

# Regenerative Biology for Healthier Lives

**Investor Presentation** 



# 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 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.

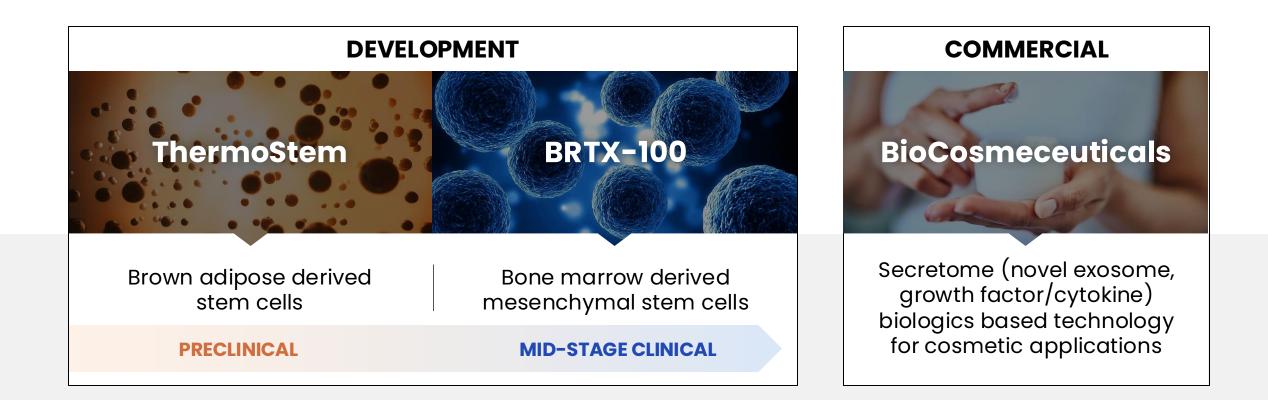
Forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause our actual results, performance or achievements, business plan or industry results, to differ materially from our expectations of future results, performance or achievements expressed 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 in

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.



Fully Integrated Regenerative Medicine Company





### **Experienced Leadership**



#### Lance Alstodt Chairman & CEO

- 30+ years leading, advising and operating companies within the Healthcare sector
- Founder of MedVest Capital, a Healthcare fund created in 2013
- Prior to that led the Medical Technology investment banking group at Bank of America Merrill Lynch and Leerink Partners



#### **Robert Kristal** Chief Financial Officer

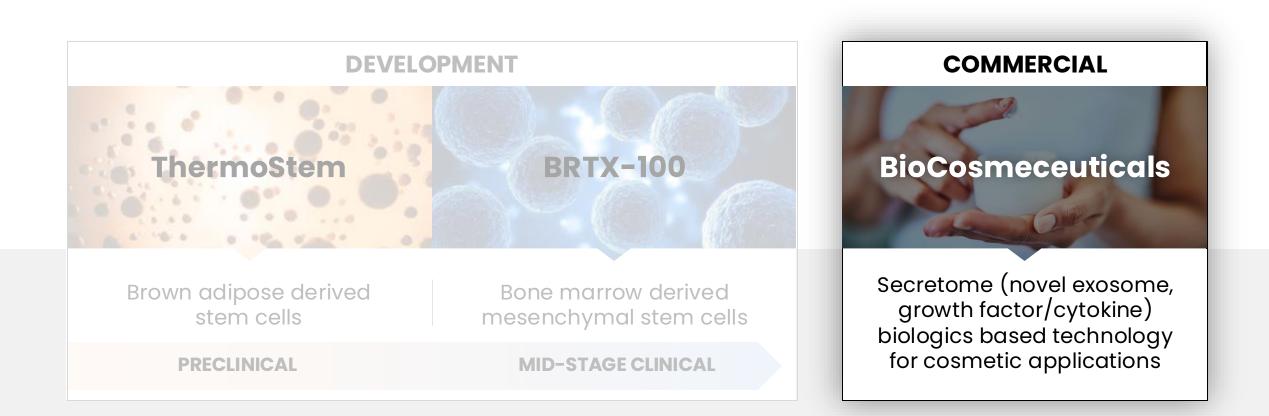
- 25+ years on Bay Street and Wall Street
- Most recently was the DOR for a Healthcare focused Investment Bank
- Career has spanned Trading, Sales, Investment Banking and Research



#### Francisco Silva Vice President of R&D

- 20+ years in the R&D of cell-based and off-the-shelf therapeutics
- As BRTX's Vice President R&D, established high throughput Stem Cell Research Program based on his academic and industrial research experience
- Has obtained several patents in cell therapy, and has manuscripts published with regards to translational stem cell research
- Recently appointed section editor of the newly launched Regenerative Medicine section of the peer-reviewed *Journal of Translational Medicine*







# Going Commercial: Biologics Based Cosmetic Products



#### **The Market**

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

Key Features of Cosmetics & Hair Growth Biologics Products



### Manufacturing

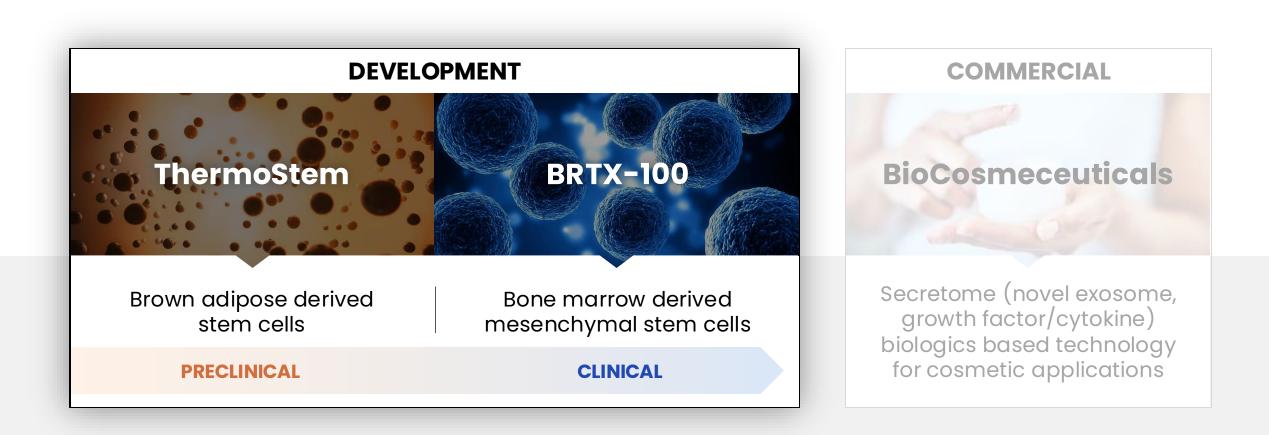
- cGMP ISO 7 Certified Facility
- Cellular Biology Engineering Expertise
- Multi use facility highlights versatility



#### Products

- Cell based biologics engineered and targeted for both clinical and aesthetic use
- Exclusive 5-year commercial agreement with Cartessa Aesthetics







# Robust Preclinical & Clinical Pipeline

			PRECLINICAL	PHASE1	PHASE 2	PHASE 3	COMMERCIAL
AUTOLOGOUS	Spine	Lumbar	Р	HASE 2 ONGOING			
		Cervical	CLEARED TO B	EGIN PHASE 2			
		Thoracic					
	Musculoskeletal System	Hips/Knees					
		Extremities					
		Avascular Zones					
ALLOGENEIC	Metabolic	Type 2 Diabetes					
		Obesity					
		PCOS					
	Brown Adipose Stem Cells	ARDS					
		Long Hauler Covid					
	Secretome / Exosome	Cosmetic					



# Chronic Lumbar Disc Disease (cLDD)

258 M U.S. adult population

American adults with chronic lower back pain prevalence

32 M

64.5 M

American adults with diagnosed and treated disc degeneration

15 M

Americans suffering pain caused by a protruding or injured disc

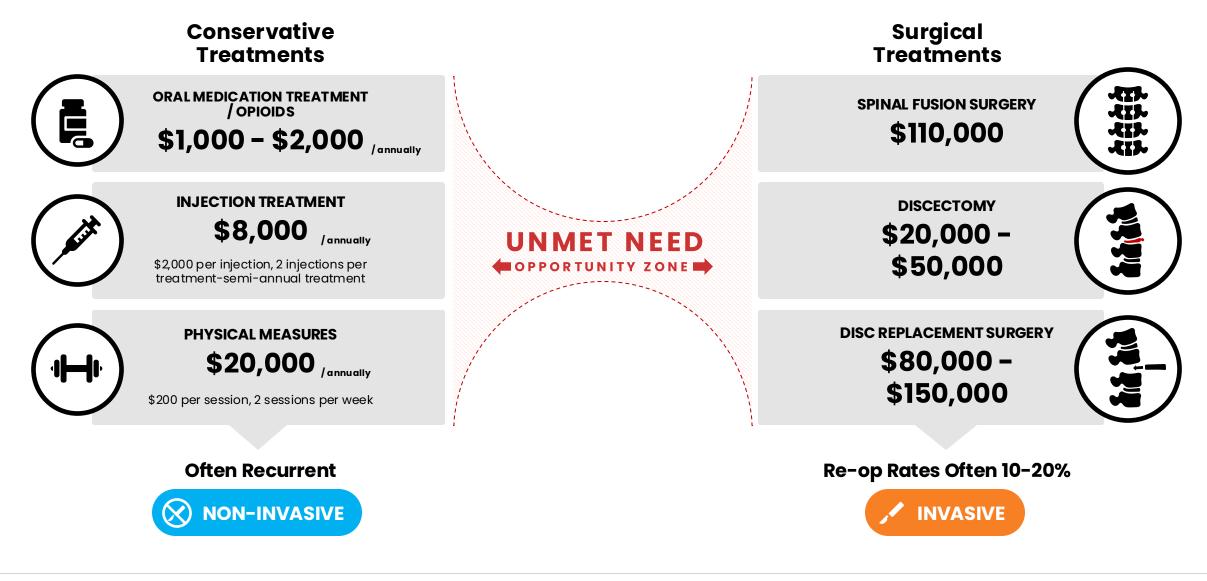
2.5 M

Invasive Surgical Procedures per year **\$40 billion** in surgeries

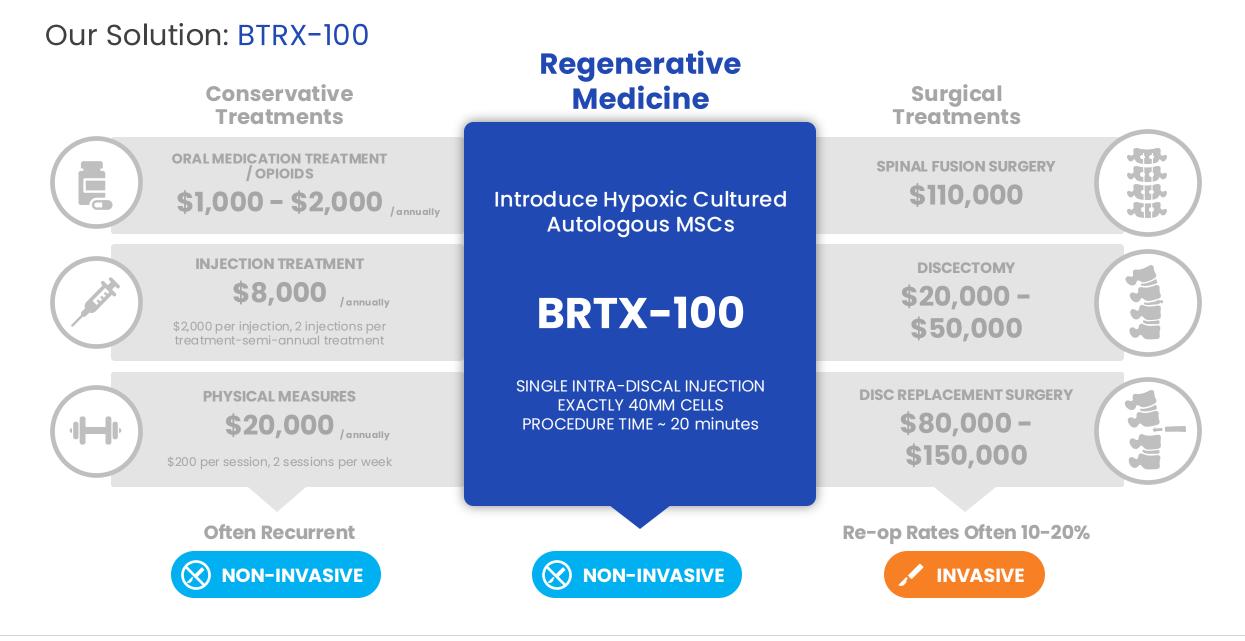




### The Problem: Clinical & Economic



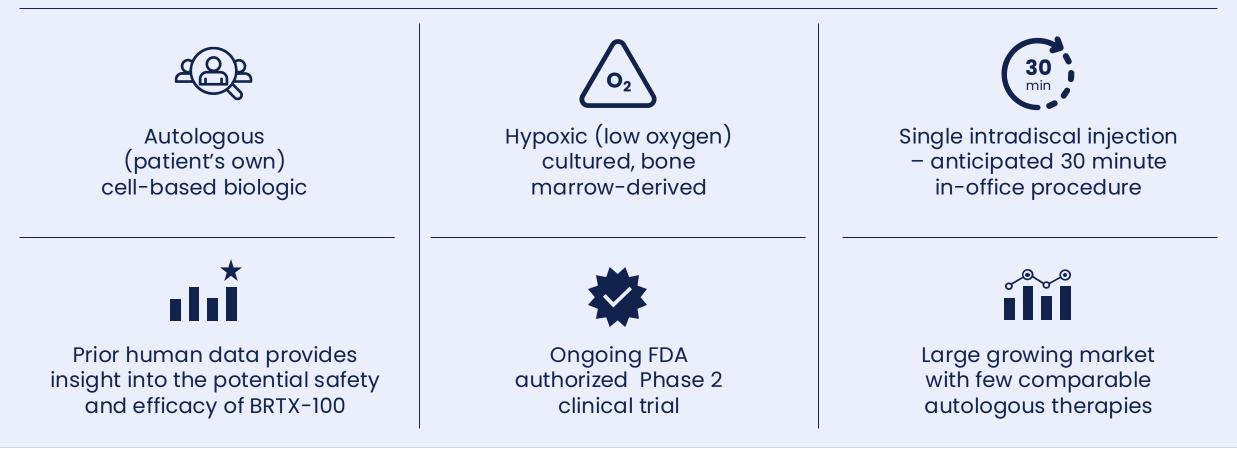






### BRTX-100: Clinical Snapshot







## **BRTX-100: Key Differentiating Factors**

	<b>Pmeso</b> blast	biorestorative therapies
SOURCE	<b>Allogeneic</b> uses human derived stem cells (not from patient) - 6 million	<b>Autologous</b> uses patients own stem cells - 40 million
CULTURING	Normoxic cultured with normal oxygen environment (~20%)	<b>Hypoxic cultured</b> in low oxygen environment (5%)
CARRIER	Hyaluronic Acid Carrier	Autologous Platelet Lysate Carrier & Adjuvant

100% Animal-Free

**Animal Products Used** 

#### **BRTX-100 Advantages**

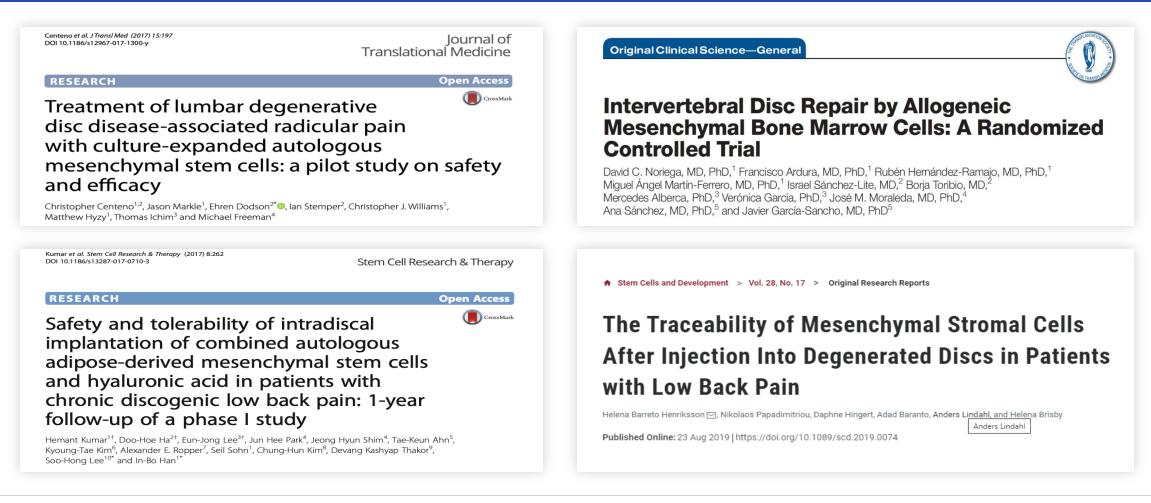
- Autologous cells means low to no risk of rejection, greater safety profile (introduction of viral/genetic), potentially streamlined regulatory path
- Hypoxic culturing creates increased cell proliferation, greater plasticity, increased paracrine effect and increased cell survival after application
- 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



MANUFACTURING

### **BRTX-100: Positive Human Data**

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





### BRTX-100 in cLDD: Phase 2 Trial Design

#### FDA Cleared IND 17275:

Phase 2 Randomized, Controlled Study Design in Patients with cLDD

### Design

- 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** 

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:**

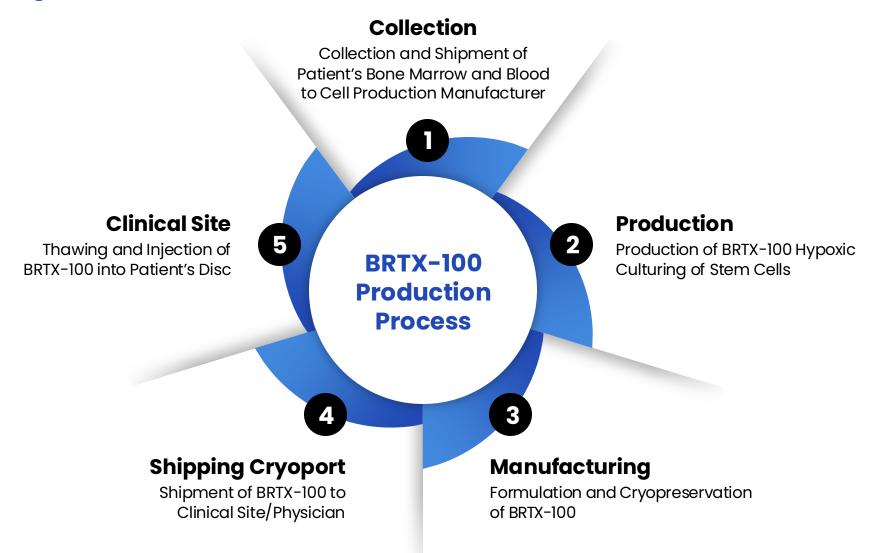
at least 30% decreased in pain as measured using a Visual Analogue Scale (VAS)

#### **Patient Population**

- 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 nonoperative therapies



# BRTX-100: Logistical /Clinical Process





### BRTX-100: 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



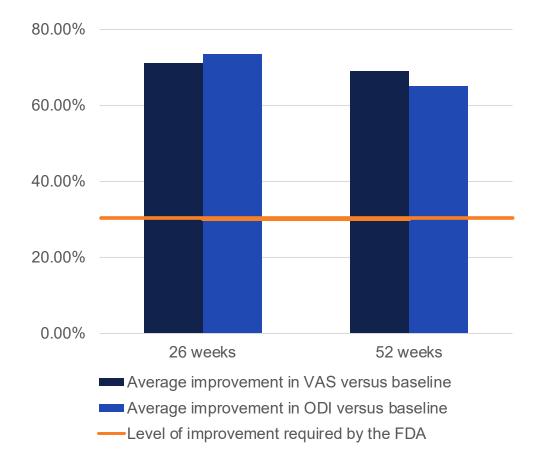
VAS, ODI, SF-12, RMDQ, and FRI scores to measure pain and function were collected



Opportunity to leverage this data and clinical package



### Preliminary Phase 2 Clinical Data: Meaningful Signals



### **Presented at ORS 2025**

52 week comparison of MRI images to baseline appear to demonstrate morphological changes, such as an increase in T2 signal (hydration), a decrease in protrusion size, as well as resolutions of annular tears, potentially demonstrating disc microenvironment remodeling



# ThermoStem Program: Allogeneic Cell-based Therapy

# **Target Conditions:** Obesity, Type 2 diabetes, and Metabolic disorders

#### Cell Type: Brown Fat

• Has been shown to regulate metabolic homeostasis in the body

#### **Components of Library:**

- Human Brown Adipose Tissue (BAT)
- White Adipose Tissue (WAT)
- Brown Adipose-derived Stem Cells (BADSC)

#### Initial Proof of Concept:

Completed in small animal model

**Patent Portfolio:** Related BAT patent portfolio, including issued patents in the U.S., Australia and Japan

#### **Platform Program:**

#### For the development of cell & small molecule therapies

Migraines, Depression, Pseudotumor Cerebri, Obstructive Sleep Apnea

Chronic Obstructive Pulmonary Disease

Non-Alcoholic Fatty Liver Disease

Gastroesophageal Reflux Disease

Polycystic Ovarian Syndrome

Stress Urinary inconsistence

Venous Stenosis

Spine Disorders

Cardiovascular Disease, Hypertension

Dyslipidemia Hypercholesterolemia

Type 2 Diabetes Mellitus, Metabolic Syndrome

**Cancer of various origins** 

**Degenerative Joint Diseases** 

Gout



# Metabolic Program Highlights





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

### File DMF with FDA

Expect filing a Drug Master File ("DMF") with the FDA to facilitate licensing opportunities around ThermoStem.

### Pre-IND Meeting with FDA

Scheduling Pre-IND meeting with FDA to discuss first-in-man fast-track regulatory pathways.

### Initiate Phase 1/2 Clinical Trial

Upon FDA approval commence Phase 1/2 clinical trial.



# Our Opportunities are Well-Protected

PROGRAM	disc×	ThermoStem
INDICATION	Disc / Spine	Metabolic
PATENT TITLES	<ul> <li>Methods and Compositions to facilitate repair of avascular tissue</li> <li>Surgical Methods and Compositions to facilitate repair of avascular tissue</li> <li>Therapeutic Delivery Device</li> </ul>	<ul> <li>Brown Fat Compositions and Methods</li> <li>Human Brown Adipose Derived Stem Cells and Uses</li> <li>Non-naturally occurring three-dimensional (3D) Brown Adipose-Derived Stem Cell aggregates and methods of generating and using the same</li> </ul>
STATUS	4	26
NO.OF APPLICATIONS	2 Issued 2 Pending	23 Issued 3 Pending



### Scientific Advisory Board

#### Wayne Marasco, MD, PDt Chairman of SAB

- Principal Faculty Member of Harvard Stem Cell Institute
- Professor in the Department of Cancer Immunology & AIDS at the Dana-Farber Cancer Institute
- Professor of Medicine at Harvard Medical School

#### **Jason Lipetz, MD** Chairman of SAB Sub Committee Disc Advisory Board

- Chief of Spine Medicine for the Northwell
   Health Spine Center
- Founder of Long Island Spine Rehabilitation Medicine

#### Harvinder Sandhu, MD Member Disc Advisory Board

- Orthopedic Spine Surgeon at the Hospital for Special Surgery
- Specializes 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

- Board-certified Interventional Neuroradiologist
- Director of Endovascular and Minimally Invasive Neurosurgery at the George Washington University Medical Center

#### Christopher Plastaras, MD Member Disc Advisory Board

 MossRehabs' Clinical Director of Musculoskeletal Spine & Sports Rehabilitation Medicine

#### Joy Cavagnaro, PhD Member

- President and Founder of Access BIO, L.C.
- Previously positions with the FDA Center for Biologics Evaluation and Research (CBER), for a decade



### Financial Summary

CURRENT CAPITALIZATION	S H A R E S
Common Shares Outstanding	8.6 Million*
Preferred Series B Shares Outstanding	Convertible to 1.4 Million Common**
Cash	\$ 9.1 Million**
Debt	\$0

\* As of 05/13/2025; includes ~1.1 million common shares held in abeyance
\*\* As of 03/31/2025



### 2024 and Recent Accomplishments

- Announced FDA clearance of important BRTX-100 clinical study protocol amendment (replaces saline injection with sham injection in control arm)
- Reported positive preliminary Phase 2 BRTX-100 study data (15 patient) in cLDD
- Received FDA Fast Track Designation for BRTX-100 in cLDD
- ✓ FDA cleared IND for Phase 2 BRTX-100 tiral in cCDP
- Developed novel exosome-based biologic for obesity
- Expanded ThermoStem patents in U.S., Europe, Israel, and Japan
- Initiated discussions with an undisclosed commercial stage regenerative medicine company on potential ThermoStem IP licensing
- Announced commercial biocosmeceutical agreement with Cartessa
- ✓ Received expanded tissue license from New York State Dept. of Health





### In Conclusion



#### 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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