August 19, 2025

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

- U.S. FDA ("FDA") confirms OST-HER2 meets biological definition of Regenerative Medicine Advanced Therapy (RMAT)
- FDA issues OST-HER2 BLA number in preparation for Accelerated Approval submission following End of Phase 2 Meeting
- FDA End of Phase 2 Meeting scheduled for August 27, 2025 to review Phase 2b clinical trial in the prevention or delay of recurrent, pulmonary metastatic osteosarcoma
- Statistically significant 12-month Event Free Survival and interim 2-year Overall Survival and strong safety data in Phase 2b trial drives global accelerated/conditional approval pathways
- Commercial partnership with Eversana positions OST-HER2 for possible U.S. launch in first half of 2026
- $4.2 million capital raise, closed July 11, 2025 via warrant exercise inducement and exchange offering, extends cash runway into mid-2026
- NYSE American-listed OSTX included in the Russell Microcap, Russell Microcap Value and Russell Microcap Growth indexes

New York, New York--(Newsfile Corp. - August 19, 2025) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), a clinical-stage cancer immunotherapy and antibody drug conjugate biotechnology company, today reported second quarter 2025 financial results ended June 30, 2025 and provided a business update.

"The Company gained significant momentum in the second quarter as we began to make meaningful clinical and regulatory progress on our path towards bringing the first new treatment for osteosarcoma to market in the United States in the last 40 years," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "Now midway through the third quarter, we have updated interim 2-year overall survival data readout that shows a statistically significant benefit for OST-HER2 treated patients, coupled with the final 12-month Event Free Survival ("EFS") that also shows statistically significant benefit for OST-HER2 treated patients, from our Phase 2b trial of OST-HER2 in the prevention or delay of recurrence in recurrent, fully resected, pulmonary metastatic osteosarcoma. The congruence between the overall survival and EFS data gives our clinical and regulatory teams confidence that we are on strong footing as we march towards our goal of receiving a Biologics Licensing Application ("BLA") by the U.S. Food and Drug Administration ("FDA") for OST-HER2 under the Accelerated Approval Program ("Accelerated Approval"). Importantly, our U.S. commercial partnership with Eversana positions us to be able to bring OST-HER2 to osteosarcoma patients in the first half of 2026."

Mr. Romness continued, "So long as we receive a BLA for OST-HER2 prior to September 30, 2026, the Company is eligible to be granted a priority review voucher ("PRV"), as a result

of OST-HER2's rare pediatric disease designation, that it intends to subsequently sell. Given that the most recent publicly disclosed PRV sale transaction was valued at $160 million in June 2025 versus a May 2025 PRV transaction that was valued at $155 million, we believe that the PRV market is likely to continue to see an increase in value moving forward."

"Additionally, we have made progress internationally with our recent Innovative Licensing and Access Pathway ("ILAP") submission, which formally begins the regulatory process for OST-HER2 with the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA") following a successful Scientific Advice Meeting ("SAM"), during which we were advised that MHRA recommends a synchronization of the approval process with the FDA via Project Orbis within 30 days of the BLA submission. We have also scheduled an October 2025 rapporteur meeting with the European Medicines Agency ("EMA") as the starting point for the approval process with Europe," noted Mr. Romness.

Second Quarter 2025 Corporate Highlights:

- Reported final EFS data (35% vs. 20%, p = 0.0197) showing a statistically significant benefit from the Company's 40 patient Phase 2b clinical trial for OST-HER2-treated patients in the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma when compared with historical control at MIB Factor
- Strong safety profile with 0 patients having experienced grade 4 or grade 5 treatment-associated adverse events
- Entered into osteosarcoma U.S. commercial partnership with Eversana and initiated logistics and distribution state licensing process to support an expected launch in the first half of 2026
- Granted new U.S. Patent & Trademark Office patent providing exclusivity for the new commercial manufacturing process for the *listeria* cancer immunotherapy platform through 2040
- Submitted International Nonproprietary Name request to World Health Organization for OST-HER2 in preparation for international regulatory approvals, with approved name(s) expected in the third quarter of 2025 and final branded name upon BLA submission
- Completed acquisition of the *listeria* cancer immunotherapy platform from Ayala Pharmaceuticals, including 4 clinical-stage and 8 preclinical-stage immunotherapy candidates, significantly expanding the Company's pipeline
- Formed subsidiary OS Animal Health to further strategic alternatives for the use of OST-HER2 in canine osteosarcoma following the announcement of positive data from canine osteosarcoma trials conducted at the University of Pennsylvania School of Veterinary Medicine, expanding the potential uses of OST-HER2 beyond osteosarcoma metastasis prevention to include the prevention of amputation and control of pulmonary metastases

Third Quarter 2025 Progress to Date and Future Milestones

Progress to Date:

- In correspondence regarding the Company's Regenerative Medicines Advanced Therapy (RMAT) and Breakthrough Therapy Designation (BTD) requests, the FDA confirmed OST-HER2 met the biological criteria to qualify as a "Regenerative Medicine Advanced Therapy" and indicated the FDA's intent to synchronize clinical safety and

efficacy data review for the RMAT and BTD requests with the Company's pending Accelerated Approval request
- FDA issued BLA number for OST-HER2 in preparation for the anticipated OST-HER2 BLA filing following the Company's August 27, 2025 End of Phase 2 Meeting
- Reported updated interim (27 patient) 2-year overall survival data (66.6% vs. 40%, p = 0.0046) showing a statistically significant benefit for OST-HER treated in the Company's Phase 2b clinical trial of OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma when compared with control
- Submitted ILAP to MHRA following successful SAM meeting, and received advice to synchronize U.S. and U.K. regulatory approval processes via Project Orbis
- Granted rapporteur meeting with EMA to begin regulatory approval process in Europe
- Closed warrant exercise inducement and exchange offering, raising $4.2 million in gross proceeds via the cash exercise of warrants expiring in 2029 with an exercise price of $1.12 and issuance of an equal number of warrants expiring in 2030 with an exercise price of $3.00 and a forced exercise provision when the price of the Company's common stock reaches $9.00, and providing cash runway into mid-2026
- NYSE American-listed OSTX common stock included in the Russell Microcap, Russell Microcap Value and Russell Microcap Growth indexes
- Entered into At-The-Market (ATM) offering sales agreement with B. Riley Securities and JonesTrading, enabling the Company to raise up to $18 million in gross proceeds through the sale of its common stock
- Shelter Me: Cancer Pioneers documentary featuring OST-HER2 treated human and canine patients nominated for 2 Daytime Emmy awards

Upcoming 2025 Milestones:

- End of Phase 2 Meeting with FDA scheduled for August 27, 2025 regarding the OST-HER2 osteosarcoma program that is anticipated to provide the Company with the necessary insight to allow it to begin a rolling BLA submission
- Projected initiation of BLA submission in late Q3 2025 for OST-HER2, targeting the prevention of recurrent, fully resected, lung metastatic pediatric osteosarcoma following End of Phase 2 Meeting with FDA
- Rapporteur meeting with EMA scheduled for October 2025
- Potential regulatory approval for OST-HER2 in the prevention or delay or recurrent, pulmonary metastatic osteosarcoma in the U.S. and U.K. as early as year-end 2025

Loss from Operations:

The Company recorded a net operating loss of $4.537 million in the second quarter of 2025, compared with a net operating loss of $1.557 million in the second quarter of 2024. The increase in net loss was largely due to expenses associated with U.S. and international regulatory activities related to the OST-HER2 Phase 2b osteosarcoma program. Net loss per share in the second quarter of 2025 was $0.19 on 25.114 million weighted average shares outstanding, compared to second quarter of 2024 where the Company delivered a net loss of $0.26 per share on 5.991 million weighted average shares outstanding.

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. OST-HER2 has received Rare Pediatric Disease Designation (RPDD) from the U.S. Food & Drug Administration and Fast-Track and Orphan Drug designations from the U.S. FDA and 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. The Company anticipates submitting a Biologics Licensing Application (BLA) to the U.S. 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 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
stephanie@elev8newmedia.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/263049

SOURCE OS Therapies