March 31, 2025

OS Therapies Reports Full Year 2024 Financial Results and Provides Business Update

- Full data from OST-HER2 Phase 2b osteosarcoma trial, including synthetic control arm data being developed at the request of FDA to support a Breakthrough Therapy Designation request, to be presented at MIB Factor in June 2025
- Rolling BLA submission expected to begin thereafter in order to gain regulatory approval by year-end 2025, triggering issuance of a Priority Review Voucher (PRV)

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 full-year 2024 financial results ended December 31, 2024 and provided a business update.

"2024 was a transformative year for OS Therapies as we completed our initial public offering and finalized the treatment phase of our Phase 2b clinical trial in the prevention of recurrence in fully resected, lung metastatic osteosarcoma," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "In parallel, the Company entered into an agreement to acquire all of the listeria monocytogenes (*Lm*)-based assets from Ayala Pharmaceuticals, supported the development of additional data for OST-HER2 in canines and positioned the Company's tunable antibody drug conjugate (tADC) program for partnering. The Company remains primarily focused on gaining a Biologics Licensing Authorization (BLA) for OST-HER2 in osteosarcoma that would trigger the issuance of a Priority Review Voucher (PRV) that the Company expect to then divest in order to capitalize with non-dilutive capital to allow the Company to fully exploit the OST-HER2 immunotherapeutic candidate and the rest of the *Lm* platform."

"While historically, from 2021 to 2024, there were significant operating losses associated with the initiation, prosecution, and completion of the OST-HER2 clinical trial in recurrent, fully resected, metastatic osteosarcoma that used significant cash resources, going forward we expect a significantly reduced outlays beginning in the second quarter of 2025 now that one-time study costs were recognized in the first quarter of 2025," said Chris Acevedo, Chief Financial Officer of OS Therapies. "We have reduced our burn rate substantially such that we expect cash on hand to last the Company into 2026, through our projected BLA milestone and the related issuance of a PRV by the FDA that we intend to sell."

OS Therapies' lead product candidate, OST-HER2, is a cancer immunotherapy biologic drug candidate comprised of HER2 bioengineered form of the *Lm* that mimics a listeria infection of HER2 overexpressing cancer cells and triggers a strong, immune response against cancer cells expressing HER2. This off-the-shelf immunotherapy is designed to prevent metastasis, delay recurrence, kill primary tumors expressing HER2 and increase overall survival.

Full-Year 2024 Corporate Highlights:

- Completed treatment phase for Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma, a rare pediatric indication
- Announced Phase 1 adult safety data of OST-HER2, primarily in breast cancer patients
- Formed Scientific, Commercial and Patient Advocacy advisory boards
- Completed $6 million initial public offering (IPO) & simultaneously converted all then-outstanding debt to equity
- Completed $6 million private placement, providing sufficient capital into 2026 as a result of significantly reduced projected 2025 spend
- Developed 2 new tunable ADC therapeutic candidates
- Accepted into Johnson & Johnson – JLABS

2025 Progress to Date and Future Milestones

Progress to Date:

- Positive Phase 2b data for OST-HER2 clinical trial in recurrent, fully resected, lung metastatic osteosarcoma
- Agreement to acquire all *LM*-based Immuno-Oncology programs and IP assets from Ayala Pharmaceuticals, adding Phase 2 lung cancer and Phase 1 prostate cancer programs to pipeline, subject to closing conditions
- Initiated commercial-ready manufacturing of OST-HER2 in preparation for BLA submission
- Formed subsidiary OS Drug Conjugates and initiated review of strategic options for tunable Drug Conjugates (tDC) and tADC platform
- Scheduled meeting with United Kingdom’s Medicines and Healthcare products Regulatory Agency's (MHRA) Scientific Advice Meeting in the third quarter of 2025 for review of OST-HER2 immunotherapy candidate for osteosarcoma

Remaining Expected 2025 Milestones:

- Presentation of full clinical data from OST-HER2 Phase 2b osteosarcoma clinical trial, including new synthetic control and biomarker data
- End of Phase 2 Meeting with FDA for OST-HER2 osteosarcoma program, subsequent BLA submission and potential approval
- 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

Loss from Operations:

The Company recorded a net operating loss of $10.886 million in the year ended 2024 compared with a net operating loss of $7.916 million in 2023. The increase in net loss was

largely due to the expenses associated with our IPO. Net loss per share in the full year 2024 was $0.88 on 12.377 million weighted average shares outstanding compared to full year 2023 where the Company delivered a loss of $1.46 per share on 5.429 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. 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 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 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 grant of a priority review voucher 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 we file 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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