



RESEARCH UPDATE

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Market Statistics in USD

Price	\$ 1.75
52 week Range	\$1.12 - \$7.00
Daily Vol (3-mo. average)	454,043
Market Cap (M)	\$ 60.4
Enterprise Value (M)	\$ 59.6
Shares Outstanding: (M)	33.5
Float (M)	22.1

Financial Summary in USD

Cash (M)	\$ 1.9
Cash/Share	\$ 0.06
Debt (M)	\$ -
Equity (M)	\$ 4.7
Equity/Share	\$ 0.11



COMPANY DESCRIPTION

OS Therapies is a clinical-stage oncology company developing OST-HER2, an immunotherapy for osteosarcoma and other solid tumors. OST-HER2 harnesses Listeria bacteria to trigger an immune response against the HER2 protein and has received Rare Pediatric Disease, Fast-Track, and Orphan Drug designations from the FDA and EMA. A Phase 2b trial in recurrent lung metastatic osteosarcoma showed a statistically significant benefit in 12-month event-free survival. The Company plans to submit a BLA in 2025 and, if approved, could receive a Priority Review Voucher. OST-HER2 has also demonstrated activity in breast cancer.

OS THERAPIES INC. (NYSE: OSTX)

Company Updates

OS Therapies advanced key clinical, regulatory, and commercial milestones in 3Q25 as it moves closer to bringing OST-HER2 to patients with recurrent, fully resected, pulmonary metastatic osteosarcoma. Final 2-year OS data from the 41-patient Phase 2b trial showed a 2-year OS rate of 75% for OST-HER2 vs 40% in historical controls, with 100% 2-year survival among patients event-free at 12 months, reinforcing durable benefit. Building on a successful End-of-Phase 2 interaction, management is preparing harmonized U.S./ex-U.S. filings with UK MHRA and FDA submissions expected around year-end, supported by its Eversana partnership and a launch plan that anticipates initial PRV monetization in 2026 and commercial OST-HER2 revenues beginning in early 2027. Subsequent to quarter-end, the Company also announced its intent to spin off OS Animal Health (OSAH) into a separately financed, standalone public company in 1H26, with OSTX shareholders expected to receive direct equity participation in the new listing.

Pipeline Overview: OST-HER2 remains the lead asset, supported by Phase 2b data showing statistically significant improvements in 12-month event-free survival and 2-year overall survival in recurrent, fully resected pulmonary metastatic osteosarcoma. OSTX continues to leverage the acquired Ayala/Advaxis listeria platform, with the OST-504 Phase 1b trial in biochemically recurrent prostate cancer completing last patient visit and an initial data readout expected in 4Q25. OS Animal Health is now expected to be housed within OSAH as a standalone public company in 1H26, targeting a substantial U.S. canine OS opportunity

Regulatory Advancements: In 3Q25, OSTX further clarified the global registration path for OST-HER2, with FDA alignment on safety, non-clinical, and CMC requirements and ongoing discussion around applying updated OS-focused oncology guidance to the existing efficacy package. In parallel, UK MHRA has accepted the use of historical controls and real-world comparators for a conditional MAA, while EMA feedback supports the use of 2-year OS from the Phase 2b trial as the primary efficacy endpoint for conditional approval. The Company has secured a UK MHRA pre-MAA meeting and a FDA Type C meeting, both in 4Q25, providing plans for a UK MAA submission and a U.S. BLA filing in January 2026 under Project Orbis.

Financial Performance: For 3Q25, OS Therapies reported a net loss of \$6.9M versus \$2.9M in 3Q24, driven primarily by higher regulatory and pre-commercial spending ahead of OST-HER2 filings. Cash and equivalents were ~\$1.9M at quarter end, supplemented by post-quarter proceeds tied to a previously announced ~\$7.8M warrant exercise and inducement exchange, extending runway into late 2026. During the quarter, OSTX terminated an ELOC and established an at-the-market program, adding flexibility as it positions the balance sheet for potential OST-HER2 approval and PRV monetization ahead of the September 30, 2026 sunset date.

Valuation: We use a probability-adjusted Discounted Cash Flow Model when valuing OSTX. Our valuation model returns a valuation range of \$5.59 to \$7.58 with a midpoint of \$6.44. We note that this model is highly levered to the out years due to the long term nature of OSTX's industry, leading to the potential for dramatic re-ratings as new information becomes available.

Business Overview

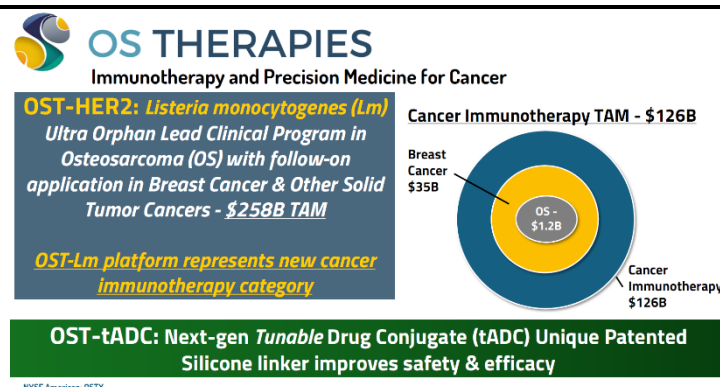
OS Therapies Inc. (NYSE: OSTX) is a clinical-stage biotechnology company dedicated to developing novel oncology therapies for rare and underserved cancers. Established in 2019 and headquartered in Maryland, the Company was founded with the mission to bring forward innovative immunotherapies where few treatment options exist. Its lead program, built on a *Listeria monocytogenes* immunotherapy platform, is advancing toward regulatory submission in osteosarcoma, a rare pediatric bone cancer that has seen no new drug approvals in over four decades. By combining scientific innovation, strong leadership, and a disciplined development strategy, OS Therapies is positioning itself as a potential first mover in rare oncology.

Management has played a central role in shaping the Company's strategy and progress to date. The organization is led by Paul Romness, MHP, Chairman & Chief Executive Officer, who brings decades of experience in healthcare policy, business development, and corporate strategy. Supporting him is Chris Acevedo, Chief Financial Officer, who has guided the Company's financial operations, capital structure, and efficiency improvements. The leadership team also includes Gerald Commissioning, Chief Business Officer, whose expertise in clinical operations and regulatory execution strengthens the Company's ability to advance programs through pivotal milestones. Together, this management team brings 100+ years of combined experience, with ~20 drug launches and ~10 licensing deals completed.

OS Therapies' strategy extends beyond a single therapy. While the Company's immediate focus is advancing its lead immunotherapy candidate through the regulatory process in the U.S. and Europe, management has taken deliberate steps to build a broader pipeline and diversify the platform's applications. This includes leveraging its proprietary antibody-drug conjugate (ADC) technology, which incorporates a novel linker-payload system designed to enhance efficacy and safety across solid tumor indications. The Company has also structured its operations to capture opportunities in both human and animal health, reflecting a long-term vision that balances near-term regulatory milestones with a diversified oncology portfolio. With the planned spin-off of OS Animal Health into a standalone, separately financed public company focused on canine osteosarcoma, OS Therapies aims to preserve strategic focus and capital for its human oncology programs while enabling shareholders to participate directly in the potential value creation of the veterinary franchise through ownership in both entities.

In recent quarters, OS Therapies has continued to demonstrate its ability to execute on its strategy. The Company has now delivered statistically significant late-stage data in osteosarcoma, including positive 12-month EFS and final 2-year overall survival results from its Phase 2b trial, while consolidating key intellectual property around its *Listeria*-based platform and expanding its portfolio through the acquired Advaxis/Ayala

Exhibit 1: Market Overview



Source: Company Reports

Exhibit 2: Investment Highlights

Platforms	Near-Term Catalytic Milestones
OST-HER2: <i>Listeria monocytogenes</i> (Lm): - Ultra Orphan Lead Clinical Program in Osteosarcoma (OS) with follow-on applications in breast cancer and other solid tumor cancers - The total addressable market (or "TAM") for these assets and follow-on applications are \$258B TAM OST-Lm platform represents new cancer immunotherapy category: cervical cancer, non-small cell lung, GBM, prostate, etc. OST-tADC: - Next-gen Tunable Drug Conjugate (or "tADC") Unique Patented Silicone linker improves safety and efficacy	Meetings with FDA/MHRA/EMA & subsequent BLA & MAA submissions for OST-HER2 in Human Osteosarcoma – December '25 – March '26 Regulatory pathway for OST-HER2 in Canine Osteosarcoma & spinoff– Q4/'25 – Q1/'26 FDA Accelerated Approval– Q2/Q3 2026 Priority Review Voucher (or "PRV") – Upon FDA Accelerated Approval - Most recent sale \$160M (Abeona, June 2026) - Rare Pediatric Disease Designation (RPDD) granted by FDA - Orphan Designation & Fast Track Designation granted by the FDA & EMA
Market and Financial Summary	
Stock Price: [\$1.87]	Shares Outstanding: [~34M]
Market Cap: [\$60M]	Cash: [~\$4M]
Monthly Cash Burn: [~\$300K]	Timing of Accelerated FDA Approval and PRV: April-September 2026
Estimated PRV/Sale Proceeds: [~\$160M]	

NYSE American: OSTX

Source: Company Reports

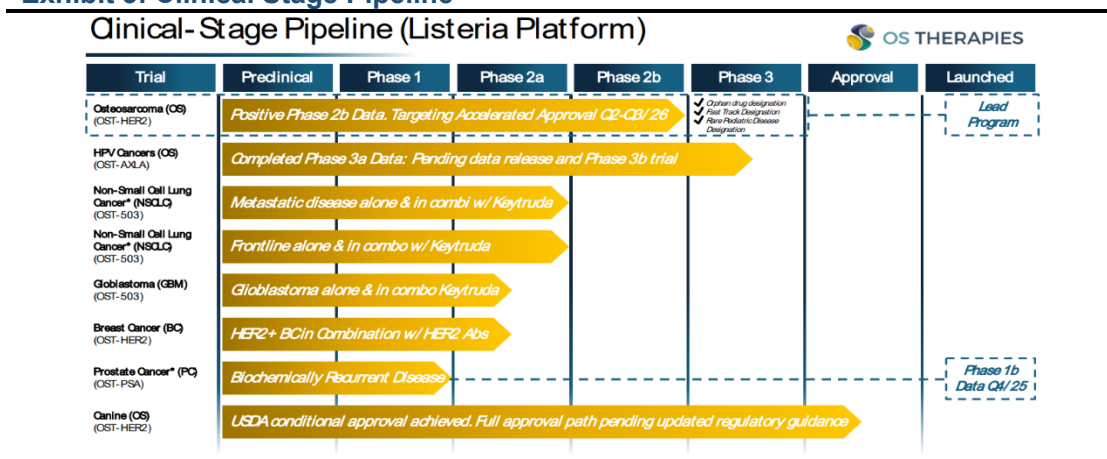
assets. At the same time, management has managed operating spend following trial completion, pre-funded critical U.S. and ex-U.S. regulatory activities, and strengthened the balance sheet through warrant exercise transactions that extend runway into late 2026. As previously mentioned, OSTX announced plans to spin off OS Animal Health into an independently financed public company, allowing the canine OST-HER2 program to be advanced with dedicated capital while OS Therapies' shareholders retain direct upside in both the human and animal health franchises. These developments underscore management's ability to advance critical programs and regulatory filings while maintaining financial discipline—an essential quality for a company operating in rare oncology.

Looking ahead, OS Therapies is well positioned with multiple high-impact regulatory interactions in late 2025, including a UK MHRA pre-MAA meeting on December 8 and a U.S. FDA Type C meeting on December 11, which are expected to finalize the path to market for OST-HER2. Based on recent feedback from FDA, MHRA and EMA, the Company is targeting closely sequenced UK conditional MAA and U.S. BLA submissions between December 2025 and January 2026, aligned with an Accelerated/conditional approval strategy centered on overall survival and supportive biomarker data. If successful, OST-HER2 could represent the first meaningful therapeutic advance in osteosarcoma in more than 40 years, with potential to extend into broader HER2-expressing settings. In parallel, the planned 1H26 spin-off of OS Animal Health provides an additional structural catalyst and a mechanism to unlock the value of the canine OST-HER2 franchise without diverting capital from the core human oncology business, giving shareholders direct exposure to growth in both markets. Backed by an experienced leadership team, a diversified immunotherapy and ADC platform, and strong engagement with patient advocates and academic experts, OS Therapies remains an emerging oncology player balancing near-term value creation with a platform capable of supporting long-term growth.

Pipeline Overview - Clinical-stage Pipeline (Listeria platform)

Osteosarcoma (OS) / OST-HER2: OST-HER2 is the Company's lead program and most advanced clinical initiative, designed to stimulate the immune system via a Listeria monocytogenes-based platform targeting HER2-expressing tumors. Osteosarcoma is a rare pediatric bone cancer with roughly 1,000 new U.S. cases annually and ~20,000 globally, with no new FDA-approved therapies in over 40 years. OS Therapies has reported positive Phase 2b data in recurrent, fully resected, pulmonary metastatic osteosarcoma, including statistically significant improvement in 12-month event-free survival and final 2-year overall survival of 75% vs 40% for historical controls, with 100% 2-year survival among patients event-free at 12 months. The Company now plans to submit a BLA for OST-HER2 under the FDA's Accelerated Approval Program in early 2026, in parallel with a UK conditional MAA, leveraging convergent regulatory feedback that emphasizes overall survival supported by biomarker data. If approved, OST-HER2 could become the first new osteosarcoma treatment in decades and would be eligible for a Priority Review Voucher (PRV), which management estimates could be monetized at roughly ~\$150 million, creating a significant non-dilutive source of capital.

Exhibit 3: Clinical Stage Pipeline



Source: Company Reports

HPV Cancers (OS) / OST-AXLA: OST-AXLA is being developed to target HPV-related cancers, leveraging the same *Listeria*-based immunotherapy platform. The program has already produced positive Phase 3a clinical data, with further confirmatory trials (Phase 3b) in planning. HPV-driven cancers remain a high-burden global disease, impacting cervical, head and neck, and other tumor types. OST-AXLA provides OS Therapies with an opportunity to extend its technology beyond pediatric bone cancer and into more prevalent indications with broader market potential. The HPV cancer market is well established, with multiple therapeutic entry points, making OST-AXLA a potential mid-term value driver if ongoing development is successful.

Non-Small Cell Lung Cancer (NSCLC) / OST-503: OST-503 is advancing through early clinical development in non-small cell lung cancer (NSCLC), both as a monotherapy and in combination with Merck's Keytruda. NSCLC is the most common form of lung cancer, accounting for approximately 85% of cases worldwide, representing a multi-billion-dollar market opportunity. OST-503 is being tested in metastatic disease settings and also in frontline combinations. By targeting immune pathways and leveraging synergy with checkpoint inhibitors, OS Therapies seeks to position OST-503 as a differentiated option in a competitive oncology space. While early in development, this program has the potential to expand the Company's footprint significantly in one of the largest oncology markets.

Glioblastoma (GBM) / OST-503: In addition to NSCLC, OST-503 is also being explored in glioblastoma multiforme (GBM), a highly aggressive brain cancer with poor survival rates and limited treatment options. The program is being developed as both a monotherapy and in combination with checkpoint inhibitors such as Keytruda. Given GBM's notoriously high unmet need and the failure of most therapeutic approaches to meaningfully extend survival, OST-503 represents a high-risk but potentially high-reward asset. If clinical data demonstrates immune activity within the central nervous system, this program could open new strategic opportunities for OS Therapies in neuro-oncology.

Breast Cancer (BC) / OST-HER2: Originally developed for breast cancer, OST-HER2 has already shown encouraging preclinical and Phase 1 data in HER2-positive breast cancer, demonstrating tumor regression in both spontaneous and metastatic models. A Phase 1 trial in advanced HER2+ solid tumors established a recommended therapeutic dose and showed early signs of efficacy, including cases of clinical improvement in heavily pre-treated patients. With a breast cancer market exceeding \$35 billion annually, reinitiating development in this indication post-osteosarcoma approval could represent a substantial expansion opportunity. Management has indicated that once OST-HER2 is on the market in osteosarcoma, renewed interest in breast cancer trials will follow.

Prostate Cancer (PC) / OST-PSA: OST-PSA is a therapeutic candidate designed for patients with biochemically recurrent prostate cancer, a stage of the disease where PSA levels rise following initial therapy but before clinical progression. This is a challenging disease state with few treatment options and represents an attractive entry point for novel immunotherapies. OST-PSA remains in early clinical development, with proof-of-concept studies planned. If efficacy is demonstrated, the program could establish a foothold in prostate cancer, one of the most prevalent cancers in men globally.

Canine OS / OST-HER2: OST-HER2 is also being developed for canine osteosarcoma through OS Animal Health, which OS Therapies now plans to spin off as a standalone public company. Conditional approval has already been granted by the USDA, and management expects a forthcoming publication on metastatic and primary disease control to support USDA reauthorization and a commercial relaunch strategy. Canine osteosarcoma represents a sizable and growing segment of the veterinary oncology market, with canine OS estimated at roughly 86% of a ~\$1.6B global veterinary oncology market and OS Therapies estimating OST-HER2's addressable U.S. canine osteosarcoma opportunity at over \$150 million. Success in this program not only provides near-term commercial revenue potential but also strengthens translational credibility for OST-HER2 in human oncology.

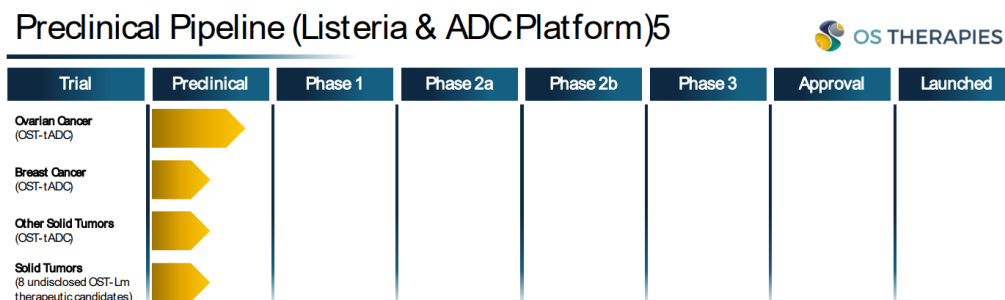
Pipeline Overview - Preclinical Pipeline (Listeria & ADC Platform)

Ovarian Cancer / OST-tADC: OS Therapies is developing OST-tADC for ovarian cancer, part of its tunable Antibody-Drug Conjugate (tADC) platform. This proprietary approach leverages a patented silicone linker and Conditionally Active Payload (CAP) technology to deliver cytotoxic payloads more precisely, improving both safety and efficacy. Ovarian cancer remains an area of high unmet need with frequent recurrence following chemotherapy. Preclinical work suggests OST-tADC has potential to overcome limitations of existing ADCs and may move toward clinical evaluation in the coming years.

Breast Cancer / OST-tADC: Beyond HER2 immunotherapy, OS Therapies is also targeting breast cancer through its tADC platform. This program remains in preclinical testing but represents a potential avenue to compete in one of the largest oncology markets by offering differentiated ADC technology. The ability to tune drug conjugates for specific tumor biology could make OST-tADC attractive as either a standalone program or in partnership with larger oncology companies seeking next-generation ADC platforms.

Other Solid Tumors / OST- tADC: The tunable ADC platform is not limited to ovarian or breast cancer. OS Therapies is exploring multiple solid tumor applications, with early-stage research indicating broad applicability. ADCs have emerged as a leading class in oncology therapeutics, and OS Therapies' proprietary CAP-enabled linker system could offer best-in-class safety and efficacy attributes. Preclinical development continues across several undisclosed tumor types, providing optionality for future clinical expansion.

Exhibit 4: Preclinical Pipeline



Source: Company Reports

Solid Tumors / 8 undisclosed OST-Lm therapeutic candidates: In addition to named programs, the Company is advancing a pipeline of eight undisclosed candidates based on its *Listeria*-monocytogenes (OST-Lm) platform. These preclinical assets are focused on a range of solid tumors and represent the depth and versatility of the Company's platform. While details remain confidential, the breadth of activity highlights management's intent to scale the *Listeria* platform beyond its initial indications, creating a diversified pipeline with multiple "shots on goal".

Growth Drivers

First-mover in osteosarcoma with a near-term regulatory path: OS Therapies is positioned to deliver the first new drug therapy for osteosarcoma in more than four decades, addressing rare pediatric cancer with high post-recurrence mortality and no approved adjuvant options to prevent relapse. Positive Phase 2b data in recurrent, fully resected, lung-metastatic osteosarcoma underpin a plan to seek U.S. Accelerated Approval, with a rolling BLA targeted for 2025. The company is building a matched external-control dataset (OST-400) to align with FDA guidance on statistical methodology for single-arm data packages in rare diseases. If approved, OST-HER2 could also yield a monetizable Priority Review Voucher (PRV).

Emerging prostate cancer program as the next growth driver: In parallel, OS Therapies is advancing its prostate cancer program, which is expected to generate additional clinical data shortly. Management views this program as the company's #2 development priority, positioned directly behind osteosarcoma while OST-HER2 progresses through FDA review. With prostate cancer representing a significantly larger commercial opportunity, this program highlights OS Therapies' ability to expand beyond rare pediatric cancers into broader oncology indications, strengthening the company's medium-term growth outlook.

Platform leverage across HER2+ and immuno-oncology: Beyond osteosarcoma, the Listeria-based immunotherapy platform (OST-HER2) has clinical and preclinical signals across HER2-expressing tumors, including breast cancer, creating optionality to expand into larger markets after an initial rare-disease foothold. Programs such as OST-503 (NSCLC/GBM, alone and in combination with checkpoint inhibitors) and OST-AXLA (HPV-associated cancers) extend the immuno-oncology footprint. This "lead-indication first, platform follow-through" approach can compound clinical learning and reduce per-program execution risk.

Second growth pillar: next-generation, tunable ADCs: OS Therapies' proprietary tADC platform couples a patented silicone linker with conditionally active payload technology designed to improve therapeutic index and enable multiple payloads per linker. The company organized OS Drug Conjugates (OSDC) to pursue partnering and indication expansion in ovarian, breast, and other solid tumors—creating a separate deal vector alongside immunotherapy. New U.S. IP covering commercial manufacturing extends platform exclusivity to ~2040, supporting durable returns on partnered and wholly owned programs.

Exhibit 5: OST-HER2 Platform Drivers

Catalyst Rich Advanced OST-HER2 Cancer Therapeutic Platform



Multiple Near-Term Clinical Milestones

- Phase 2b trial for OST-HER2 in Osteosarcoma positive data: Announced Jan 2025
- Path to Pivotal OST-HER2 Canine OS study to support full approval pending USDA alignment: 1H/25
- Key FDA Meeting: Q2/25
- BLA Submission: Q3/25
- Accelerated Approval: Q4/25

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Significant Market Opportunity

- TAM Human Osteosarcoma – \$1.2B
- Market Opportunity for OST-HER2 in Osteosarcoma: \$500M
- TAM Canine Osteosarcoma – \$150M+
- tADC platform – \$311 billion



Favorable Regulatory Review Process

- Osteosarcoma (Human and Animal): No new approvals in 40+ years
- Orphan, Fast Track, Rare Pediatric Disease Designations granted by the FDA and EMA for OST-HER2
- Priority Review Voucher – if OST-HER2 approved, PRV value = \$150M



Experienced, Successful Leadership

- Proven management team with large & early-stage pharma experience with multiple successful product launches
- Expert OS scientific advisory board
- Strong patient advocacy & commercialization advisors
- Cash on hand into mid-2026

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Osteosarcoma ("Bone Cancer") is a solid tumor of the bone

- 1,000 cases/year in US; 20,000 globally
- Most Cases Present In Patients 15-20 Years Of Age
- No New Treatments In Over 40 Years
- METS (Lung) In ~40-50%+ Of Patients: **400 to 500 patients**
- High Lung METS Recurrence: Fatality Rate: ~ 90%
- Time To Mortality Upon METS Recurrence: ~12 Months
- Only Treatment for Recurrent METS: Lung METS Surgery
 - No drug therapy used (chemotherapy failed)
- Objective = Prevent Recurrence - Increase Overall Survival

Standard of Care (SOC):

- Primary OS – a) Amputation of leg, extremity b) orthopedic implant and highly toxic 9-month chemotherapy regimen with 10% treatment-associated mortality
- Secondary OS / Recurrent Disease: None

NYSE American: OSTX

Source: Company Reports

Ecosystem alignment—regulators, advocates, and partners: The Company has advanced multi-agency dialogues (FDA Type D, End-of-Phase-2; UK MHRA Scientific Advice; EMA pathway planning) and has been featured in the osteosarcoma community (MIB Factor keynote), supported by leading advocacy groups. Operationally, OS Therapies partnered with J&J Innovation (JLABS) for lab/office resources—useful for capital-efficient scale-up. These relationships can accelerate review cycles, trial enrollment, and real-world adoption at launch.

Financial catalysts and capital efficiency: Management continues to emphasize capital efficiency as it transitions from clinical execution to regulatory and pre-commercial activities. As of September, 2025, the Company reported cash and equivalents of approximately \$1.9 million, supplemented by proceeds from a \$7.8 million warrant exercise and inducement program that funded one-time regulatory payments and, together with a streamlined cost structure, is expected to extend the operating runway into late 2026. The termination of the prior equity line of credit and implementation of an at-the-market equity program add further flexibility ahead of potential OST-HER2 approval. A potential PRV upon successful pediatric approval remains a key non-dilutive catalyst, with historical PRV sales ranging from ~\$100–\$300 million and company materials pointing to an illustrative ~\$150 million value.

Market Overview

Osteosarcoma: small incidence, high unmet need, concentrated decision-makers.

In the U.S., bone and joint cancers occur at roughly 1.0 per 100,000 annually, with osteosarcoma the most common primary bone sarcoma and incidence peaking in adolescence; global osteosarcoma cases are commonly cited around ~20,000 per year with ~1,000 in the United States. Standard of care involves resection and intensive chemotherapy, yet outcomes after lung metastasis remain poor and 5-year survival has plateaued for decades. This creates a rare-disease market in which a first-in-class adjuvant-type therapy that demonstrably reduces recurrence could see rapid uptake among a concentrated network of pediatric oncology centers (e.g., COG institutions).

Clinical endpoints and regulatory incentives shape adoption.

Clinical endpoints and regulatory incentives are central to OST-HER2's potential adoption. While 12-month Event-Free Survival (EFS) served as the primary endpoint in the Phase 2b trial—capturing time to recurrence, treatment discontinuation, or death in a setting where relapse prevention is critical—recent FDA, MHRA, EMA and workshop feedback has shifted emphasis toward 2-year overall survival, supported by immune-activation biomarker data, as the preferred efficacy driver for Accelerated/conditional approval. In parallel, OST-HER2's Rare Pediatric Disease Designation makes OS Therapies eligible for a transferable Priority Review Voucher upon approval, providing a well-established, non-dilutive financing mechanism to help bridge launch, post-marketing commitments, and continued platform development.

Exhibit 6: Bone and Joint Cancer Statistics



Source: National Cancer Institute

HER2-positive malignancies: large follow-on addressable pools.

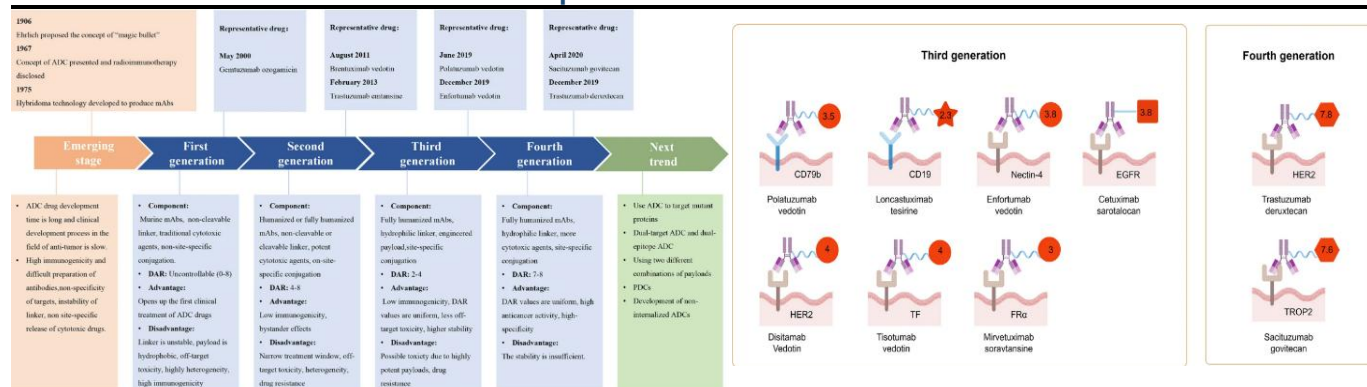
Approximately 20%–30% of breast cancers overexpress HER2, a well-validated target with multiple approved antibodies and ADCs. While HER2-directed standards are established, an approved Listeria-based immunotherapy could open combination or maintenance strategies in select HER2+ settings after the initial osteosarcoma foothold, particularly where T-cell priming and epitope spreading may complement antibody or ADC mechanisms.

Immuno-oncology and ADC context: rising modalities with room for differentiation.

Checkpoint inhibitors transformed several adult solid tumors, yet pediatric sarcomas remain underserved—supporting regulatory openness to novel immunotherapies with persuasive clinical evidence. In parallel, Antibody-Drug Conjugates (ADCs) have become a leading modality; a 2025 review notes ~15 ADCs approved

globally by 2024, with robust pipelines and sustained pharma business-development interest. OS Therapies' tADC approach (silicone linker + conditionally active payloads) is designed to push the efficacy–safety frontier, a key adoption driver as payers and clinicians scrutinize tolerability and durability across crowded tumor segments.

Exhibit 7: ADCs: Current and Future Biopharmaceuticals



Source: Journal of Hematology & Oncology

Veterinary oncology: translational proof and incremental revenue.

Canine osteosarcoma is common and biologically relevant to the human disease. Published veterinary trials of Listeria-HER2 constructs (UPenn) have shown immune responses and promising survival extensions, and OS Therapies has already achieved conditional USDA approval in dogs. A dedicated animal-health pathway offers earlier commercialization potential and real-world evidence that can inform human oncology strategy—while addressing a market the company estimates at \$150M+.

Total addressable markets and launch dynamics.

Company materials frame large adjacencies: cancer immunotherapy (> \$100B class), breast cancer (>\$30B), and human osteosarcoma (~\$1.2B), with a U.S. topline opportunity suggested at \$500M+ for OST-HER2 in osteosarcoma if broadly adopted—figures that reflect the mix of small patient numbers, high severity, concentrated prescriber bases, and premium orphan pricing. While these are company estimates rather than external forecasts, they outline the strategic logic: win a scarce, high-need pediatric indication first, then leverage the platform into larger HER2+ and ADC-amenable markets.

Bottom line.

The market thesis rests on three intersecting trends: (1) a high-unmet-need, guideline-driven pediatric niche where a recurrence-preventing therapy can become standard quickly; (2) modalities with momentum (IO, ADC) where OS Therapies' platforms can differentiate and partner; and (3) policy incentives (PRVs, orphan/fast-track frameworks) that can accelerate access and defray capital needs. Together, these vectors support a credible launch arc in osteosarcoma with meaningful expansion pathways across HER2+ and ADC-addressable solid tumors.

Risks

As with any investment, there are certain risks associated with OS Therapies' operations as well as with the surrounding economic and regulatory environments common to the pharmaceutical industry.

- The Company has no history of net income, dividends, or cash flow and there can be no assurance that the Company will be profitable going forward. In the case that the Company cannot create enough revenue to sustain on-going business activities, the Company's most likely source of financing will be through the sale of existing securities or high-cost borrowing.
- Currently the Company has enough funds to sustain it through the foreseeable future and does not pose a going concern risk. We do however recognize that at some point the Company may need to raise more funds to sustain its operations until it begins revenue generation. Should the Company be unable to raise the necessary funds this would create a going concern risk.
- The Company is subject to regulatory risk as pharmaceutical activities are subject to laws and regulations imposed by local and state government authorities. Any future changes in the laws, regulations, agreements, or judicial rulings could impact or stop the Company from generating a profit on portions or all of its asset portfolio.
- The Company has several patents for intellectual property that the Company has developed. The Company is constantly on guard and ready to defend its intellectual property using litigation if necessary. Should judgements go against the Company this could materially weaken its edge among peers. Additionally, having to pursue litigation as mediation for any infringement could be costly for the Company, regardless of the outcome.
- Should the Company bring any or all its assets to market, there is no guarantee that a profitable market will exist for those treatments. While we have sufficient reason to believe that a market will exist for the Company's assets, this is a fast-moving industry so no guarantees can be made.

VALUATION SUMMARY

We use a probability-adjusted Discounted Cash Flow Model when valuing OSTX. Our valuation model returns a valuation range of \$5.59 to \$7.58 with a midpoint of \$6.44 based on a discount rate range of 12.50% to 17.50% and a current risk adjustment range of 13% to 18%. Key assumptions in this valuation include a current Cancer Immunotherapy market size of approximately 126.0B, a total market size CAGR of 2.4% over the foreseeable future, and a steadily increasing market capture percentage. We also apply a low discount rate to the PRV Sale which we expect to total \$150.0M and be recognized in FY26. Uncertainties that would have a significant impact on this model would be variances in the time to market for any of the leading drug candidates which would impact the risk rating, the capital needs of OSTX going forward which would impact the shares outstanding, and any changes to market capture due to a number of variables that would influence the Company's revenue potential. We note that this model is highly levered to the out years due to the long term nature of OSTX's industry, leading to the potential for dramatic re-ratings as new information becomes available. Currently we believe the Company will begin revenue generation as early as FY26, with operating profitability beginning in FY30 following an annual expense increase of ~2.5%.

BALANCE SHEET

OS Therapies Incorporated													
Consolidated Balance Sheets (\$M)													
Fiscal Year End: December													
ASSETS	Q1 Mar-23	Q2 Jun-23	Q3 Sep-23	Q4 Dec-23	FY 2023	Q1 Mar-24	Q2 Jun-24	Q3 Sep-24	Q4 Dec-24	FY 2024	Q1 Mar-25	Q2 Jun-25	Q3 Sep-25
Cash	0.0	0.0	0.0	0.0	0.0	0.1	0.1	1.9	5.5	5.5	3.0	2.8	1.9
Related Party Advance	-	-	-	-	-	-	-	-	-	-	0.0	-	-
Deferred Offering Cost	0.8	0.8	0.8	0.8	0.8	0.9	1.2	-	-	-	-	-	-
Prepaid Expenses	-	-	-	-	-	-	-	0.0	-	-	1.1	0.8	0.4
Employee Advances	-	-	-	-	-	-	0.1	0.1	-	-	-	-	0.0
Total Current Assets	0.8	0.8	0.8	0.8	0.8	1.0	1.3	2.0	5.5	5.5	4.1	3.6	2.3
Fixed Asset (Net)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other assets	-	-	-	-	-	-	-	-	-	-	0.2	6.8	6.6
Total Assets	0.8	0.8	0.8	0.8	0.8	1.0	1.3	2.0	5.5	5.5	4.2	10.3	9.0
LIABILITIES AND SHAREHOLDERS' EQUITY													
Accounts Payable	2.7	2.7	2.7	2.7	2.7	2.8	2.9	1.8	1.7	1.7	1.6	2.7	3.4
Accrued Interest on Convertible Notes	2.0	2.0	2.0	2.0	2.0	2.3	2.5	-	-	-	-	-	-
Accrued Expenses	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.5	0.5	0.4	0.4	0.4
Accrued Payroll and Payroll Taxes	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.1	0.1	0.0	-	0.0
Redemption Premium	4.6	4.6	4.6	4.6	4.6	5.1	5.3	-	-	-	-	-	-
Short-Term Loan	-	-	-	-	-	0.1	0.3	-	-	-	-	-	-
Preferred Dividends Payable	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Convertible Notes – A (Net Debt Discount)	1.1	1.1	1.1	1.1	1.1	1.1	1.1	-	-	-	-	-	-
Convertible Notes – A (Related Party Net Debt Discount)	0.1	0.1	0.1	0.1	0.1	0.1	0.1	-	-	-	-	-	-
Convertible Notes – B (Net Debt Discount)	5.2	5.2	5.2	5.2	5.2	5.2	5.2	-	-	-	-	-	-
Convertible Notes – C (Net Debt Discount)	3.9	3.9	3.9	3.9	3.9	3.9	3.9	-	-	-	-	-	-
Convertible Notes – D (Net Debt Discount)	2.0	2.0	2.0	2.0	2.0	2.0	2.0	-	-	-	-	-	-
Convertible Notes – E (Net Debt Discount)	1.1	1.1	1.1	1.1	1.1	1.1	1.1	-	-	-	-	-	-
Convertible Notes – F (Net Debt Discount)	1.4	1.4	1.4	1.4	1.4	2.1	3.1	-	-	-	-	-	-
Warrant Liability (Net of Discount)	-	-	-	-	-	-	-	-	2.0	2.0	1.2	-	-
Make-whole Stock Liability	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	-	-	-	-	-
Total Current Liabilities	24.7	24.7	24.7	24.7	24.7	26.5	28.3	2.6	4.6	4.6	3.5	3.5	4.1
TEDCO Grant	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total Liabilities	24.8	24.8	24.8	24.8	24.8	26.6	28.4	2.7	4.7	4.7	3.6	3.6	4.2
MEZZANINE EQUITY	-	-	-	-	-	-	-	-	6.1	6.1	4.8	1.8	1.1
Total Mezzanine Equity	-	-	-	-	-	-	-	-	6.1	6.1	4.8	1.8	1.1
Common Stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Preferred Stock	0.0	0.0	0.0	0.0	0.0	-	-	-	-	-	-	-	-
Additional paid-in capital	5.5	5.5	5.5	5.5	5.5	5.5	5.5	34.7	35.1	35.1	38.1	51.8	57.3
Accumulated deficit	(29.5)	(29.5)	(29.5)	(29.5)	(29.5)	(31.0)	(32.6)	(35.4)	(40.4)	(40.4)	(42.3)	(46.9)	(53.7)
Total Parent Net Equity	(24.0)	(24.0)	(24.0)	(24.0)	(24.0)	(25.5)	(27.1)	(0.7)	(5.2)	(5.2)	(4.2)	4.9	3.6
TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT	0.8	0.8	0.8	0.8	0.8	1.0	1.3	2.0	5.5	(0.5)	4.2	10.3	9.0

Source: Company Reports, Stonegate Capital Partners

INCOME STATEMENT

OS Therapies Incorporated

Consolidated Statements of Income (in US\$ M, except per share amounts)

Fiscal Year End: December

	FY 2023	Q1 Mar-24	Q2 Jun-24	Q3 Sep-24	Q4 Dec-24	FY 2024	Q1 Mar-25	Q2 Jun-25	Q3 Sep-25	Q4 E Dec-25	FY 2025E	Q1 E Mar-26	Q2 E Jun-26	Q3 E Sep-26	Q4 E Dec-26	FY 2026E
Revenue	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 3.0	\$ 14.0	\$ 17.0
Total Revenues	-	-	-	-	-	-	-	-	-	-	-	-	-	3.0	14.0	17.0
Administration expenses	1.1	0.3	0.4	1.2	2.1	4.0	3.7	2.3	3.1	3.1	12.3	2.5	2.5	2.5	2.5	10.0
Research & Development	3.2	0.4	0.4	1.2	0.9	2.8	1.3	2.5	3.8	3.8	11.3	2.0	2.0	2.0	2.0	8.0
Total Operating Expenses	4.3	0.6	0.8	2.4	3.0	6.8	5.0	4.8	6.9	6.9	23.6	4.5	4.5	4.5	4.5	18.0
Operating Income	(4.3)	(0.6)	(0.8)	(2.4)	(3.0)	(6.8)	(5.0)	(4.8)	(6.9)	(6.9)	(23.6)	(4.5)	(4.5)	(3.6)	(0.3)	(12.9)
Interest & Investment income	0.0	-	-	-	-	-	0.0	0.0	0.0	-	0.0	-	-	-	-	-
Interest expense	(3.4)	(0.8)	(0.8)	(0.4)	(0.0)	(2.1)	-	-	-	-	-	-	-	-	-	-
Other gains/losses	-	-	-	-	(0.0)	(0.0)	1.1	0.3	-	-	1.4	-	-	-	-	-
Profit Before Taxes	(7.8)	(1.5)	(1.6)	(2.9)	(3.0)	(8.9)	(3.9)	(4.5)	(6.9)	(6.9)	(22.2)	(4.5)	(4.5)	(3.6)	(0.3)	(12.9)
Provision for Income Tax	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Income	(7.8)	(1.5)	(1.6)	(2.9)	(3.0)	(8.9)	(3.9)	(4.5)	(6.9)	(6.9)	(22.2)	(4.5)	(4.5)	(3.6)	(0.3)	(12.9)
Cumulative Series A Dividend	(0.1)	(0.0)	-	-	-	(0.0)	-	-	-	-	-	-	-	-	-	-
Deemed Dividend Series A Convertible P	-	-	-	-	(2.0)	(2.0)	-	-	-	-	-	-	-	-	-	-
Net Income To Common Stkhldrs	(7.9)	(1.5)	(1.6)	(2.9)	(5.0)	(10.9)	(3.9)	(4.5)	(6.9)	(6.9)	(22.2)	(4.5)	(4.5)	(3.6)	(0.3)	(12.9)
Basic EPS	\$ (1.46)	\$ (0.13)	\$ (0.26)	\$ (0.18)	\$ (0.31)	\$ (0.88)	\$ (0.18)	\$ (0.19)	\$ (0.22)	\$ (0.22)	\$ (0.69)	\$ (0.14)	\$ (0.14)	\$ (0.11)	\$ (0.01)	\$ (0.40)
Diluted EPS	\$ (1.46)	\$ (0.13)	\$ (0.26)	\$ (0.18)	\$ (0.31)	\$ (0.88)	\$ (0.18)	\$ (0.19)	\$ (0.22)	\$ (0.22)	\$ (0.69)	\$ (0.14)	\$ (0.14)	\$ (0.11)	\$ (0.01)	\$ (0.40)
WTD Shares Out - Basic	5.4	11.4	6.0	15.9	16.2	12.4	21.2	25.1	32.0	32.0	32.0	32.0	32.0	32.0	32.0	32.0
WTD Shares Out - Diluted	5.4	11.4	6.0	15.9	16.2	12.4	21.2	25.1	32.0	32.0	32.0	32.0	32.0	32.0	32.0	32.0

Growth Rate Y/Y

Total cost of revenues	N/M	-39.9%	-48.5%	291.7%	156.4%	56.9%	693.2%	520.5%	182.3%	131.9%	246.3%	-10.0%	-7.0%	-34.6%	-34.6%	-23.7%
Net Income	N/M	-21.0%	-37.8%	45.6%	104.2%	14.0%	165.7%	191.3%	139.3%	130.0%	149.6%	16.1%	-0.8%	-47.7%	-95.6%	-41.8%

Source: Company Reports, Stonegate Capital Partners estimates

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