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BioRestorative Therapies Provides First Quarter 2024 Business Update

MELVILLE, N.Y., May 14, 2024 (GLOBE NEWSWIRE) -- [BioRestorative Therapies, Inc.](#) ("BioRestorative", "BRTX" or the "Company") (NASDAQ:[BRTX](#)), a clinical stage company focused on stem cell-based therapies, today provided an update on its business.

"We have successfully executed against key strategic priorities since the start of the year," said Lance Alstodt, BioRestorative's Chief Executive Officer. "The most important of those were to advance our lead clinical program, BRTX-100, and expand our core preclinical program, ThermoStem[®], while also laying the groundwork for our commercial BioCosmeceuticals business to start generating significant revenues this year. We expect that this, combined with the \$16.4 million cash, cash equivalents, and marketable securities the Company held as of the end of the first quarter, will provide additional financial flexibility."

Recent Highlights

DEVELOPMENT

Disc/Spine Program

- A [poster](#) presented in February at the Orthopaedic Research Society (ORS) 2024 Annual Meeting described preliminary 26 and 52 week blinded data from the ongoing Phase 2 clinical trial of the Company's lead clinical candidate, BRTX-100, in subjects with chronic lumbar disc disease ("cLDD"). The preliminary clinical data showed meaningful signals in patients enrolled in the study and, importantly, no notable safety signals.
- Following manufacturing/clinical process enhancements made by BioRestorative that tripled its monthly trial capacity, it entered into a collaboration with Galen Patient Recruitment, Inc. designed to support completion of patient enrollment in the Phase 2 BRTX-100 study in cLDD before the end of 2024.
- On the heels of that, the Company announced U.S. Food and Drug Administration ("FDA") clearance of an important amendment to the Phase 2 study protocol, removing saline injection in the control arm of the study and replacing it with a sham injection.

Metabolic Program

- Last week, the Company disclosed the development of a novel exosome-based biologic program targeting obesity. The new therapeutic candidate, developed using the Company's patented ThermoStem[®] platform, has the potential to serve as an adjuvant to existing pharmaceuticals that are FDA approved and marketed towards

weight loss. BioRestorative currently anticipates initiating the formal FDA process for this ThermoStem[®]-based therapeutic candidate by filing a Drug Master File (DMF) in the third quarter of 2024, and aims to initiate first-in-human clinical studies before the end of the year.

COMMERCIAL

BioCosmeceuticals

- In late April, the Company entered into an exclusive five (5)-year commercial agreement with Cartessa Aesthetics, LLC (“Cartessa”), pursuant to which BioRestorative will supply pre-set minimum quantities of finished vials of a proprietary cell-based biologic serum to Cartessa annually as private label under Cartessa’s Chronos ExoCR mark.
- With this transformative commercial partnership, BioRestorative is poised to potentially enter into a stage of anticipated rapid growth in the biocosmeceuticals business.

Conference Call Details

BioRestorative will host a conference call to discuss the 2024 first quarter business update today at 4:30 p.m. ET. The dial-in number for the conference call is 1-888-506-0062 (United States) or 1-973-528-0011 (International); access code 357232. Participants are asked to dial in approximately 10 minutes before the conference call is scheduled to begin. The call can also be accessed via webcast on the Company's website at www.biorestorative.com/investor-relations under “Events.” The webcast will be archived and accessible for approximately 90 days.

About BioRestorative Therapies, Inc.

BioRestorative (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 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