UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): February 5, 2024

BioRestorative Therapies, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**001-37603**	**30-1341024**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

40 Marcus Drive Melville, New York	**11747**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code (631) 760-8100

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	BRTX	NASDAQ Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter):

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On February 5, 2024, BioRestorative Therapies, Inc. (the "Company") issued a press release (the "Press Release") announcing the public availability of a poster (the "Poster") titled "Autologous Stem Cell Therapy for Chronic Lumbar Disc Disease, Initial Phase 2 Clinical Safety and Feasibility Data of Intradiscal Injections of Hypoxic Cultured Mesenchymal Stem Cells". The Poster, which was presented on February 4, 2024 by the Company's Vice President of Research and Development, Francisco Silva, at the Orthopaedic Research Society (ORS) 2024 Annual Meeting (the "ORS Annual Meeting"), describes preliminary 26–52 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. In the Press Release, the Company also announced again that it will hold a webcasted conference call with an associated slide presentation on February 5, 2024 at 8:30 a.m. ET to review the Poster. A copy of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The Company intends to use the Poster from time to time on and after February 4, 2024 in presentations about the Company's business. As indicated above, the Company used the Poster at the ORS Annual Meeting on February 4, 2024 and may use the Poster, possibly with modification, in other presentations to current and potential investors, lenders, creditors, insurers, vendors, customers, employees and others with an interest in the Company and its business.

The information contained in the Poster is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements that the Company may make by press release or otherwise from time to time. The Poster speaks as of the date of this Current Report on Form 8-K. While the Company may elect to update the Poster in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, the Company specifically disclaims any obligation to do so. The Poster is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Poster will also be posted in the Investor Relations section of the Company's website, www.biorestorative.com, for 90 days.

The information referenced under this Item 7.01 (including Exhibits 99.1 and 99.2 referenced in Item 9.01 below) of this Current Report on Form 8-K is being "furnished" under "Item 7.01. Regulation FD Disclosure" and, as such, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information set forth in this Current Report on Form 8-K (including Exhibits 99.1 and 99.2 referenced in Item 9.01 below) shall not be incorporated by reference into any registration statement, report or other document filed by the Company pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 **Financial Statements and Exhibits**.

(d) Exhibits.

Number	Description
99.1	Press release, dated February 5, 2024, issued by BioRestorative Therapies, Inc.
99.2	Poster
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIORESTORATIVE THERAPIES, INC.

Dated: February 5, 2024

By: /s/ Lance Alstodt
Lance Alstodt
President and CEO

BioRestorative Therapies Presents Preliminary Clinical Data from Phase 2 Study of BRTX-100 in Chronic Lumbar Disc Disease

— Preliminary data includes 26 and 52-week follow-up end points as part of ongoing Phase 2 trial —

— Company to host webcasted conference call today at 8:30am EST —

MELVILLE, N.Y., February 5, 2024 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative", "BRTX" or the "Company") (NASDAQ:BRTX), a clinical stage company focused on stem cell-based therapies, today announced the public availability of a poster, presented yesterday at the Orthopaedic Research Society (ORS) 2024 Annual Meeting, which describes 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 presented poster, titled "Autologous Stem Cell Therapy for Chronic Lumbar Disc Disease; Initial Phase 2 Clinical Safety and Feasibility Data of Intradiscal Injections of Hypoxic Cultured Mesenchymal Stem Cells" can be accessed on the Company's website at www.biorestorative.com under "Scientific Publications" in the Product Candidate section. During a webcasted conference call scheduled for 8:30am EST today, BioRestorative management will be available to discuss data from the presentation as well as provide a clinical update.

Previous clinical studies have demonstrated that the harsh microenvironment of the disc could impact cell dose viability and result in a non-efficacious or the worsening of clinical outcomes. Although this is blinded and early clinical data, it is important to note that the Visual Analog Scale, Oswestry Disability Index, Roland Morris Disability Questionnaire, and Functional Rating Index collected at weeks 26 and 52 post-injection demonstrated a positive trend compared to baseline. In addition to safety outcomes, changes to these pain and function scales compared to baseline are used by the U.S. Food and Drug Administration (FDA) to determine whether the trial will be allowed to proceed and ultimately gain Biologics License Application (BLA) approval.

"We are thrilled with the progress of our ongoing clinical development programs. With regard to the Phase 2 study investigating the use of BRTX-100 in the treatment of cLDD, we are strongly encouraged by the preliminary data presented at ORS 2024. The preliminary clinical data shows meaningful signals in patients enrolled in the study and, importantly, no notable safety signals," said Lance Alstodt, Chief Executive Officer of BioRestorative.

Conference Call & Webcast Information

BioRestorative management will host a webcasted conference call with an associated slide presentation today, February 5, at 8:30AM EST. To join the conference call via phone and participate in the live Q&A session, please dial 888-506-0062 (United States) or 973-528-0011 (International), participant access code 234972. The live webcast and audio archive of the presentation may be accessed on the investor section of the BioRestorative website at https://www.biorestorative.com/investor-relations/. An archived replay will be available for approximately 90 days following the event.

About BRTX-100

BRTX-100, a novel cell-based therapeutic engineered to target areas of the body that have little blood flow, is the Company's lead clinical candidate. The safety and efficacy of BRTX-100 in treating cLDD is being evaluated in a Phase 2, prospective, randomized, double-blinded and controlled study. A total of up to 99 eligible subjects will be enrolled at up to 16 clinical sites in the United States. Subjects included in the trial will be randomized 2:1 to receive either *BRTX-100* or control.

About BioRestorative Therapies, Inc.

BioRestorative Therapies, Inc. (www.biorestorative.com) develops therapeutic products using cell and tissue protocols, primarily involving adult stem cells. Our two core programs, as described below, relate to the treatment of disc/spine disease and metabolic disorders:

• 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 a cell-based therapy candidate to target obesity and metabolic disorders using brown adipose (fat) derived stem cells to generate brown adipose tissue ("BAT"). 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.

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.

CONTACT:

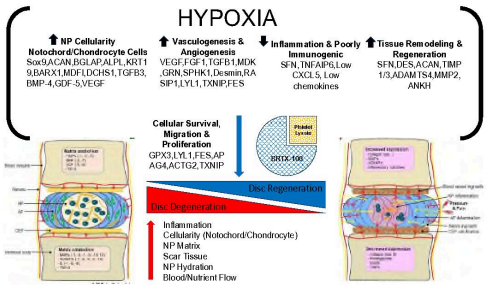
Email: ir@biorestorative.com

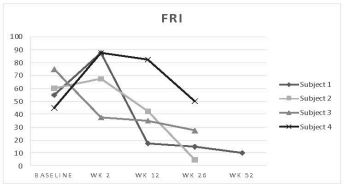
Autologous Stem Cell Therapy for Chronic Lumbar Disc Disease; Initial Phase 2 Clinical Safety and Feasibility Data of Intradiscal Injections of Hypoxic Cultured Mesenchymal Stem Cells

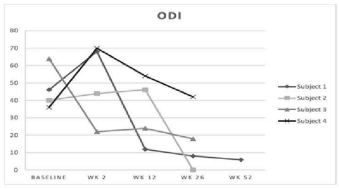
Francisco Silva[1], Scott Bainbridge[1,2], Jason Lipetz[3]
[1]BioRestorative Therapies, Melville, NY, [2]Denver Spine and Pain Institute, Greenwood Village, CO, [3]Northwell Health Spine, East Meadow, NY
Disclosure: Francisco Silva, Jason Lipetz own equity in BioRestorative Therapies

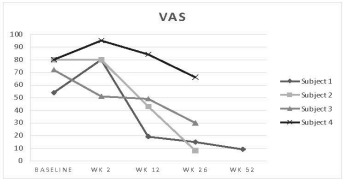
INTRODUCTION: Chronic lumbar disc disease (cLDD) is a common, often confounding problem for patients and physicians. In the United States (U.S.), at least 80% of adults experience at least one episode of lower back pain during their lifetime. Low back pain is the most common cause of disability among Americans between 45 and 65 years of age and imposes the highest economic burden on the U.S. healthcare system. The standard of care for treating cLDD involves conservative non-surgical approaches or surgical interventions that target symptomatic relief and musculoskeletal stabilization. Currently, there is no clinical therapy targeting the reversal of disc degeneration or that addresses intervertebral disc cell homeostasis. Hypoxic culturing of mesenchymal stem cells (MSCs) produces many desirable biological effects that may impact the therapeutic activity of the MSCs post-transplant into the limited nutrient, low oxygen tension microenvironment of the degenerative disc. The use of this cell-based biologic for treating cLDD is a promising therapeutic strategy, due to their *ex vivo* hypoxic engineering and known orthobiologic, immuno-modulatory and anti-inflammatory properties. Here we report early blinded clinical safety and feasibility data in subjects (n=4) treated as part of the safety run-in cohort in a Phase 2 trial to targeting cLDD (NCT04042844).

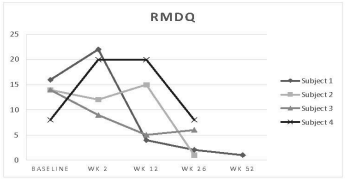
METHODS: An ongoing Phase 2, double-blind randomized, saline-controlled, multicenter study designed to evaluate the safety and efficacy of a single intradiscal injection of autologous hypoxic cultured mesenchymal stem cells (hMSCs) combined with autologous platelet lysate in subjects with single disc chronic lumbar disc disease (cLDD) with 12-month safety and efficacy and 24-month long-term safety endpoints. Approximately 99 subjects will be randomized 2:1 to the treatment or control arm. Because this is a first-in-man study a safety run-in component with a 3+3 design for the initial subjects dosed with 40 × 10^6 cells was performed. To accomplish this, the randomization scheme was shifted to a 3:1 allotment of intradiscal hMSCs or saline. A 14-day safety follow-up period elapsed between dosing of each of the first four (4) subjects. Dosing of each subject in the safety run-in component was reviewed by an independent medical monitor which included physical examinations, laboratory values and reported AEs/SAEs, pain and function scales used; Visual Analog Scale (VAS), Oswestry Disability Index (ODI), Short Form Survey (SF-12), Roland Morris Disability Questionnaire (RMDQ), and Functional Rating Index (FRI). At the end of dosing of all four subjects an independent medical monitor and the Data and Safety Monitoring Board (DSMB) reviewed the data in order to determine whether any AEs/SAEs were associated to dose limiting toxicities (DLTs). This study is sponsored and funded by BioRestorative Therapies and conducted under an FDA Investigational New Drug application and IRB approved.











RESULTS: All four subjects underwent successful dosing of either a 40 × 10^6 cell dose of hMSCs or saline at a 3:1 randomization ratio. Two subjects experienced a moderate (Grade 2) adverse event, one possibly related to the investigational product and one not related to the investigational product, and one of two subjects that experienced an AE also experienced a severe (Grade 3) adverse event not related to the investigational product and one event definitely related to the study therapy. All AEs were non-serious and related to expected increased post-procedural back pain. The two remaining subjects of the safety run-in cohort did not experience any AEs/SAEs during and post dosing of either a 40 × 10^6 cell dose of hMSCs or saline. DSMB review of the clinical data of the safety run-in component of this trial demonstrated that there were no AEs/SAEs that were related to dose limiting toxicities, and that the Phase 2 trial using a 40 × 10^6 cell dose of hMSCs could continue without any protocol changes and enter into open enrollment across all 16 sites in the U.S. Patient reported outcomes VAS, ODI, SF-12, RMDQ, and FRI used to measure pain and function were also collected during the safety run-in period.

DISCUSSION: This safety run-in component of our ongoing Phase 2 clinical trial using autologous hypoxic cultured MSCs formulated with autologous platelet lysate demonstrated for the first time that a cell dose of 40 × 10^6 did not result in AEs/SAEs that were related to dose limiting toxicity. Previous clinical studies have demonstrated that the harsh microenvironment of the disc could impact high cell dose viability and result in a non-efficacious or the worsening of clinical outcomes. Although this is blinded and early clinical data it is important to note that the VAS, ODI, SF-12, RMDQ, and FRI collected during the safety run-in period at week 26 and 52 post injection demonstrated a positive trend and did not show significant worsening of pain and function.