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): June 13, 2025

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
BRTX	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 June 13, 2025, BioRestorative Therapies, Inc. (the "Company") issued a press release (the "Press Release") announcing that Francisco Silva, Vice President of Research and Development, presented new preliminary, blinded clinical data from approximately 30 patients enrolled in its ongoing Phase 2 trial of BRTX-100 for the treatment of chronic lumbar disc disease ("cLDD") at the prestigious International Society for Stem Cell Research ("ISSCR") 2025 Annual Meeting, taking place June 11-14, 2025 in Hong Kong. Mr. Silva's presentation was entitled Stem Cell Therapy for Chronic Lumbar Disc Disease: Phase 2 Clinical Safety and Feasibility Data of Intradiscal Injections of Hypoxic Cultured Mesenchymal Stem Cells. A copy of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

At the ISSCR Annual Meeting, certain presentation materials (the "Presentation Materials") were be utilized by Mr. Silva. The Company intends to use the Presentation Materials from time to time on and after the date of this Current Report on Form 8-K in presentations about the Company's business. As indicated above, the Company used the Presentation Materials at the ISSCR Annual Meeting on June 13, 2025 and may use the Presentation Materials, 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 Presentation Materials 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 Presentation Materials speak as of the date of this Current Report on Form 8-K. While the Company may elect to update the Presentation Materials 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 Presentation Materials are furnished as Exhibit 99.2 to this Current Report on Form 8-K and are incorporated herein by reference. The Presentation Materials will also be posted on the Company's website, www.biorestorative.com, under "Scientific Publications" in the Product Candidate section, 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 June 13, 2025, issued by BioRestorative Therapies, Inc.
99.2	Presentation Materials
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: June 13, 2025

By: /s/ Robert Kristal
Robert Kristal
Chief Financial Officer

Exhibit 99.1

BioRestorative Reports Compelling Preliminary Data for FDA-Fast-Tracked BRTX-100 – an Autologous Stem Cell Therapy to Treat Chronic Lumbar Disc Disease

– The International Society for Stem Cell Research ("ISSCR") 2025 Annual Meeting is the world's foremost gathering of stem cell and regenerative medicine leaders –

– Updated data presented at ISSCR 2025 demonstrates >50% improvement in pain and function in a significant portion of cLDD subjects –

– Number of evaluated subjects increases by more than two-fold since last update —

MELVILLE, N.Y., June 13, 2025 (GLOBE NEWSWIRE) – BioRestorative Therapies, Inc. ("BioRestorative," "BRTX" or the "Company") (NASDAQ: BRTX), a clinical-stage regenerative medicine company developing stem cell-based therapies for serious musculoskeletal conditions, today announced the presentation of promising preliminary blinded data from the first 36 subjects in its ongoing Phase 2 clinical trial of BRTX-100, an autologous stem cell therapy for chronic lumbar disc disease (cLDD). This data was shared at the prestigious ISSCR 2025 Annual Meeting in Hong Kong by Francisco Silva, Vice President of Research and Development.

The U.S. Food and Drug Administration ("FDA") is requiring at least a greater than 30% improvement in function in the Oswestry Disability Index ("ODI") and a greater than 30% reduction in pain on the Visual Analog Scale ("VAS") in determining whether the clinical trial will be allowed to proceed and ultimately gain Biologics License Application (BLA) approval.

Key Highlights:

- **Patient Numbers Growing:** The number of subjects evaluated has increased from 15 to 36 since the Company's last press release — an important milestone toward full Phase 2 enrollment (up to 99 subjects).
- **Compelling Clinical Signals:**
  - Over 74% of subjects showed >50% improvement in function (ODI) by 52 weeks;
  - Over 72% of subjects reported >50% reduction in pain (VAS) by 52 weeks;
  - Combined >50% improvement in both ODI and VAS measures was achieved by a meaningful portion of subjects across all timepoints.
- **Excellent Safety Profile:** No serious adverse events (SAEs) or dose-limiting toxicities reported between 26 and 104 weeks at the target dose (40 million cells).
- **Strengthening Data:** Each new data analysis has outperformed prior releases, highlighting an upward trend in efficacy markers.

The following is a detailed breakdown of the subjects that had greater than 50% improvement in function, as measured by ODI, greater than 50% decrease in pain, as measured by VAS, and greater than 50% improvement in both ODI and VAS:

Week	Percentage of Subjects With >50% Average Improvement in ODI	Percentage of Subjects With >50% Average Improvement in VAS	Number of Subjects With >50% Average Improvement in Both ODI and VAS
Baseline	0.00%	0.00%	0/36
12	67.57%	73.82%	5/25
26	74.04%	76.94%	6/15
52	74.63%	72.35%	8/10
104	75.13%	68.54%	2/4

“With every new analysis, our confidence grows that BRTX-100 is positioned to meet and potentially exceed the FDA’s functional and pain reduction thresholds,” said Lance Alstodt, Chief Executive Officer of BioRestorative. “We are excited by the trajectory of this material milestone and its potential to address a massive unmet need in chronic lower back pain — one of the largest global healthcare burdens. We believe this data moves us one step closer to bringing a much-needed, non-surgical therapeutic option to market and should add to further value enhancing inflection points in the near-term.”

The data were presented as part of the Clinical Innovations track at ISSCR 2025, an event that attracts the world’s top stem cell and regenerative medicine researchers, clinicians, and investors.

About the BRTX-100 Phase 2 Trial

BRTX-100 is a novel, autologous cell-based therapy designed to treat patients suffering from painful lumbosacral disc degeneration. The Phase 2 trial is a randomized, double-blinded, placebo-controlled study that will enroll up to 99 subjects at 16 leading U.S. sites. Subjects are randomized 2:1 to receive either BRTX-100 or placebo via a minimally invasive outpatient procedure.

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 also operate a commercial BioCosmeceutical platform:

• 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. We have also obtained U.S. Food and Drug Administration (“FDA”) Investigational New Drug (“IND”) clearance to evaluate BRTX-100 in the treatment of chronic cervical discogenic pain.

• 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 IND-enabling studies, with the aim of pioneering 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.

CONTACT:

Stephen Kilmer
Investor Relations
Direct: (646) 274-3580
Email: skilmer@biorestorative.com

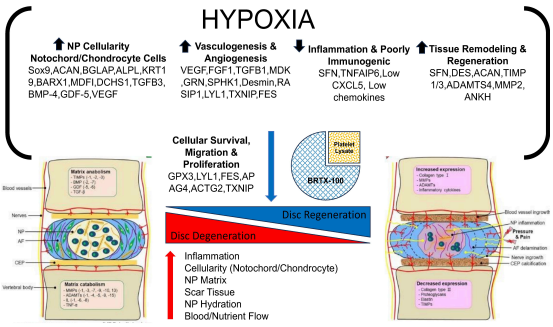
Exhibit 99.2

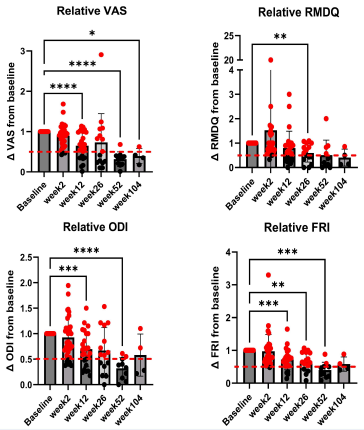
Stem Cell Therapy for Chronic Lumbar Disc Disease: Phase 2 Clinical Safety and Feasibility Data of Intradiscal Injections of Hypoxic Cultured Mesenchymal Stem Cells

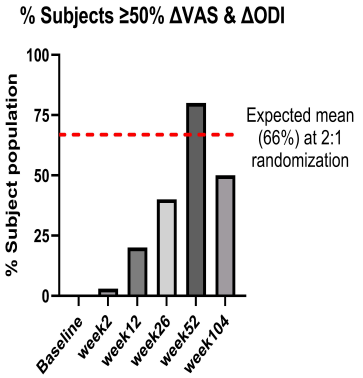
Francisco Silva[1], Jason Lipetz[2]
[1]BioRestorative Therapies, Melville, NY, [2]Northwell Health Spine, East Meadow, NY
Disclosure: Francisco Silva, Jason Lipetz own equity in BioRestorative Therapies

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. Once it was determined that the subject met all inclusion and exclusion criteria, bone marrow and blood were collected. Hypoxic cultured mesenchymal stem cells were expanded and formulated with autologous platelet lysate. The mesenchymal stem cells were cryopreserved and shipped to the clinical sites using a temperature controlled shipper for injection. An intradiscal injection of 40 × 10^6 cells was performed in 36 subjects. Follow up was performed on all subjects at week 2, week 12, week 26, week 52 and week 104. At each follow up visit physical examinations, laboratory values and reported AEs/SAEs to determine if there were any dose limiting toxicities (DLTs), 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). This study is sponsored and funded by BioRestorative Therapies and conducted under an FDA Investigational New Drug application and IRB approved.







DISCUSSION: Our primary end point is safety and our secondary end point is at least a 30% improvement in **both** VAS and ODI at week 52. This blinded data of 36 subjects in 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 and appears to be trending towards demonstrating efficacy.

RESULTS: All 36 subjects underwent successful dosing of either a 40 × 10^6 cell dose of hMSCs or a sham injection at a 2:1 randomization ratio. At 26 weeks 46.672% of patients report > 50% improvement **VAS score** (n=15). At 52 weeks 90% of patients report > 50% Improvement **VAS score** (n=10) At 104 weeks 75% of patients report > 50% Improvement **VAS score** (n=4).12 week avg. improvement > 50% = 73.82%, 26 week avg. improvement > 50% = 76.94%, 52 week avg. improvement > 50% = 72.35%, 104 week avg. improvement > 50% = 68.54%. At 26 weeks 40% of patients report > 50% improvement **ODI score** (n=15). At 52 weeks 80% of patients report > 50% Improvement **ODI score** (n=10). At 104 weeks 50% of patients report > 50% Improvement **ODI score** (n=4). 12 week avg improvement > 50% = 67.57%, 26 week avg improvement > 50% = 74.04%, 52 week avg improvement > 50% = 74.63%, 104 week avg improvement > 50% = 75.13%. **Patients with ≥ 50% improvement (RMDQ)** Baseline = 0/36 (0%), week 2 = 3/34 (8.8%) week 12 = 9/25 (36%), week 26 = 7/15 (46.67%), week 52 = 6/10 (60%) week 104 =3/4 (75%). **Patients with ≥ 50% improvement (FRI) .** Baseline = 0/36 (0%), week 2 = 1/34 (2.94%), week 12 = 4/25 (16%), week 26 = 4/15 (26.67%), week 52 = 8/10 (80%), week 104 =2/4 (50%). There were AEs/SAEs related to dose limiting toxicities of a 40 × 10^6 cell dose. **Patients with ≥ 50% improvement in both VAS and ODI** Baseline = 0/36 (0%), week 2 = 1/34 (2.94%), week 12 = 5/25 (20%), week 26 = 6/15 (40%), week 52 = 8/10 (80%), week 104 =2/4 (50%)