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): November 6, 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 November 6, 2024, BioRestorative Therapies, Inc. (the "Company") issued a press release (the "Press Release") announcing that additional preliminary 26–52 week blinded data from the ongoing Phase 2 clinical trial of BRTX-100 in subjects with chronic lumbar disc disease will be presented by Francisco Silva, Vice President of Research and Development, at the Orthopaedic Research Society (ORS) Philadelphia Spine Research Society (PSRS) 7th International Spine Research Symposium, taking place November 10-14, 2024 in Skytop, Pennsylvania. The presentation is scheduled for November 13, 2024. In the Press Release, the Company also announced that it will hold a webcasted conference call with an associated slide presentation on November 13, 2024 at 4:30 p.m. ET to review the BRTX-100 presentation, as well as review its third quarter 2024 financial results and provide a business update. A copy of the Press Release is furnished as Exhibit 99.1 hereto.

The information in the Press Release is being furnished, not filed, pursuant to this Item 7.01. Accordingly, the information in the Press Release will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this Report with respect to the Press Release is not intended to, and does not, constitute a determination or admission by the Company that the information in this Report with respect to the Press Release is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01 **Financial Statements and Exhibits**.

(d) Exhibits.

Number	Description
99.1	Press release, dated November 6, 2024, issued by BioRestorative Therapies, Inc.
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: November 6, 2024

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

Exhibit 99.1

BioRestorative Therapies to Present New Clinical Data at the ORS PSRS 7th International Spine Research Symposium

– New blinded preliminary safety and efficacy data from the ongoing Phase 2 clinical trial of BRTX-100 to be described in podium presentation on November 13, 2024 –

– Data will be on a significantly higher number of study subjects over a longer period of time than has been presented previously —

– Company will also release its third quarter 2024 financial results and provide a business update on November 12, 2024 –

– Webcasted conference call to review both the BRTX-100 data and Q3-2024 financial results scheduled for November 13th at 4:30pm EST –

MELVILLE, N.Y., November 06, 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, today announced that new preliminary 26–52 week blinded data from the ongoing Phase 2 clinical trial of BRTX-100 in subjects with chronic lumbar disc disease ("cLDD") will be presented by Francisco Silva, Vice President of Research and Development, at the Orthopaedic Research Society (ORS) Philadelphia Spine Research Society (PSRS) 7th International Spine Research Symposium, taking place November 10-14, 2024 in Skytop, Pennsylvania. BioRestorative will also make the data available through a public announcement.

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 placebo (sham injection).

The podium presentation, titled "Stem Cell Therapy for Chronic Lumbar Disc Disease: Phase 2 Clinical Safety and Feasibility Data of Intradiscal Injections of Hypoxic Cultured Mesenchymal Stem Cells," is scheduled for Wednesday, November 13, 2024 between 9:40am-10:00am EST.

"We are excited by this opportunity to share new and additional preliminary data from the ongoing Phase 2 clinical trial of BRTX-100 in the treatment of cLDD," said Lance Alstodt, Chief Executive Officer of BioRestorative. "In February 2024, we were strongly encouraged that the Visual Analog Scale, Oswestry Disability Index, Roland Morris Disability Questionnaire, and Functional Rating Index collected at 26 and 52 weeks after injection indicated a positive trend compared to the baseline with the first four patients enrolled in the study. Now at ORS PSRS 2024 next week, we expect to reveal blinded data on a significantly higher number of study subjects over a longer period of time."

Conference Call & Webcast Details

BioRestorative management will host a webcasted conference call with an associated slide presentation at 4:30pm EST on Wednesday, November 13, 2024 to review the BRTX-100

presentation, as well as review its third quarter 2024 financial results and provide a business update. To join the conference call via phone and participate in the live Q&A session, please dial 877-545-0320 (United States) or 973-528-0002 (International), participant access code 823128. The live webcast (with slides) 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 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, 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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