
**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): March 27, 2025

BioRestorative Therapies, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction
of incorporation)

001-37603

(Commission
File Number)

30-1341024

(IRS Employer
Identification No.)

**40 Marcus Drive
Melville, New York**

(Address of principal executive offices)

11747

(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 March 27, 2025, BioRestorative Therapies, Inc. (the “Company”) issued a press release announcing that its financial results for the year ended December 31, 2024 will be released after market close on March 27, 2025 (the “Press Release”). The Press Release included details with regard to a conference call to be hosted by the Company’s management following the release. On the call, the Company’s management will review the financial results and provide a business update. A copy of the Press Release is furnished as Exhibit 99.1 hereto.

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 March 27, 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: March 27, 2025

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



BioRestorative Therapies Reports 2024 Financial Results and Provides Business Update

MELVILLE, N.Y., March 27, 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 year ended December 31, 2024 and provided an update on its business.

"2024 was a transformative year for BioRestorative, highlighted by significantly improved financial performance and meaningful clinical program advancement," said Lance Alstodt, BioRestorative's Chief Executive Officer. "Looking ahead, we remain focused on aggressively executing our growth strategy, and very much look forward to updating investors as we progress."

Recent Highlights

DEVELOPMENT

- In November, BioRestorative received a provisional license from the New York State Department of Health ("NYSDOH") for the processing of allogeneic (non-autologous) donor tissue material for the isolation, expansion and cryopreservation of various cell types, including stem cells, for medical research. Previously, the Company was licensed by the NYSDOH to act as a tissue bank for the processing of mesenchymal stem cells derived from autologous donors only.

Disc/Spine Program

- In a podium presentation at the 2025 Orthopaedic Research Society ("ORS") Annual Meeting in February, the Company'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 (40×10^6 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 an increase in T2 signal (hydration), a 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.
 - On the heels of the ORS presentation, BioRestorative announced that 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. The Company hopes that such designation will lead to Priority Review and Accelerated Biologics License Application (BLA) Approval for BRTX-100.
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- Also in February, 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 the treatment of both chronic lower back and neck pain.

Metabolic Program

- 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.
- BioRestorative also continues to explore a first-in-human clinical trial for its ThermoStem® metabolic platform technology.

COMMERCIAL

BioCosmeceuticals

- The Company derived \$300,000 in revenue from BioCosmeceuticals in 2024.

Summary 2024 Results

Total revenue for the year ended December 31, 2024 was \$401,000, a 175% increase over \$146,000 for 2023.

The Company's 2024 loss from operations was \$11.6 million, a 24% improvement from a loss of operations of \$15.2 million for 2023.

The Company's 2024 net loss was \$9.0 million, or \$1.16 per share, a 14% improvement from a net loss of \$10.4 million, or \$2.47 per share, for 2023.

Cash used in operating activities in 2024 was \$8.2 million.

The Company ended the year in a strong financial position, with cash, cash equivalents, and investments held in marketable securities of \$10.7 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 2024 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 726526. The call will also be webcast live and archived on the investor section of the Company's website at www.biorestorative.com under "Events" in the Investors and Media 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 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. 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 as a third party contract manufacturer, 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, 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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