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): May 16, 2025

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

May 16, 2025

Item 2.02. Results of Operations and Financial Condition.

On May 16, 2025, OS Therapies Incorporated, a clinical-stage cancer immunotherapy and ADC biotechnology company, issued a press release announcing its financial results for the quarter ended March 31, 2025.

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 May 16, 2025.
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: May 16, 2025

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

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

- Feeback from Type D FDA Meeting expected by mid-June 2025 to confirm statistical analysis methods to be used to support pending Accelerated Approval, Regenerative Medicine Advanced Therapy & Breakthrough Therapy designation requests
- Completed Phase 2b trial data analysis using methods agreed to by FDA to be presented at MIB Factor on June 28, 2025
- Company remains on track for Q3 2025 BLA filing for OST-HER2 in the prevention of recurrent, fully resected, lung metastatic pediatric osteosarcoma

New York, NY, May 16, 2025 – OS Therapies Inc. (NYSE-A: OSTX) ("OS Therapies" or "the Company"), a clinical-stage cancer immunotherapy and antibody drug conjugate biotechnology company, today reported first quarter 2025 financial results ended March 31, 2025 and provided a business update.

"The first quarter of 2025 was a crucial execution quarter for OS Therapies, as we announced positive data from our OST-HER2 Phase 2b clinical trial in the prevention of recurrent, fully resected, lung metastatic pediatric osteosarcoma and will be leveraging this data to seek Accelerated Approval from the FDA," said Paul Romness, MHP, Chairman & CEO of OS Therapies. "Additionally, we consolidated ownership of the *listeria* immunotherapy platform, adding three clinical stage and eight preclinical assets to our pipeline, and extended the exclusivity protection for its commercial runway into 2040 with the issuance of a new manufacturing patent. Moreover, we secured research coverage from Wall Street analysts who have shown significant interest in the revival of the *listeria* immunotherapy platform. We have started important interactions with the FDA, with a view towards an Accelerated Approval, and will begin more substantially engaging with the osteosarcoma community for its support in the FDA process. We believe we are well positioned to bring the first new treatment for osteosarcoma to market in over 40 years."

"As outlined in communications surrounding our 2024 Annual Report on Form 10-K, the first quarter saw some significant one-time expenses related to closing out the treatment phase of the Phase 2b trial, as well as start-up costs for regulatory preparations ahead of our submission," said Chris Acevedo, Chief Financial Officer of OS Therapies. "Those one-time expenses are now largely behind us, and we have dramatically reduced our burn rate, positioning us to operate into mid-2026."

First Quarter 2025 Corporate Highlights:

- Reported positive data for our Phase 2b clinical trial of OST-HER2 in the prevention of recurrent, fully resected, lung metastatic osteosarcoma, a rare pediatric indication
- Announced agreement to acquire three clinical stage, eight preclinical stage and all intellectual property surrounding the*listeria* cancer immunotherapy platform from Ayala Pharmaceuticals

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- Initiated manufacturing protocols to support the commercial launch of OST-HER2
- Received a Notice of Allowance from the US Patent & Trademark Office related to the pending issuance of a patent protecting a new commercial manufacturing process for the *listeria* cancer immunotherapy platform into 2040
- Formed subsidiary OS Drug Conjugates (OSDC) to create a focused business development opportunity for the Company's proprietary pH-sensitive tunable Antibody Drug Conjugates and tunable Drug Conjugates platform
- Secured a Scientific Advice Meeting with the UK Medicines and Healthcare products Regulatory Agency to discuss seeking approval in the UK for OST-HER2 in the prevention of recurrent, fully resected, lung metastatic osteosarcoma
- Received the keynote presentation at the osteosarcoma community's leading conference MIB Factor for June 28, 2025 in Salt Lake City, Utah

Second Quarter 2025 Progress to Date and Future Milestones

Progress to Date:

- Secured a Type D meeting with the FDA to gain alignment on the statistical analysis plan for the OST-HER2 trial needed to support pending Accelerated Approval, Regenerative Medicine Advanced Therapy and Breakthrough Therapy designation requests
- Completed the acquisition of the *listeria* cancer immunotherapy clinical, preclinical and IP assets from Ayala Pharmaceuticals
- Announced positive data from canine osteosarcoma trials expanding the potential use of OST-HER2 into the prevention of amputation and control of lung metastases
- Reported the formal issuance of the patent protecting proprietary commercial manufacturing methods for the listeria cancer immunotherapy platform
- Formed subsidiary OS Animal Health to focus on commercialization of OST-HER2 in canine osteosarcoma

Upcoming 2025 Milestones:

- Feedback from Type D meeting with the FDA on the proposed statistical analysis plan of the OST-HER2 osteosarcoma program that will be used to support pending Accelerated Approval, Regenerative Medicine Advanced Therapy and Breakthrough Therapy designation requests
- Presentation of the OST-HER2 Phase 2b osteosarcoma program data analyzed based upon FDA feedback at MIB Factor on June 28, 2025
- End of Phase 2 Meeting with FDA in Q3 2025 to review OST-HER2 Phase 2b osteosarcoma program data
- Projected BLA submission in Q3 2025 for OST-HER2 in the prevention of recurrent, fully resected, lung metastatic pediatric osteosarcoma
- Summer 2025 Scientific Advice Meeting (SAM) with MHRA for OST-HER2 osteosarcoma program, ILAP application submission and MHRA Conditional Marketing Authorisation application & decision

- EMA National Competent Authority Scientific Advice Meeting Request (Medicines Evaluation Board, Netherlands) for OST-HER2 osteosarcoma program, EMA PRIME, EMA-FDA Parallel Scientific Advice application and EMA Conditional Marketing Authorisation application & decision

- USDA meeting for OST-HER2 canine osteosarcoma program, conditional approval and initiation of pivotal clinical studies in preventive and therapeutic applications of OST-HER2 in osteosarcoma via subsidiary OS Animal Health

Loss from Operations:

The Company recorded a net operating loss of $3.876 million in the first quarter of 2025 compared with a net operating loss of $1.490 million in the first quarter of 2024. The increase in net loss was largely due to expenses associated with closing of the OST-HER2 Phase 2b osteosarcoma trial and expenses associated with initiating regulatory affairs activities associated with seeking Accelerated Approval with US FDA for OST-HER2 in osteosarcoma. Net loss per share in the first quarter of 2025 was $0.18 on 21.249 million weighted average shares outstanding compared to first quarter of 2024 where the Company delivered a loss of $0.25 per share on 5.991 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.

About OS Therapies

OS Therapies is a clinical stage oncology company focused on the identification, development, and commercialization of treatments for osteosarcoma 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. OST-HER2 has received Rare Pediatric Disease Designation (RPDD) from the US Food & Drug Administration and Fast-Track and Orphan Drug designations from the US FDA and European Medicines Agency. The Company has demonstrated positive data in its Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma demonstrating statistically significant benefit in the 12-month event free survival (EFS) primary endpoint of the study. The Company anticipates submitting a BLA to the US FDA for OST-HER2 in osteosarcoma in 2025 and, if approved, would become eligible to receive a Priority Review Voucher that it could then sell. OST-HER2 has completed a Phase 1 clinical study primarily in breast cancer patients, in addition to showing 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) and Drug Conjugates (DC), known as*tunable ADC* (tADC), which features tunable, tailored antibody-linker-payload candidates. This platform leverages the Company's proprietary silicone Si-Linker and Conditionally Active Payload (CAP) 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. Those statements include statements regarding the intent, belief or current expectations of OS Therapies and members of its management, as well as the assumptions on which such statements are based. OS Therapies cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this news release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to the approval of OST-HER2 by the US FDA and other risks and uncertainties described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's most recent Annual Report on Form 10-K and other subsequent documents the Company files with the Securities and Exchange Commission. 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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