

OS Therapies Provides OST-HER2 Metastatic Osteosarcoma Program Update and Announces Upcoming Conference Attendance

- *Management will participate at Jefferies Global Healthcare Conference, H.C. Wainwright Global Investment Conference, ROTH Healthcare Opportunities Conference*
- *Management and business development advisors will attend BioJapan*
- *Interim 3-year overall survival data, U.S. FDA Type C Statistical Methods meeting and U.K. MHRA Statistical Methods Scientific Advice Meeting expected in September 2026*
- *RMAT and Rolling Review decisions expected to follow U.S. FDA meeting*
- *Final 3-year overall survival data, U.S. FDA Pre-BLA Meeting, BLA submission, MHRA CMAA submission, and EMA CMAA submission expected in Q4 2026*
- *Confirmatory Phase 3 Clinical Trial Application to follow MHRA meeting for Q4 2026 trial commencement*
- *OS Animal Health to attend Moody Capital Disruptive Growth & Life Sciences Conference*

New York and Rockville, Maryland--(Newsfile Corp. - September 2, 2026) [**OS Therapies, Inc. \(NYSE American: OSTX\)**](#) ("**OS Therapies**" or the "**Company**") the world leader in gene-edited, Listeria-based cancer immunotherapies, today announced that its management team, its business development advisors and the management team of its wholly-owned subsidiary OS Animal Health will participate in upcoming conferences, and provided a program update for OST-HER2 in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma (the "Metastatic Osteosarcoma Program"):

- Jefferies Global Healthcare Conference: London - November 16-19, 2026
- H.C. Wainwright Global Investment Conference: New York - September 14-16, 2026
- ROTH Healthcare Opportunities Conference: New York - September 29, 2026
- BioJapan: Yokohama, Japan - October 7-9, 2026
- Moody Capital Disruptive Growth & Life Sciences: New York - September 9-10, 2026

OS Therapies management is scheduled to host one-on-one meetings with investors and strategic partnering attendees during these conferences. Investors and strategic partners interested in arranging one-on-one meetings should contact their respective institutional representative or the Company.

OS Therapies may attend additional investor, medical, scientific, partnering, or conferences in addition to the above.

OST-HER2 Pulmonary Metastatic Osteosarcoma Program Update

"We have reached a pivotal moment in the history of OS Therapies," said Paul Romness, MPH, Chairman and CEO of OS Therapies. "The coming months are expected to define our path as a company as we look to translate the over 20 years and \$300 million of investment in our listeria monocytogenes cancer immunotherapy platform into its first commercial product that we expect to reach patients in 2027. Following regulatory interactions expected throughout the month of September 2026 with the U.S. Food & Drug Administration (FDA), the U.K. Medicines and Healthcare products Regulatory Agency (MHRA), and the European Medicines Agency (EMA), we expect to submit regulatory approval requests for early market access in the U.S., U.K., Europe and Australia. We expect minutes from both the FDA Type C Statistical Methods Meeting and the MHRA Statistical Methods Scientific Advice Meeting in October 2026. Additional rounds of regulatory meetings are expected throughout the rest of the fourth quarter of 2026, followed by FDA, MHRA and EMA regulatory decisions."

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 BLA in the United States, it will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell. The [most recent PRV sale occurred in August 2026 for \\$220 million](#). However, there can be no assurance that the Company would realize a comparable value, if any, in connection with any future PRV sale. OS Therapies has completed resubmission of a Regenerative Medicine Advanced Therapy (RMAT) request and the Company's Commissioner's National Priority Review Voucher (CNPV) letter of intent has been accepted by FDA. The Company intends to request a Rolling Review of the ongoing Biologics License Application (BLA) under the Accelerated Approval Program following its upcoming mid-September 2026 FDA Type C Statistical Methods Meeting. OS Therapies is seeking to obtain a BLA under the Accelerated Approval Program in the U.S. and Conditional Marketing Authorization Applications (CMAAs) in the Europe, the U.K. and Australia for OST-HER2 in metastatic osteosarcoma in the fourth quarter of 2026.

OS Animal Health Update

OS Animal Health (OSAH) has submitted a meeting request to the U.S. Department of Agriculture (USDA) to gain alignment on the path to reinstating the Company's previous conditional approval for OST-HER2 in canine osteosarcoma. OSAH expects the meeting to occur in the fourth quarter of 2026 and thereafter expects to launch a crowdfunding campaign.

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 gene-edited, 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 is designed to target two mutated extracellular epitopes and one mutated intracellular epitope of the HER2 oncogene, requiring only one of these three epitopes to be present in a tumor (or micro-metastasis) to trigger the desired immune response. 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 Advanced Therapy Medicinal

Products (ATMP) from the European Medicines Agency.

The Company reported positive data in its Phase 2b clinical trial of OST-HER2 in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma, demonstrating clinically significant benefit in the 12-month event free survival (EFS) primary endpoint of the study and the overall survival (OS) secondary endpoint. The Company is seeking 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 Authorisation Applications 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 was previously conditionally approved by the U.S. Department of Agriculture for the treatment of canines with osteosarcoma. The Company has also completed dosing in a Phase 1 study of OST-504 for castration-resistant prostate cancer.

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 silicon 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 regarding future expectations, plans, prospects or performance, as well as any other statements that are not historical facts, may constitute forward-looking statements within the meaning of the federal securities laws. Forward-looking statements are generally identified by words such as "anticipate," "believe," "could," "expect," "intend," "may," "plan," "potential," "should," "will" and similar expressions, although not all forward-looking statements contain these words. These statements are based on the current expectations and assumptions of OS Therapies and its management and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the Company's expectations regarding its cash runway; the timing, amount and receipt of VAT refunds and R&D tax credits; the Company's ability to obtain additional financing on acceptable terms or at all; the timing and outcome of regulatory submissions and potential approval of OST-HER2 by the U.S. Food and Drug Administration and applicable foreign regulatory authorities; and other risks and uncertainties described under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and in its other filings with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date of this press release, and OS Therapies undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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