biorestorative therapies

Regenerative Biology for Healthier Lives

Investor Presentation

January 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.

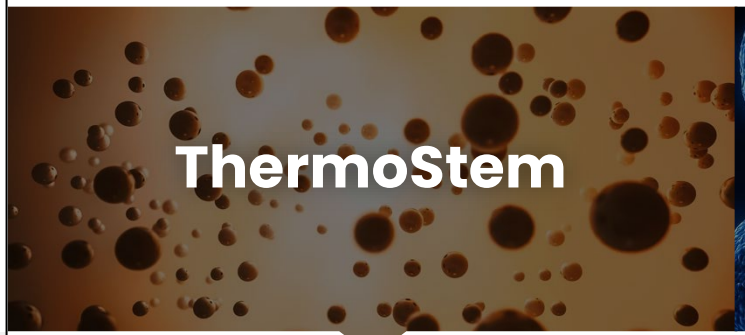
Forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause our actual results, performance or achievements, business plan or industry results, to differ materially from our expectations of future results, performance or achievements expressed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



Brown adipose derived stem cells

PRECLINICAL

Bone marrow derived mesenchymal stem cells

MID-STAGE CLINICAL

COMMERCIAL

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

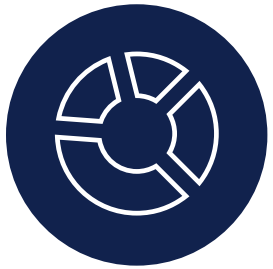
COMMERCIAL

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

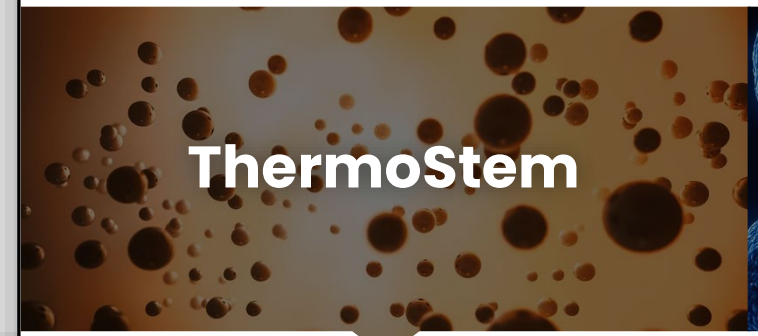
Manufacturing

- 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



Brown adipose derived stem cells

PRECLINICAL

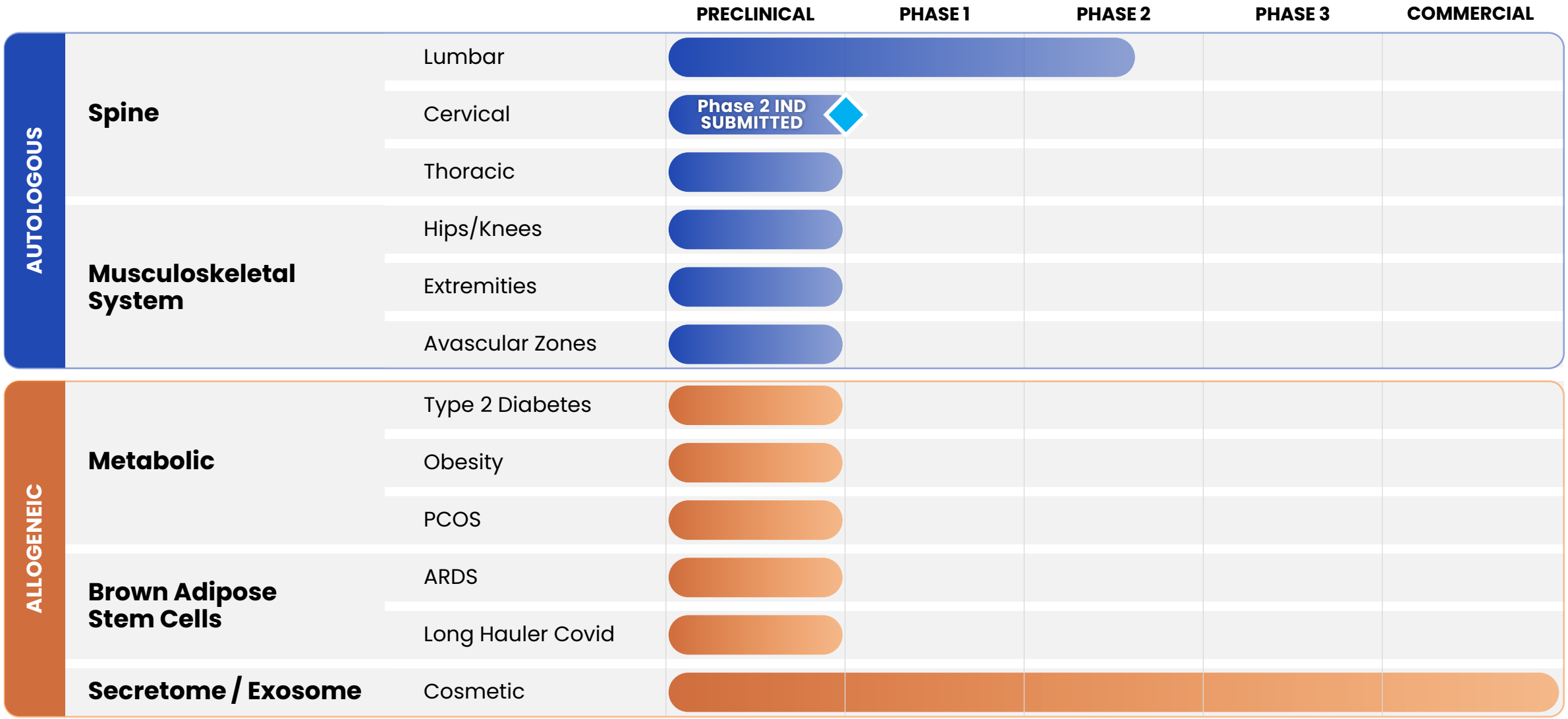
Bone marrow derived mesenchymal stem cells

CLINICAL

COMMERCIAL

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

Robust Preclinical & Clinical Pipeline



* Polycystic ovarian syndrome

Chronic Lumbar Disc Disease (cLDD)

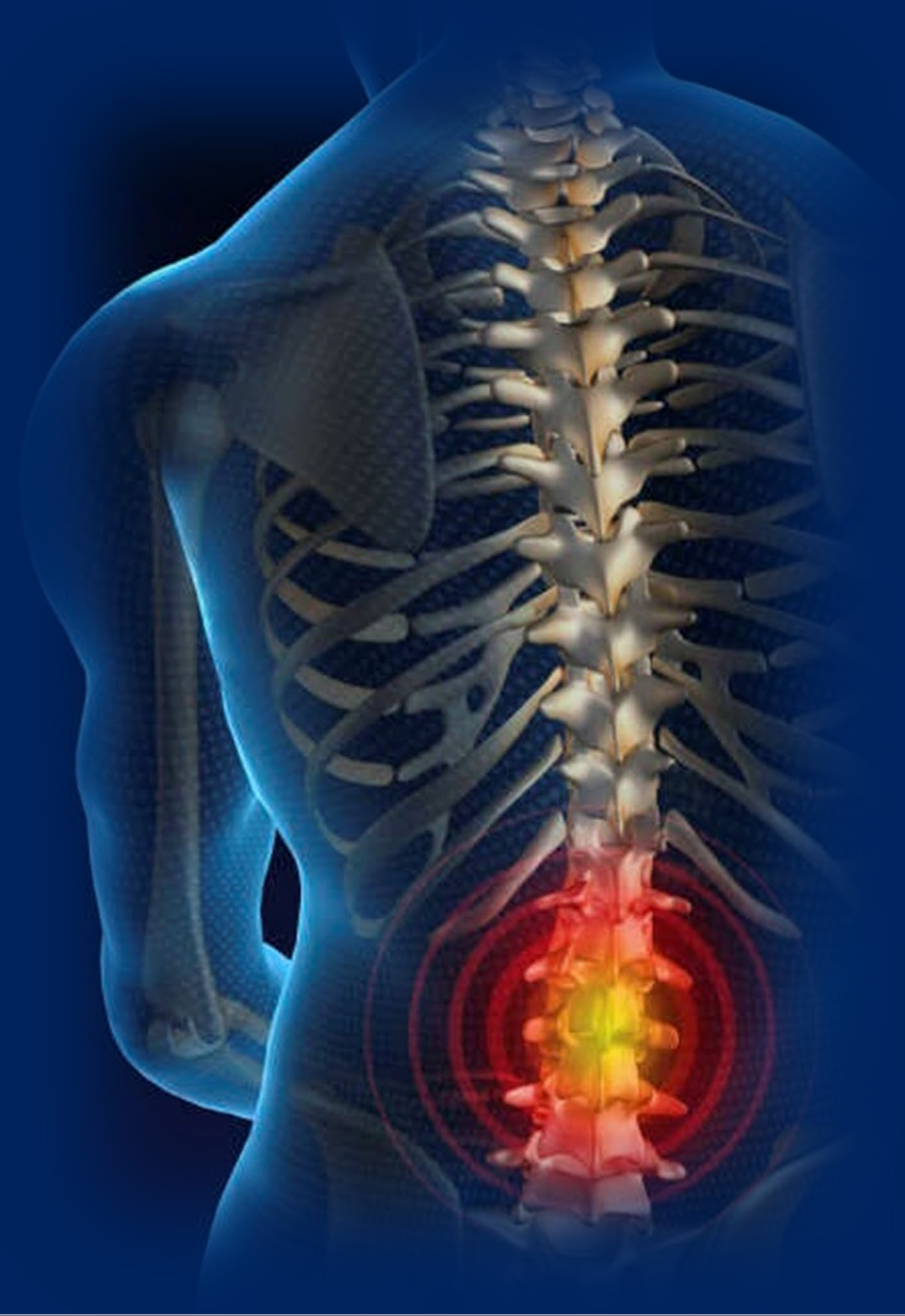
258 M U.S. adult population

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



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

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

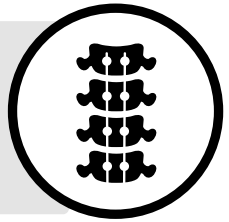
UNMET NEED

OPPORTUNITY ZONE

Surgical Treatments

SPINAL FUSION SURGERY

$110,000



DISCECTOMY

$20,000 - $50,000

DISC REPLACEMENT SURGERY

$80,000 - $150,000

Re-op Rates Often >30%

INVASIVE

Our Solution: BTRX-100

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

Regenerative Medicine

Introduce Hypoxic Cultured Autologous MSCs

BRTX-100

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

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 >30%

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

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

BRTX-100: Key Differentiating Factors

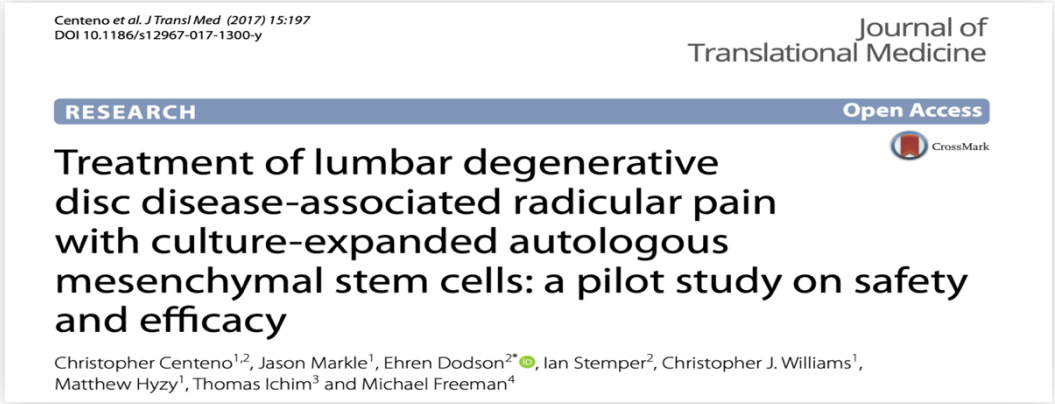
	mesoblast	biorestorative therapies
SOURCE	**Allogeneic** uses human derived stem cells (not from patient) - 6 million	**Autologous** uses patients own stem cells - 40 million
CULTURING	**Normoxic cultured** with normal oxygen environment (~20%)	**Hypoxic cultured** in low oxygen environment (5%)
CARRIER	**Hyaluronic Acid Carrier**	**Autologous Platelet Lysate Carrier & Adjuvant**
MANUFACTURING	**Animal Products Used**	**100% Animal-Free**

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

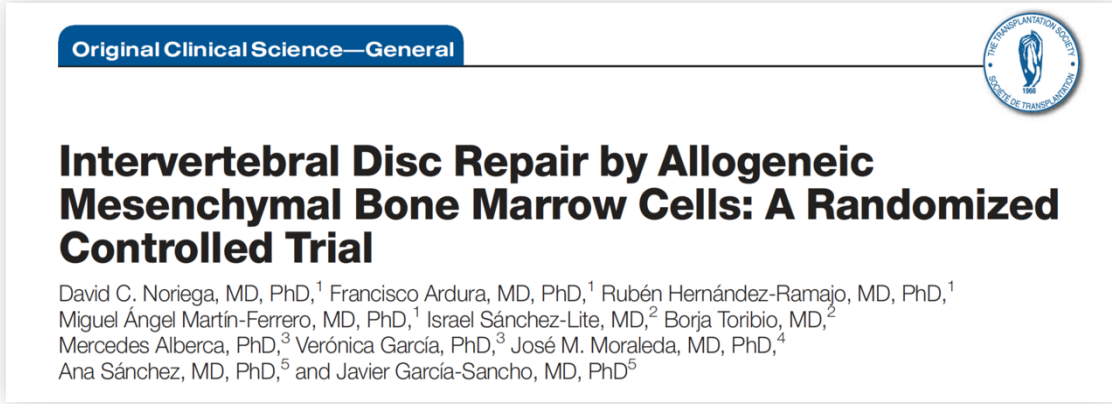
Journal of Translational Medicine

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

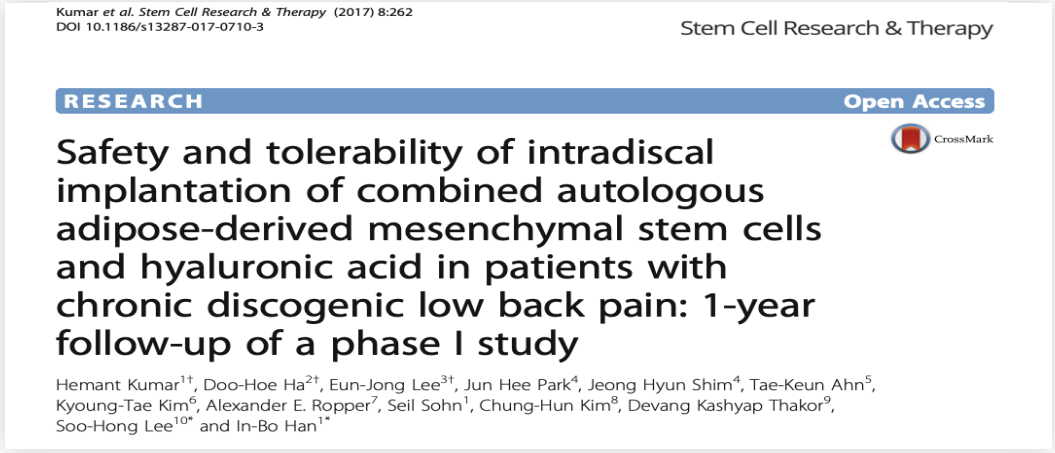
Christopher Centeno[1,2], Jason Markle[1], Ehren Dodson[2*], Ian Stemper[2], Christopher J. Williams[1], Matthew Hyzy[1], Thomas Ichim[3] and Michael Freeman[4]



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]



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[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*]

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

biorestorative therapies

BRTX-100: 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

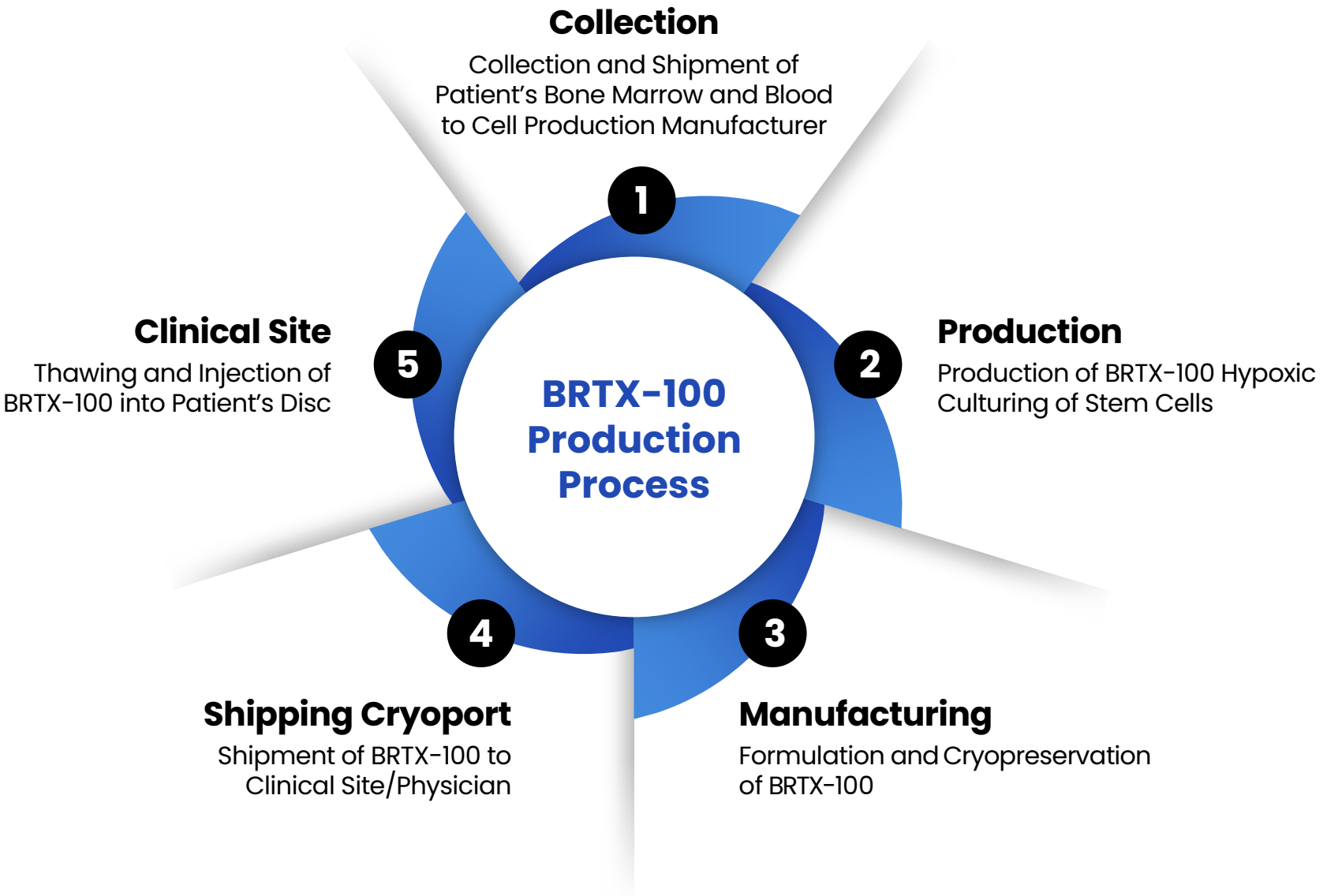
Improvement in function:
at least 30% increase in function based on Oswestry Disability Index questionnaires (ODI)

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



biorestorative therapies

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 PSRS 7th International Spine Research Symposium, November 2024

- 10 subjects who underwent successful dosing of either a 40 × 10^6 cell dose of hMSCs or saline at a 3:1 randomization ratio

- No serious adverse events (SAEs) were reported in any of the 10 safety run-in subjects; Notably, there was also no dose (40X10^6 cells) limiting toxicity at 26-52 weeks

- At 26 weeks 70% of the patients are reporting a greater than 30% increase in function and a more than 30% decrease in pain*

** 30% is the minimal threshold which must be met for both pain and function by the FDA*

The Blinded Preliminary Efficacy Endpoint Data Presented

At 26 weeks	• 70% of subjects (n=10) reported a **>30% improvement** in VAS versus baseline
At 52 weeks	• 100% of subjects (n=4) reported a >**30% improvement** in VAS versus baseline (n=4)
At 12 & 26 weeks	• 70% of subjects (n=10) had a **>30% improvement** in ODI versus baseline
At 52 weeks	• 100% of subjects (n=4) had a **>30% improvement** in ODI versus baseline
At 26 weeks	• 70% of subjects (n=10) reported a **>30% decrease** in pain (VAS) and a >**30% increase** in function (ODI)

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)

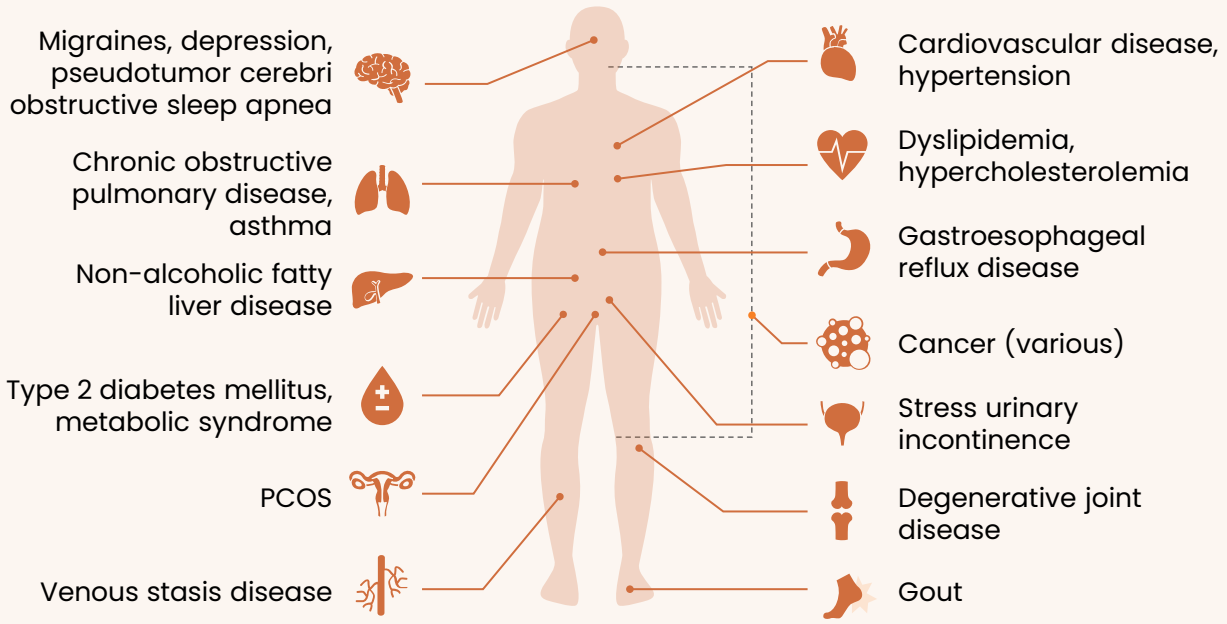
Initial Proof of Concept:

✓ Completed in small animal model

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

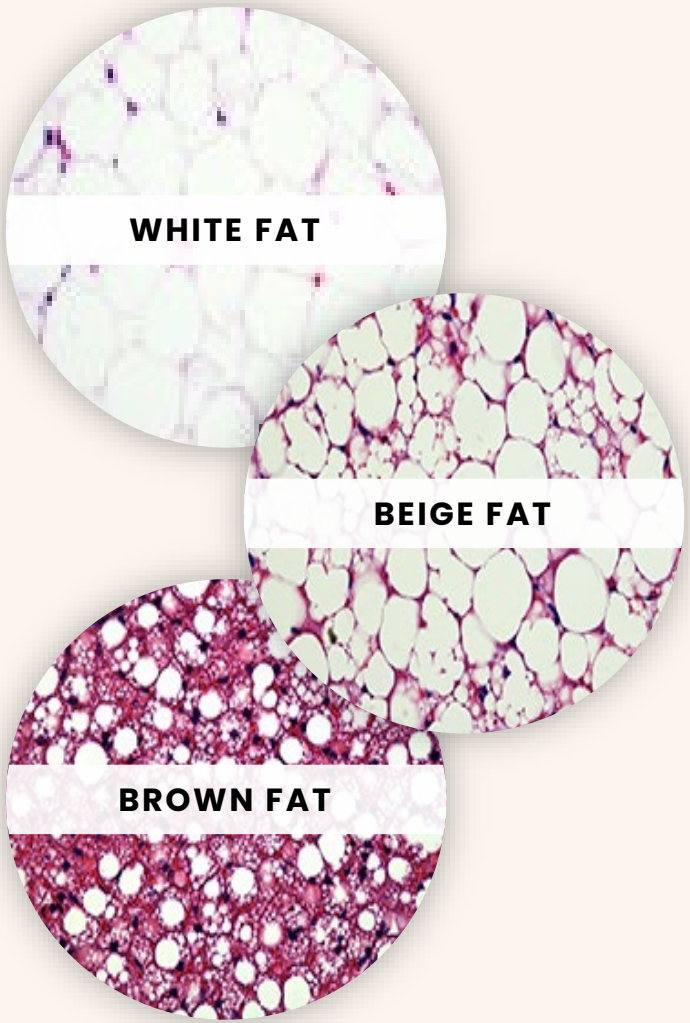
Platform Program:

For the development of cell & small molecule therapies



biorestorative therapies

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	brtdiscx	ThermoStem
INDICATION	Disc / Spine	Metabolic
PATENT TITLES	• Methods and Compositions to facilitate repair of avascular tissue • Surgical Methods and Compositions to facilitate repair of avascular tissue • Therapeutic Delivery Device	• 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
STATUS	4	26
NO. OF APPLICATIONS	2 Issued 2 Pending	21 Issued 5 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	SHARES
Common Shares Outstanding	**8.1 Million****
Preferred Series B Shares Outstanding	**Convertible to 1.4 Million Common**
Cash	**$ 13.1 Million**
Debt	**$0**

* As of 09/30/2024
** Includes ~1.2 million common shares held in abeyance

2024 Accomplishments

- Announced FDA clearance of important BRTX-100 clinical study protocol amendment (replaces saline injection with sham injection in control arm)
- Reported positive preliminary BRTX-100 study data (10 patient)
- Developed a novel exosome-based biologic program targeting obesity
- Expanded ThermoStem patent portfolio in U.S., Israel and Japan
- Began to engage in discussions with an undisclosed commercial stage regenerative medicine company regarding a potential license of ThermoStem IP
- Announced commercial biocosmeceutical agreement with Cartessa
- Received expanded tissue license from New York State Dept. of Health

BRTX cGMP Clean Room

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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