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): August 13, 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 2.02. Result of Operations and Financial Condition.

On August 13, 2024, BioRestorative Therapies, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2024 (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 second quarter results. 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 August 13, 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: August 13, 2024

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

BioRestorative Therapies Reports Second Quarter 2024 Financial Results and Provides Business Update

MELVILLE, N.Y., August 13, 2024 (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 second quarter June 30, 2024 and provided an update on its business.

"We have had an exciting and productive first half of 2004 and are energized by the many potential value enhancing inflection points we see ahead," said Lance Alstodt, BioRestorative's Chief Executive Officer. "From an operating perspective, we are thrilled with our second quarter results, as we are seeing initial progress on our path to sustainable profitability."

Recent Highlights

DEVELOPMENT

- To support the launch of its new Regenerative Medicine section in July, the prestigious *Journal of Translational Medicine* named Francisco Silva, BioRestorative's Chief Scientist and Vice President of Research and Development, as its Section Editor. This peer-reviewed open-access journal had a 2021 impact factor of 8.440, ranking it among the top 3% of journals worldwide, according to Journal Citation Reports.

Disc/Spine Program

- In April, the Company announced U.S. Food and Drug Administration ("FDA") clearance of an important amendment to the protocol of the ongoing Phase 2 BRTX-100 study in chronic lumbar disc disease (cLDD), removing saline injection in the control arm of the study and replacing it with a sham injection. This positive change in the protocol brings additional safety to the trial's subject participants, and helps preclude the possibility of transient clinical outcomes in the control group.

- BioRestorative continues to work toward achieving completion of patient enrollment in the Phase 2 BRTX-100 study, as well as providing additional preliminary data updates, before the end of 2024.

Metabolic Program

- In May, the Company revealed the development of a novel exosome-based biologic program targeting obesity. BioRestorative currently anticipates initiating the formal FDA process for this ThermoStem®-based therapeutic candidate by filing a Drug Master File ("DMF") in the third quarter of 2024. The DMF is expected to facilitate the timely initiation of first-in-human clinical studies.

- On the heels of that announcement, BioRestorative reported that it had begun to engage in substantive discussions with an undisclosed commercial stage regenerative medicine company with regard to a potential license of BioRestorative's allogeneic, off-the-shelf ThermoStem® metabolic intellectual property. Those discussions are continuing; however, no assurances can be given that a license agreement will be entered into whether on commercially reasonable terms or otherwise.

- In July, BioRetorative received a notice of allowance from the Japanese Patent Office for patent application No. 2021-564135 related to the ThermoStem® platform. This, the fifth Japanese patent to issue for the technology platform, covers a method of making three-dimensional brown adipose derived stem cell aggregates in the absence of differentiation medium. The Company believes that continuing to proactively expand its already formidable ThermoStem® intellectual property estate will help drive licensing opportunities and long-term market exclusivity for this core development program.

COMMERCIAL

BioCosmeceuticals

- In April, the Company entered into an exclusive five (5)-year commercial agreement with Cartessa Aesthetics, LLC ("Cartessa"), pursuant to which BioRestorative will supply pre-set minimum quantities of finished vials of a proprietary cell-based biologic serum to Cartessa annually as private label under Cartessa's Chronos ExoCR mark.

- BioRestorative began to derive some initial product revenue from the exclusive supply agreement with Cartessa in the second quarter, and expects that its BioCosmeceuticals product sales revenues will increase in future periods as it executes on its contract and expands its pipeline with Cartessa.

Summary Second Quarter 2024 Results

For the quarter ended June 30, 2024, the Company had a loss from operations of $2.5 million, a 19% year-over-year improvement from the $3.1 million loss for the comparable period of 2023, and a 39% improvement sequentially from the $4.1 million loss in the first quarter of 2024.

The Company's net loss for the 2024 second quarter was $4.0 million, or $0.50 per share, a 28% year-over-year improvement from the loss of $5.7 million, or $1.47 per share, for the comparable period in 2023.

Cash used in operating activities in the second quarter of 2024 was $1.9 million.

The Company ended the second quarter in a very strong financial position, with cash, cash equivalents, and marketable securities of $14.7 million, with no outstanding debt, as of June 30, 2024.

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 will host a conference call to discuss the 2024 second quarter financial results today at 4:30 p.m. ET. The dial-in number for the conference call is 1-877-545-0523 (United States) or 1-973-528-0016 (International); access code 151026. Participants are asked to dial in approximately 10 minutes before the conference call is scheduled to begin. The call can also be accessed via webcast on the Company's website at www.biorestorative.com/investor-relations under "Events." The webcast will be archived and accessible for approximately 90 days.

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 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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