UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 15, 2024

OS THERAPIES INCORPORATED
(Exact name of registrant as specified in its charter)

Delaware	001-42195	82-5118368
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

115 Pullman Crossing Road, Suite 103 Grasonville, Maryland	21638
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (410) 297-7793

N/A
(Former name or former address, if changed since last report.)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	OSTX	NYSE American

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. □

CURRENT REPORT ON FORM 8-K

OS Therapies Incorporated

November 15, 2024

Item 2.02. Results of Operations and Financial Condition.

On November 15, 2024, OS Therapies Incorporated, an ADC and immunotherapy research and clinical-stage biopharmaceutical company, issued a press release announcing its financial results for the third quarter ended September 30, 2024.

A copy of the press release is furnished with this report as Exhibit 99.1. Such information, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under 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.

Exhibit Number	Description
99.1	Press Release issued by OS Therapies Incorporated on November 15, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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.

OS THERAPIES INCORPORATED

Dated: November 15, 2024

By: /s/ Paul A. Romness, MPH
Name: Paul A. Romness, MPH
Title: President and Chief Executive Officer

Exhibit 99.1

OS Therapies Reports Third Quarter 2024 Financial Results and Provides Business Update

- Topline Data from Phase 2b clinical trial of OST-HER2 in Osteosarcoma expected to be released in December 2024

New York, NY, November 15, 2024 – OS Therapies, Inc. (NYSE-A: OSTX) ("OS Therapies" or "the Company"), a clinical-stage cancer immunotherapy and antibody drug conjugate biotechnology company, today reported financial results for the third quarter of 2024 ended September 30, 2024 and provided a business update.

"The third quarter was pivotal for OS Therapies as we completed our initial public offering and finished dosing the final patient enrolled in our Phase 2b clinical trial of OST-HER2 in resected, recurrent osteosarcoma," said Paul Romness, MHP, Chairman & CEO of OS Therapies. "We are now looking forward to releasing topline data in December and then engaging with the FDA regarding getting this potentially life-saving cancer immunotherapy to patients that have no other potential treatment options as quickly as possible."

OS Therapies' lead product candidate, OST-HER2, is a cancer immunotherapy biologic drug candidate comprised of HER2 bioengineered form of the bacteria Listeria monocytogenes (Lm) that infects HER2 presenting cancer cells and triggers a strong immune response against cancer cells expressing HER2. This off-the-shelf treatment is designed to prevent metastasis, delay recurrence, kill primary tumors expressing HER2 and increase overall survival. The Company has fully enrolled and finished treating all patients in a potentially pivotal Phase IIb clinical trial in recurred, resected osteosarcoma, dosing 41 patients with OST-HER2 at 21 clinical trial sites across the United States. OST-HER2 has received Rare Pediatric Disease Designation (RPDD) from the Food and Drug Administration (FDA), and Fast Track and Orphan Drug Designations by the FDA and European Medicines Agency (EMA). OS Therapies is in active discussions with FDA regarding Breakthrough Therapy Designation for OST-HER2. Upon any Biologics Licensing Authorization (BLA) from the FDA for OST-HER2 in osteosarcoma, the Company will be granted a Priority Review Voucher based upon the RPDD. OST HER2 has also completed a Phase 1 clinical trial primarily in breast cancer patients, in addition to strong preclinical data demonstrating efficacy on a standalone basis and in combination with HER2-targeting therapeutic antibodies such as Herceptin®.

Third Quarter Corporate Highlights:

- Completed treatment phase for Phase 2b clinical trial of OST-HER2 in resected, recurrent osteosarcoma
- Accepted into Johnson & Johnson - JLABS

Financial Highlights for the Third Quarter:

The Company is a pre-revenue biotechnology company. The Company anticipates beginning to generate revenue through the sale of a priority review voucher it expects to be issued by FDA upon approval of its rare pediatric disease designated drug candidate OST-HER2 and licensing rights to its products and product candidates as they achieve upcoming de-risking clinical and regulatory milestones.

Loss from Operations:

The Company recorded a net operating loss of $2.875 million in the third quarter of 2024 compared to an operating loss of $2.006 million in the third quarter of 2023. The increase in net loss was largely due to the expenses associated with the initial public offering. Net loss per share in the third quarter of 2024 was $0.18 on 15.897 million weighted average shares outstanding compared to the third quarter of 2023 where the Company delivered a loss of $0.38 per share on 5.340 million weighted average shares outstanding.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any securities.

For more information, please see the Company's website at www.ostherapies.com

About OS Therapies

OS Therapies is a clinical stage oncology company focused on the identification, development and commercialization of treatments for Osteosarcoma (OS) and other solid tumors. OST-HER2, the Company's lead asset, is an immunotherapy leveraging the immune-stimulatory effects of Listeria bacteria to initiate a strong immune response targeting the HER2 protein. The Company has completed enrollment for a 41-patient Phase 2b clinical trial of OST-HER2 in resected, recurrent osteosarcoma, with results expected in the fourth quarter of 2024. OST-HER2 has completed a Phase 1 clinical study primarily in breast cancer patients, in addition to showing strong preclinical efficacy data in various models of breast cancer. OST-HER2 has been conditionally approved by the U.S. Department of Agriculture for the treatment of canines with osteosarcoma. In addition, OS Therapies is advancing its next generation Antibody Drug Conjugate (ADC) platform, known as *tunable ADC* (tADC), which features tunable, tailored antibody-linker-payload candidates. This platform leverages the Company's proprietary silicone linker technology, enabling the delivery of multiple payloads per linker. For more information, please visit www.ostherapies.com.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of the federal securities laws. These forward-looking statements and terms such as "anticipate," "expect," "intend," "may," "will," "should" or other comparable terms involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. OS Therapies' drug development efforts, clinical trial results, patient enrollments, FDA regulatory approvals, designations, and intellectual property protections. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, including those described under the caption "Risk Factors" and elsewhere in the prospectus filed with the SEC relating to the offering and that actual results may differ materially from those indicated by such forward-looking statements. Any forward-looking statements contained in this press release speak only as of the date hereof, and, except as required by the federal securities laws, OS Therapies specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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