February 4, 2025

OS Therapies Provides Corporate Update

- *Strong cash position relative to monthly burn and cash needs into mid-2026*
- *Significant regulatory milestones upcoming in OST-HER2 osteosarcoma program*
- *Pending acquisition paves the way for commercialization and partnerships*
- *Evaluating strategic options for tunable Antibody Drug Conjugate platform*

NEW YORK--(BUSINESS WIRE)-- OS Therapies, Inc. (NYSE-A: OSTX), a clinical-stage biotechnology company advancing immunotherapies and targeted drug conjugates for cancer treatment, today provided a corporate update to the marketplace to contextualize recent positive clinical data, corporate and financial developments.

“January 2025 was the most significant month in the Company’s history,” said Paul Romness, MHP, Chairman & CEO of OS Therapies. “We started OS Therapies because someone very close to my family developed osteosarcoma and we realized that if first line therapy failed, the metastasis that could follow had very poor long-term prognosis. The data we generated in our Phase 2b trial with OST-HER2 provides the first glimmer of hope in over 40 years that a paradigm shift could radically change the course of this deadly disease. We intend to stay laser focused on our mission of bringing this therapy to market so that when the next family that gets the devastating news of an osteosarcoma diagnosis, they’ll know that treatment options might exist in the event that chemotherapy and resection/amputation fail to prevent metastasis, which is the case in approximately 50% of patients.”

Cash position and burn rate

On January 14, 2025, the Company disclosed that it completed a $7.1 million financing round (the “Preferred Round”) designed to fund the Company through a Biologics Licensing Authorization (BLA) decision from the US Food & Drug Administration (“FDA”) regarding the OST-HER2 program in the prevention of metastases in osteosarcoma. This was in addition to the $6 million initial public offering the Company completed in August 2024. Taken together, this $13.1 million that the Company raised over the last 6 months provides sufficient capital to fund:

- Final payments for the OST-HER2 osteosarcoma trial (inclusive of any expected non-clinical work required by FDA).
- Commercial manufacturing required for FDA approval and product launch.
- Strategic & operational costs related to FDA & EMEA correspondence, meetings, and regulatory submissions.
- Commercial launch preparations.
- Acquisition of the *Listeria monocytogenes* (“*Listeria*”) platform from Ayala.
- Corporate overhead.

Under the terms of the Preferred Round, the Company is precluded from raising additional capital for 6 months, in addition to being precluded from selling shares under its Equity Line of Credit (“ELOC”) so long as the price of the common stock is below $12.00. Additionally, the warrants issued in connection with the Preferred Round have certain forced exercise

provisions when the common stock trades above $12.00.

An additional condition of the Preferred Round was the appointment of Mr. Karim Galzahr as a new member of the Company's Board of Directors to help the Company navigate towards value creation for shareholders. The Preferred Round was funded over 90% by pre-IPO and IPO investors of the Company, including leading funders from the osteosarcoma community. As a result of the significant investment made to help advance OS Therapies' mission, certain investors are now considered affiliates of the Company by virtue of owning at least 10% of the common shares. It is important to note that while this significant ownership entitles the investors to representation, it also binds them to certain SEC requirements as it relates to liquidity, thus providing a layer of protection for all shareholders. To read more about affiliate Trading Volume Formula please visit: https://www.sec.gov/about/reports-publications/investorpubsrule144. We also acknowledge the Company's shares have experienced significant volatility in recent months. We believe this in large part due to the expiration of the lockup of pre-IPO shares that occurred on the week of January 27, 2025. The vast majority of our pre-IPO shareholders invested in the Company to succeed in its mission of delivering a new treatment option for osteosarcoma patients.

The Company expects to complete a number of key milestones towards FDA approval. We are engaging with new institutional and retail investors to expand our shareholder base. Approval of OST-HER2 for osteosarcoma on or before September 30, 2026 (the Company is targeting a late 2025 approval) would grandfather into the FDA's sunsetting Priority Review Voucher ("PRV") program by virtue of the Rare Pediatric Disease Designation ("RPDD") the FDA granted to the Company in 2021. This would result in non-dilutive capital, expected in the $150 million range.

Regulatory Path to Approval for OST-HER2 in Osteosarcoma

On January 15, 2025, the Company announced that it achieved the primary endpoint with statistical significance in its Phase 2b clinical trial of OST-HER2 in the prevention of recurrent, fully resected, lung metastatic osteosarcoma. In discussions prior to the initiation of the Phase 2b study, FDA recommended 12-month Event Free Survival as the primary endpoint for a successful objective treatment response ("Responders"). The data showed that in comparison with the best available historical control group from United States published literature (the "Published Control"):

- 33% of OST-HER2 patients were Responders vs. 20% in the Published Control.
- A greater proportion of OST-HER2 treated patients vs. the Published Control were alive at the post-Resection interim 12-month timepoint (91% vs. 80%) and 24-month timepoints (61% vs. 40%) than the Published Control, in the 3-year overall survival secondary endpoint.
- 100% of patients on OST-HER2 who were disease free at 12 months were alive at the 12-month, 18-month, 24-month and 30-month timepoints, as of each of their last dates of contact.
- OST-HER2 was well tolerated, with a strong safety profile that is sufficient to support regulatory approval.

Additionally, in preparation for further regulatory discussions with FDA regarding submission of OST-HER2 for accelerated or full approval, the Company sourced the only available database of osteosarcoma patients treated with the standard of care in the US to establish a

matched historical external control arm (the “Matched Control”). We did this after receiving feedback from FDA regarding a Breakthrough Therapy Designation (“BTD”) request that noted the clinical subpopulation we studied in the Phase 2b trial met the BTD criteria and that a matched historical external control would be required to determination clinical efficacy. The Matched Control will provide the clinical comparator required by FDA to support approval, based on advice from senior regulatory advisors with experience in getting pediatric orphan therapies approved. While there were insufficient numbers of data points available to finalize the submission package for FDA as of January 2025, the interim data collected on the Primary Endpoint showed:

- 33% of OST-HER2 treated patients were Responders vs. 11% in Matched Control
- In Non-Responders, the average time to recurrence was 5.9 months in OST-HER2 treated patients vs. 4.7 months in Matched Control.

In further discussions with key members of our Regulatory and Scientific Advisory Board, subgroup analyses that focused on the response to therapy among patients at different stages of disease offered important insight into the potential importance of OST-HER2 for patients and clinicians in osteosarcoma. In the OST-HER2 treated group:

- Patients who had multiple Resections (2+) showed greater propensity (55%) for achieving 12-month EFS than patients who had previously had only one Resection (25%);
- Patients who previously had only one Resection (25%) still performed better than patients from the Published Control (20%) and the Matched Control (11%).

The likelihood that patients who have had multiple lung metastasis resections were Responders at a 55% rate was important to clinicians because patients with 1 prior Resection will likely progress to having multiple resections, with near 100% certainty. This makes OST-HER2 a therapy likely appropriate for a large proportion of patients.

Taken together, the Company believes the efficacy data Matched Control will ultimately support regulatory approval in the prevention of metastases in osteosarcoma, considering the lack of options available in the market, the poor survival outcomes for patients and the strong safety profile of OST-HER2. The Company is working with both domestic and European osteosarcoma research groups to gather additional non-concurrent control arm data for FDA review.

The Company intends to request a meeting (either Type B or Type C) with FDA to review the data and discuss the path towards BLA once the additional Matched Control data is ready for submission, expected in the first quarter of 2025. The Company expects meeting with FDA early in the second quarter of 2025. Later in the second quarter we plan to file the BLA, provided positive feedback from FDA. Upon filing the BLA, the Company expects approval within 6 months.

Additionally, the Company owns the rights to OST-HER2 in canines, with strong efficacy data previously published. While the Company has prioritized development of OST-HER2 for humans with osteosarcoma, it does intend to make progress in making the conditionally-approved treatment available where possible while it works to secure full regulatory approval so that it can be made broadly accessible. Additional information will be forthcoming on this effort in the months ahead.

Acquisition of Clinical Assets and IP from Ayala

On January 29, 2025, the Company announced that it entered into an agreement to acquire certain clinical and intellectual property assets from Ayala (the "Acquisition"). As a result of the Acquisition, the Company gained rights to two new *Listeria*-based clinical-stage immunotherapy candidates: ADXS-503 for lung cancer and ADXS-504 for prostate cancer. While the clinical data for these candidates is encouraging, the primary reason the Company moved forward with the Acquisition was to eliminate an expected near-term cash milestone of $3.5 million due upon the earlier of receiving FDA approval of OST-HER2 or initiating a pivotal trial for OST-HER2 in a clinical indication. Given the likelihood that the recently completed Phase 2b clinical trial of OST-HER2 would be considered pivotal by virtue of the expectation that FDA will allow the data gathered to become the primary efficacy data utilized for BLA submission, this agreement reduces our expected cash needs for 2025. Additionally, the Acquisition reduces the Company's royalty rate from 10% to 1.5% of net sales and eliminates $16.5 million in milestones on the first $100 million in sales, dramatically improving the potential margin gained by the Company in the early years for OST-HER2 in osteosarcoma.

The Company is now positioned as the clear market leader in *Listeria*-based immunotherapy, a long-promising class of cancer immunotherapy. We expect it to become an important treatment option in situations where no treatments exist, such as recurrent, metastatic osteosarcoma, as well as an adjunct to the standard of care where treatment fails or is insufficient. There was previously considerable enthusiasm around the use of Listeria as an immunotherapy platform in cancer, and we believed this enthusiasm will renew as OST-HER2 makes its way through the FDA approval process.

Strategic options for our tunable Antibody & other Drug Conjugate platform

With the solidification of OS Therapies as the market leader in Listeria-based immunotherapy, we expect that the development funding priorities post-approval of OST-HER2 in osteosarcoma will be to evaluate OST-HER2 in other HER2-related oncology areas, as well as identify paths forward for ADXS-503 (to be renamed OST-503) in lung cancer and ADXS-504 (to be renamed OST-504) in prostate cancer - two large therapeutic areas with significant unmet medical need.

The Company will accelerate the development of our groundbreaking tunable drug conjugate platform based on pH-sensitive tunable linker technology, capable of linking multiple different therapeutic payload combinations with multiple different targeting antibodies - without using our existing cash resources for development. Given the continued market interest in combining therapeutic interventions, such as antibody and vascular targeted drugs to target specific cancer cells, we believe our tunable drug conjugate platform could play an outsized role in creating combination therapies that will improve outcomes while reducing side effects.

We will announce strategic options in the near future.

Conclusion

Our journey as a newly public company resulted in significant clinical and business accomplishments, alongside known challenges for biotechnology companies with relatively

small capitalizations. OS Therapies is different from others because the Company has completed its capital-intensive clinical development phase. We are fully funded through a potential PRV sale - a significant revenue generating milestone. These distinctions could separate OS Therapies from others in this challenging biotech funding environment as the market becomes aware of our positioning.

We thank the patients, families, clinicians and investors who believe in the mission of the Company to improve outcomes for osteosarcoma, and other solid tumors.

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, fast-track and orphan drug designations from the US FDA. The Company has completed enrollment for a 41-patient Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma, with positive results released in the first quarter of 2025. 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) platform, known as *tunable ADC* (tADC), which features tunable, tailored antibody-linker-payload candidates. This platform leverages the Company's proprietary silicon linker technology, enabling the delivery of multiple payloads per molecule. 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 registration statement on Form S-1 filed with the Securities and Exchange Commission (the “SEC”) on November 12, 2024, as amended on November 27, 2024, and other subsequent documents

we file with the SEC, including but not limited to our Quarterly Reports on Form 10-Q. 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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