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# BioRestorative Therapies in Substantive Discussions for Potential License Agreement for ThermoStem® Metabolic Disease Program

- *Brown adipose derived stem cells with brown adipogenic potential would represent a new modality for the treatment of obesity and related metabolic disorders –*
- *ThermoStem® is an off-the-shelf platform, well-protected by a comprehensive portfolio of issued patents that cover both the U.S. and international markets –*
- *Potential license partner is a leading commercial stage regenerative medicine company –*

MELVILLE, N.Y., June 13, 2024 (GLOBE NEWSWIRE) -- [BioRestorative Therapies, Inc.](#) ("BioRestorative", "BRTX" or the "Company") (NASDAQ:[BRTX](#)), a clinical stage company focused on stem cell-based therapies, today reported that it has had substantive discussions with an undisclosed commercial stage regenerative medicine company with regard to a license of BioRestorative's allogeneic, off-the-shelf ThermoStem® metabolic intellectual property.

Previously published peer-reviewed preclinical data from a study conducted in collaboration with the University of Utah School of Medicine demonstrated a clonogenic population of metabolically active brown adipose tissue ("BAT") stem cells residing in adult humans that: (i) can be expanded *in vitro*; (ii) exhibit multilineage differentiation potential (osteogenic, chondrogenic and adipogenic); and (iii), functionally differentiate into metabolically active brown adipocytes. In addition, the preclinical results confirmed that multipotent brown adipose derived stem cells ("BADSCs") induced to differentiate into brown adipocytes exhibit the mature functional properties of these cells, including increased mitochondrial activity, an important functional characteristic of BAT.

BADSCs with brown adipogenic potential would represent an exciting new modality for the treatment of obesity and related metabolic disorders. To explore this possibility, BioRestorative developed a 3D Porous Extracellular Matrix-Derived Scaffold for effective cell delivery. Data obtained in high-fat fed NOD-SCID mice transplanted with differentiated BADSCs supported by the 3D scaffold showed significant reductions in weight, triglyceride and blood glucose levels compared to saline-only injected controls.

No assurances can be given that a license agreement will be entered into whether on commercially reasonable terms or otherwise. The Company does not intend to make any further announcements with regard to the license unless and until an agreement is entered into.

“It has been captivating to watch the scale, scope and speed with which potential license partners have begun to show interest in our proprietary off-the-shelf ThermoStem<sup>®</sup> platform,” said Lance Alstodt, BioRestorative’s Chief Executive Officer. “We are particularly pleased that our pioneering animal studies, which demonstrated that BADSCs show promise in correcting the weight gain and hyperglycemia associated with high fat feeding, and that our 3D scaffolds, which are capable of retaining viable transplanted cells for at least five weeks post-implantation, have attracted the caliber of commercial stage regenerative medicine company with which we are now engaged in substantive licensing discussions.”

### **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<sup>™</sup>):** 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<sup>®</sup>):** 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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Source: BioRestorative Therapies, Inc