March 31, 2026

OS Therapies Completes Submission of Biomarker & Clinical Data for U.S. FDA Pre-BLA Meeting, Reports Full Year 2025 Financial Results and Provides Business Update

- *December 2025 Type C Meeting confirmed immune biomarkers suitability to establish surrogate clinical efficacy that could support BLA under Accelerated Approval Pathway*
- *Pre-specified clinical outcomes data correlates with Immune biomarker signature*
- *Company positioned to review completed Phase 2b clinical & biomarker data and confirmatory Phase 3 trial protocol with U.S. FDA, EMA and U.K. MHRA in 2Q/26*
- *Company expects to initiate confirmatory Phase 3 trial in Australia in 3Q/26*
- *Company anticipates receiving a BLA under Accelerated Approval Program in the U.S. and Conditional Marketing Authorizations in Europe and in the U.K. in 2H/26*

New York, New York--(Newsfile Corp. - March 31, 2026) - **OS Therapies, Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, today announced that it has completed the submission on clinical and biomarker data from the Company's Phase 2b clinical trial of OST-HER2 in the prevention of delay of recurrent, fully resected, pulmonary metastatic osteosarcoma to the U.S. Food & Drug Administration in preparation for the Company's upcoming Pre-BLA Meeting, reported full-year 2025 financial results for the period ended December 31, 2025 and provided a business update. The Company expects the Pre-BLA Meeting to occur in May 2026.

"The biomarker and clinical data packages are now with FDA as we begin preparations for our upcoming Pre-BLA Meeting with FDA," said Robert Petit, PhD, Chief Medical & Scientific Officer of OS Therapies. "In December 2025, FDA agreed that OST-HER2 had a strong safety profile and further aligned with the Company around pre-specified immune biomarker strategies being suitable to serve as surrogate clinical efficacy endpoints based upon well-established science. Now that the data is with FDA, we are focused on completing our pending Marketing Authorization Application requests to U.K.'s Medicines and Healthcare products Regulatory Agency and the European Medicines Agency in April 2026 with the expectation that we will receive approval decisions in each of these three jurisdictions in the second half of 2026."

2025 Year in Review

"2025 marked a year of focused regulatory alignment and strong operational execution at OS Therapies," said Paul Romness, MPH, CEO of OS Therapies. "We began the year by reporting highly encouraging 12-month event free survival data (EFS) in January of 2025 from our Phase 2b trial of OST-HER2 in the prevention of delay of recurrent, fully resected,

pulmonary metastatic osteosarcoma that met the pre-specified threshold to be eligible for further assessment. Shortly thereafter, we announced the acquisition of the entire *listeria monocytogenes* cancer immunotherapy platform from Ayala Pharmaceuticals, thus eliminating $20 million in development and commercial milestone payments while reducing net royalties owed to 1.5%. Following the FDA Oncology Center of Excellence's August 2025 elevation of Overall Survival (OS) to a primary endpoint in many oncology clinical trial settings via new guidance, the Company reported 75% 2-year overall survival in October of 2025."

Mr. Romness continued, "On the heels of FDA and Osteosarcoma Institute's October 2025 workshop reviewing the current status of osteosarcoma research, particularly the strong utility of spontaneous canine osteosarcoma as a predictive model for human disease, the Company aligned with FDA on the use of biomarkers identified in clinical trials of OST-HER2 in canine osteosarcoma as pre-specified surrogate clinical efficacy endpoints for efficacy assessment of the Phase 2b trial data, for the purposes of assessing a Biologics License Application (BLA) under the Accelerated Approval Program (Accelerated Approval). Additionally, we made significant progress with the European Medicines Agency (EMA) and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) on the path to gaining Conditional Marketing Authorisations (CMAs) in those jurisdictions. As we also update on the progress made throughout the first quarter of 2026, we have now completed the clinical and biomarker study reports from the Phase 2b trial in preparation for upcoming meetings with FDA, EMA, MHRA and the Australian Therapeutics Goods Administration (TGA) to evaluate the safety and efficacy of OST-HER2, as well as upcoming meetings to review the proposed Phase 3 clinical protocol that we intend to initiate in Australia in the third quarter."

OST-HER2 has received Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the FDA, and ODD, FTD and ATMP from the EMA. Under the RPDD program, if the Company receives a Biologics License Application (BLA) in the United States, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell, subject to market conditions. The most recent publicly disclosed PRV transaction occurred in February 2026 at a reported value of $205 million; however, there can be no assurance that the Company would realize a comparable value, if any, in connection with any future PRV sale. The Company is seeking to obtain a BLA under the Accelerated Approval Program for OST-HER2 in osteosarcoma in the second half of 2026.

Full-Year 2025 Corporate Highlights:

- Phase 2b clinical trial of OST-HER2 achieves EFS with statistical significance
- Phase 2b clinical trial of OST-HER2 achieves elevated Overall Survival (OS) endpoint with statistical significance
- Successful Type C, End of Phase 2 and 2nd Type C Meetings with U.S. FDA
- Successful Scientific Advice Meetings (SAMs) and Pre-Marketing Authorisation Application (MAA) meetings with EMA and MHRA
- U.S. OST-HER2 commercialization partnership with Eversana
- Acquisition of *listeria monocytogenes* assets from Ayala Pharmaceuticals
- Issuance of patents covering commercial manufacturing of OST-HER2 and rest of *listeria monocytogenes* platform, extending patent runway into 2040

- Documentary 'Shelter Me: Cancer Pioneers' featuring OST-HER2-treated human and canine patients nominated for 2 Daytime Emmy Awards
- Positive data for OST-HER2 in fully resected metastatic osteosarcoma, unresectable pulmonary osteosarcoma and unresected primary osteosarcoma
- Non-proprietary name for OST-HER2 granted by World Health Organization
- FDA PDUFA fee waiver granted

First Quarter 2026 Highlights to Date:

- Raised $5.5 million in capital
- Reauthorization of Pediatric Priority Review Voucher (PRV) program
- Positive pre-specified biomarker data from Phase 2b clinical trial
- Initiation and completion of BLA filing with FDA for OST-HER2
- EMA grants OST-HER2 Advanced Therapy Medicinal Product (ATMP) designation
- OS Animal Health subsidiary files Form S-1 for spinoff transaction to fund commercialization of OST-HER2 in canine osteosarcoma
- Positive Patient Advocacy and Key Opinion Leader (KOL) Meetings aligning around regulatory and clinical pathways

Pending 2026 Milestones:

- April 2026 meeting TAG to review Phase 2b data and Phase 3 protocol design
- 2Q/26 meetings with FDA, EMA and MHRA to review safety & efficacy data for OST-HER2 Phase 2b clinical trial to support accelerated market access requests (BLA in U.S., CMAs in Europe & U.K.)
- 2Q/26 meetings with FDA, EMA and MHRA to review proposed confirmatory Phase 3 protocol
- 2Q/26 complete OST-HER2 submissions of BLA for Accelerated Approval in U.S. and MAAs for CMAs in Europe and U.K.
- 2H/26 gain accelerated market access for OST-HER2 in the U.S. (BLA), Europe (CMA) and the U.K. (CMA)

Loss from Operations:

The Company recorded a net operating loss of $28.75 million in the year ended 2025 compared with a net operating loss of $8.82 million in 2024. The increase in net loss was largely due to the expenses associated with research and development, and general and administrative expenses. Net loss per share in the full year 2025 was $0.98 on 290235 million weighted average shares outstanding compared to full year 2024 where the Company delivered a loss of $1.28 per share on 6.950 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 (OS) and other solid tumors. The Company is the world leader in listeria-based cancer immunotherapies. 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 Orphan Drug Designation (ODD), Fast Track Designation (FTD) and Rare Pediatric Disease Designation (RPDD) from the U.S. Food & Drug Administration and has received ODD, FTD and ATMP from the European Medicines Agency. The Company reported 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 and the overall survival (OS) secondary endpoint. The Company anticipates receiving a Biologics License Application (BLA) from the U.S. FDA for OST-HER2 in osteosarcoma in 2026 and, if approved, would become eligible to receive a Priority Review Voucher that it could then sell. The Company also anticipates receiving Conditional Marketing Authorisations from the U.K.'s Medicines and Healthcare products Regulatory Agency and the EMA for OST-HER2 in 2026. 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. The Company also anticipates reading out data from a Phase 1b study of OST-504 in castration resistant prostate cancer in the first half of 2026.

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 press 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 U.S. FDA and other risks and uncertainties described in "Risk Factors" in the Company's most recent Annual Report on Form 10-K, most recent Quarterly Report on Form 10-Q 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.

OS Therapies Contact Information:

Investor Relations
Harrison Seidner, PhD
WaterSeid Partners
OSTX@waterseid.com

Public Relations
Stephanie Chen
Elev8 New Media
media@ostherapies.com

https://x.com/OSTherapies
https://www.instagram.com/ostherapies/
https://www.facebook.com/OSTherapies/
https://www.linkedin.com/company/os-therapies/

To view the source version of this press release, please visit
https://www.newsfilecorp.com/release/290639

SOURCE OS Therapies