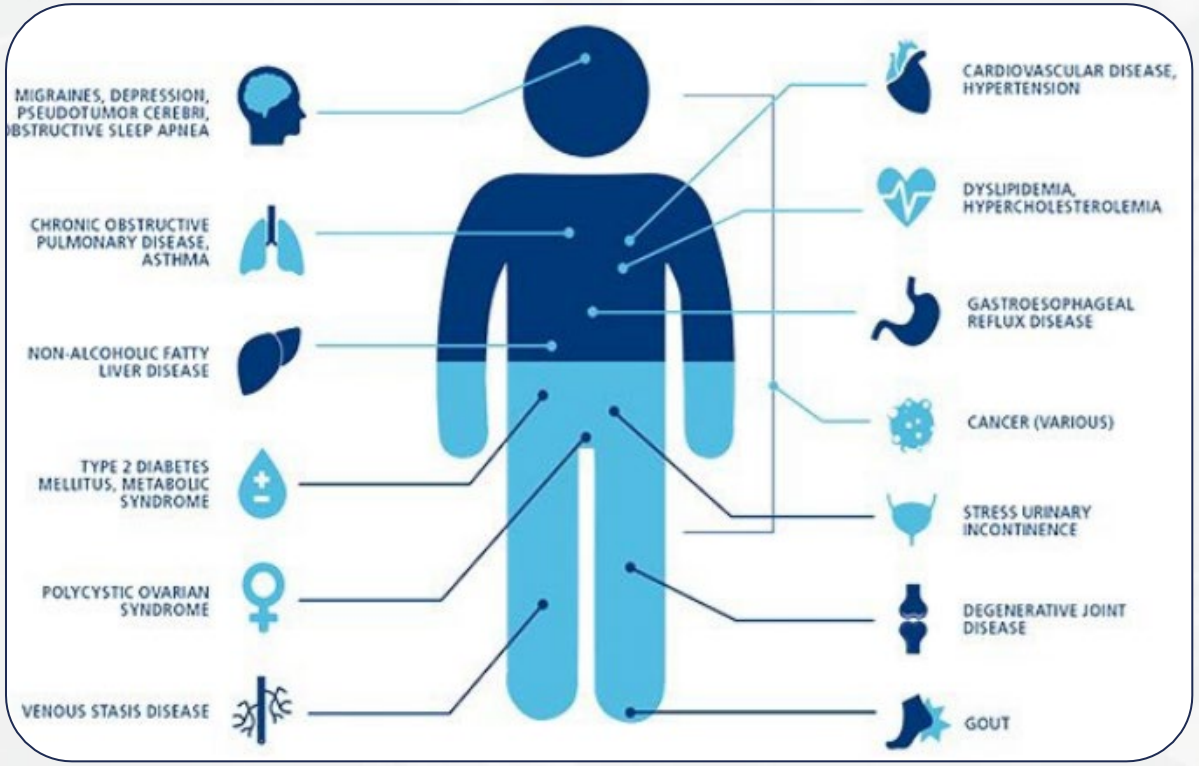
KEY ATTRIBUTES

BRTX-100 ADVANTAGES:

- Autologous cells means low to no risk of rejection, greater safety profile (introduction of viral/genetic), potentially streamlined regulatory path
- Hypoxic culturing creates increased cell proliferation, greater plasticity, increased paracrine effect and increased cell survival after application
- Autologous platelet lysate provides growth factors that interact with the cells, allowing for better cell survival
- Low to no risk of safety concerns related to immunological and zoonotic (animal to people) transmission
- Strong runway for value creation with successful clinical results

BIORESTORATIVE THERAPY PROGRAMS

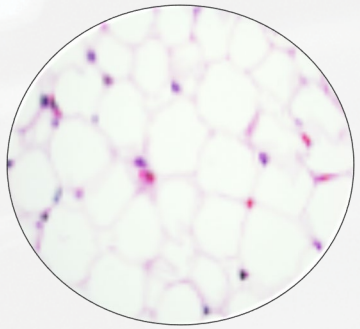
Metabolic Program



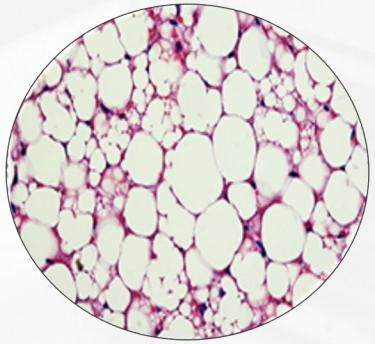
ThermoStem Program

- "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

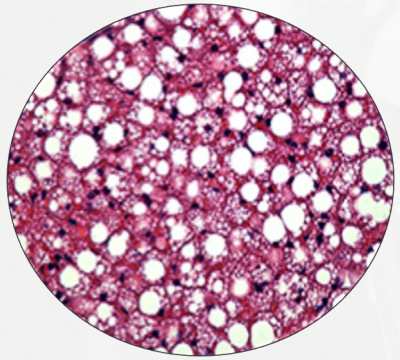
METABOLIC PROGRAM HIGHLIGHTS



White Fat



Beige Fat



Brown Fat

- 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 TIMELINE

Expected filing a Drug Master File ("DMF") with the FDA to facilitate licensing opportunities

Schedule pre-IND (Investigational New Drug) meeting with FDA to discuss first-in-man fast-track regulatory pathways.

Upon FDA approval commence Phase 1/2 clinical trial.

INTELLECTUAL PROPERTY

PROGRAM:
DISC/SPINE

brt disc^{x}

PATENT TITLES

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

OF APPLICATIONS

- 12

STATUS

- 2 ISSUED | 10 PENDING

PROGRAM:
METABOLIC (THERMOSTEM)

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

OF APPLICATIONS

- 25

STATUS

- 16 ISSUED | 9 PENDING

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 and a cGMP facility to manufacture a cosmetic product

SCIENTIFIC ADVISORY BOARD

WAYNE MARASCO, MD, PhD *Chairman of SAB*	Wayne Marasco, M.D., Ph.D. 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.
JASON LIPETZ, MD *Chairman of SAB Sub Committee Disc Advisory Board*	Dr. Lipetz 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*	Dr. Harvinder Sandhu 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*	Dr. Olan 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.
CHRISTOPHER PLASTARAS, MD *Member Disc Advisory Board*	Dr. Plastaras is MossRehabs' Clinical Director of Musculoskeletal Spine & Sports Rehabilitation Medicine.
JOY CAVAGNARO, PHD *Member*	Dr. Joy Cavagnaro is currently the President and Founder of Access BIO, L.C., located in Boyce, Virginia, a company specializing in science-based regulatory strategies. Dr. Cavagnaro held positions with the FDA Center for Biologics Evaluation and Research (CBER), for a decade.

COMPANY HIGHLIGHTS

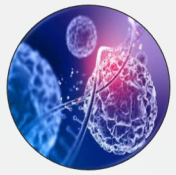
- ✓ cGMP ISO-7 Certified Clean room
- ✓ Disruptive Platform Technologies in Cellular Therapy
- ✓ Strong Preliminary Data Indicative of Positive Trial Outcomes
- ✓ Active Phase 2 Trial in Spine
- ✓ Addressing Multi-Billion Dollar Markets with Unmet Needs
- ✓ Opportunity for Key Strategic Partnerships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

FINANCIAL SUMMARY

Current Capitalization	Shares
Basic Shares Outstanding	4,667,641
Cash	13 MILLION
Debt	$0

Data as Q2 filing
08/11/2023

BioRestorative Upcoming Milestones/Catalysts

	Events	Timing	Outcome
	**Site Enrollment Announcements** **Patient Recruitment/Enrollment**	**Ongoing**	• Continue to announce p0restigious sites and notable KOLs for BRTX 100 enrollment • Periodically update for meaningful enrollment milestones
	**Expand Patent Portfolio**	**Ongoing**	• Additional patents announcements - Brown Fat • Provisional Patent around BRTX 200 (next generation)
	University Collaborations	**Ongoing**	• University of Stockholm Brown Fat Cells - Project Space Nontherapeutic uses
	**PRE IND-Announcement** **Additional Indication / IND** **Regenerative Medicine MFG**	**2023** **2023** **2023**	• Brown Fat Related • Leverage BRTX-100 platform technology into other indications • Leverage our Manf facility/skill in the cosmetic space

biorestorative therapies