

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): August 15, 2024

OS THERAPIES INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-42195
(Commission File Number)

82-5118368
(IRS Employer
Identification No.)

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

21638
(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

August 15, 2024

Item 2.02. Results of Operations and Financial Condition.

On August 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 second quarter ended June 30, 2024.

A copy of the press release is furnished with this report as Exhibit 99.1. Such information, including the Exhibit attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, 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 August 15, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: August 15, 2024

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

OS Therapies Reports Second Quarter 2024 Financial Results

- Successful IPO that raised \$6.4 million on July 31, 2024, without issuing any warrants, occurred after the end of the second quarter and is not reflected in reported financials
- Conversion of all reported outstanding preferred shares and debt into equity occurred as of the date of the IPO and is not reflected in the reported financials
- After IPO and preferred shares and debt conversion share issuances, there are 20.85 million common shares outstanding, with 1.86 million common shares available to be traded
- Underwriter lockups limit potential for deposit or trading of remaining 18.99 million common shares
- As of the date of the IPO, Company had no debt, cash runway for lead program OST-HER2 into mid-2025

Rockville, MD, August 15, 2024 – OS Therapies, Inc. (NYSE: OSTX) (“OS Therapies” or “the Company”), an ADC and Immunotherapy research and clinical-stage biopharmaceutical company, today reported financial results for the second quarter of 2024 ended June 30, 2024.

As of the date of our successful initial public offering (IPO) that occurred on July 31, 2024 on the NYSE American stock exchange, the Company successfully converted all of its outstanding preferred shares and debt into equity, raising \$6.4 million in gross proceeds that provides the Company with cash runway through mid-2025, and received the support from the vast majority of its shareholders who signed 6-month underwriter lockup agreements, crucially through the fourth quarter 2024 readout of the fully-enrolled human Phase 2b clinical trial in resected, recurrent osteosarcoma, allowing the IPO to occur without the issuance of any warrants. The Company now has sufficient capital to meet the key objectives for its lead program OST-HER2, including the completion of the Phase 2b human osteosarcoma trial, as well as the completion of a pivotal safety study that would allow for the conditional approval already received by the US Department of Agriculture for OST-HER2 in canine osteosarcoma to be converted into a full approval, paving the way for commercialization nationwide. There are approximately 1,000 new human osteosarcoma diagnoses over 10,000 canine osteosarcoma diagnoses reported annually in the United States.

Second Quarter Corporate Highlights:

- Interim data from the ongoing, fully enrolled clinical trial of OST-HER2 in resected, recurrent osteosarcoma with results from 39 out of the 41 patients from the fully enrolled clinical study. The final results with all 41 patients will be released in the fourth quarter of 2024
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Subsequent Event Highlights:

- Positive safety data from Phase 1 clinical study of OST-HER2 primarily in breast cancer and positive pre-clinical data in multiple therapeutic models of breast cancer demonstrating anti-primary tumor and anti-metastasis properties on a standalone basis and synergistic effect with HER2 targeting antibodies
- Successful IPO raising \$6.4 million in gross proceeds without the issuance of warrants
- Formation of Patient Advocacy Advisory Board in Osteosarcoma
- Formation of Scientific and Medical Advisory Board in Osteosarcoma

Financial Highlights for the Second Quarter:

The Company is a pre-revenue biotechnology company. The Company anticipates beginning to generate revenue through the sale of 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 \$1.557 million in the second quarter of 2024 compared to an operating loss of \$2.505 million in the second quarter of 2023. The decrease in net loss was largely due to the majority of patients enrolled in the Phase 2b OST-HER2 clinical trial having completed the 1-year treatment phase and moving into the observation only phase evaluating overall survival. Net loss per share in the second quarter of 2024 was \$0.26 on 5.991 million weighted average shares outstanding compared to the second quarter of 2023 where the Company delivered a loss of \$0.47 per share on 5.340 million weighted average shares outstanding.

OS Therapies' pipeline lead OST-HER2 is a *Lm* vector-based off-the-shelf Immunotherapy intended to prevent metastasis, delay recurrence, and increase overall survival. The Company has screened/enrolled 54 and dosed 41 patients per protocol of its AOST-2121 Phase 2b clinical trial in recurrent, resected osteosarcoma testing OST-HER2 (*Listeria monocytogenes*). There are 21 clinical trial sites open across the United States. OST-HER2 has received Rare Pediatric Disease Designation (RPDD) from the FDA and Fast Track and Orphan Drug Designations from the FDA and European Medicines Agency (EMA). OS Therapies is seeking Breakthrough Therapy Designation for OST-HER2 for osteosarcoma from the FDA based on data from its Phase IIb clinical trial. Upon any BLA from the FDA for OST-HER2 in osteosarcoma, the Company will be granted a Priority Review Voucher based upon the RPDD. In 2023, the US FDA approved 28 drugs and 12 biologics for the treatment of orphan diseases.

OST-HER2 has 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®. The Company intends to pursue therapeutic development of OST-HER2 in breast cancer following FDA approval for OST-HER2 in osteosarcoma.

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. 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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