November 17, 2025

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

- Type C Meeting with US FDA set for December 11, 2025 to address key items following August 27, 2025 End of Phase 2 Meeting regarding Phase 2b clinical trial of OST-HER2: prevention or delay of recurrent, fully-resected pulmonary metastatic osteosarcoma
- US Biologics Licensing Application (BLA) and UK MHRA Marketing Authorization Application filings for OST-HER2 expected in January 2025 leveraging Project Orbis
- UK MHRA pre-Marketing Authorization Application (MAA) meeting scheduled for December 8, 2025; EMA pre-MAA meeting request now granted, awaiting scheduling
- $7.8 million warrant exercise inducement allowed for key one-time regulatory-related payments and provided Company with capital into late 2026 by delaying launch to 2027
- Company remains eligible to receive Priority Review Voucher (PRV) based on Pediatric Rare Pediatric Disease Designation (RPDD) for Osteosarcoma if approved by September 30, 2026

New York, New York--(Newsfile Corp. - November 17, 2025) -**OS Therapies Inc. (NYSE American: OSTX)** ("OS Therapies" or "the Company"), the world leader in listeria-based cancer immunotherapies, today reported third quarter 2025 financial results for the period ended September 30, 2025 and provided a business update.

"The next six to twelve months will be transformative for OS Therapies," said Paul Romness, MPH, Chairman & CEO of OS Therapies. "OST-HER2's recently reported strong 2-year overall survival data that allows the Company to align our regulatory strategy with FDA Draft Guidance August 18, 2025 'Approaches to Assessment of Overall Survival in Oncology Clinical Trials' for Industry. The Company expects to align on the expectations for our pending BLA for OST-HER2 under the Accelerated Approval Program at our December 11, 2025 FDA Type C Meeting. We expect to file the BLA in January 2026."

Mr. Romness continued, "We continue to harmonize our US FDA and UK Medicines and Healthcare products Regulatory Agency (MHRA) regulatory filings documentation so that we can quickly file the BLA and UK MAA based on the feedback from our December 8, 2025 UK MHRA and our December 11, 2025 US FDA meetings. 2026 revenue resulting from the regulatory approval for OST-HER2 is expected from the sale of the PRV that would be issued to the Company upon approval. As a result, delaying the launch to early 2027 is not expected to significantly impact 2026 earnings, with 2027 revenue expected to be comprised of US, UK and EU product sales. The Company has received an increase in compassionate use requests, primarily from clinical sites who participated in the Company's Phase 2b trial and will continue to support patient access when possible. Accelerated Approval for OST-HER2 in osteosarcoma would catalyze further clinical development in osteosarcoma and

other HER2-related cancers."

"The data we are generating with OST-HER2 in osteosarcoma are giving us hope that we can reduce and delay recurrence, allowing us to improve mortality rates significantly, along with quality of life for these primarily teen and young adult patients," said Dr. Robert Petit, Chief Medical & Scientific Officer for OS Therapies. "We are expecting biomarker data to be available for FDA and MHRA meetings that we hope will guide and support our post-market confirmatory clinical development program and market surveillance commitments. Additionally, with data soon forthcoming from our OST-504 Phase 1b program at Columbia University in castration resistant prostate cancer, we also see significant potential for our pipeline development beyond OST-HER2. We intend to seek FDA Platform Designation for our listeria cancer immunotherapy platform once we become eligible."

Third Quarter 2025 Corporate Highlights:

- Successful End of Phase 2 Meeting with US FDA, subsequent informal teleconference, and email correspondence to align key items for FDA requested December 2025 Type C Meeting
- Successful Scientific Advice Meeting with UK MHRA and subsequent information correspondence to align key items for invited December 2025 pre-MAA meeting
- Last patient enrolled in Phase 1b clinical trial for OST-504 Prostate completes last scheduled visit
- $7.8 million warrant exercise allowed for key one-time regulatory-related payments and provided Company with capital through mid-2026
- Termination of Equity Line of Credit replaced by At-The-Market (ATM) agreement with B. Riley and Jones Trading

Third Quarter 2025 Progress to Date and Future Milestones

Progress to Date:

- Reported Final 2-year Overall Survival Data (75% vs. 40%, $p < 0.0001$) showing a statistically significant benefit for OST-HER2 treated patients vs. historical control. Select sub analyses include:
  - 73.8% (19/26, 3 lost to follow-up) of patients with first pulmonary metastatic presentation vs. 30% natural history comparator ($p < 0.0001$) achieved 2-year overall survival with first metastatic presentation
  - 100% of patients (14/14, 1 lost to follow-up) who achieved 12-month event free survival achieved 2-year overall survival
  - 1-year Event Free Survival in patients who have previously had two or greater complete metastatic surgical resections: 50% (6/12, 0 lost to follow-up)
  - 2-year Overall Survival in patients who have previously had two or greater complete metastatic surgical resections : 80.0% (8/10, 2 lost to follow-up)
- Shelter Me: Cancer Pioneers documentary featuring OST-HER2 treated human and canine patients nominated for Anthem Awards
- Scientific Advice Meeting granted by European Medicines Agency
- The Company received $1.5 million after the September 30, 2025 period, primarily from the previously announced $7.8 million warrant exercise and inducement exchange offer
  - Available for operations in addition to the $1.9 million available from the

Company's balance sheet at the end of the third quarter 2025

Upcoming 2025 Milestones:

- Type C with FDA scheduled for December 11, 2025 to address key items following August 27, 2025 End of Phase 2 Meeting about Phase 2b clinical trial of OST-HER2 in preparation for January 2026 BLA filing
- UK MHRA pre-MAA meeting scheduled for December 8, 2025 in preparation for January 2026 MAA filing

Loss from Operations:

The Company recorded a net operating loss of $6.879 million in the third quarter of 2025, compared with a net operating loss of $2.875 million in the third quarter of 2024. The increase in net loss was largely due to pre-paying expenses associated with U.S. and international regulatory, as well as required pre-commercial activities related to the OST-HER2 Phase 2b pulmonary metastatic osteosarcoma program. Net loss per share in the third quarter of 2025 was $0.21 on 31.956 million outstanding weighted-average shares; this compares to third quarter of 2024, where the Company delivered a net loss of $0.18 per share on 15.897 million outstanding weighted-average shares.

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 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 early 2026 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/

OS THERAPIES

To view the source version of this press release, please visit
https://www.newsfilecorp.com/release/274747

SOURCE OS Therapies