

Biorestorative Therapies develops, manufactures and delivers cell therapy that harbors great promise in conditioning human bodies' own regenerative potential to treat major diseases, addressing the root problems, instead of the current standards of care which focus mostly on treating the symptoms.

The company currently has two developing programs and platform technologies with multiple applications:

- 1. The Musculoskeletal platform treats chronic lumbar disc disease caused by disc degeneration as one application, and is currently in a stage 2 clinical phase
- 2. The Metabolic platforms that targets metabolic disorders including obesity and type II diabetes, and is in a preclinical phase



Problems and unmet needs in chronic musculoskeletal disorders:

About 65 million U.S. adults have chronic lower back pain prevalence, and about half of them are diagnosed and treated for disc degeneration. The current standards of care are: 1) oral medications and injection of pain management medicine which can potentially lead to addiction and further exacerbate the current opioid crisis in the U.S., 2) surgical Interventions which are invasive, extremely expensive, with longer recovery times, and with unacceptably high failure rates which required retreatments down the road.





The solution to the problem lies in BRTX 100

BioRestorative is developing a lead asset, BRTX-100, initially targeting the treatment of chronic lower back pain as one application. BRTX-100 is an autologous, bone-marrow derived mesenchymal cell therapy.

BRTX-100 is autologous, and its production involves collecting bone marrow, isolation, and culturing under proprietary conditions, and then reintroducing 40 million cultured cells back into the injured areas of the patient. This is compared to conventional non-invasive treatment that only addresses symptoms and often recurrent, and invasive high cost surgical treatment which has re-operation rate of 10-20%. If approved and commercialized, BRTX 100 represents a ground breaking solution to address a massive unmet need. A link to an interview with Dr Jason Lipetz, Chief of Spine Medicine at Northwell Health Spine Center and Member of the company's Scientific Advisory Board.





Potential opportunity is sizable

The disc degeneration opportunity alone and in itself is sizable, and BioRestorative is sitting at the intersection between the \$40 billion 2.5 million patient invasive surgery market and the \$32 billion conventional pain management non-invasive market (32 million U.S. population diagnosed and treated with disc degeneration, estimating\$1k per year for oral pain management)

Key differentiation is centered around the culturing process and autologous nature

What differentiated BRTX 100 from other novel cell therapies stems from the culturing process where cells are being cultured under hypoxic or low oxygen conditions, making them more survivable in avascular environments such as the intervertebral disc.

This proprietary process also generates promising opportunities in other applications in targeted areas that are largely avascular, providing a potential high value highly differentiated pipeline for the company in the future with BRTX 100 as its leading asset.



Source: BioRestorative Corporate Presentation

MILTIPLE OPPORTUNITIES

- > BRTX 100 is a platform technology with multiple applications
- First indication is cLDD currently approved for a Phase 2 Clinical Study
- > Applications include all avascular zones in the body
- Cervical application expected to be initiated Q4 2022
- Stem Cell processing and management opportunities through banking
- > Create an "off the shelf" autologous platform

Also, being autologous which means cells come from the patient himself, BRTX 100 reduces risks of rejection and enhances the safety profile of the therapy. Contrary to the misperception that autologous (cells from patient) is not as scalable as allogeneic (cells that are "off-the-shelf" from other donors), BioRestorative has a well-thought out logistic process to ensure scalability success.

Logistics process flow is key to the autologous approach

BioRestorative Therapies, unlike other novel cell therapy companies, has its own manufacturing and logistics capabilities which are essential for the process and scalability success as autologous approach involves input material taken from the patients, brought to the manufacturing facility, and then returned to the patient in the clinical environment for delivery of the cultured cells.



Phase II trial is underway

BRTX-100 is currently undergoing a P2 clinical trial in N=99 patients. It's a 99 patient prospective, randomized, double blinded, controlled study, the gold standard within the FDA, with 30% reduction in pain as the end point of the trial.

Phase II trial 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 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

Competition

Competition in treating degenerative disc comes from conventional pain management medication and invasive surgery, as well as Mesoblast which is also in novel cell therapy but is using a different and potentially less effective approach. Mesoblast is undergoing the phase III trial and can potentially achieve commercialization earlier, paving a way for novel cell therapy to treat disc degenerative disorder for BioRestorative Therapies.



The metabolic platform is centered around brown fat therapy

The global type 2 diabetes market is said to almost double from \$31.2billion in 2015 to \$58.7 billion by 2025. This set the stage for novel cell therapy to regulate metabolism. BioRestorative Therapies metabolic platform is an allogeneic cell derived from brown fat tissue. This preclinical program has been tested in animals showing tremendous potential given the strength and potency of these cells to regulate one's metabolic activity. Biorestorative lab-based work independently and with collaborators have been published in journals which are highly regarded as best in class academic papers. There are collaborations with some of the largest pharmaceutical companies in the world and academic institutions such as University of Pennsylvania, University of Washington and Stockholm University.

This is a link to an interview with Dr. Tore Bengtsson, a professor a the Department of Molecular Biosciences at Stockholm University with whom BioRestorative Therapies are collaborating.

The high energy consumption attribute of brown fat as a therapy to combat obesity and diabetes

Brown fat tissue, which exists more abundantly in children's bodies but less in adults' bodies, is specialized for producing heat energy, taking energy away from normal fat tissue and increasing metabolism. Multiple studies have demonstrated a negative association of human brown fat tissue activity with BMI, fat mass and glucose concentrations. The implantation of brown fat also has demonstrated significant reductions in blood glucose levels and body weights in high- fat diet mouse models.



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 issues patents in the U.S., Australia and Japan
- > Platform program for the development of cell and small molecule therapies

Metabolic program timeline

BioRestorative is planning to submit a drug master file with the FDA in 2022, followed by a Pre-IND meeting. Following FDA authorization, the company intends to initiate a Phase I and II clinical trial targeting 2023. Currently, the company is working to optimize its cell therapy candidates.



Funding requirement and balance sheet

The company went through a transition in November 2021, uplisted on Nasdaq, raised over \$23 million, currently has a pristine balance sheet with no debt, convertible notes and historical warrants. With \$4-\$5 million in quarterly expenses and cash balance of about \$17 million exiting Q2 2022, the company is funded through these milestones into 1H23.



A PROVEN MANAGEMENT TEAM



Lance Alstodt, Chairman & CEO

Lance spent over 30 years leading , advising and operating companies with the Healthcare sector. He's 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, CFO

Robert has a versatile background of over 25 years on Bay Street and Wall Street. Robert most recently was the Director of Research for a Healthcare focused investment bank. His career has spanned trading, sales, banking and research.



Francisco Silva, VP of R&D

Francisco has over 20 years of experience in the development of cell based and off the shelf therapeutics. Francisco has obtained a number of issued patents in cell therapy and has manuscripts published with regard to translational stem cells research.



Value creation events/upcoming catalysts

Top key opinion leaders are highly engaged and their clinical sites are joining the phase II trial

BRTX-100- Phase II safety data read out is expected in Q1 2023. It will have a significant impact as it allows for acceleration of enrollment of the balance of the patients, and validates approach on how to handle the trial. In first half of 2023 BioRestoractive will likely add more indications or applications on the BRTX-100 platform

Other events while less impactful as the Phase II BRTX 100 safety data read out, but are important to call out include the brown fat platform drug master filed with FDA in Q4 2022, and pre-IND meeting in first half of 2023 as mentioned earlier.

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

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BROWN FAT

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