May 18, 2026

# OS Therapies Reports First Quarter 2026 Financials and Provides Business Update

- *$5.5 million financing that closed on April 2, 2026 together with $5.7 million in capital raised in Q1-2026, expected to provide Company with cash runway into 2027*
- *$4.5 million of accrued VAT refunds and R&D refundable tax credits from UK subsidiary begin maturing, including $1.9 million VAT cash refund expected in June 2026*
- *Successful EMA and Australia TGA (ATGA) meetings aligned around use of existing biomarker and pending release of 3-year overall survival data to support Conditional Marketing Authorisations (CMAs) for OST-HER2 in prevention or delay of recurrence in fully-resected, pulmonary metastatic osteosarcoma ("Metastatic Osteosarcoma")*
- *2.5-year overall survival data expected to be released during ASCO 2026*
- *EMA and ATGA have aligned on key design aspects of confirmatory Phase 3 Metastatic Osteosarcoma protocol required to have commenced prior to grant of CMAs or FDA BLA, including alignment on 3-year overall survival as a primary clinical efficacy endpoint*
- *Upcoming U.S. FDA Type C meeting and U.K. MHRA SAM meeting to align with EMA & ATGA prior to Australia Clinical Trial Notification submission for Phase 3, including alignment on 3-year overall survival as a primary clinical efficacy endpoint. U.S. FDA ("FDA") Pre-BLA meeting to confirm alignment on surrogate and primary clinical efficacy endpoints with EMA/ATGA, including alignment on 3-year overall survival as a primary clinical efficacy endpoint, and seek decisions on rolling review acceptance and RMAT designation following the EMA and U.K. MHRA granting ATMP designation (EMA/MHRA RMAT equivalent) for OST-HER2 in Metastatic Osteosarcoma*
- *OS Animal Health S-1 filing for proposed 'Go-Public' transaction and receipt of SEC comments*

New York, New York and Rockville, Maryland--(Newsfile Corp. - May 18, 2026) - **OS Therapies, Inc. (NYSE American: OSTX) ("OS Therapies" or "the Company")**, the world leader in gene-edited, listeria-based cancer immunotherapies, reported first quarter 2026 financial results and provided a business update centered on the Company's lead program for OST-HER2 in the prevention or delay of recurrence in fully-resected, pulmonary metastatic osteosarcoma ("Metastatic Osteosarcoma").

"In the first quarter of 2026 we successfully implemented our international research & development approach, aligning regulatory and tax strategies via our wholly-owned U.K.-based subsidiary OS Therapies UK Ltd. We made significant investments in order to be able to benefit from return of cash via value-added tax (VAT) reimbursements and refundable research & development tax credits ("R&D Tax Credits")," said Chris Acevedo, CPA, Chief Financial Officer of OS Therapies. "With approximately $2 million in non-dilutive cash expected to be returned to the Company in June 2026, together with the $5.5 million registered direct offering that closed on April 2, 2026, as well as the aggregate $5.7 million of proceeds from the January 2026 Warrant Inducement & Exchange Offering and March 2026

bridge financing, each with pre-existing high net worth investors, we believe the Company is well positioned financially as we approach critical clinical and regulatory milestones. In addition, the April 2, 2026 registered direct offering resulted in the full conversion into common stock and warrants of the convertible debt issued in the March 2026 bridge financing, which had been reflected as outstanding in the Company's Quarterly Report Form 10-Q for the first quarter of 2026."

Mr. Acevedo continued, "As we continue with our tax strategy in the U.K. - a jurisdiction that provides attractive incentives for developers of treatments for orphan diseases - we have accrued an additional $2.5 million in cash expected to be returned to the Company through VAT reimbursement and R&D Tax Credits beginning in July 2026. We expect this strategy to continue generating recurring non-dilutive cash inflows driven by our planned monthly R&D expenditures."

**First Quarter 2026 Corporate Highlights**

- Completed submissions to FDA of clinical efficacy and biomarker surrogate clinical efficacy data for OST-HER2 in Metastatic Osteosarcoma in preparation for the Company's upcoming Type B Pre-Biologics License Application (BLA) Meeting (the "Pre-BLA Meeting") following U.S. Food & Drug Administration's (FDA) elevation of the initially-granted Type D meeting into a Type B Pre-BLA Meeting, and concurrent request that the related clinical and biomarker data be submitted in advance to facilitate alignment prior to formal submission as the BLA clinical module
- Non-clinical and chemistry, manufacturing and controls (CMC) BLA module submissions to FDA completed alongside request for rolling review
- U.S. government reauthorization of Pediatric Priority Review Voucher (PRV) program
- Compelling OST-HER2 pharmacodynamic response biomarker Metastatic Osteosarcoma data
- Filing of a patent application covering a novel immune biomarker signature of seroconversion in response to OST-HER2 treatment that is predictive of survival
- Granted Advanced Therapy Medicinal Product (ATMP) designation granted by EMA and MHRA; European equivalent of FDA's Regeneration Medicine Advanced Therapy (RMAT)
- Submitted RMAT designation request submitted to FDA
- Filing of Form S-1 with the U.S. Securities Exchange Commission (SEC) for the proposed 'Go-Public' transaction of wholly-owned subsidiary OS Animal Health, Inc. and received initial SEC comments
- Completed January 2026 warrant inducement and exchange offering and March 2026 bridge financing that provided an aggregate of $5.7 million in cash proceeds to the Company for the quarter ended March 30, 2026
- Implementation of U.K. tax strategy via wholly-owned subsidiary expected to provide approximately $2 million of non-dilutive cash returns to the Company

"The first quarter was a period of intense biomarker, clinical and regulatory execution for the Company as we initiated filing of our BLA for OST-HER2, completed biomarker analyses from the OST-HER Metastatic Osteosarcoma Phase 2b trial showing strong correlation between seroconversion and survival," said Paul Romness, MPH, Chair & CEO of OS Therapies. "We also received ATMP status in Europe, raised the capital needed into 2027 and formally began preparations for the Go-Public transaction of OS Animal Health that has

now been pushed into the second half of 2026 in order to allow for a planned regulatory meeting with the U.S. Department of Agriculture (USDA) to define the regulatory path forward for OST-HER2 in canine osteosarcoma, including the potential expansion of therapeutic uses into frontline treatment, that we believe is important before setting a valuation for the transaction. We expect clinical data on OST-HER2's potential in frontline canine osteosarcoma, initially reported in April 2025, to be published in the near future in a peer-reviewed journal that will further underscore the tremendous potential for OST-HER2 to change the standard of care for canine patients."

Mr. Romness continued, "We are actively preparing for upcoming meetings with FDA and U.K. Medicines and Healthcare products Regulatory Agency (MHRA) following successful meetings with the European Medicines Agency (EMA) and Australia's Therapeutic Goods Administration (ATGA). There we gained alignment on the clinical efficacy and surrogate clinical efficacy endpoints required to support early market access for of OST-HER2 under upcoming conditional MAA requests, as well as alignment on the provisional design of our confirmatory Phase 3 OST-HER2 Metastatic Osteosarcoma trial. EMA has now initiated rolling review of our conditional MAA, which is also a major regulatory milestone."

**Second Quarter 2026 Highlights to Date and Upcoming Milestones**

*Highlights to date*

- EMA initiation of rolling review for the Company's conditional MAA request
- Appointment of industry leader Dr. Craig Eagle as Chief Medical Advisor
- Appointment of biotech luminary Dr. Robert Langer as strategic advisor
- $5.5 million registered direct offering and conversion of all outstanding debt
- Conference call reviewed biomarker pharmacodynamic response data that is being used as a surrogate clinical efficacy endpoint to support conditional MAAs and BLA requests

*Upcoming milestones*

- 2.5-year overall survival data expected to be released during the meeting of the American Society of Clinical Oncology (ASCO)
- FDA Type B meeting to gain alignment on the confirmatory Phase 3 OST-HER2 Metastatic Osteosarcoma trial design that is a pre-requisite to being granted a BLA under the Accelerated Approval Program
- MHRA Scientific Advice Meeting to gain alignment on confirmatory Phase 3 OST-HER2 Metastatic Osteosarcoma trial design that is a pre-requisite to being granted a conditional MAA in the U.K.
- Completion of BLA filing with 2.5-year overall survival data
- Completion of conditional MAA request to MHRA with 2.5-year overall survival data
- Update conditional MAA request to EMA with 2.5-year overall survival data
- Submission of the Clinical Trial Notification (CTN) to ATGA in preparation for initiation of the confirmatory Phase 3 Metastatic Osteosarcoma trial
- Receipt of approximately $2 million expected in cash VAT refund to U.K. subsidiary
- Data from Phase 1b trial of OST-503 in castration-resistant prostate cancer
- Publication of OST-HER2 clinical data in frontline canine osteosarcoma

**Key Second Half of 2026 Milestones**

- Complete submission of conditional MAA request to ATGA
- Initiation of confirmatory Phase 3 trial in Australia
- 3-year overall survival data
- FDA decision on BLA request under Accelerated Approval Program
- EMA decision on conditional MAA request
- MHRA decision on conditional MAA request
- ATGA decision on conditional 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 April 2026 for $195 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 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 CMAs in Europe, the U.K. and Australia.

**Loss from Operations:**

The Company recorded a net operating loss of $10.396 million in the quarter ended March 30, 2026 compared with a net operating loss of $3.876 million in the quarter 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 wholly-owned subsidiary OS Therapies UK Ltd. and general and administrative expenses. Net loss per share in the quarter ended March 30, 2026 was $0.27 on 38.674 million weighted average shares outstanding compared to the quarter ended March 30, 2025 where the Company delivered a loss of $0.18 per share on 21.249 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 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 ATMP from the 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 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 anticipates receiving 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 Authorisations 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 has been conditionally approved by the U.S. Department of Agriculture for the treatment of canines with osteosarcoma. The Company also anticipates reading out data from a Phase 1b study of OST-504 in castration resistant prostate cancer in the first half of 2026.

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 our cash runway expectations, our expected cash returns through VAT reimbursement and R&D Credits, the potential approval of OST-HER2 by the U.S. FDA and foreign regulatory agencies, and other risks and uncertainties described in "Risk Factors" 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.

**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/




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