August 17, 2026

OS Therapies Reports Second Quarter 2026 Financials and Provides Business and Regulatory Updates

- *Up to $10 million debt financing supported by U.K. subsidiary VAT refunds and reimbursable R&D tax credits, including $5 million funded at the August 10, 2026 first closing*
- *FDA Type C Statistical Methods Meeting mid-September 2026 meeting to review 2.5-year Overall Survival data and confirmatory Phase 3 trial design to gain alignment on statistical analysis plan for BLA submission under the Accelerated Approval Program*
- *Interim 3-year Overall Survival data expected in early September 2026 ahead of MHRA Statistical Methods Scientific Advice Meeting for Conditional MAA submission acceptance criteria*
- *Final 3-year Overall Survival data to be included in FDA BLA Accelerated Approval Program submission ahead of Type B Pre-BLA Meeting previously granted in Q2/26*
- *U.K. waives Pediatric Investigation Plan (PIP) requirement*

New York and Rockville, Maryland--(Newsfile Corp. - August 17, 2026) -**OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or the "Company")**, the world leader in gene-edited, Listeria-based cancer immunotherapies, today reported financial results for the second fiscal quarter ended June 30, 2026, and provided business and regulatory updates. The Company is seeking to obtain a Biologics License Application (BLA) under the Accelerated Approval Program of the U.S. Food & Drug Administration (FDA), and equivalent Conditional Marketing Accelerated Authorisations (CMAAs) from the Medicines and Healthcare products Regulatory Agency (MHRA) and European Medicines Agency (EMA), for OST-HER2 in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma (the "Metastatic Osteosarcoma Program").

"In the second quarter of 2026, we navigated the administrative processes associated with becoming approved to receive Value Added Tax (VAT) refunds and completing submissions for the reimbursable Research and Development (R&D) Credit Program for which our U.K. subsidiary (OST U.K.) was eligible," said Paul Romness. "With over $3 million in VAT refunds receivable as of the end of the second quarter, and the expect addition of approximately $1 million in VAT refunds and at least $4.2 million in refundable R&D tax credits expected to be accrued on the Company's balance sheet by the end of the third quarter, we recently raised sufficient minimally dilutive capital, supported by these tax refunds, from certain of our long-term, pre-IPO high-net-worth investors. This is expected to provide us with a financial roadmap into 2027, by which time the Company expects to have completed regulatory submissions in the U.S., U.K. and Europe for approval of OST-HER2 in the prevention or delay of recurrence in fully resected, pulmonary metastatic osteosarcoma."

"We are now preparing for our mid-September Type C Statistical Method Meeting with FDA

that will review our previously disclosed 2.5-year overall survival data to align upon the statistical analysis plan, and also review the design of our confirmatory Phase 3 study expected to be launched in the exclusively in the U.K. to satisfy BLA and CMAA pre-conditions, as well as our Statistical Methods Scientific Advice Meeting (SAM) with MHRA," said Dr. Craig Eagle, Chief Medical Advisor and Director of OS Therapies. "We have also been making significant progress on the Pediatric Investigation Plans (PIPs), or equivalents, required to be included as part of the Accelerated Approval Program BLA and EMA CMAA submission packages. We were pleased to receive a waiver of the PIP requirement in the U.K. by MHRA that obviates that need for our pending MHRA CMAA request. We are hopeful to achieve regulatory alignment that will provide a clear pathway for regulatory our upcoming submissions for early market access in the U.S. and U.K., having already achieved EMA alignment in the second quarter of 2026."

Second Quarter 2026 Corporate Highlights

- Achieved statistically significant 2.5-year Overall Survival data (75% vs. 47%, p = 0.003) with no new deaths between 2-year and 2.5-year timepoints in OST-HER2-treated group
- Alignment achieved with EMA and Australian Therapeutic Goods Administration (TGA) 3-year Overall Survival data and biomarker data as approvable CMA endpoints
- Phase 3 trial design alignment achieved between FDA, EMA, MHRA and TGA
- Advanced Therapy Medicinal Product (ATMP) designation granted by EMA triggering Rolling Review in Europe
- Patent filed for OST-HER2 pharmacodynamic response biomarker
- Dr. Craig Eagle appointed Chief Medical Advisor
- Dr. Robert Langer appointed as Strategic Advisor
- Publication of four articles in Drug Discovery World
- Publication of statistically significant 2-year Overall Survival (20% vs. 1%, p = 0.00995) for OST-HER2 plus radiation in frontline unresected canine osteosarcoma vs. radiation-alone

Third Quarter 2026 Highlights to Date

- Appointed Dr. Craig Eagle to the Board of Directors
- Type C Statistical Methods Meeting scheduled with FDA for mid-September 2026
- Statistical Methods SAM scheduled with MHRA expected in September 2026
- FDA grants Biomarker Qualification Program Meeting, expected in September 2026
- Conference call reviewed biomarker pharmacodynamic response data being used as a surrogate clinical efficacy endpoint to support CMAAs and BLA requests
- Submission of regulatory dossier to U.S. Department of Agriculture (USDA) for OST-HER2 in canine osteosarcoma by wholly owned subsidiary OS Animal Health

Expected Remaining Second Half 2026 Milestones

- Interim 3-year Overall Survival data
- Type C Statistical Methods Meeting with FDA in mid-September 2026
- Statistical Methods SAM scheduled with MHRA in mid-September 2026
- FDA Biomarker Qualification Program (BQP) Meeting
- Full 3-year Overall Survival data
- Submission of the Clinical Trial Notification (CTN) to MHRA in preparation for initiation

of confirmatory Phase 3 Metastatic Osteosarcoma Program.
- Receipt of at least $3 million in cash from VAT refund by OST U.K.
- Formal submission for at least $4.2 million in reimbursable R&D Tax Credit by OST U.K.
- Acceptance of OS Animal Health regulatory submission by USDA followed by meeting
- Complete submission of BLA request to FDA
- Complete submission of CMAA requests to MHRA, EMA and TGA
- FDA decisions on Regenerative Medicine Advanced Therapy (RMAT), Breakthrough Therapy Designation and Commissioner's National Priority Review Voucher (CNPV)
- Initiation of confirmatory Phase 3 trial in the U.K.
- FDA decision on BLA request under Accelerated Approval Program
- EMA decision on CMAA request
- MHRA decision on MAA request
- TGA decision on MAA request

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. The Company's Commissioner's National Priority Review Voucher (CNPV) letter of intent has been accepted by FDA. The Company is seeking to obtain a BLA under the Accelerated Approval Program for OST-HER2 in osteosarcoma in the second half of 2026, in addition to CMAAs in Europe, the U.K. and Australia.

Loss from Operations:

The Company recorded a net operating loss of $8.576 million in the quarter ended June 30, 2026, compared with a net operating loss of $4.839 million in the quarter ended March 30, 2025. The increase in net loss was largely due to the expenses associated with biomarker research & development and regulatory activities in the Company's newly formed whollyowned subsidiary OS Therapies UK Ltd. and general and administrative expenses. Net loss per share in the quarter ended June 30, 2026 was $0.20 on 43.904 million weighted average shares outstanding, compared to the quarter ended June 30, 2025, where the Company delivered a loss of $0.19 per share on 25.114 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. 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 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 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.

OS Therapies Contact Information:

Investor Relations
Harrison Seidner, PhD
WaterSeid Partners
OSTX@waterseid.com

Public Relations
Stephanie Chen
Elev8 New Media
media@ostherapies.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/309887

SOURCE OS Therapies