

November 5, 2024



# BioRestorative Therapies Receives Expanded Tissue License from New York State Department of Health

*– Allows for the processing of allogeneic (non-autologous) donor tissue material, including stem cells, for medical research –*

MELVILLE, N.Y., Nov. 05, 2024 (GLOBE NEWSWIRE) -- [BioRestorative Therapies, Inc.](https://www.biorestorative.com) ("BioRestorative", "BRTX" or the "Company") (NASDAQ:[BRTX](https://www.biotxt.com)), a clinical stage regenerative medicine innovator focused on stem cell-based therapies and products, today announced that it has received a provisional license from the New York State Department of Health ("NYSDOH") for the processing of allogeneic (non-autologous) donor tissue material for the isolation, expansion and cryopreservation of various cell types, including stem cells, for medical research. Previously, BioRestorative was licensed by the NYSDOH to act as a tissue bank for the processing of mesenchymal stem cells derived from autologous donors only.

The expanded license allows BioRestorative to leverage its state-of-the-art cGMP manufacturing capabilities to enable the processing, banking and distribution of clinical grade allogeneic (off-the-shelf) biologics.

NYSDOH licensure is an intensive and diligent process, and is required for all tissue and cell-related activities in New York, including collection, processing, storage, and distribution, as well as for any facility distributing tissues to other states. Holders of a New York State license are required to comply with regulations to ensure safe and ethical handling of tissues. Through a comprehensive on-site survey process, facilities are inspected and assessed for acceptable standards of practice and regulatory compliance in order to receive a full license.

"We believe being awarded this expanded provisional license from the NYSDOH serves as a testament to both the ground-breaking nature of our clinical work with stem cell therapies and products, and the outstanding quality of our clinical grade cell therapy cGMP manufacturing facility," said Lance Alstodt, BioRestorative's Chief Executive Officer. "Importantly, it will significantly enhance our ability to develop an unrivaled clinical pipeline of off-the-shelf cell-based biologic products."

## About BioRestorative Therapies, Inc.

BioRestorative ([www.biorestorative.com](https://www.biorestorative.com)) develops therapeutic products using cell and tissue protocols, primarily involving adult stem cells. As described below, our two core clinical development programs relate to the treatment of disc/spine disease and metabolic disorders, and we have also recently begun offering BioCosmeceutical products:

- Disc/Spine Program (brtxDISC™): Our lead cell therapy candidate, BRTX-100, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells collected from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complementary therapeutic to a surgical procedure. The BRTX-100 production process utilizes proprietary technology and involves collecting a patient's bone marrow, isolating and culturing stem cells from the bone marrow and cryopreserving the cells. In an outpatient procedure, BRTX-100 is to be injected by a physician into the patient's damaged disc. The treatment is intended for patients whose pain has not been alleviated by non-invasive procedures and who potentially face the prospect of surgery. We have commenced a Phase 2 clinical trial using BRTX-100 to treat chronic lower back pain arising from degenerative disc disease.

- Metabolic Program (ThermoStem®): We are developing cell-based therapy candidates to target obesity and metabolic disorders using brown adipose (fat) derived stem cells ("BADSC") to generate brown adipose tissue ("BAT"), as well as exosomes secreted by BADSC. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. BADSC secreted exosomes may also impact weight loss.

- BioCosmeceuticals: We operate a commercial BioCosmeceutical platform. Our current commercial product, formulated and manufactured using our cGMP ISO-7 certified clean room, is a cell-based secretome containing exosomes, proteins and growth factors. This proprietary biologic serum has been specifically engineered by us to reduce the appearance of fine lines and wrinkles and bring forth other areas of cosmetic effectiveness. Moving forward, we also intend to explore the potential of expanding our commercial offering to include a broader family of cell-based biologic aesthetic products and therapeutics via Investigational New Drug (IND)-enabling studies, with the aim of pioneering U.S. Food and Drug Administration (FDA) approvals in the emerging BioCosmeceuticals space.

## **Forward-Looking Statements**

*This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. You are cautioned that such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events or results to differ materially from those projected in the forward-looking statements as a result of various factors and other risks, including, without limitation, those set forth in the Company's latest Form 10-K, as amended, filed with the Securities and Exchange Commission. You should consider these factors in evaluating the forward-looking statements included herein, and not place undue reliance on such statements. The forward-looking statements in this release are made as of the date hereof and the Company undertakes no obligation to update such statements.*

## **CONTACT:**

Stephen Kilmer  
Investor Relations

Direct: (646) 274-3580

Email: [skilmer@biorestorative.com](mailto:skilmer@biorestorative.com)



Source: BioRestorative Therapies, Inc