

December 5, 2024



# BioRestorative Therapies Announces Notice of Allowance of Key New Patent Protecting ThermoStem® Metabolic Disease Program

– Covers cGMP manufacturing processes –

– Expected to provide protection until April 29, 2040 –

MELVILLE, N.Y., Dec. 05, 2024 (GLOBE NEWSWIRE) -- [BioRestorative Therapies, Inc.](#) (“BioRestorative”, “BRTX” or the “Company”) (NASDAQ:[BRTX](#)), a clinical stage regenerative medicine innovator focused on stem cell-based therapies and products, is pleased to announce that the European Patent Office has issued a Notice of Allowance for a new patent application (European Patent Appl. No. 20798130.9) covering key aspects of the Company’s allogeneic, off-the-shelf ThermoStem® metabolic disease platform.

Claims granted under the new patent cover a method of making a non-naturally occurring three-dimensional brown adipose derived stem cell aggregate.

“This patent allowance further validates the novel advancements we have made in our metabolic disease program,” said Lance Alstodt, BioRestorative’s Chief Executive Officer. “Given the tremendous market opportunity for ThermoStem®-based BADSCs to potentially transform the GLP-1 dominated treatment landscape for obesity and related metabolic diseases in important geographies around the world, we are particularly pleased that this patent provides broad coverage of our proprietary technology platform.”

In May 2024, BioRestorative [announced](#) the development of a novel exosome-based biologic program targeting obesity, advising that the Company plans to initiate the formal U.S. Food and Drug Administration (FDA) process for this ThermoStem®-based therapeutic candidate by filing a Drug Master File (DMF). On the heels of that announcement, BioRestorative [reported](#) that it had begun to engage in substantive discussions with an undisclosed commercial stage regenerative medicine company with regard to a potential license of BioRestorative’s allogeneic, off-the-shelf ThermoStem® metabolic intellectual property. Those discussions are continuing; however, no assurances can be given that a license agreement will be entered into whether on commercially reasonable terms or otherwise.

## About BioRestorative Therapies, Inc.

BioRestorative ([www.biorestorative.com](http://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.*

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