May 16, 2025

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

- Feedback from Type D FDA Meeting expected by mid-June 2025 to confirm statistical analysis methods 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--(BUSINESS WIRE)-- **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 and other regulatory authorities," 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. We extended the exclusivity protection for its commercial runway into 2040 with the issuance of a new manufacturing patent. Additionally, we have 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, with the Osteosarcoma community supporting in the ongoing 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
- 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 on or before June 16, 2025
- 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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