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): May 14, 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
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 2.02. Result of Operations and Financial Condition.

On May 14, 2025, BioRestorative Therapies, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2025 (the "Press Release"). The Press Release also provided a business update and included details with regard to the conference call to be held to discuss the first quarter results and business update. A copy of the Press Release is furnished as Exhibit 99.1 hereto.

The information contained in the Press Release 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 information furnished with this Item 2.02, including Exhibit 99.1, shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

See Item 2.02 above.

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 unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this Current Report on Form 8-K 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 Current Report on Form 8-K 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 May 14, 2025, 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: May 14, 2025

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

Exhibit 99.1

BioRestorative Therapies Reports First Quarter 2025 Financial Results and Provides Business Update

MELVILLE, N.Y., May 14, 2025 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative", "BRTX" or the "Company") (NASDAQ:BRTX), a regenerative medicine innovator focused on stem cell-based therapies and products, today reported financial results for the first quarter ended March 31, 2025 and provided an update on its business.

"We have continued to execute well across our business, including the achievement of key clinical program milestones, since the start of 2025," said Lance Alstodt, the Company's Chief Executive Officer. "Moving forward, we remain focused on aggressively executing our growth strategy while carefully managing our resources, and we see many potential value enhancing inflection points ahead."

Recent Highlights

Corporate

- In April, the Company confirmed that it currently faces no material exposure to newly imposed U.S. tariffs. BioRestorative believes that its 'made-in-America' production and manufacturing strategy, combined with its use of domestic inputs, enables it to effectively manage costs amid global supply chain shifts.

- Also in April, BioRestorative's Chief Executive Officer, Lance Alstodt, was interviewed during the Benzinga All-Access Show. An archive of the interview can be accessed here.

Disc/Spine Program

- In a February podium presentation at the Orthopaedic Research Society ("ORS") Annual Meeting, BioRestorative's Vice President of Research and Development, Francisco Silva, presented 26–52 week blinded data from the first 15 patients with chronic lumbar disc disease ("cLDD") enrolled in the ongoing Phase 2 clinical trial of BRTX-100. No serious adverse events (SAEs) were reported, and there was no dose ($40X10^6$ cells) limiting toxicity at 26-52 weeks. Preliminary blinded Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) data collected at weeks 26 and 52 post-injection demonstrated an exceptionally positive trend compared to baseline. Furthermore, 52 week comparison of MRI images to baseline appear to demonstrate morphological changes, such as increase in T2 signal (hydration), decrease in protrusion size, as well as resolutions of annular tears, potentially demonstrating disc microenvironment remodeling as a result of cLDD treatment with BRTX-100.

- Also in February 2025, the U.S. Food and Drug Administration ("FDA") granted Fast Track designation to the BRTX-100 program for the treatment of cLDD. Fast Track designation reflects the positive preliminary Phase 2 safety and efficacy data reported to date, and may lead to Priority Review and Accelerated Biologics License Application (BLA) Approval for BRTX-100.

- On the heels of granting BRTX-100 Fast Track designation for cLDD, the FDA cleared the Company's Investigational New Drug (IND) application for BRTX-100 for the treatment of chronic cervical discogenic pain (cCDP), expanding BioRestorative's advanced clinical pipeline for BRTX-100 to include treatment of both chronic lower back and neck pain.

- Last week, preliminary 26-, 52- and 104-week blinded preliminary data from the first 15 patients with cLDD enrolled in the ongoing Phase 2 clinical trial of BRTX-100 was presented by Mr. Silva at the International Society for Cell & Gene Therapy (ISCT) 2025 Annual Meeting. The preliminary blinded data continues to be in-line to meet the primary safety endpoint of the study, and preliminary efficacy trends continue as well.

Metabolic Program

- In March 2025, the European Patent Office issued a Notice of Allowance for a new patent application (European Patent Appl. No. 20798130.9) covering key aspects of BioRestorative's allogeneic, off-the-shelf ThermoStem® metabolic disease platform.

- The Company's previously reported substantive discussions with an undisclosed commercial stage regenerative medicine company with regard to a potential license of BioRestorative's ThermoStem® metabolic intellectual property are continuing; however, no assurances can be given that a license agreement will be entered into whether on commercially reasonable terms or otherwise.

Summary First Quarter 2025 Financial Results

First quarter 2025 revenues were $25,000, compared to $35,000 in the same period last year. First quarter 2025 deferred revenues were $150,000, compared to $nil in the first quarter of 2024.

For the three months ended March 31, 2025, the Company had a loss from operations of $4.8 million, compared to a loss from operations of $4.1 million for the comparable period of 2024.

The Company's first quarter 2025 net loss was $5.3 million, or $0.64 per share, compared to a net loss of $2.2 million, or $0.33 per share, for the first quarter of 2024. The change was primarily due to a gain on the exchange of warrants in Q1-2024.

Cash used in operating activities in the first quarter of 2025 was $2.8 million as compared to $2.3 million in the first quarter of 2024.

The Company ended the 2025 first quarter in a strong financial position, with cash, cash equivalents, and investments held in marketable securities of $9.1 million, with no outstanding debt.

For complete financial results, please see BioRestorative's filings at www.sec.gov, and on the Company's website at www.biorestorative.com under "SEC Filing" in the Investors and Media section.

Conference Call Details

BioRestorative management will host a webcasted conference call with an associated slide presentation today at 4:30pm EDT to review its first quarter 2025 financial results and provide a business update. To join the conference call via telephone and participate in the live Q&A session,

please dial 888-506-0062 (United States) or 973-528-0011 (International), participant access code 924151. The call will also be webcast live and archived on the investor section of the Company's website at www.biorestorative.com under "News & Events/IR Calendar"' in the Investors section.

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 FDA 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 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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