



# Regenerative Biology for Healthier Lives

Investor Presentation

April 2025



# 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.

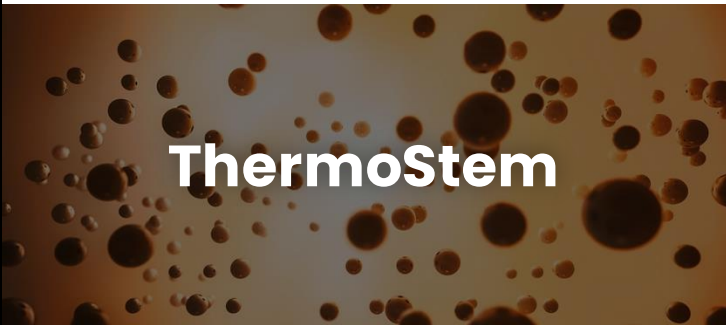

Forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause our actual results, performance or achievements, business plan or industry results, to differ materially from our expectations of future results, performance or achievements expressed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

# Fully Integrated Regenerative Medicine Company

**DEVELOPMENT**

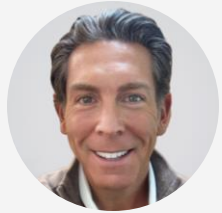
|  |   |
|--|---|
|  <p><b>ThermoStem</b></p> |  <p><b>BRTX-100</b></p> |
| Brown adipose derived stem cells   | Bone marrow derived mesenchymal stem cells  |
| <b>PRECLINICAL</b>   | <b>MID-STAGE CLINICAL</b>   |

**COMMERCIAL**

**BioCosmeceuticals**

Secretome (novel exosome, growth factor/cytokine) biologics based technology for cosmetic applications

# 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*

## DEVELOPMENT

**ThermoStem**

Brown adipose derived  
stem cells

**PRECLINICAL**

**BRTX-100**

Bone marrow derived  
mesenchymal stem cells

**MID-STAGE CLINICAL**

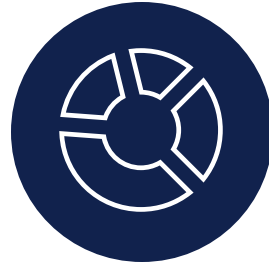
## COMMERCIAL

**BioCosmeceuticals**

Secretome (novel exosome,  
growth factor/cytokine)  
biologics based technology  
for cosmetic applications

# Going Commercial: Biologics Based Cosmetic Products

## Key Features of Cosmetics & Hair Growth Biologics 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



### 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

## DEVELOPMENT



**ThermoStem**

Brown adipose derived stem cells

**PRECLINICAL**



**BRTX-100**

Bone marrow derived mesenchymal stem cells

**CLINICAL**

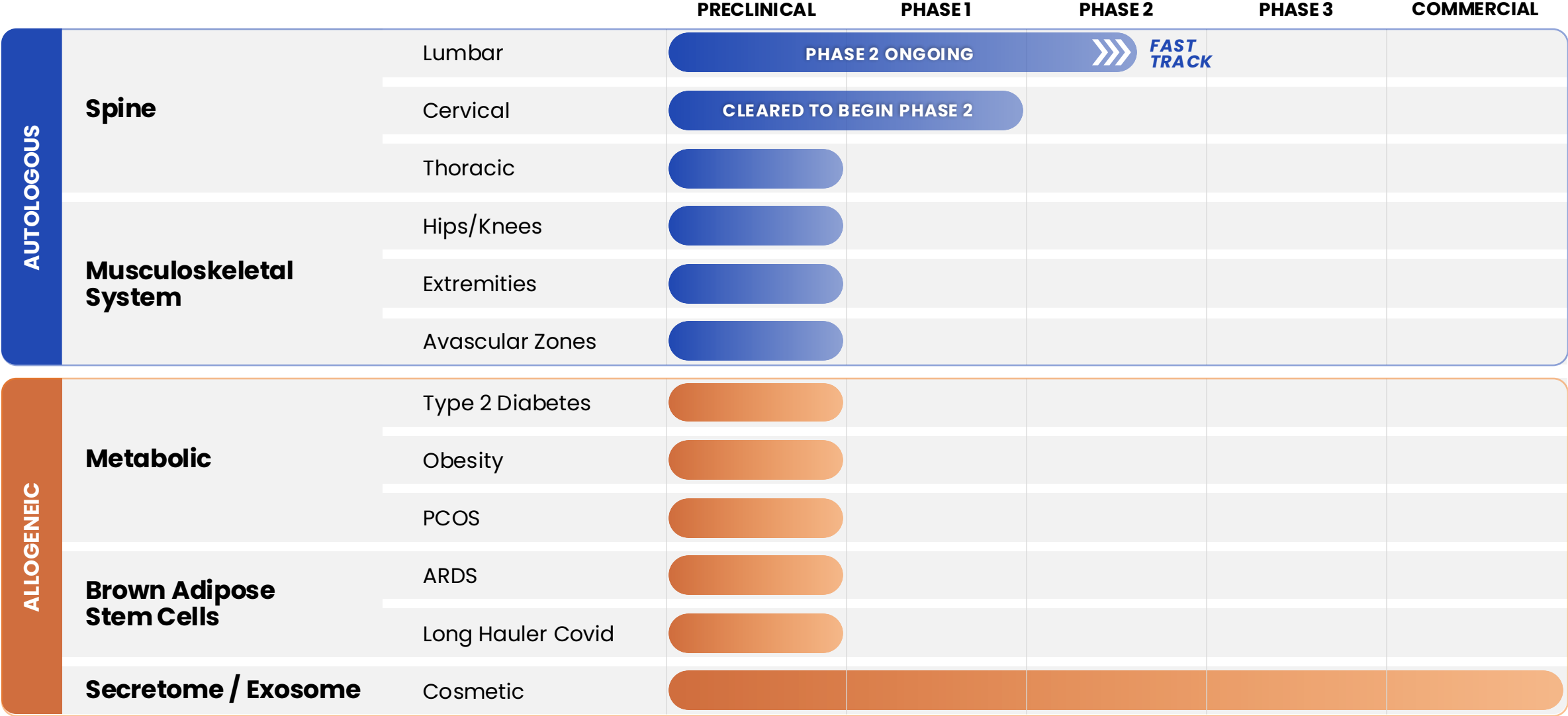
## COMMERCIAL



**BioCosmeceuticals**

Secretome (novel exosome, growth factor/cytokine) biologics based technology for cosmetic applications

# Robust Preclinical & Clinical Pipeline





# Chronic Lumbar Disc Disease (cLDD)

**258 M**

U.S. adult population

**64.5 M**

American adults with chronic lower back pain prevalence

**32 M**

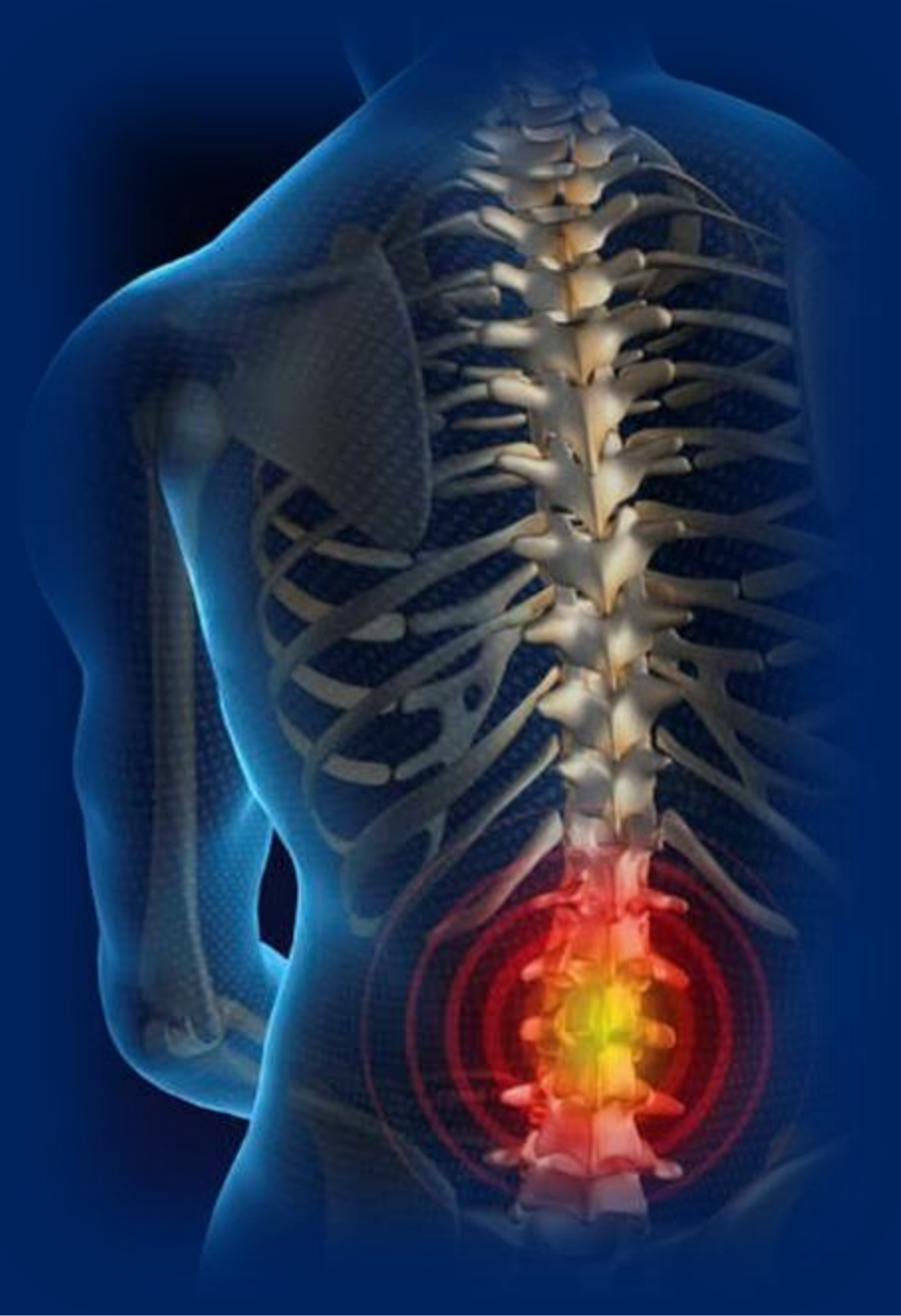
American adults with diagnosed and treated disc degeneration

**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

## Conservative Treatments



ORAL MEDICATION TREATMENT  
/ OPIOIDS  
**\$1,000 - \$2,000** / annually



INJECTION TREATMENT  
**\$8,000** / annually  
\$2,000 per injection, 2 injections per  
treatment—semi-annual treatment



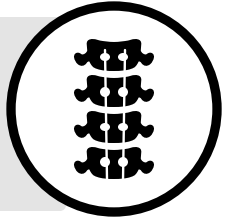
PHYSICAL MEASURES  
**\$20,000** / annually  
\$200 per session, 2 sessions per week

Often Recurrent

**NON-INVASIVE**

## Surgical Treatments

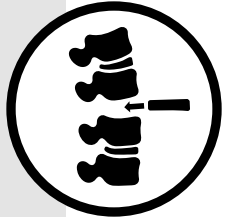
SPINAL FUSION SURGERY  
**\$110,000**



DISCECTOMY  
**\$20,000 - \$50,000**



DISC REPLACEMENT SURGERY  
**\$80,000 - \$150,000**



Re-op Rates Often 10-20%

**INVASIVE**

**UNMET NEED**  
← OPPORTUNITY ZONE →

# Our Solution: BTRX-100

## Regenerative Medicine

## Surgical Treatments



ORAL MEDICATION TREATMENT  
/ OPIOIDS

**\$1,000 - \$2,000** / annually



INJECTION TREATMENT

**\$8,000** / annually

\$2,000 per injection, 2 injections per  
treatment—semi-annual treatment



PHYSICAL MEASURES

**\$20,000** / annually

\$200 per session, 2 sessions per week

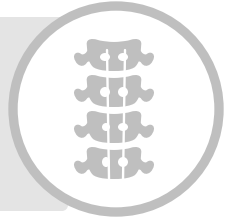
Introduce Hypoxic Cultured  
Autologous MSCs

# BRTX-100

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

SPINAL FUSION SURGERY

**\$110,000**



DISCECTOMY

**\$20,000 -  
\$50,000**



DISC REPLACEMENT SURGERY

**\$80,000 -  
\$150,000**



Often Recurrent



**NON-INVASIVE**



**NON-INVASIVE**

Re-op Rates Often 10-20%



**INVASIVE**

# BRTX-100: Clinical Snapshot



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



Ongoing FDA  
authorized Phase 2  
clinical trial



Large growing market  
with few comparable  
autologous therapies

# BRTX-100: Key Differentiating Factors



|                      |  |   |
|----------------------|--|---|
| <b>SOURCE</b>        | <b>Allogeneic</b><br>uses human derived stem cells (not from patient)<br>- 6 million | <b>Autologous</b><br>uses patients own stem cells<br>- 40 million |
| <b>CULTURING</b>     | <b>Normoxic cultured</b><br>with normal oxygen environment (~20%)                    | <b>Hypoxic cultured</b><br>in low oxygen environment (5%)         |
| <b>CARRIER</b>       | <b>Hyaluronic Acid Carrier</b>   | <b>Autologous Platelet Lysate Carrier &amp; Adjuvant</b>          |
| <b>MANUFACTURING</b> | <b>Animal Products Used</b>  | <b>100% Animal-Free</b>   |

## 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


# 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

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

Journal of Translational Medicine

RESEARCH Open Access

 CrossMark


## 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<sup>1,2</sup>, Jason Markle<sup>1</sup>, Ehren Dodson<sup>2\*</sup>, Ian Stemper<sup>2</sup>, Christopher J. Williams<sup>1</sup>, Matthew Hyzy<sup>1</sup>, Thomas Ichim<sup>3</sup> and Michael Freeman<sup>4</sup>

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

Stem Cell Research & Therapy


RESEARCH Open Access

 CrossMark

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

Original Clinical Science—General



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

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

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

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

Anders Lindahl

# 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)

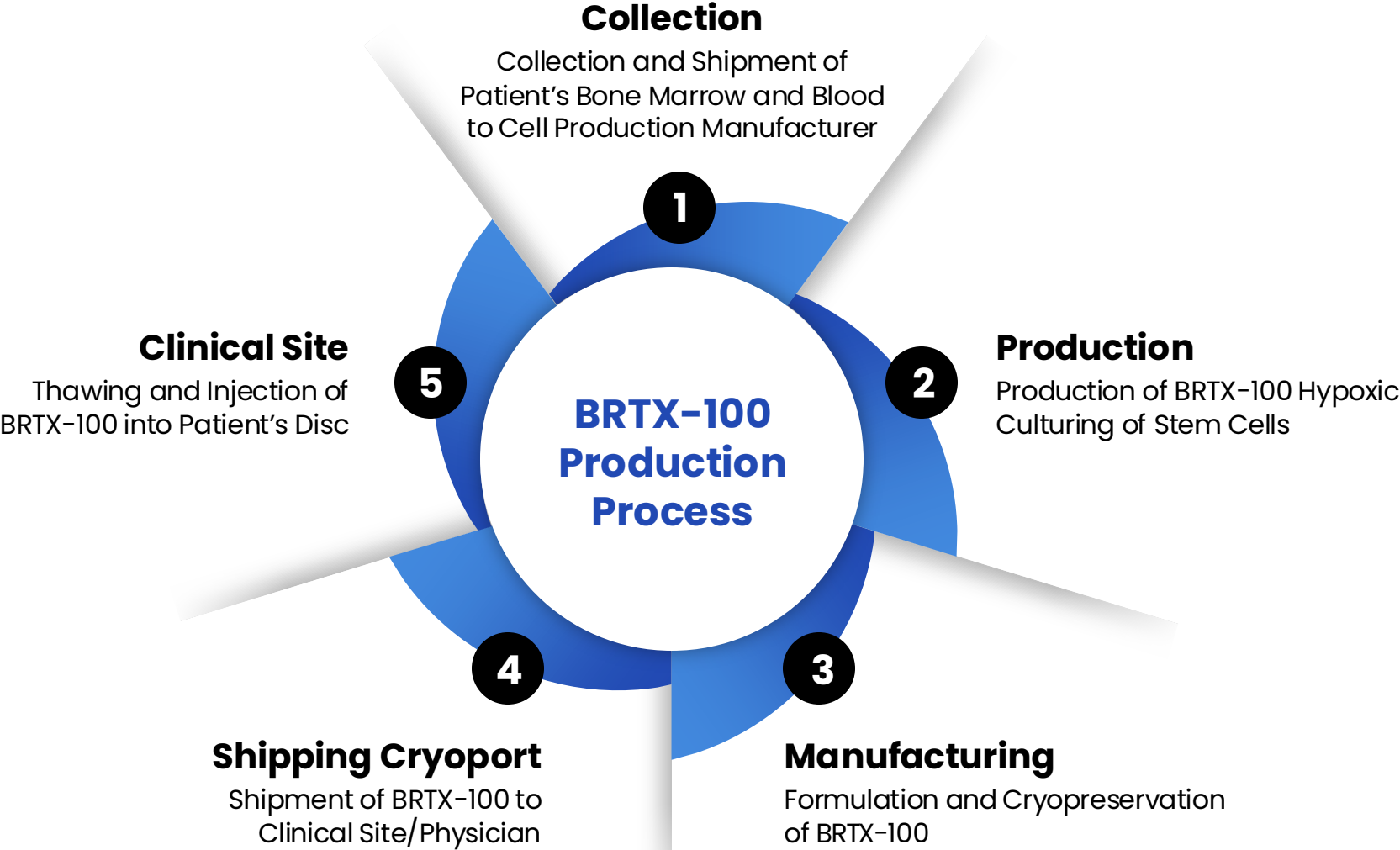
#### **Reduction of pain:**

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 non-operative therapies

# BRTX-100: Logistical /Clinical Process





## BRTX-100: Cleared DSMB June 2023

✓ Unanimous approval by the DSMB to continue trial without changes

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✓ BRTX-100 is safe and well tolerated

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✓ All 4 subjects successfully dosed with either 40 mil hMSCs or placebo

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✓ First time 40 million cells injected in a human subject

✓ 3:1 randomization

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✓ No Significant Adverse Events

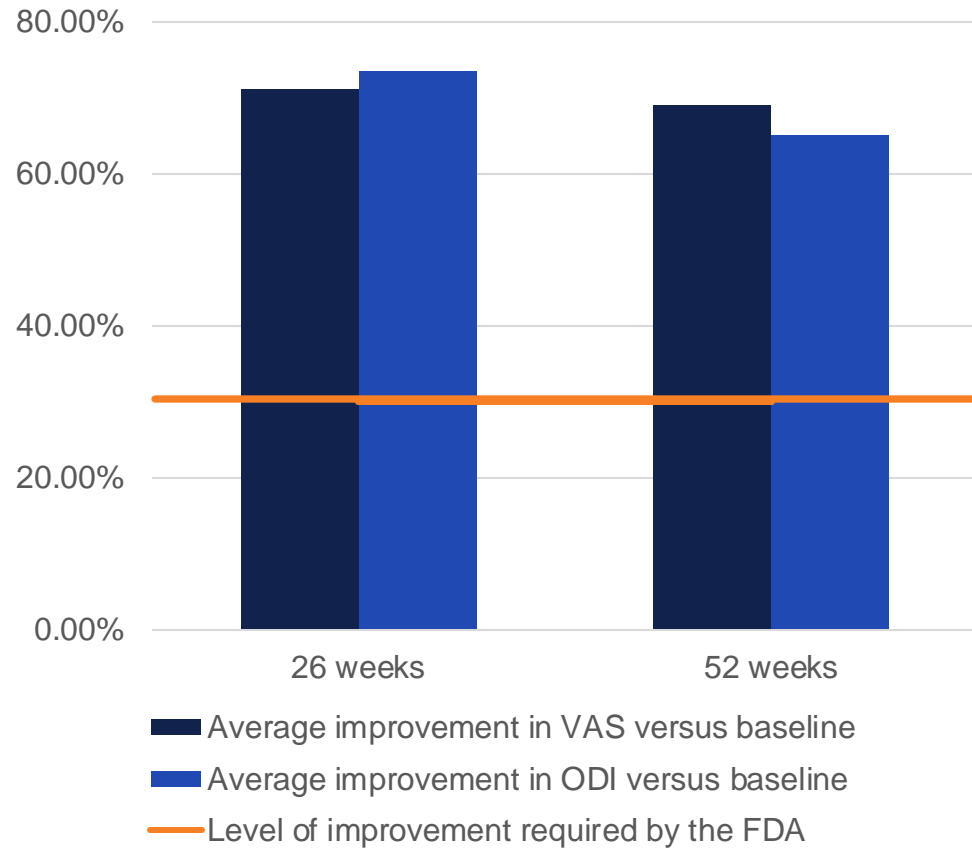
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✓ VAS, ODI, SF-12, RMDQ, and FRI scores to measure pain and function were collected

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✓ 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)

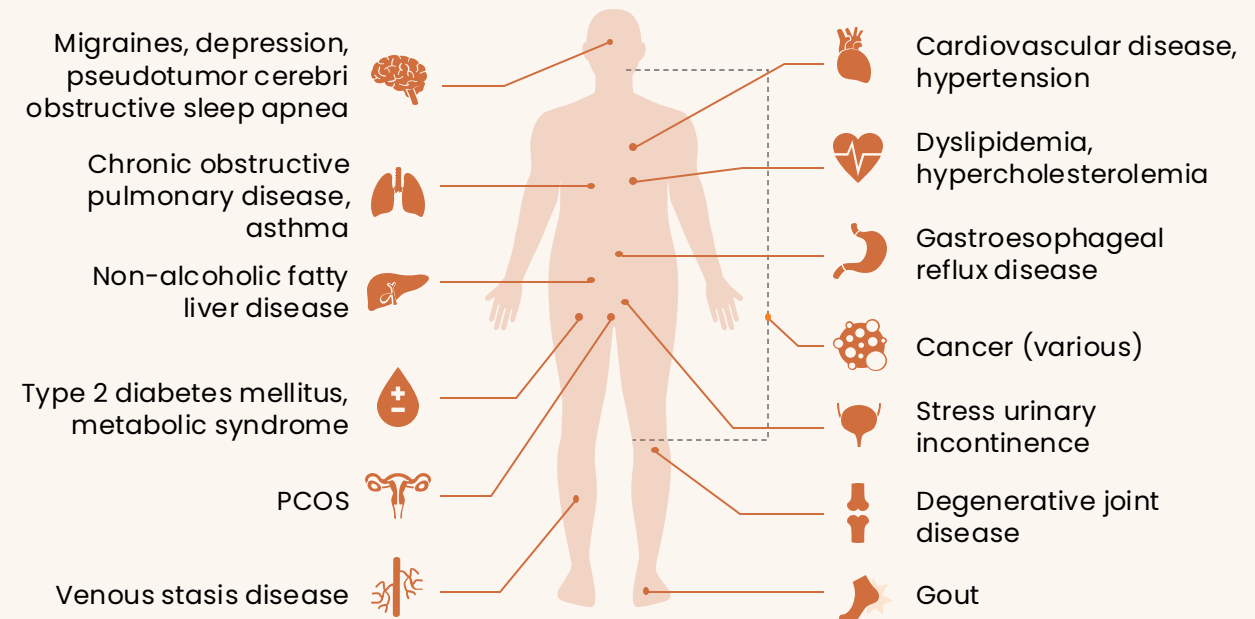
**Initial Proof of Concept:**

- ✓ Completed in small animal model

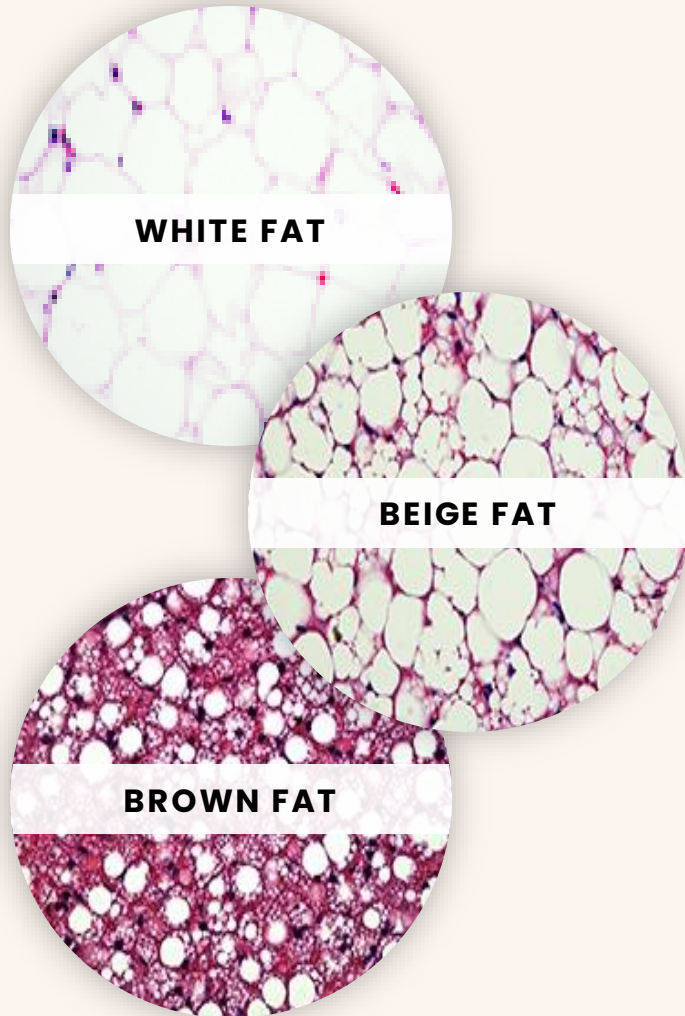
**Patent Portfolio:** Related BAT patent portfolio, including issued patents in the U.S., Australia and Japan

**Platform Program:**

For the development of cell & small molecule therapies



# Metabolic Program **Highlights**



- ★ First human stem cell derived BAT transfer

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- ★ Creation of first human 3D engineered artificial brown adipose tissue construct (aBAT)

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- ★ Successful delivery of 3D aBAT construct in mouse model

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- ★ Transplantation of aBAT lowered blood glucose levels

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- ★ Transplantation of aBAT decreased weight in obese mice

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- ★ 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             |    | ThermoStem  |
|---------------------|--|---|
| INDICATION          | Disc / Spine   | Metabolic   |
| PATENT TITLES       | <ul style="list-style-type: none"> <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 style="list-style-type: none"> <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<br>2 Pending  | 23 Issued<br>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

| <b>CURRENT CAPITALIZATION</b>                | <b>SHARES</b>                              |
|--|--|
| <b>Common Shares Outstanding</b>             | <b>7.5 Million*</b>                        |
| <b>Preferred Series B Shares Outstanding</b> | <b>Convertible to 1.4 Million Common**</b> |
| <b>Cash</b>                                  | <b>\$ 10.7 Million**</b>                   |
| <b>Debt</b>                                  | <b>\$0</b>                                 |

\* As of 03/26/2025; includes ~1.2 million common shares held in abeyance

\*\* As of 12/31/2024



# 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 trial 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

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★ Disruptive Platform Technologies in Cellular Therapy

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★ Strong Preliminary Data Indicative of Positive Trial Outcomes

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★ Active Phase 2 Trial in Spine

★ Addressing Multi-Billion Dollar Markets with Unmet Needs

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★ Opportunity for Key Strategic Partnerships in Cosmetic Space

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★ Strong Intellectual Property Protection

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★ Experienced Management Team & Scientific Advisory Board



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