



OS Therapies Inc.
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Exchange: Ticker	NYSE American: OSTX
Recent Price (01/09/26)	\$1.54
52-week Range	\$1.12 - \$7.00
Shares Outstanding	37.4 mm
Market Capitalization	\$57.6 mm
Average volume	376,472
Insider Ownership +>5%	7.4%
Institutional Ownership	4.9%
EPS (Qtr. ended 09/30/25)	(\$0.21)
Employees	~5



Source: Google Finance, 1-year, as of January 8, 2026.

LISTERIA-BASED PIPELINE		
Candidate	Indication(s)	Development Stage
OST HER2	Osteosarcoma	Phase 2b
	Breast Cancer	Phase 2
	Canine Osteosarcoma	Conditional approval
OST AXAL	HPV-associated cancers	Phase 3
OST 503	NSCLC	Phase 2
	Glioblastoma	Phase 2
OST 504	Prostate Cancer	Phase 1
Add'l Candidates	Various solid tumors	Preclinical

Source: OS Therapies Inc.

COMPANY DESCRIPTION

OS Therapies Inc. (“OS Therapies” or “the Company”) is a clinical-stage cancer immunotherapy company focused on discovering, developing, and commercializing treatments for **osteosarcoma†** and other solid tumors. The Company has built a diversified pipeline around two novel technology platforms: OST-Lm, a bioengineered form of **Listeria monocytogenes** designed to drive robust immune responses against **HER2**-expressing cancer cells; and OST-tADC, a next-generation tunable **antibody-drug conjugate** platform. The lead OST-Lm program, OST-HER2, is in clinical development for osteosarcoma and breast cancer and holds conditional approval for canine osteosarcoma. A Phase 2b clinical trial in resected lung-metastatic osteosarcoma has completed its treatment phase and has demonstrated statistically significant improvements in 12-month **Event-Free Survival (EFS)** (primary endpoint) and **overall survival (OS)** (secondary endpoint), with a favorable safety profile. OS Therapies’ pipeline also includes multiple mid- and early-stage assets—OST-AXAL (HPV-related cancers), OST-503 (NSCLC and glioblastoma), and OST-504/PSA (prostate cancer)—along with additional preclinical programs targeting more than 30 solid tumor types. OS Therapies is also advancing its proprietary OST-tADC platform, currently in pre-clinical development. The Company is initially assessing the use of this platform on ovarian and breast cancer. The Company established a subsidiary, OS Drug Conjugates, to develop the OST-tADC platform internally and pursue licensing and partnership opportunities.

KEY POINTS

- OST-HER2 received the FDA’s **rare pediatric disease** designation (RPDD), together with **orphan drug** and **fast track designations** from the FDA and the EMA for its osteosarcoma program. Its RPDD makes it eligible for a **Priority Review Voucher (PRV)**, which the Company plans to sell.
- OST-HER2’s Phase 2b osteosarcoma trial met its primary endpoint, achieving a 35% 12-month EFS rate versus roughly 20% in historical controls. Interim two-year assessments of the secondary endpoint (three-year OS) were also positive, with 75% of patients still alive versus about 40% in historical controls.
- OS Therapies intends to submit a **Biologics License Application (BLA)** for OST-HER2 in osteosarcoma by the end of January 2026, aiming for FDA Accelerated Approval in Q3 2026. The Company intends to submit for conditional **Marketing Authorization Application (MAA)** to the UK’s MHRA (end of January 2026) and the EMA (end of February 2026).
- OS Therapies formed OS Animal Health, Inc., focused on OST-HER2 for canine osteosarcoma. The Company aims to file documentation for a ‘go-public’ transaction in January 2026.
- On August 7, 2025, the Company announced that its NYSE listing was included in the Russell Microcap, Russell Microcap Value, and Russell Microcap Growth indexes.
- As of September 30, 2025, OS Therapies held \$1.876 million in cash, and received an additional \$1.5 million after quarter-end, primarily from the previously announced warrant exercise inducement and exchange offer.

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Executive Overview

OS Therapies Inc. (“OS Therapies” or “the Company”) is a clinical-stage cancer immunotherapy company focused on developing and commercializing treatments for osteosarcoma (OS) and other solid tumors. Founded to address a major unmet need in bone cancer, particularly in pediatric and young adult patients, the Company is pursuing a focused development and commercialization plan that emphasizes clinical execution, disciplined use of capital, and strategic partnerships. OS Therapies has built a diversified pipeline across multiple solid tumor indications, based on two novel technology platforms:

- OST-Lm, a bioengineered form of bacterium *Listeria monocytogenes* designed to elicit a potent immune response against HER2-expressing cancer cells; and
- OST-tADC, a next-generation tunable antibody-drug conjugate (tADC) platform featuring a patented silicone-based component that enhances both safety and efficacy.

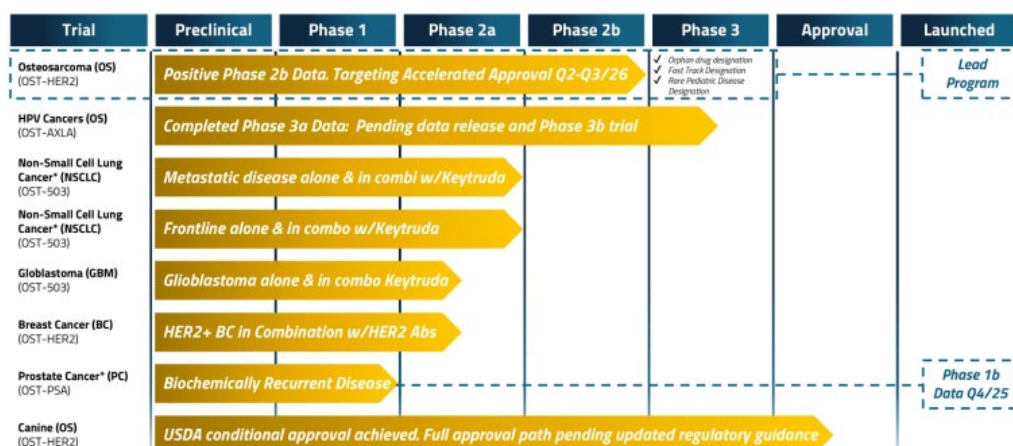
LISTERIA MONOCYTOGENES (LM) PLATFORM

OS Therapies is advancing a next-generation immuno-oncology platform built on a proprietary *Listeria monocytogenes* (Lm) vector that activates the immune system to generate a potent, targeted anti-tumor response. The Company’s live-attenuated *Listeria* construct delivers **tumor-associated antigens (TAAs)**—proteins or other molecules that are found in tumor cells and can be recognized by the immune system—directly to **antigen-presenting cells (APCs)**, to generate strong immediate and durable immune responses capable of addressing **micrometastatic** and residual disease, key challenges in osteosarcoma and other solid tumors.

A core advantage to this approach is its ability to drive highly specific anti-tumor activity with minimal off-target toxicity. By encoding TAAs, the platform concentrates immune activation on malignant cells while sparing healthy tissue. Its modular design also enables rapid adaptation to new cancer antigens, supporting a scalable pipeline across multiple solid tumor indications. In addition, the mechanism is compatible with other treatment modalities, including **checkpoint inhibitors**, creating opportunities for synergistic combination regimens.

OS Therapies’ Lm-based pipeline (Figure 1) provides both near-term value as well as mid- and long-term growth opportunities. The platform’s lead program, OST-HER2, is in clinical development for osteosarcoma and breast cancer and holds conditional approval for canine osteosarcoma. The osteosarcoma program is the nearest to regulatory submission and has received U.S. Food and Drug Administration (FDA) rare pediatric disease, as well as orphan drug and fast track designations from the FDA and the European Medicines Agency (EMA).

Figure 1
LISTERIA-BASED PIPELINE



Source: OS Therapies Inc.

Additional mid- and early-stage assets—including OST-AXAL (HPV cancers), OST-503 (NSCLC and glioblastoma), and OST-504/PSA (prostate cancer)—extend the platform across multiple high-value oncology indications. Preclinical programs in other solid tumors further expand long-term potential and growth opportunities.

OS Therapies' first licensed ADXS-HER2 (now OST-HER2) from Advaxis in 2018 and, in April 2025, acquired Advaxis/Ayala's entire Listeria-based immuno-oncology program and intellectual property (IP). This acquisition solidified OS Therapies as a leader in Listeria cancer immunotherapy and expanded its pipeline with three clinical assets—OST-AXAL, OST-503, and OST-504/OST-PSA—plus eight preclinical programs covering over 30 solid tumor indications. It also provided the Company with full ownership of the core Listeria platform IP supporting OST-HER2.

OST-HER2 in Osteosarcoma

OST-HER2, the Company's lead program, is an off-the-shelf immunotherapy that harnesses a highly attenuated, bioengineered *Listeria monocytogenes* vector to target HER2-expressing cancers, including osteosarcoma, breast cancer, and esophageal cancer. By delivering a HER2 tumor-associated antigen payload directly to the immune system, OST-HER2 generates a potent and durable anti-tumor response, enhancing the body's ability to prevent metastasis, delay recurrence, and improve overall survival.

The Company's lead indication is recurrent, resected lung-metastatic osteosarcoma. The treatment is administered as an intravenous infusion and could represent the first new treatment in over 40 years for pediatric osteosarcoma. A Phase 2b clinical trial (AOST-2121) is currently underway, with positive early clinical data showing statistically significant improvement in 12-month Event-Free Survival (EFS) (the primary endpoint) and overall survival (OS), when compared to historical controls.

Osteosarcoma

Osteosarcoma is a rare but highly aggressive cancer that primarily affects children and young adults. About 1,000 cases are diagnosed annually in the U.S., representing 2% to 3% of pediatric cancers. The disease is marked by rapid progression and early metastasis, most often to the lungs, making it difficult to treat and a major driver of poor outcomes.

Five-year survival for localized disease is 60% to 75% but drops sharply to 5% to 30% for patients with metastatic or recurrent osteosarcoma. Relapses are common, occurring in 30% to 50% of patients with localized disease and up to 80% of those metastatic at diagnosis. Standard treatment remains complete surgical resection combined with multi-agent chemotherapy (Source: American Cancer Society). Despite advances in surgery and chemotherapy, no new therapies for osteosarcoma have been approved in more than three decades, representing both a critical unmet medical need and a significant therapeutic opportunity. The global osteosarcoma treatment market was valued at \$1.2 billion in 2022, and is expected to reach \$1.8 billion by 2030, a CAGR of 5.50% (Source: Data Bridge Market Research's *Global Osteosarcoma Drug Market - Industry Trends and Forecast to 2030, 2023*).

Clinical Trials

In July 2021, OS Therapies initiated an open-label, multicenter Phase 2b trial enrolling 41 patients with recurrent, fully resected, lung-metastatic osteosarcoma to evaluate the efficacy of OST-HER2. The regimen included 16 infusions administered every three weeks over 48 weeks, followed by a three-year survival-monitoring period. The treatment phase concluded on September 30, 2024, and patients are now in long-term follow-up. OST-HER2 showed a favorable safety profile relative to standard therapy, with treatment generally well-tolerated and adverse events primarily mild to moderate.

On January 15, 2025, OS Therapies reported that the Phase 2b trial met its primary endpoint, 12-month Event-Free Survival (EFS) against historical U.S. data, with statistical significance. OST-HER2 achieved a 35% 12-month EFS rate, compared with roughly 20% in historical controls. Of 40 evaluable patients, 14 remained event-free at one year, demonstrating OST-HER2's therapeutic potential in this high-risk population.

Interim assessments of the study's secondary endpoint, three-year overall survival (OS), demonstrate a statistically significant positive trend in favor of OST-HER2-treated patients. At the two-year mark, 75% of patients (27 of the 36 evaluable patients) remained alive compared to approximately 40% in the historical control group. These findings indicate a promising survival advantage for OST-HER2-treated patients and support continued follow-up to assess long-term overall survival at the three-year endpoint.

Subgroup analyses indicate especially strong outcomes in certain patient populations, supporting the potential for targeted labeling or stratified treatment strategies. Notably, 100% of patients who achieved 12-month EFS were also alive at two years, compared with 59% of those who did not meet the 12-month EFS milestone. All patients who were disease-free at 12 months have remained alive as of their latest follow-up. These results highlight the strong link between early disease control and improved long-term survival, particularly among patients with lung-only metastases.

Regulatory Activities

OS Therapies believes that the demonstrated efficacy results, together with the favorable safety profile and the significant unmet clinical need in osteosarcoma, support the potential for accelerated regulatory approval of OST-HER2, allowing the Company to advance OST-HER2 through the regulatory approval process without the need for a Phase 3 clinical trial.

Based on Phase 2b results, OS Therapies plans to initiate a rolling Biologics License Application (BLA) submission for OST-HER2 in osteosarcoma (Q1 2026), targeting FDA Accelerated Approval by Q3 2026. The Company is also preparing conditional Marketing Authorization Application (MAA) for the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and EMA (Q1 2026), aiming to align submissions under **Project Orbis**.

On October 17, 2025, the FDA granted OS Therapies a second Type C meeting for December 11, 2025. The meeting reviewed updated overall survival and biomarker data to clarify the requirements for Accelerated Approval and inform requirements for full approval, positioning OST-HER2 for rapid regulatory and commercial advancement in this high unmet-need, rare pediatric cancer.

OST-HER2's Rare Pediatric Disease Designation (RPDD) makes it eligible for a Priority Review Voucher (PRV) if Accelerated Approval is granted before September 30, 2026, which the Company intends to sell. PRVs, which provide a six-month priority FDA review for another human drug application, are transferable and can represent a significant source of non-dilutive capital, with recent sales reported in the roughly \$155-\$160 million range.

Other Indications

OS Therapies plans to expand OST-HER2 and its Lm platform beyond osteosarcoma into other solid tumors, including breast, lung, prostate, and HPV-related cancers, following regulatory approval in its primary indication. The program shows strong potential to address multiple high-value oncology indications.

- *OST-HER2 (breast cancer)*. The Company completed a Phase 1 clinical study of OST HER2 in HER2 expressing solid tumors, with 12 patients enrolled (10 with breast cancer, 1 with esophageal cancer, and 1 with GE junction cancer). While the primary active development path is in osteosarcoma, the breast cancer data serves as proof of concept, providing a potential expansion opportunity post osteosarcoma.
- *OST-AXAL (HPV Related cancers)*. OST-AXAL is a cancer immunotherapy developed to treat cancers driven by persistent HPV infection, including cervical, head and neck, and anal cancers. The program includes the pivotal AIM2CERV Phase 3 clinical trial in high-risk, locally advanced cervical cancer.
- *OST-503 (NSCLC)*. The development rationale for this program is based on positive results of a Phase 2 study involving the use of OST-503 in NSCLC in frontline and metastatic disease when used in combination with Merck's Keytruda®. Overall, OST-503 appears to demonstrate favorable signals of immunogenicity and disease-control when combined with a checkpoint inhibitor

- *OST-504/OST-PSA (Prostate)*. In September 2025, the Company announced that the last patient visit in its Phase 1b trial of OST-504 in biochemically recurrent prostate cancer had been completed, with clinical data expected in Q1 2026. Depending on results, the Company may determine the next phase of development.

OST-HER2 in Canine Osteosarcoma

OS Therapies has established a dedicated subsidiary, OS Animal Health, Inc. (OSAH), to advance OST-HER2 for the treatment of canine osteosarcoma. The subsidiary plans to seek re-establishment of conditional U.S. Department of Agriculture (USDA) approval, with a targeted submission for Q1 2026. OS Animal Health is expected to operate independently, with dedicated funding and strategic partnerships tailored to the veterinary market.

In November 2025, OS Therapies announced plans to spin off OSAH into an independent public company to be listed on a U.S. national stock exchange, with completion of the spin-off and listing expected in the first half of 2026. The decision follows successful preliminary discussions with NYSE representatives and potential investors. Following the spin-off, OS Therapies shareholders will receive direct equity participation in the newly listed company.

The canine OST-HER2 program offers strategic benefits for human development through **comparative oncology**, the idea that cancers in dogs that mirror human disease can be used as a translational bridge to support human clinical trials, as naturally occurring osteosarcoma in dogs shares approximately 96% genetic homology with the human disease. This large-animal model enables evaluation of efficacy, safety, and immune responses that strengthen the case for regulatory alignment and human development. Success in the veterinary indication also enhances near-term commercial potential while reinforcing OST-HER2's credibility for human oncology applications.

Advaxis obtained a USDA conditional license for ADXS-HER2 (now OST-HER2) in canine osteosarcoma in December 2017. OS Therapies inherited this license after acquiring the program but allowed it to lapse to incorporate manufacturing improvements. The Company plans to reapply for conditional licensure using updated data and an enhanced manufacturing process protected by a patent through 2040, with a conditional launch targeted for 2026. Full USDA approval will require additional data on metabolism, shedding, and robust evidence of safety, purity, potency, and efficacy. To support this, OS Therapies intends to sponsor a confirmatory trial at the University of Pennsylvania starting in 2026.

tADC PLATFORM

OS Therapies is also advancing its proprietary OST-tADC platform, a next-generation tunable antibody-drug conjugate (tADC) technology designed to enhance efficacy and safety through precision **linker** chemistry and **conditionally active payloads (CAPs)**. The Company established a dedicated subsidiary, OS Drug Conjugates (OSDC), to develop the platform internally and pursue external licensing and partnership opportunities. OST-tADC serves as a second growth engine, enabling creation of novel ADC therapeutics, expansion of OS Therapies' oncology pipeline, and strategic value generation through collaborations, without limiting the Company's own development programs.

Antibody-Drug Conjugates (ADCs) are targeted cancer therapies that combine the specificity of **monoclonal antibodies (mAbs)** with the potency of cytotoxic drugs, delivering treatment directly to cancer cells while sparing healthy tissue, minimizing off-target toxicity. Each ADC consists of (1) an antibody (ligand); (2) a linker; and (3) a cytotoxic therapeutic payload. The ligand, normally a mAb, is designed to bind to tumor-specific antigens overexpressed on cancer cells but minimally present on normal tissue. Once bound, the ADC-antigen complex is internalized, allowing delivery of the therapeutic payload directly into the cancer cell.

OS Therapies' OST-tADC technology addresses key limitations of traditional ADCs by incorporating a modular system that addresses key challenges of the traditional technology (i.e., tumor penetration, payload release specificity, bystander effect, and payload multiplicity) through improvements of each of the ADC components.

Targeting Moiety (Ligand): OST-tADCs utilize smaller targeting moieties, which enhance deeper tumor penetration and facilitate rapid clearance from the body, reducing systemic toxicity. In addition, while regular tADCs use antibodies as the ligand, the OST-tADC platform is compatible with different ligands, such as small molecules, peptides, and mRNA therapeutics, which allows the Company to expand the functionality and the oncology indications the platform can target.

Linker: The linker connects the antibody and the cytotoxic payload, serving as a key determinant of when and where the drug is released. OS Therapies employs its patented SiLinkers™, silicon-based, pH-sensitive linkers that provide enhanced stability, allowing precise control of payload release. Unlike traditional linkers that may cleave prematurely in circulation, leading to dose-limiting toxicities, SiLinkers™ remains stable at physiological pH and only release their cytotoxic payload in the acidic tumor microenvironment. This targeted activation minimizes off-target toxicity and enhances therapeutic efficacy. The SiLinker system also supports the incorporation of multiple payloads on a single linker, offering opportunities for multi-mechanistic conjugates capable of achieving synergistic effects.

Payload (Cytotoxic Agent): The payload is an ultra-potent small molecule cytotoxin, far stronger than standard chemotherapy drugs. Because these agents are extremely toxic, precise control of delivery is vital to prevent systemic side effects. The Company's Conditionally Active Payloads (CAPs) are inert under normal physiological conditions, and only cross cell membranes and kill cancer cells under acidic conditions, trapping them within the tumor cells. Since they do not enter normal cells, their use minimizes the risk to healthy tissues, reducing collateral damage while allowing higher effective dosing within tumors.

Together, these elements result in a highly tunable and customizable framework, allowing for precise optimization of drug load, payload selection, and linker configuration to align with the unique biological characteristics of each tumor type, enhancing both efficacy and therapeutic potential.

OST-tADC Development Activities

The OST-tADC program is currently in preclinical development, with its lead program, OST-tADC-FRA-H, targeting **folate receptor alpha**, a protein involved in cell signaling, replication, and division, which is overexpressed in several cancers, including ovarian and endometrial cancers. OST-tADC has demonstrated positive preclinical proof-of-concept data in models of ovarian cancer with its tADC candidate, achieving potent tumor suppression with a favorable safety profile. The Company is initially assessing the use of its platform on ovarian and breast cancer, as well as other solid tumors, with Phase I trials for ovarian cancer expected to begin in 2027. The discovery and preclinical development of this compound are being conducted at Syngene International Limited, an integrated contract research organization (CRO) located in Bangalore, India.

Corporate History and Headquarters

OS Therapies Incorporated is a Delaware corporation incorporated on June 24, 2019. It is based in Rockville, Maryland. The Company is the successor to an LLC formed in 2018 and has three wholly-owned subsidiaries: (1) OS Animal Health, Inc. (OSAH), to advance OST-HER2 in veterinary markets; (2) OS Drug Conjugates (OSDC), to develop its tADC technology platform; and (3) OS Therapies UK LTD, a corporation formed in the United Kingdom, with OS Therapies planning to move all research and development activities to this entity. The Company trades on the NYSE American under the ticker symbol OSTX. On August 7, 2025, OS Therapies announced that its NYSE listing was included in the Russell Microcap, Russell Microcap Value, and Russell Microcap Growth indexes.

Intellectual Property

OS Therapies continues to strengthen its intellectual property (IP) position to support long-term value creation and its competitive advantage within oncology therapeutics. The Company's IP strategy is centered on broad protection of its proprietary immunotherapy platforms and associated manufacturing processes, as well as the expansion of patent coverage for its next-generation cancer vaccine technologies.

In the past year, OS Therapies completed the acquisition of listeria monocytogenes (Lm)-based immunotherapy assets, expanding its foundational IP portfolio to include key patents and know-how covering recombinant Lm vectors, antigen delivery systems, and associated methods of use in solid tumor indications. OS Therapies originally licensed ADXS-HER2 (now its lead program OST-HER2) from Advaxis, Inc. in early September 2018. Subsequently, on April 9, 2025, the Company's acquired the listeria monocytogenes-based immuno-oncology program and related IP assets from Ayala Pharmaceuticals (formerly Advaxis, Inc.).

The assets acquired by the Company included three clinical cancer immunotherapy candidates: (1) AXAL/ADXS/HPV (renamed OST-AXAL) for human papilloma virus (HPV)-associated cancers; (2) ADXS-503 (OST-503) for non-small cell lung cancer (NSCLC) and glioblastoma; and (3) ADXS-504/ADXS31142 (OST-PSA/OST-504) for prostate cancer. In addition, the assets also included eight pre-clinical candidates targeting over 30 solid tumor cancers. The acquisition allowed the Company to gain direct ownership of the key underlying IP assets related to its Listeria monocytogenes immunotherapy platform and its lead asset OST-HER2. This acquisition significantly enhances OS Therapies' position in the immuno-oncology landscape by providing both freedom to operate and strategic leverage for partnership or licensing opportunities.

Complementing this, OS Therapies has pursued an active IP development program, resulting in the issuance of new patents across the U.S. and international markets. In May 2025, the Company announced the issuance of U.S. Patent #12,230,738 protecting proprietary commercial manufacturing methods for the Company's Lm cancer immunotherapy platform technology into 2040. This patent covers its lead asset—OST-HER2 in osteosarcoma—as well as its other Lm-based programs, including its eight pre-clinical stage immunotherapy candidates and the use of OST-HER2 in canine osteosarcoma.

These recent activities extend protection around novel tumor-associated antigen constructs, formulation methods that improve immunogenicity and stability, and combination regimens that synergize with checkpoint inhibitors. Additional patent applications remain pending, reflecting a robust pipeline of innovation aimed at expanding therapeutic reach and lifecycle protection for core assets. Collectively, these efforts demonstrate OS Therapies' commitment to building a comprehensive and defensible IP estate, positioning the company to capture long-term commercial potential as its clinical programs advance.

Company Leadership

Management

OS Therapies' leadership team has accumulated decades of expertise across immunotherapy research, clinical development, and advanced manufacturing, with a proven track record of drug development, commercialization, and M&A exits.

Paul Romness, MHP, President and Chief Executive Officer

Mr. Paul Romness leads OS Therapies with over 25 years of experience in the biopharmaceutical industry having served every function within major companies like Johnson & Johnson, Amgen, and Boehringer Ingelheim. He has been directly involved in the launch of nine major products in the industry covering indications for oncology, surgery, HIV, FSD, COPD, IPF, cardiovascular, and diabetes. Throughout his professional career and within his community, he has focused on and advocated for unmet medical need and getting treatments to patients. Mr. Romness has a B.S. in Finance from American University and a Master of Health Policy from George Washington University Medical Center.

Robert Petit, Ph.D., Chief Medical & Scientific Officer, Founding Scientists (OST-HER2)

Dr. Robert Petit is an accomplished biopharma executive, innovator/inventor, company builder, and medical scientist. His personal mission is to develop new products and treatments that improve and extend the lives of patients. Dr. Petit has C-Suite experience leading several public and private therapeutic companies in the biotechnology, oncology, immunology, and infectious disease spaces. He has a consistent track record of excellence in corporate strategy, clinical development, scientific development, pipeline determination, medical and regulatory affairs. He has been instrumental in initial public offerings (IPOs), mergers and acquisitions (M&As), and in raising over \$400 million in public and \$100 million in private capital and equity transactions. Dr. Petit's extensive development experience includes the design, planning, and execution of programs for more than 13 drugs, 3 immunotherapies, 3 cellular immunotherapies, and a dozen therapeutic cancer vaccine/immunotherapies. Dr. Petit's education includes Doctoral Degrees from The Ohio State University College of Medicine in Immunology and Viral Oncology/Medical Microbiology, with medical training.

Gerald Commissiong, Chief Business Officer

Mr. Gerald Commissiong is a healthcare executive with over 15 years of experience serving in C-suite roles in emerging growth companies developing and commercializing novel therapeutics, diagnostics, and natural products to address acute and chronic diseases. He previously served as President & CEO of Amarantus Bioscience Holdings, Inc. and Todos Medical, Ltd. raising over \$100 million in equity and debt capital. His experience spans neurology, regenerative medicine, oncology, and infectious diseases. Mr. Commissiong received a BS in Management Science & Engineering with a focus on financial decisions from Stanford University, and played professional football in the Canadian Football League for the Calgary Stampeders.

Jack Doll, Chief of Staff

Mr. Jack Doll, a biological engineering graduate from the University of Georgia, specializes in electron microscopy and genetic engineering. With experience examining binding affinities in amyloid proteins as well as CRISPR mediated edits to environmental toxin immune pathways in *Caenorhabditis elegans*. Now in his sixth year at OS Therapies, Mr. Doll has experience in planning, implementation, and the regulatory development process for clinical trials, especially in rare pediatric disease; capital raising in both public and private markets, grant writing, and go-public strategy.

Jutta Wanner, Ph.D. Advisor and Founding Scientist (OST-tADC)

Dr. Jutta Wanner brings her Advanced ADC technology and deep experience in oncology, inflammation, and virology from her role as Chief Scientific Officer at BlinkBio. Previously, she held senior discovery chemistry responsibilities at Roche, where she served as a co-lead in discovery chemistry. Dr. Wanner received her PhD from the University of Kansas and completed her postdoctoral training at The Scripps Research Institute in San Diego.

Christopher P. Acevedo CPA/CFO/MBA, Chief Financial Officer

Mr. Christopher Acevedo has served as the Chief Financial Officer of OS Therapies since July 2023. Prior to taking that position, he was the Company's lead accountant and interim CFO since June 5, 2020. Mr. Acevedo owns and operates a certified public accounting firm with offices in Delaware and Maryland, serving a wide range of individuals and businesses in the service sector since 2010. The firm is the accounting arm of OS Therapies and manages the accounting and finance for the Company. Prior to returning to public accounting, Mr. Acevedo held CFO positions at five companies (three were related entities) with revenues ranging from \$10 million to \$50 million, all in the service sector and all privately owned. He holds CPA certificates in the states of Delaware, Maryland, and Pennsylvania. Mr. Acevedo graduated from the University of Delaware with an M.B.A. in Business Administration and a B.S. degree in accounting, minoring in Finance.

BOARD OF DIRECTORS

OS Therapies' Board of Directors brings diverse experience and vision, guiding the Company toward its mission of improving outcomes in osteosarcoma and other solid tumors.

Paul Romness, MHP President and Chief Executive Officer, Chair

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John Ciccio, Board Member

Mr. John Ciccio is President and CEO of Adheris Health, a MedAdvisor company that provides dynamic patient management solutions that activate patients, improve outcomes, and elevate brand performance with customized patient behavioral models built on extensive data insights and analytics. Prior to joining Adheris Health, Mr. Ciccio served as President of the healthcare professional social network Skipta, which he helped lead to exponential growth and eventual sale. Mr. Ciccio has also worked closely with several top 10 pharma companies to develop product launch strategies in the U.S. and Europe. Mr. Ciccio received his undergraduate degree from Harvard University.

Theodore Search, Pharm. D., Board Member

Dr. Theodore Search is the General Manager and CEO of Real-World Data for Norstellia. Prior to his role at Norstellia, Dr. Search served as the CEO of Real-World Networks-Pharma Intelligence at Informa and was the Founder and CEO of Skipta, now a Norstellia company. He has been invited to speak at various conferences around the country and named among the Top 100 Most Inspiring People in the Life Sciences Industry in 2015 and among the Top 100 Elite Entrepreneurs in the pharmaceutical and healthcare industry in 2016. Dr. Search holds a Doctor of Pharmacy degree from the University of Pittsburgh, is a board licensed Pharmacist in the Commonwealth of Pennsylvania, and has benefited from practical pharmacy experience in both the retail and clinical settings.

Avril McKean Dieser, Board Member

Ms. Avril McKean Dieser is currently Vice President, Head of Legal Patient Evidence at UCB, Inc., a subsidiary of UCB S.A., a global biopharmaceutical company focused on severe diseases of the immune system and central nervous system. She has held senior roles at UCB since 2008, including her current position since August 2016 and a prior tenure from April 2008 to April 2013. In her current role, she leads a team of attorneys supporting UCB's global assets, payer functions, and regulatory, medical, and patient-focused activities, including clinical development. From May 2013 to July 2016, Ms. McKean Dieser served on the AbbVie Inc. legal team, providing global product support for its immunology and oncology franchises and acting as the government pricing lawyer for all pharmaceutical and combination products. Before entering the pharmaceutical industry, she practiced corporate law in Atlanta, Georgia,

at two nationally recognized law firms. She earned her J.D. from The Catholic University of America Columbus School of Law and is admitted to practice in Georgia and Illinois. She also holds an M.A. in Public Administration from the University of Maryland, European Division, and a B.A. in English Literature from Duquesne University. Ms. McKean Dieser lost her son, Edward, to osteosarcoma in January 2024 at the age of 21.

Olivier R. Jarry, Board Member

Mr. Oliver Jarry is currently the Co-founder and Chief Executive Officer of Libera Bio S.L., a private Spanish biopharmaceutical company devoted to the development of a new class of precision therapeutics to address intracellular cancer targets, since April 2018. He also serves as the Chief Operating Officer of Advantage Therapeutics Inc., an investigational-stage company focused on the diseases of aging, since May 2023 and as Chief Financial Officer of Rational Vaccines, Inc., an investigational-stage infectious disease company focused on combating herpes simplex virus 1 (HSV-1) and herpes simplex virus 2 (HSV-2) infections, since August 2021. Mr. Jarry served as an advisor to DarioHealth Corp. (Nasdaq: DRIO) from November 2016 to September 2017, and then as its President and Chief Commercial Officer until January 2020. Between 2015 and 2016, he served as Senior Vice President of the Consumer Sector and Officer at Intrexon Corp. (NYSE: XON), a biotechnology company focused on engineering biological systems to enable DNA-based control over the function and output of living cells. Prior to Intrexon, from 2011 to 2012, Mr. Jarry served as the Head of Strategy, Operations and Market Access, focusing on Emerging Markets, for Bristol-Myers Squibb (NYSE: BMY), where he oversaw the product launch and growth of innovative medicines relating to oncology, virology, rheumatology, cardiovascular, and diabetes. Prior to that, between 2009 and 2010, Mr. Jarry served as the Global Business Unit Head of Bayer Diabetes Care, a division of Bayer HealthCare Pharmaceuticals LLC. Prior to his time at Bayer HealthCare, from 2001 to 2009, Mr. Jarry served in several leadership roles at Novartis International AG (NYSE: NVS), including working as Global Division Head of Strategy, Business Development & Licensing at Novartis Headquarters in Switzerland, Senior Vice President and Region Head for Latin America and for Asia-Pacific for Novartis' Consumer Health Division, Head of India Rural Business and Head of Western/Eastern Europe, Russia, CIS - Vaccines division. Mr. Jarry holds a M.Sc. degree from Ecole Centrale de Paris, a MEng. degree from Délégation Générale pour l'Armement, and a Trium Executive MBA degree jointly awarded by NYU Stern School of Business, London School of Economics and Political Science and Hautes Études Commerciales Paris.

Olivia Egge, Emerita Board Member

Ms. Olivia Egge was diagnosed with osteosarcoma (OS) in February 2017, following a severe treatment protocol that has not advanced in forty years. Ms. Egge has given OS Therapies the inspiration to search for new cures for OS, while continually giving the Company the patient perspective. She graduated from the University of Virginia in May 2023 and has recently been accepted into medical school for the Fall of 2025.

Karim Galzahr, Board Member

Mr. Karim Galzahr is managing partner at OKG Capital, a medtech and life science investor. Mr. Galzahr brings over 30 years of experience in all aspects of finance including M&A, asset management, corporate development, and strategic advisory work across the technology sector and medical technology sectors. Throughout his career, Mr. Galzahr has played a pivotal role in driving growth, securing high-value investments, and advising industry leaders on financial strategy and business expansion. His expertise spans the intersection of finance, technology, and healthcare innovation, positioning him as a key player in advancing medtech solutions.

SCIENTIFIC & MEDICAL ADVISORY BOARD

OS Therapies’ Scientific & Medical Advisory Board comprises leading osteosarcoma clinicians and researchers who provide critical guidance to the Company’s scientific and clinical initiatives. These experts are dedicated to pioneering new treatments and advancing patient care in the fight against osteosarcoma. Figures 2 and 3 list the Company’s advisory board for its osteosarcoma and its tADC program, respectively.

Figure 2
OSTEOSARCOMA ADVISORY BOARD



Source: OS Therapies Inc.

Figure 3
ADC ADVISORY BOARD

Dr. Jutta Wanner	Founding Scientist	BlinkBio & OS Therapies
Dr. Borys Shor	President and CEO	Manhattan BioSciences
Chris Benecchi	Chief Business Officer	Sage Therapeutics
Scott Styles	Managing Partner	Styles Strategy
Edward Robb, DVM	Chief Strategy Officer	Anivive Animal Health

Source: OS Therapies Inc.

PATIENT ADVISORY BOARD

The Company’s Patient Advisory Board (Figure 4) unites patients, parents, physicians, advocates, and survivors through its partnership with the Osteosarcoma Collaboration. This collective effort ensures that patient perspectives are integral to OS Therapies’ mission, fostering a comprehensive approach to combating osteosarcoma.

Figure 4
OSTEOSARCOMA PATIENT ADVOCACY



Source: OS Therapies Inc.

Milestones and Strategic Catalysts

Over the past year, OS Therapies has achieved significant operational, clinical, and regulatory milestones as it advances toward bringing the first new treatment for osteosarcoma in over 40 years to the U.S. market.

General Operations

- Strengthened intellectual property position, as it was granted a U.S. Patent protecting the new commercial manufacturing process for the Listeria cancer immunotherapy platform through 2040.
- Enhanced financial position and market visibility:
 - Closed a \$4.2 million (July 2025) and a \$3.7 million (September 2025) warrant exercise inducement and exchange offerings, extending cash runway into mid-2026.
 - Closed a private placement financing, raising approximately \$6 million in gross proceeds before expenses.
 - OSTX common stock included in the Russell Microcap, Russell Microcap Value, and Russell Microcap Growth indexes.

OST-HER2 Osteosarcoma Development

- Completed the acquisition of the Listeria cancer immunotherapy platform from Ayala Pharmaceuticals, adding four clinical-stage and eight preclinical-stage assets, substantially expanding the Company's oncology pipeline.
- Completed the patient treatment phase of the Phase 2b trial evaluating OST-HER2 in the prevention of recurrence in fully resected, lung metastatic osteosarcoma.
- Reported positive Phase 2b data, demonstrating a statistically significant 12-month Event-Free Survival (EFS) and 2-year overall survival (OS) benefit.
- Accomplished key regulatory engagements:
 - Completed second Type C Meeting with the FDA on December 11, 2025, following its successful End of Phase 2 Meeting, to support a Biologics License Application (BLA). The Company gained clarity on surrogate efficacy endpoint analysis to support a BLA under the Accelerated Approval Program and received meaningful feedback on the Company's proposed confirmatory study design.
 - Completed a pre-MAA meeting with the UK's MHRA to discuss proposed clinical and surrogate clinical efficacy endpoints, and the Company's proposed confirmatory study design.
 - EMA's Committee for Medicinal Products for Human Use (CHMP) granted Union Marketing Authorization eligibility for OST-HER2. EMA CHMP requested an accelerated Marketing Authorization Application (MAA) submission for the metastatic osteosarcoma program by February 28, 2026.
- Entered a U.S. commercial partnership with EVERSORA®, initiating logistics and state licensing to support an expected U.S. Commercial launch of OST-HER2 following receipt of a BLA from U.S. FDA under the Accelerated Approval Program.

Canine Osteosarcoma Program

- Formed OS Animal Health, a wholly-owned subsidiary to advance OST-HER2 in canine osteosarcoma, following positive data from University of Pennsylvania studies.

- Featured in “Shelter Me: Cancer Pioneers”, a documentary highlighting OST-HER2-treated human and canine patients, nominated for two Daytime Emmy Awards.
- Announced plans to spin off OS Animal Health into a standalone public company to advance commercialization of OST-HER2 for canine osteosarcoma, with OS Therapies shareholders to receive direct equity participation.

tADC Platform

- Established OS Drug Conjugates (OSDC) to advance the Company’s proprietary pH-sensitive tunable Antibody Drug Conjugate (tADC) and tunable Drug Conjugate platforms.

FUTURE MILESTONES: PATH TO COMMERCIALIZATION AND EXPANSION

Looking ahead, OS Therapies remains focused on regulatory execution, commercialization readiness, and value creation through its OST-HER2 and Listeria-based immunotherapy platforms.

OST-HER2 Key Milestones (2025-2026)

- U.S. FDA BLA submission by end of January 2026; approval expected in Q3 2026
- EMA MHRA conditional MAA submission by end of January 2026; approval expected in Q2 2026
- SEMA pre-Marketing Authorization Application (MAA) meeting granted, expected to occur in Q1 2026
- European EMA conditional MAA submission by end of February 2026; approval expected by Q4 2026
- Commercial launch preparation in partnership with EVERESANA® for 1H 2027 product launch
- Potential sale of Priority Review Voucher (PRV) following BLA approval - Q3 2026
- Anticipated transition to cash-flow positive in 2026 following sale of PRV

Canine OST-HER2 Development

- Gain alignment with USDA on path to re-establishing conditional approval in Q1 2026
- Spin-off its subsidiary OS Animal Health, inc. by Q2 2026

Other Indications

- Receive clinical data from the OST-504 Phase 1b program at Columbia University in castration resistant prostate cancer in Q1 2026

tADC Platform Expansion

- Advance OST-tADC program through completion of preclinical and GLP toxicology studies
- Submit IND application to initiate a Phase I clinical trial in ovarian cancer
- Pursue strategic out-licensing of the SiLinker and CAPs drug conjugate platforms, generating potential non-dilutive revenue streams

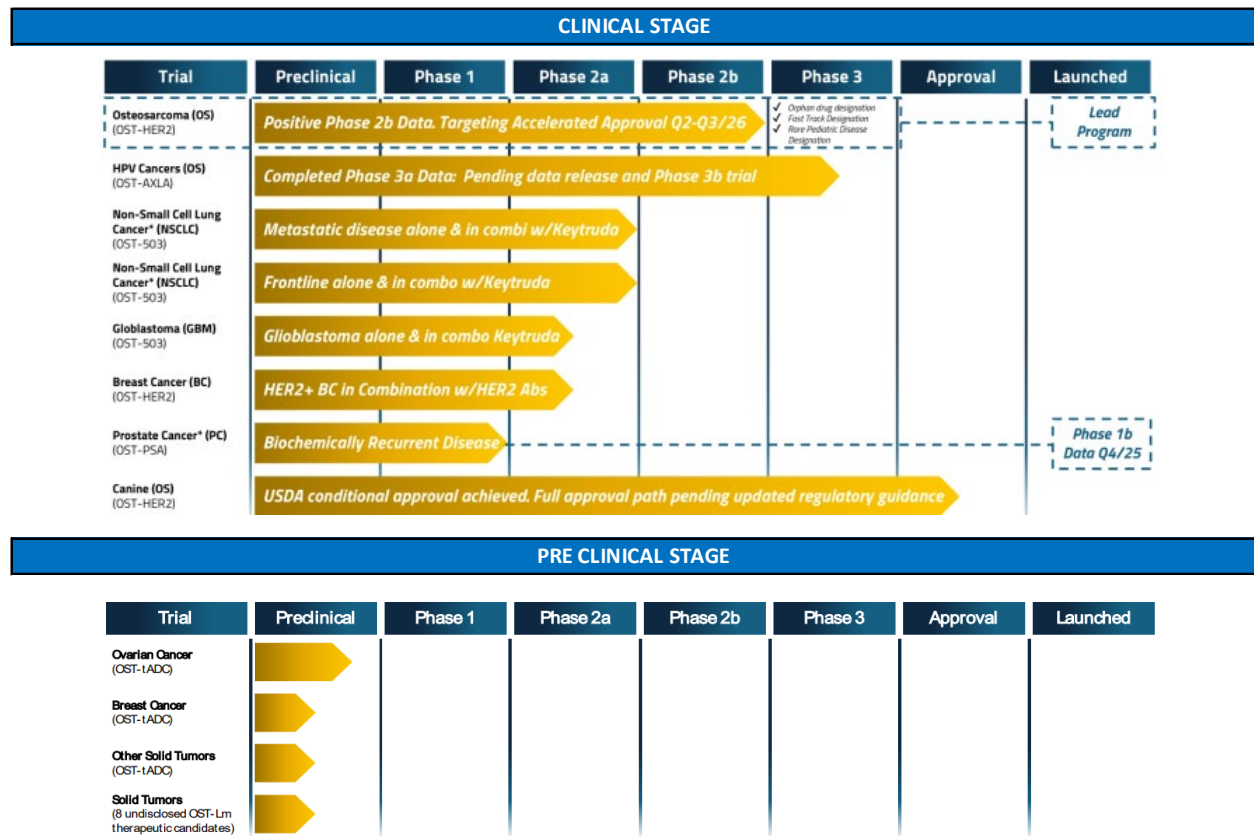
Core Story

OS Therapies Inc. (“OS Therapies” or “the Company”) is a clinical stage cancer immunotherapy company focused on the identification, development, and commercialization of treatments for osteosarcoma (OS) and other solid tumors. The Company was established to address a significant unmet medical need in oncology, developing new and effective treatments for bone cancers in both pediatric and adult populations.

Osteosarcoma, a rare and highly aggressive cancer, continues to pose significant therapeutic challenges due to its complex biology, difficult tumor locations, and high rates of recurrence. With no new approved treatments in more than three decades, this disease represents both a critical unmet medical need and a substantial market opportunity. OS Therapies is harnessing cutting-edge scientific innovation and a focused development approach to deliver the first meaningful advances in osteosarcoma treatment in decades, with therapies designed to transform patient outcomes and generate lasting value for patients, caregivers, and stakeholders.

OS Therapies has built a pipeline of product candidates targeting multiple indications for solid cancers, as seen in Figure 5, based on two novel drug technology platforms: (1) OST-Lm: a bioengineered form of the bacterium *Listeria monocytogenes* used to trigger a strong immune response against HER2-expressing cancers; and (2) OST-tADC: a next-generation tunable drug conjugate (tADC) platform, with a unique patented silicone component that improves safety and efficacy.

Figure 5
DEVELOPMENT PIPELINE



Source: OS Therapies Inc.

The Company's OST-Lm technology platform leverages the stimulatory effects of listeria bacteria to activate the immune system and initiate a strong immune response to kill cancers that express the HER2 protein, such as osteosarcoma, breast cancer, colorectal cancer, and other solid tumors. Through the use of this platform, OS Therapies has identified a lead candidate in OST-HER2, an off-the-shelf immunotherapy for osteosarcoma with a goal of rapid clinical development, regulatory review, and approval.

The Company is conducting a Phase 2b clinical trial to evaluate the efficacy of OST-HER2 in patients with resected, recurrent osteosarcoma, with positive preliminary data demonstrating statistically significant benefit in the 12-month Event Free Survival (EFS), the primary endpoint of the study. OST-HER2 has been awarded rare pediatric disease designation (RPDD) from the U.S. Food & Drug Administration (FDA) and fast-track and orphan drug designations from the FDA and European Medicines Agency (EMA). The Company anticipates submitting a rolling Biologics License Application (BLA) to the FDA for OST-HER2 in osteosarcoma by Q1 2026, with the goal of obtaining FDA Accelerated Approval by Q3 2026. The Company is also planning to apply for a Marketing Authorization Application (MAA) for the European market and is seeking to align BLA and MAA submission timing, in accordance with Project Orbis.

OS Therapies then plans to extend the applications of its lead candidate and OST-Lm platform into other solid tumors with the same recurrence mechanism of action, including breast, esophageal, and lung cancer. In addition to the development of OST-HER2 for solid cancers in humans, OST-HER2 is also a product candidate for veterinary use in canines, with OST-HER2 conditionally approved by the U.S. Department of Agriculture for the treatment of canines with osteosarcoma. In May 2025, the Company announced the launch of OS Animal Health, Inc., a wholly owned subsidiary focused on commercializing OST-HER2 in the veterinary space.

OS Therapies is also advancing its next-generation Tunable Antibody Drug Conjugate (tADC) platform, which features antibody-linker-payload candidates. This platform leverages the Company's proprietary tunable, tailored silicone linker technology, enabling the delivery of multiple payloads directly into and in the vicinity of solid tumors, including antibodies, chemotherapeutics, cytotoxins and potentially mRNA treatments. This technology is currently in pre-clinical studies.

OS Therapies' Growth and Commercialization Strategy

OS Therapies is pursuing a focused growth and commercialization strategy designed to build long-term value through the advancement of its oncology pipeline, efficient capital deployment, and strategic partnerships. The Company's mission is to extend and improve the lives of patients with rare and underserved cancers by developing novel targeted immunotherapies and antibody-drug conjugates (ADCs).

1. Advancing a Diversified Oncology Pipeline

OS Therapies is advancing a portfolio of proprietary biologic candidates targeting both orphan and non-orphan oncologic indications. The Company's lead candidate, OST-HER2, is being developed for the treatment of osteosarcoma and other HER2-expressing solid tumors. In parallel, OS Therapies is progressing OST-tADC for the treatment of ovarian and endometrial cancers, as well as certain osteosarcomas.

The Company's near-term growth will be driven by:

- Obtaining marketing approval for OST-HER2 in osteosarcoma, followed by expansion into other HER2-positive indications, such as breast, esophageal, lung, and other solid tumors, through a master protocol approach.
- Advancing OST-tADC through preclinical and IND-enabling studies, with a planned Phase I trial in ovarian cancer. Positive results from preclinical studies may also stimulate potential out-licensing activity for the tADC platform, without restricting ongoing therapeutic development.
- Support operations of its wholly-owned OS Animal Health, Inc. subsidiary, to re-establish USDA conditional approval for OST-HER2 in canine osteosarcoma.

2. Capital-Light Commercialization Model

The Company has adopted a capital-efficient commercialization model, leveraging best-in-class third-party infrastructure to accelerate time-to-market and reduce fixed overhead. In preparation for the anticipated launch of OST-HER2, OS Therapies has partnered with EVERSORA[®], a leading commercialization services provider, to deploy its fully integrated EVERSORA ONCOLOGY platform. This collaboration encompasses market access, medical affairs, field deployment, patient services, and stakeholder engagement. The Company believes that its collaboration with EVERSORA[®] provides the necessary infrastructure, expertise, and agility to successfully commercialize OST-HER2 without requiring significant capital investment in building an internal commercial organization. The partnership enables OS Therapies to potentially bring OST-HER2 to market rapidly and cost-effectively, supporting the Company’s mission to transform the treatment landscape for pediatric metastatic osteosarcoma while efficiently managing pre-Biologics License Application (BLA) expenses.

3. Strategic Manufacturing Partnerships

OS Therapies employs a fully outsourced manufacturing model, relying on Good Manufacturing Practice (GMP)-compliant third-party contract manufacturing organizations (CMOs) to produce clinical and commercial materials as well as for any potential commercial manufacturing needs. This approach minimizes capital requirements and allows the Company to focus on research, development, and commercialization.

The Company is currently working with ReciBioPharma to establish scalable supply chain agreements for the production of active pharmaceutical ingredients (APIs) and drug products. As programs advance and development progresses, OS Therapies plans to secure secondary backup suppliers for OST-tADC and other product candidates to mitigate potential supply chain risks and ensure continuity of production.

4. Business Development and Partnering Opportunities

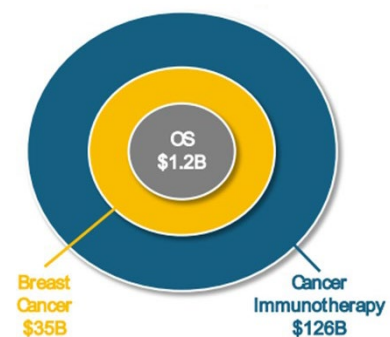
The Company intends to retain significant development and commercial rights to its product candidates and, upon obtaining marketing approval, plans to commercialize these products independently or in partnership within the U.S. and other global regions. While maintaining this focus on internal commercialization, the Company continues to evaluate strategic collaboration opportunities with pharmaceutical and biotechnology partners. A notable example includes the partnership with BlinkBio, Inc., through which the Company in-licensed its OST-tADC technology, demonstrating a broader strategy of leveraging proprietary technology and expertise to advance innovative oncologic therapies.

5. Long-Term Value Creation

By combining a focused R&D investment, lean operating structure, and strategic commercialization partnerships, OS Therapies aims to build a sustainable growth platform with multiple value inflection points over the next 24 to 36 months. Near-term milestones, including OST-HER2 regulatory submission and early-stage clinical data from OST-tADC, are expected to drive both clinical validation and shareholder value creation.

The Company’s OST-Lm technology initially targets the osteosarcoma market, valued at \$1.2 billion (Source: Data Bridge Market Research’s *Global Osteosarcoma Drug Market-Industry Trends and Forecast to 2030*, 2023). However, future applications of OS Therapies’ technology may result in the expansion of indications targeted by the Company, to include segments such as the breast cancer therapeutics markets, within the growing cancer immunotherapy overall market, as shown in Figure 6.

Figure 6
OS THERAPIES TAM



Source: OS Therapies Inc.

OSTEOSARCOMA

Osteosarcoma is the most common primary malignant tumor of the bone, originating from primitive bone-forming mesenchymal cells that produce osteoid, or immature bone tissue. It most often develops in the long bones, e.g., femur, tibia, humerus, although it can also occur in other skeletal regions, such as the pelvis, jaw, and shoulder.

The disease demonstrates a distinct bimodal age distribution, with a primary incidence peak during adolescence and young adulthood (ages 10-20), coinciding with periods of rapid skeletal growth, and a smaller secondary peak in older adults, typically linked to prior radiation exposure or preexisting bone disorders such as Paget's disease. Osteosarcoma's predilection for areas of active bone formation contributes to its higher prevalence among children, teenagers, and young adults.

Clinically, osteosarcoma is characterized by its aggressive nature and strong propensity for early metastasis, most commonly to the lungs. This rapid metastatic potential significantly complicates treatment and remains a major factor contributing to the persistently low survival rates observed in advanced disease.

Incidence and Survival Rates

Although rare, osteosarcoma represents one of the most aggressive cancers affecting young individuals. In the U.S., approximately 1,000 new cases are diagnosed each year, accounting for roughly 2% to 3% of all pediatric cancers (Source: American Cancer Society). Globally, the incidence is estimated to be 3.4 new cases per million people per year, with osteosarcoma representing 4% of all newly diagnosed malignancies in children. Using the most recent world population estimates (around 8 billion), this would translate to approximately 27,000 new cases annually worldwide, though precise global figures are difficult to ascertain due to data limitations (Source: NIH National Library of Medicine's *Osteosarcoma (Osteogenic Sarcoma)*, 2024).

Survival outcomes for osteosarcoma vary widely depending on disease stage at diagnosis. For patients with localized, non-metastatic disease, five-year survival rates range from 60% to 75%. However, prognosis remains poor for patients with metastatic or recurrent disease, with five-year survival typically ranging between 5% and 30% (Source: American Cancer Society).

Metastasis in Osteosarcoma

Despite advances in surgical techniques and chemotherapy optimization, overall survival rates for metastatic osteosarcoma have not improved meaningfully over the past three decades. This is of significance, as approximately 30% to 50% of patients with localized osteosarcoma and 80% of patients with metastatic disease at diagnosis experience relapse. For those patients, the most common site for both metastasis and recurrence are the lungs, with median time to recurrence between 14 and 18 months and about 95% of relapses occurring within the first five years of diagnosis (Source: Texas Oncology).

Metastatic disease remains the most powerful prognostic factor. Current 5-year overall survival (OS) for newly diagnosed patients with localized disease is 70%, while for those with metastatic or non-resectable disease, OS does not exceed 30%. In a recent study, 5-year OS and Event Free Survival (EFS) were 61% and 56.6%, respectively, with patients with localized disease exhibiting 5-year OS of 75.5% and EFS of 69.3%. However, patients with metastatic or recurrent disease exhibit 5-year OS and EFS of 22.2% and 22.2%, respectively (Source: *Clinical and Translational Oncology*, Vol. 27 (9):3781-3792, 2025). Additional studies provide similar results, with OS rates for patients with recurrent or metastatic disease at 2, 5, and 10 years at 38%, 23%, and 18%, respectively (Source: *Journal of Clinical Oncology*, Vol.;23(3):559-68, 2005). Median survival after first recurrence was 31 months (Source: *Pediatric Blood Cancer*, Vol. 47(3):255-9, 2006). Figure 7 (page 19) provides an overview of OS and EFS data for osteosarcoma.

Figure 7
OSTEOSARCOMA OVERALL SURVIVAL (OS) AND EVENT FREE SURVIVAL (EFS) DATA

Clinical and Translational Oncology, Vol. 27 (9), 2025			Journal of Clinical Oncology, Vol. 23(3), 2005	
	5 yr OS	5 yr EFS	OS	
Overall	61.0%	56.6%	2 yr	38%
Localized disease	75.5%	69.3%	5 yrs	23%
Metastatic or Recurrent	22.2%	22.2%	10 yr	18%

Sources: *Clinical and Translational Oncology*, and *Journal of Clinical Oncology*.

Standard of Care (SOC)

Osteosarcoma is primarily managed through surgical excision of both the primary tumor and, when feasible, secondary lesions. However, surgery alone, as practiced in the 1960s, yielded poor outcomes, with overall survival rates of only about 11%. Within one year of treatment, up to 90% of patients experienced disease relapse, most commonly presenting with pulmonary metastases. A major breakthrough in osteosarcoma therapy occurred in the 1980s, when the addition of multi-agent chemotherapy was shown to significantly improve survival compared with surgery alone (Source: *Cancers*, Vol. 13(8):1757, 2021).

The current standard of care (SOC) combines complete surgical resection with multi-agent systemic chemotherapy administered both before (neoadjuvant) and after (adjuvant) surgery for high-grade disease. This regimen typically includes methotrexate, doxorubicin, and cisplatin, with some protocols substituting or adding ifosfamide. The multimodal approach aims to eradicate micro-metastatic disease, assess histologic tumor necrosis, and enhance surgical outcomes. Advances in imaging and reconstructive techniques have also made limb-sparing procedures increasingly feasible. Despite these improvements, the treatments remain highly toxic and show limited efficacy in recurrent or metastatic settings.

Over the past four decades, survival outcomes for osteosarcoma have shown little improvement. Relapsed, unresectable, or treatment-refractory osteosarcoma continues to present a major clinical challenge, with poor prognosis. Aside from liposomal muramyl tripeptide phosphatidylethanolamine (L-MTP-PE), which is not approved for use in the U.S., no new chemotherapeutic, targeted, or immunotherapeutic agents have demonstrated meaningful activity against this disease (Source: *Journal of Clinical Oncology*, 34(25), 2016).

Consequently, survival rates have remained largely unchanged. Despite aggressive multimodal treatment, including surgery, chemotherapy, and occasionally radiotherapy, the five-year survival rate for localized osteosarcoma remains approximately 60% to 70%. For patients with recurrent or metastatic disease, most often involving the lungs, available therapeutic options are extremely limited, and outcomes remain dismal. In metastatic osteosarcoma, survival rates drop dramatically to 15% to 30%, highlighting the urgent need for novel and effective therapeutic strategies. Currently, surgical removal of pulmonary metastases remains the only potentially beneficial intervention for recurrent disease, as all tested systemic therapies, including conventional chemotherapy, checkpoint inhibitors (e.g., pembrolizumab), and targeted agents (e.g., trastuzumab), have failed to show significant benefit.

Treatment Market

The global osteosarcoma treatment market remains relatively small in absolute terms but represents a compelling orphan oncology opportunity. The market was valued at \$1.2 billion in 2022, and is expected to reach \$1.8 billion by 2030, a CAGR of 5.50%. This growth is driven by the high mortality and severity of osteosarcoma in the pediatric and adolescent populations, coupled with the development and introduction of advanced treatment options, such as targeted therapies. The rarity of the disease, coupled with its high unmet medical need and limited competition, supports the potential for premium pricing and regulatory incentives, such as orphan drug designation in major markets (Source: Data Bridge Market Research's *Global Osteosarcoma Drug Market - Industry Trends and Forecast to 2030*, 2023).

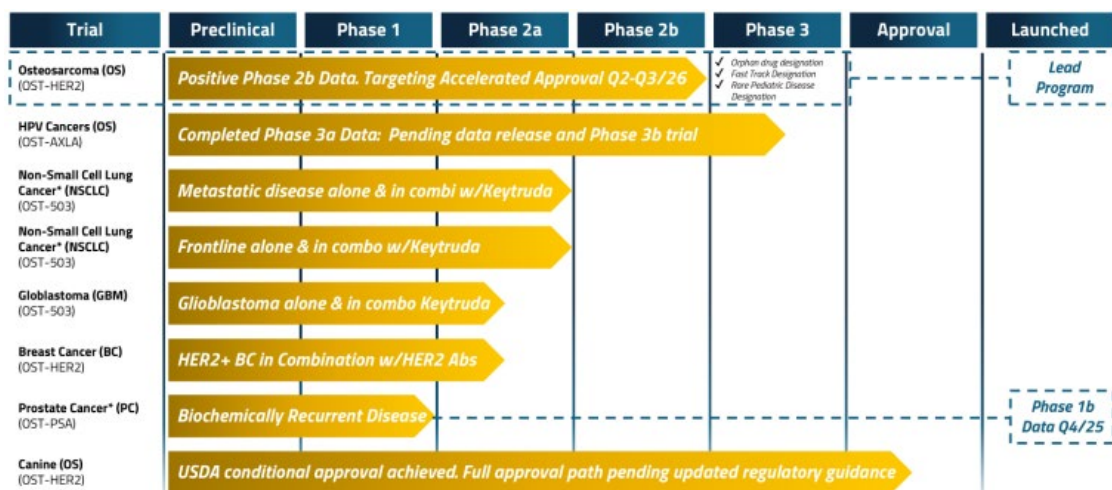
LISTERIA MONOCYTOGENS PLATFORM (OST-Lm)

OS Therapies is advancing a next-generation immuno-oncology platform based on a proprietary *Listeria monocytogenes* (Lm) vector designed to activate the body’s immune system to generate a potent, targeted anti-tumor response, recognizing and destroying cancer cells. The Company’s live-attenuated *Listeria* construct delivers tumor-associated antigens (TAA)—proteins or other molecules that are found in tumor cells and can be recognized by the immune system—directly to antigen-presenting cells, stimulating both innate and adaptive immune pathways, and generating strong immediate and long-term anti-tumor responses. By engaging both innate and adaptive immunity, the platform has the potential to generate durable, systemic protection capable of targeting micrometastatic and residual disease, critical challenges in osteosarcoma and other solid tumors. This mechanism enables robust and durable T-cell-mediated immunity against cancer cells expressing the targeted antigen, such as HER2 in osteosarcoma.

The key advantage of OS Therapies’ approach lies in its ability to elicit a potent, tumor-specific immune response with minimal off-target toxicity. By encoding tumor-associated antigens, the platform focuses immune activity on malignant cells while sparing healthy tissue. The platform’s modular design also allows for rapid adaptation to different cancer antigens, creating a scalable pipeline opportunity across multiple oncology indications by substituting or combining antigen targets. Moreover, its mechanism of action is compatible with existing therapeutic modalities, such as checkpoint inhibitors and other immunotherapies, offering a potential path to combination regimens that could further enhance efficacy.

The Company’s *Listeria*-based platform is anchored by OST-HER2, being investigated in two clinical programs for osteosarcoma and breast cancer, in addition to having conditional approval for use in canine osteosarcoma. The osteosarcoma indication is the closest to potential regulatory submission, with the investigational candidate having previously been granted rare pediatric disease designation, orphan drug designation, and fast track designation by the FDA. The other mid-stage and early-stage assets (OST-AXAL for HPV, OST-503 for non-small cell lung cancer and glioblastoma, and OST-504/PSA for prostate cancer) broaden the platform’s reach into multiple cancer types, providing strategic diversification. The Company’s pipeline also includes preclinical programs in multiple solid tumor indications that further extend the platform’s value and potential. OS Therapies’ Lm-based pipeline, shown in Figure 8, gives the Company both near-term value (OST-HER2 regulatory path) and longer-term upside (pipeline expansion across indications). The technology platform’s strong preclinical rationale, early clinical validation, and orphan oncology focus position OS Therapies as a leader in a differentiated segment of immuno-oncology.

Figure 8
LISTERIA-BASED PIPELINE



Source: OS Therapies Inc.

Acquisition of Ayala Pharmaceuticals, Inc.

OS Therapies originally licensed ADXS-HER2 (now its lead program OST-HER2) from Advaxis, Inc. in early September 2018. Subsequently, on April 9, 2025, the Company’s acquired the listeria monocytogenes-based immuno-oncology program and related intellectual property (IP) assets from Ayala Pharmaceuticals (OTC: ADXS) (formerly Advaxis, Inc.). The agreement bolstered the Company’s development pipeline, positioning it as a world leader in Listeria-based cancer immunotherapy.

The assets acquired by the Company included three clinical cancer immunotherapy candidates: (1) AXAL/ADXS/HPV (renamed OST-AXAL) for human papilloma virus (HPV)-associated cancers; (2) ADXS-503 (OST-503) for non-small cell lung cancer (NSCLC) and glioblastoma; and (3) ADXS-504/ADXS31142 (OST-PSA/OST-504) for prostate cancer. In addition, the assets also included eight pre-clinical candidates targeting over 30 solid tumor cancers.

The acquisition also allowed the Company to gain direct ownership of the key underlying IP assets related to its Listeria monocytogenes immunotherapy platform and its lead asset OST-HER2. This agreement also eliminates certain milestones, projected sales, and royalty payment obligations related to OST-HER2 in osteosarcoma. As a result, OS Therapies believes that this transaction has enhanced both the clinical and financial position of the Company. Under the terms of the agreement, OS Therapies has agreed to pay \$0.5 million in cash and issue \$7.5 million worth of common shares to Ayala.

LISTERIA MONOCYTOGENES OVERVIEW

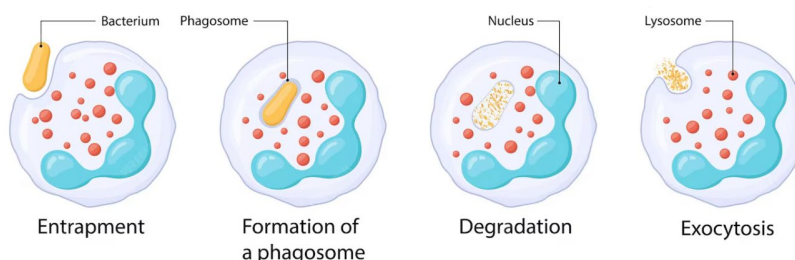
OS Therapies’ Listeria-based immunotherapy platform represents a differentiated approach within the immuno-oncology landscape. By leveraging the body’s own immune system to selectively target tumor antigens, the platform offers both meaningful clinical potential and an opportunity for significant value creation in rare and underserved cancer indications such as osteosarcoma.

Listeria-Monocytogenes

Listeria-based immunotherapies use a live, attenuated (weakened) form of Listeria monocytogenes to activate the body’s immune system to recognize and attack cancer cells. These modified bacteria are engineered to express tumor-associated antigens (TAAs), unique markers found on cancer cells that trigger a targeted T-cell and immune response against the tumor. This approach offers several advantages: Listeria is a powerful immune activator, can be customized to deliver a wide range of tumor antigens, and has demonstrated encouraging results in both preclinical studies and early clinical trials (Source: *Frontiers in Immunology*, Vol. 12, 2021).

Scientists modify Listeria to express one or more TAA (e.g., HER2, PSA, HPV-E7). Once administered, the attenuated bacteria infect antigen-presenting cells (APCs)—such as dendritic cells and macrophages—key orchestrators of the immune response by aiding T-cells to recognize and attack foreign invaders. APCs normally engulf a pathogen, encapsulate a **phagosome** membrane inside the cell, and destroy it into smaller pieces, a process called **phagocytosis** (Figure 9). They then excrete or present these pieces (antigens) on their surface to trigger an immune response.

Figure 9
PHAGOCYTOSIS



Source: Freepik.com.

However, what differentiates *Listeria monocytogenes* from its vaccine peers and makes it a superior vector for delivery of cancer antigens is its unique life cycle. *Lm* is readily taken up by macrophages and dendritic cells and, once within the phagosome, expresses and secretes a pore-forming toxin listeriolysin-O (LLO), which disrupts the integrity of the phagosome and facilitates the escape of *Lm* from the phagosome and into the cytoplasm. Once there, *Lm* secretes the encoded antigen payload (e.g. HER2 antigens), which are then processed, degraded, and presented on the surface of the cell, subsequently stimulating specific T-cells and eliciting a robust and long-lasting immunological response.

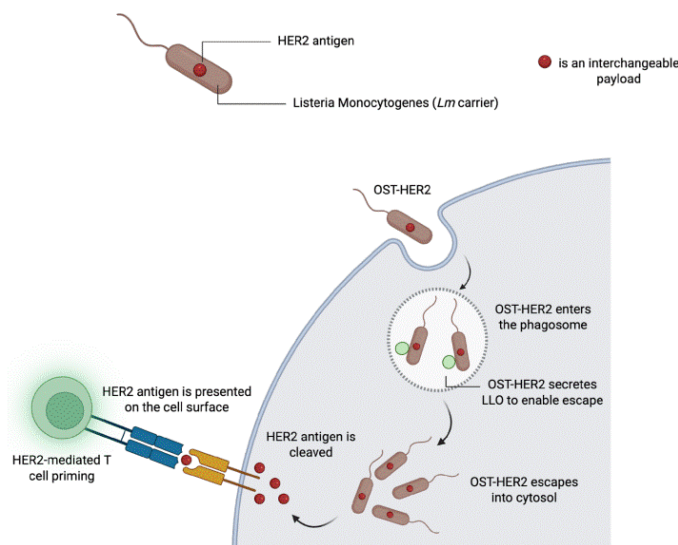
In addition to its distinctive life cycle, *Listeria monocytogenes* offers several key advantages as a vector for tumor immunotherapy. Studies have shown that antigens delivered by *Listeria*-based constructs are more efficiently processed and presented by immune cells than those delivered by other bacterial vectors. Moreover, *Listeria* exhibits a natural tropism for both primary and metastatic tumors and can overcome immune tolerance by reducing regulatory T-cells within the tumor microenvironment. This mechanism enables the *Lm* platform to actively reprogram the tumor microenvironment, transforming it from immunosuppressive (cold) to immunoreactive (hot), and thereby enhancing anti-tumor immune activity.

Attenuated strains of *Lm* have been successfully utilized as vaccine vectors for both infectious diseases and cancer. Preclinical studies across multiple tumor types have demonstrated that *Listeria*-based vaccines can effectively activate potent anti-tumor immune responses and, in many cases, eradicate tumors. These attributes position *Lm*-based therapies as a promising approach both as standalone treatments and in combination with immune checkpoint inhibitors, adoptive cell therapies, or radiotherapy, offering the potential for enhanced efficacy with reduced toxicity (Source: *Frontiers in Immunology*, Vol. 14:1278011, 2023).

Listeria-based cancer vaccines uniquely combine the target specificity of a therapeutic vaccine with the immune potency of an oncolytic agent. Unlike some immunotherapies that require ex vivo cell modification, *Listeria* naturally targets and infects immune cells within the body, enabling a more streamlined and effective immune response. Additionally, *Listeria* strongly stimulates both the innate and adaptive immune systems without the need for adjuvants, enhancing overall immunogenicity. The platform’s flexibility allows it to be engineered with a wide range of tumor antigens, offering broad potential across multiple cancer types.

OS Therapies’ *Lm* technology platform mechanism of action (MOA) is shown In Figure 10 and described below.

Figure 10
LM MECHANISM OF ACTION



Source: OS Therapies Inc.

1. Vector Engineering and Antigen Delivery

A live but highly attenuated strain of *Listeria monocytogenes* is used as a delivery “vector.” The bacterium is genetically engineered to carry a specific cancer-associated antigen payload, which is delivered directly into the body to stimulate a targeted immune response.

2. Escaping the Phagosome

Once administered, the attenuated *Listeria* bacteria infect antigen-presenting cells (APCs). After internalization, *Listeria* secretes LLO, enabling it to escape from the phagosome and release the encoded tumor-associated antigens (TAAs) into the cytoplasm.

3. Secretion and Presentation of TAA Payload

The released TAAs are processed and presented on the cell surface via MHC class I molecules, leading to the activation of T-cells. This process stimulates a robust and specific cytotoxic T-cell response directed against tumor cells expressing the targeted antigens.

4. Continuous Immune Response

Activated T-cells proliferate, circulate throughout the body, and infiltrate sites of primary and metastatic tumors. Within the tumor microenvironment, *Listeria*-induced immune activation reduces populations of regulatory T-cells (Tregs) and myeloid-derived suppressor cells (MDSCs), which typically protect tumors from immune attack. As T-cells destroy cancer cells, new tumor antigens are exposed, reinforcing a self-sustaining cycle of immune activation and long-lasting anti-tumor effects.

*5. Clearance of *Listeria**

The attenuated bacteria are designed for rapid elimination from the body, typically cleared by antibiotics within hours after administration. Despite bacterial clearance, the adaptive immune response continues to target and eliminate cancer cells, sustaining therapeutic benefit.

OST-HER2—OSTEOSARCOMA

Recent advances in osteosarcoma research are aimed at improving outcomes for patients with refractory or metastatic disease. Current efforts focus on the development of targeted therapies directed at specific molecular alterations, novel immunotherapies, and antibody-drug conjugates (ADCs) designed to enhance tumor specificity while minimizing systemic toxicity. Emerging strategies also emphasize biomarker-driven patient selection, combinations with immune checkpoint inhibitors, and continued advancements in surgical and imaging technologies. Despite these promising developments, no new therapies have received FDA approval for osteosarcoma in more than three decades, highlighting the urgent need for innovative treatment options. Given the persistent challenges of chemotherapy resistance and high recurrence rates, the development of targeted and next-generation immune-based therapies, such as those pioneered by OS Therapies, represents a potential critical advancement in the fight against osteosarcoma.

The Company's lead program, OST-HER2, is a novel "off-the-shelf" immunotherapy designed to harness the immune-stimulating power of *Listeria monocytogenes* to fight HER2-expressing tumors such as osteosarcoma, breast, and esophageal cancers. The therapy uses a live, bioengineered, and highly attenuated form of *Listeria* to deliver a HER2 tumor-associated antigens payload, eliciting a robust immune response by training T-cells to recognize and destroy cancer cells expressing the HER2 protein. This approach not only targets the HER2 antigen but also stimulates a broad, durable immune response against multiple tumor antigens, enhancing the body's ability to prevent metastasis, delay recurrence, and improve overall survival. By leveraging this novel mechanism, OST-HER2 represents a next-generation immunotherapy platform with potential to address significant unmet needs in osteosarcoma and other HER2-positive solid tumors.

OST-HER2's lead indication is recurrent, resected lung-metastatic osteosarcoma. The treatment is administered as an intravenous infusion every three weeks for up to 48 weeks and could potentially represent the first new treatment in over 40 years for pediatric osteosarcoma. A Phase 2b clinical trial is currently underway, with positive early clinical data showing statistically significant improvement in 12-month Event-Free Survival (EFS) (the primary endpoint) and overall survival (OS), when compared to historical controls. The treatment was well-tolerated, with most side effects being mild to moderate. OST-HER2 has been awarded the following designations:

- Rare Pediatric Disease Designation (RPDD) from the FDA;
- Fast-Track designations from the FDA and the EMA; and
- Orphan Drug designations from the FDA and the EMA.

Based on the Phase 2b study results, the Company anticipates starting a Biologics License Application (BLA) rolling submission for OST-HER2 in osteosarcoma in Q1 2026, with the goal of obtaining FDA Accelerated Approval by Q3 2026. The Company is also planning to apply for a Marketing Authorization Application (MAA) for the European market and is seeking to align BLA and MAA submission timing, in accordance with Project Orbis. These efforts are detailed on pages 28-29.

Under the RPDD program (created to encourage development of drugs in areas of high unmet medical need by giving an additional commercial/reward upside), the FDA can issue a Priority Review Voucher (PRV) to the sponsor of a qualifying drug/biological product that, once redeemed, grants a priority review of another human drug application. A "priority review" generally means the FDA's goal is to act on the application in 6 months (instead of the standard ~10 months) from filing. The voucher is transferable (can be sold or assigned). Due to its RPDD designation, if OS Therapies receives Accelerated Approval of OST-HER2 prior to September 30, 2026, it will become eligible to receive a PRV that it intends to sell. The most recent PRV sale, completed in June 2025 for \$160 million (following a May 2025 transaction valued at \$155 million), reflects continued strength in the PRV market. The Company believes PRV values are likely to appreciate further, providing an attractive source of potential non-dilutive capital to support ongoing clinical development and future growth initiatives.

OST-HER2 Clinical Trials

The Company is advancing regulatory efforts to obtain FDA approval for its lead asset, OST-HER2, for the treatment of recurrent, fully resected, lung-metastatic osteosarcoma. The OST-HER2 clinical program includes both a Phase 1 safety and dose-finding study and a Phase 2b trial that achieved statistically significant improvements in Event-Free Survival (EFS) and overall survival (OS) (Figure 11). Beyond osteosarcoma, OST-HER2 has demonstrated strong preclinical efficacy in HER2-positive breast cancer and other solid tumor models, supporting broader potential applications.

Figure 11
OST-HER2 CLINICAL PROGRAM OVERVIEW

	Indication	Patients	Key Endpoints
Phase 1b	HER2-expressing solid tumors (breast, esophageal, GE junction)	12 patients	Safety / tolerability (dose selection)
Phase 2b	Phase 2b Recurrent, fully-resected lung-metastatic osteosarcoma	~41 patients enrolled across ~21 U.S. sites.	Primary: 12-month Event Free Survival (EFS) Secondary: 3-year Overall Survival (OS)

Sources: OS Therapies Inc. and Crystal Research Associates, LLC.

OST-HER Phase 1 Trial

From September 2015 to May 2017, Advaxis conducted a Phase 1b clinical trial evaluating ADXS-HER2 (now OST-HER2) in patients with HER2-positive solid tumors. This multicenter, dose-escalation study was designed to establish the maximum tolerated dose (MTD) and determine the recommended Phase 2 dose. A total of 12 patients were enrolled—10 with breast cancer, 1 with esophageal cancer, and 1 with gastroesophageal junction cancer—and received escalating doses of ADXS-HER2 administered every three weeks over a 12-week treatment cycle. After completing treatment, all participants entered a three-year safety and disease surveillance period.

The primary objective of the study was to evaluate the safety and tolerability of ADXS-HER2. Overall, the results indicated that intravenous infusion of ADXS-HER2 was well tolerated among the 12 treated subjects, with no evidence of dose-limiting toxicities, significant safety concerns, or treatment discontinuations observed. Based on these findings, a recommended Phase 2 dose of 1×10^9 CFU was established, as it demonstrated a favorable safety profile and supported progression to the pivotal Phase 2b trial in recurrent osteosarcoma.

While this study was not designed to assess the efficacy of the OST-HER2 compound in treating HER2-expressing tumors, the Company reported preclinical findings in parallel (in HER2 transgenic mouse model of breast cancer) that support OST-HER2's potential therapeutic benefit. Key preclinical results included:

- 78% reduction in tumor size (3 mm in OST-HER2-treated mice vs. 14 mm in controls) at day 75 in the HER2 breast cancer model;
- Prevention of tumor formation in 33% of OST-HER2-treated mice compared with 0% in the control group at week 50;
- 20% additional reduction in tumor size when OST-HER2 was combined with a HER2-targeted antibody, compared with antibody treatment alone, in a tumor regression model; and
- 65% reduction in metastatic cell concentration in OST-HER2-treated mice compared with controls in a brain metastasis model.

These results are further detailed under the OST-HER2 Breast section of the Core Story, on pages 30-31.

OST-HER2 Phase 2b Trial (AOST-2121 / NCT04974008)

In July 2021, a Phase 2b clinical trial was initiated to evaluate the efficacy of OST-HER2 in patients with recurrent, fully resected, lung-metastatic osteosarcoma. This open-label, multicenter, single-arm study enrolled 41 patients aged 12 to 39 years who had experienced at least one episode of pulmonary recurrence of osteosarcoma that had been completely resected. Participants were recruited from approximately 21 sites across 18 U.S. states. The study primary and secondary endpoints are listed in Figure 12.

Figure 12
PHASE 2b STUDY ENDPOINTS

Primary Endpoint: 12 month Event Free Survival (EFS)
The relative proportion of patients experiencing event-free (recurrence-free) survival at 12 months, compared to historical controls. Patients will be evaluated for recurrence every 3 months, consistent with the standard of care.
Secondary Endpoint: 3 year Overall Survival (OS)
Overall survival of patients for three years will be compared to the 3-year overall survival of historical controls.

Sources: OS Therapies Inc. and Crystal Research Associates, LLC.

The treatment regimen consisted of 16 infusions of OST-HER2 administered every three weeks over a 48-week period, followed by a final follow-up visit four weeks after the last infusion. Upon treatment completion, all patients entered a three-year survival follow-up phase. The treatment phase of the trial was completed on September 30, 2024, and patients are currently being monitored for long-term survival outcomes.

Safety was assessed throughout the treatment period of 48 weeks, measuring the incidence of treatment-emergent adverse events. Assessments of potential persistence of the vector are being conducted every 3 months for an additional 3 years after treatment.

Phase 2b Trial Results

During the trial, OST-HER2 demonstrated a favorable safety profile compared with the standard of care. Among the 40 patients evaluated, 13 experienced serious adverse events (SAEs), of which 7 were considered treatment-associated adverse effects (TSAEs). All reported TSAEs were Grade 3 in severity; no Grade 4 or Grade 5 TSAEs were observed. Importantly, none of the patients experiencing TSAEs discontinued participation in the study. Results are outlined in Figure 13 and detailed below.

Figure 13
PHASE 2b STUDY RESULTS

	OST-HER2	Historical Control	P-Value
Primary Endpoint: 12 month EFS	35%	20%	0.0196
Secondary Endpoint (interim): 2-year OS	75%	40%	<0.0001
Subgroup Analysis: 2-year OS			
Patients with lung-only first metastatic event	73.8%	30%	< 0.0001
Patients who achieved EFS past 12 months	100%		
Patients who did not achieve EFS past 12 months	59%		

Sources: OS Therapies Inc. and Crystal Research Associates, LLC.

Primary Endpoint Results—12-month EFS vs historical control

On January 15, 2025, OS Therapies announced that its Phase 2b clinical trial of OST-HER2 achieved its primary endpoint with statistical significance. The study's primary outcome measure was 12-month Event-Free Survival (EFS), defined as the absence of metastatic osteosarcoma recurrence compared to the best available historical control data from U.S. published literature.

Results demonstrated that 35% of OST-HER2-treated patients achieved 12-month EFS, compared with approximately 20% in the historical control group, representing a statistically significant improvement. Among the 40 patients treated and evaluable (1 lost to follow-up), 14 achieved one-year EFS, highlighting OST-HER2's potential to provide meaningful clinical benefit for patients with recurrent, fully resected, lung-metastatic osteosarcoma and supporting the therapeutic potential of OST-HER2 in this difficult-to-treat population.

Secondary Endpoint Results—Three-year OS vs. historical control

The secondary outcome measure of the Phase 2b trial is overall survival (OS) assessed over a three-year period and compared with published historical control data. Patients are being evaluated every three months throughout the three-year follow-up period.

Ongoing analyses demonstrate a strong trend in favor of OST-HER2-treated patients in both the one-year and two-year interim assessments of the secondary endpoint. At the two-year mark, 27 of the 36 evaluable patients (five were lost to follow-up), 75% remained alive compared with approximately 40% in the historical control group, representing a statistically significant difference. These findings indicate a promising survival advantage for OST-HER2-treated patients and support continued follow-up to assess long-term overall survival at the three-year endpoint.

Subgroup Analysis Results

The Company conducted subgroup analyses following its participation in the FDA and The Osteosarcoma Institute (OSI) Workshop: Advancing Osteosarcoma Drug Development—Connecting Research and Regulatory Pathways for Improved Outcomes held on October 10, 2025.

The analyses demonstrated a strong correlation between 12-month EFS and long-term outcomes. Specifically, 100% of patients who achieved 12-month EFS also achieved 2-year OS, compared with 59% of patients who did not achieve 12-month EFS. Notably, all patients who were disease-free at 12 months remained alive at 12, 18, 24, and 30 months at their most recent follow-up.

Subgroup evaluations suggest particularly favorable outcomes among certain patient populations, supporting the potential for targeted labeling or stratified treatment approaches, with the following key subgroup findings:

Patients with a lung-only second or later metastatic event:

- 2-year OS: 80.0% (8/10; 2 lost to follow-up)
- 1-year EFS: 50% (6/12; no loss to follow-up)

Patients with a lung-only first metastatic event:

- 2-year OS: 73.8% (19/26; 3 lost to follow-up) versus 30% in the natural history comparator ($p < 0.0001$)
- 1-year EFS: 28.6% (8/28; 1 lost to follow-up)

These findings underscore the association between early disease control and improved long-term survival, particularly in subgroups with lung-only metastases.

Regulatory Activities

OS Therapies intends to pursue U.S. Food and Drug Administration (FDA) approval for OST-HER2 in the rare pediatric cancer osteosarcoma. The Company plans to submit a Biologics License Application (BLA) to the FDA’s Center for Biologics Evaluation and Research (CBER) in Q1 2026, seeking approval to market the drug candidate under the FDA’s Accelerated Approval Program. Once the application is submitted, the FDA typically completes its review of a BLA within six to ten months, subject to any requests for additional information.

In parallel, the Company is preparing to submit Marketing Authorization Applications (MAAs) utilizing the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) Conditional Approval pathways. The Company remains on track to submit a conditional MAA to the MHRA, a BLA to the FDA, and an MAA to the EMA in Q1 2026. A list of key milestones needed for the regulatory approval of OST-HER2 are shown in Figure 14.

Figure 14
OST-HER2 MILESTONES FOR APPROVAL

STRATEGY: OVERALL SURVIVAL + BIOMARKERS	
Milestones to Accelerated Approval (US) & Conditional Approval (UK/ EMA)	Timeline
UK MHRA Pre-MAA Meeting (2-year overall survival + biomarker correlation)	December 2025
US FDA Type C Meeting (2-year overall survival + biomarker correlation)	December 11, 2025
EMA SAM Meeting (2-year overall survival + biomarker correlation)	December 2025
UK MHRA MAA Filing for Approval (2-3 month review after filing)	Q1 2026
US FDA BLA Filing for Approval (3-6 month review after filing)	Q1 2026
EMA MAA Filing for Approval (3-6 month review after filing)	Q1 2026

Source: OS Therapies Inc.

Accelerated Approval

OS Therapies believes that the demonstrated efficacy results, together with the favorable safety profile and the significant unmet clinical need in osteosarcoma, support the potential for accelerated regulatory approval of OST-HER2, allowing the Company to advance OST-HER2 through the regulatory approval process without the need for a Phase 3 clinical trial.

The Company views the FDA’s August 18, 2025, “Overall Survival in Oncology Clinical Trials Guidance” as an important advancement for the field, emphasizing outcomes that matter most to patients: long-term survival and quality of life. The guidance considers overall survival as an objective, clinically meaningful endpoint: easy to measure (death is a clear event) and directly meaningful to patients (living longer is inherently valued). The guidance also states that overall survival should be prioritized as the primary endpoint when feasible. For accelerated approval or conditional approvals, overall survival improvement is considered strong evidence of effectiveness.

According to the Company, representatives from the FDA, EMA, and MHRA have each indicated, in various ways, that overall survival may serve as an appropriate clinical endpoint to support a conditional marketing authorization, particularly when supported by biomarker correlation data. The rationale for combining overall survival with immune activation biomarkers is further reinforced by compelling findings from recent canine osteosarcoma studies conducted by researchers at the University of Pennsylvania.

OS Therapies believes that the results of the recent FDA/Osteosarcoma Institute workshop “Advancing Osteosarcoma Drug Development” (October 10, 2025) was pivotal in supporting the Company’s regulatory strategy. Participants recognized strong scientific support for using naturally occurring canine osteosarcoma as a comparative model for human osteosarcoma, with canine model considered useful to help define and validate biomarkers that could then feed into human trial design. The workshop also reached consensus that overall survival should be considered the ultimate efficacy outcome endpoint in osteosarcoma trials when feasible.

The Company intends to propose the use of an immune activation biomarker in combination with overall survival data as a surrogate efficacy endpoint to support an application for Accelerated Approval. This proposal was presented during an FDA Type C Meeting on December 11, 2025.

Regulatory Meetings Overview

OS Therapies has had productive regulatory meetings with the U.S. Food & Drug Administration (FDA), the UK's Medicines and Healthcare products Regulatory Agency (MHRA), and the European Medicines Agency's (EMA), as the Company seeks to align BLA and MAA submission timing, in accordance with Project Orbis.

FDA

On October 17, 2025, the Company reported that the FDA granted it a second Type C Meeting following its successful End-of-Phase 2 Meeting for OST-HER2. The purpose of the meeting was to obtain FDA alignment on clinical efficacy endpoints intended to support submission of a BLA under the Accelerated Approval Program. The meeting was focused on reviewing updated overall survival and new biomarker correlation data. The Company also intends to evaluate whether immune-activation biomarker data, when correlated with two-year interim overall survival results, could be considered a surrogate marker of efficacy suitable for supporting Accelerated Approval.

The meeting took place on December 11, 2025, allowing sufficient time for the Company to integrate pending biomarker data from the Phase 2b trial, which are expected to establish the relationship between immune activation and clinical outcomes. Overall, these regulatory interactions are expected to clarify the data package required for potential submission of OST-HER2 under the Accelerated Approval pathway and to guide subsequent discussions regarding full approval requirements.

EMA and MHRA

In parallel, the Company continued its regulatory activities with the EMA and the MHRA. During an October 2025 meeting, EMA representatives advised that the overall survival results from the Phase 2b study, demonstrating statistically significant data, together with data from other *Listeria monocytogenes* candidates, representing more than 500 patients treated across four other therapeutic indications, may be sufficient to support a conditional marketing authorization (CMA). A potential pathway was also established to support a confirmatory, randomized clinical development program, which could explore additional osteosarcoma settings and potentially expand the product label upon full marketing authorization. The EMA has granted the Company pre-MAA Meeting, with OS Therapies now awaiting final scheduling.

The Company has also started a conditional Marketing Authorization Application (MAA) submission process to the MHRA following feedback received during its August 2025 Scientific Advice Meeting (SAM). The MHRA has indicated alignment on the use of peer-reviewed historical control data as an appropriate comparator arm to support the Company's conditional MAA submission. In addition, the MHRA has agreed to facilitate OS Therapies' efforts to obtain case-matched external control arm data by providing access to the UK Clinical Practice Research Datalink (CPRD). In October 2025, the MHRA granted the Company a pre-MAA Meeting for its OST-HER2 metastatic osteosarcoma program, scheduled for December 8, 2025.

OST-HER2—BREAST AND OTHER SOLID TUMORS

The Company has indicated plans to expand from its primary indication in osteosarcoma into HER2-expressing solid tumors, including breast cancer, once the osteosarcoma indication gains regulatory approval. OS Therapies’ OST-HER2 breast cancer program shows promising early translational/preclinical and safety work, with the bulk of the current regulatory and clinical investment, is in the osteosarcoma indication.

Breast Cancer Market

The global breast cancer therapeutics market is substantial and growing, with 2024 estimates around \$33.1 billion and projections reaching approximately \$79.1 billion by 2034 (Source: Market.us, *Global Breast Cancer Treatment Market, Trends and Forecast 2025-2034, 2025*). This presents a significant expansion opportunity for OST-HER2, extending its addressable market well beyond the estimated \$1.2 billion osteosarcoma treatment market (2022). OS Therapies estimates that the potential market opportunity for OST-HER2 in breast cancer treatment could exceed \$1 billion.

Clinical and Pre-Clinical Activities

The Company completed a Phase 1 clinical study of OST-HER2 in HER2 expressing solid tumors, with 12 patients enrolled (10 with breast cancer, 1 with esophageal cancer, 1 with GE junction cancer). This is the same Phase 1 study OS Therapies utilized for its osteosarcoma program (described on page 25), which yielded positive safety data. While the primary active development path is in osteosarcoma, the breast cancer data serve as proof of concept for HER2 positive solid tumors, especially breast cancer, providing a potential expansion opportunity post osteosarcoma.

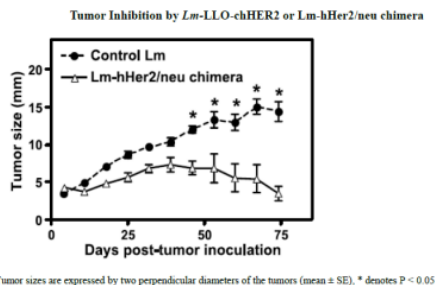
Animal/Preclinical Breast Cancer Work

In multiple preclinical breast cancer models, OST-HER2 (then named OST31-164) demonstrated robust antitumor activity, including prevention of brain metastases, inhibition of primary tumor growth in combination with HER2-targeted antibodies, and reduction in tumor formation relative to controls. The reduction in tumor growth with OST31-164 was directly associated with the induction of HER2-specific immune responses. These findings suggest significant potential for OST-HER2 to address both metastatic and primary HER2-positive breast cancers, supporting the rationale for clinical development in this larger therapeutic market and highlighting its potential to expand the Company’s commercial opportunity beyond rare cancers.

Animal Data: Inhibition of Growth of Breast Cancer Tumors

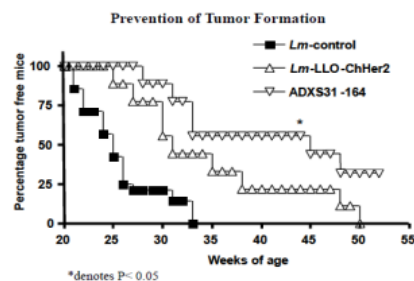
In an FVB/N HER2 transgenic mouse model of breast cancer, OST-HER2 (Lm-LLO-chHER2 component) demonstrated marked anti-tumor activity, producing an approximately 78% reduction in tumor size (3 mm in treated mice versus 14 mm in controls at Day 75) (Figure 15). In a prevention model using the same transgenic system, approximately 33% of treated mice remained tumor-free through Week 50, compared with 0% in the control group (Figure 16).

Figure 15
OST-HER2 BREAST CANCER TREATMENT MODEL



Source: OS Therapies Inc.

Figure 16
OST-HER2 BREAST CANCER PREVENTION MODEL

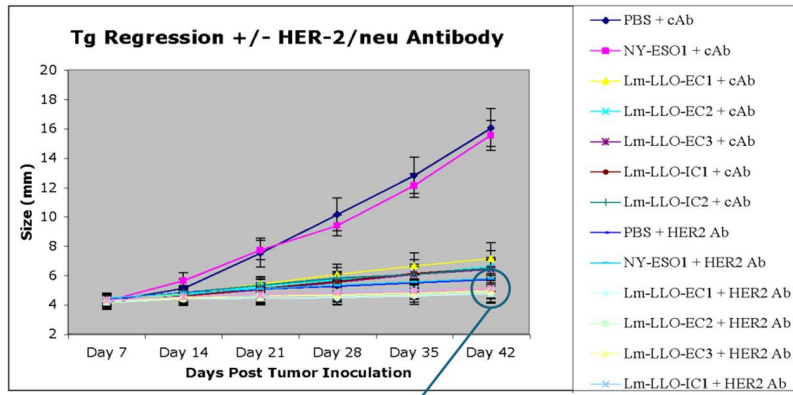


Source: OS Therapies Inc.

Animal Data: OST-HER2 in Combination with HER2 Targeted Antibodies

In a transgenic tumor regression model, combination therapy with OST-HER2 and a HER2-targeted antibody demonstrated enhanced antitumor efficacy compared with antibody monotherapy. The combination achieved approximately 20% greater reduction in tumor size at Day 42 relative to treatment with the HER2 antibody alone (Figure 17). These findings support the feasibility of OST-HER2 in HER2-positive breast cancer and suggest potential synergistic activity when used in combination with existing HER2-targeted therapies.

Figure 17
OST-HER2 BREAST CANCER TREATMENT POTENTIAL



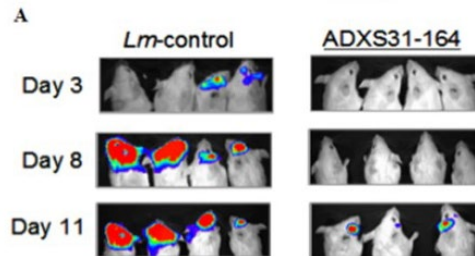
The Combination of OST-HER2 + HER2 Antibody (e.g. Herceptin, et al) shows strong improvement vs. HER2 Antibody alone (PBS + HER2 Ab)
* Lm-LLO-(XXX) = OST-HER2 component

Source: OS Therapies Inc.

Animal Data: Suppression of Growth of Metastatic Breast Cancer in the Brain

To evaluate the ability of OST-HER2 to inhibit the growth of metastatic breast cancer in the brain, BALB/c mice (n=4 per group) received 5×10^8 CFU of OST-HER2 or Lm control via intraperitoneal injection once weekly for three weeks. Following the final dose, luciferase-labeled EMT6 breast carcinoma cells were injected intracranially into anesthetized mice. Treated animals exhibited an approximately 65% reduction in metastatic cell concentration compared with controls, with tumor growth observed in all control mice but none of the OST-HER2-treated mice (Figure 18).

Figure 18
DELAY OF METASTATIC BRAIN CANCER IN THE BRAIN



Source: OS Therapies Inc.

Additional Solid Tumor Treatment Potential

Beyond its current development in osteosarcoma and breast cancer, OST-HER2 demonstrates strong potential to address a range of additional HER2-expressing solid tumors, including bladder, esophageal, and colorectal cancers. These malignancies represent important unmet medical needs, particularly in patients who have relapsed or are refractory to standard HER2-targeted therapies. HER2 overexpression has been documented in subsets of these tumor types—estimated in approximately 5-15% of bladder cancers, 10-30% of esophageal adenocarcinomas, and up to 5% of colorectal cancers—providing a defined biomarker population for targeted immunotherapy approaches.

Preclinical studies and early clinical experience with OST-HER2 suggest that its Listeria-based immunotherapeutic mechanism may overcome resistance mechanisms that limit the durability of antibody-based HER2 treatments. The platform's ability to activate robust, antigen-specific cytotoxic T-cell responses positions it to complement or enhance existing HER2-directed modalities, including monoclonal antibodies and antibody-drug conjugates. Given its demonstrated safety profile and early evidence of immune activation in multiple tumor models, OST-HER2 has the potential to be developed as a tumor-agnostic HER2 immunotherapy, applicable across multiple solid tumor types where HER2 expression drives disease progression.

ASSETS ACQUIRED FROM AYALA PHARMACEUTICALS

On April 9, 2025, the Company's acquired the Lm-based immuno-oncology program from Ayala Pharmaceuticals (formerly Advaxis, Inc.), as described on page 21. The acquisition expanded the Company's pipeline, adding three clinical cancer immunotherapy candidates: (1) renamed OST-AXAL for human papilloma virus (HPV)-associated cancers; (2) OST-503 for non-small cell lung cancer (NSCLC) and glioblastoma; and (3) OST-PSA/OST-504 for prostate cancer. In addition, the assets also included eight pre-clinical candidates targeting over 30 solid tumor cancers.

OST-AXA: HPV Related Malignancies

OST-AXAL is a cancer immunotherapy developed to treat cancers driven by persistent HPV infection, including cervical, head and neck, and anal cancers. OS Therapies acquired the AXAL/ADXS-HPV program (now OST-AXAL) through its purchase of the clinical and preclinical assets of Advaxis Immunotherapies from Ayala Pharmaceuticals in April 2025. The program is currently in Phase 3-stage within OS Therapies' pipeline and includes the pivotal AIM2CERV Phase 3 clinical trial in high-risk, locally advanced cervical cancer.

Strategically, OST-AXAL broadens OS Therapies' immuno-oncology portfolio beyond its lead asset, OST-HER2, and positions the Company in a large addressable market of HPV-driven malignancies. The therapy's Listeria-based immunotherapeutic mechanism offers potential advantages in treatment settings where current options are limited, where resistance to checkpoint inhibitors or vaccines has emerged, or where immune response durability remains inadequate. With a Phase 3-ready clinical profile, OST-AXAL represents a late-stage opportunity that may enable near-term regulatory milestones depending on data maturation and agency alignment.

The AIM2CERV Phase 3 Clinical Trial

The AIM2CERV Phase 3 clinical trial was conducted by Advaxis, Inc., in collaboration with the GOG Foundation (Gynecologic Oncology Group/RG Oncology), to evaluate AXAL (now OST-AXAL) as adjuvant immunotherapy in women with high-risk locally advanced cervical cancer (HRLACC) following definitive chemoradiation and brachytherapy.

The trial was a global, randomized, double-blind, placebo-controlled study designed to enroll approximately 450 patients and was conducted under a Special Protocol Assessment (SPA) agreement with the FDA. Participants were randomized in a 2:1 ratio to receive either AXAL or placebo, with disease-free survival (DFS) as the primary endpoint and overall survival and safety as key secondary endpoints. The study aimed to determine whether adjuvant immunotherapy with OST-AXAL could reduce the risk of disease recurrence and improve long-term survival outcomes following standard therapy.

Although the trial advanced under FDA Fast Track designation, it was terminated early due to budgetary constraints before reaching full enrollment, and final efficacy results have not been published. Earlier clinical experience from the preceding Phase 2 GOG-0265 trial demonstrated a 12-month overall survival rate of approximately 38%, supporting the biologic activity of AXAL in HPV-associated cervical cancer. Across trials, the therapy exhibited a manageable safety profile, with most adverse events characterized as mild-to-moderate immune-related or flu-like symptoms consistent with Listeria-based immunotherapies.

Despite the premature discontinuation of AIM2CERV, its design and regulatory alignment reflected the Company's intent to pursue a pivotal, registration-enabling study in HPV-driven cervical cancer. In addition, the earlier Phase 2 evidence provided proof-of-concept of AXAL's clinical activity in HPV-associated cervical cancer. The program, now known as OST-AXAL, remains one of OS Therapies' most advanced assets, representing a potential immunotherapeutic approach for a range of HPV-associated malignancies.

To advance the development of this product candidate, OS Therapies plans to continue engagement with regulatory authorities, including the FDA, MHRA, and EMA, to refine trial design, efficacy endpoints, and data submission strategy for a Phase 3b study. Key focus areas include clinical efficacy outcomes, such as overall and progression-free survival, immune response biomarkers, and safety and tolerability, alongside manufacturing and patient selection considerations for HPV antigen-positive populations. In parallel, the Company is evaluating combination strategies, for example, integrating OST-AXAL with checkpoint inhibitors, to enhance efficacy in HPV-related cancers.

OST-503: NSCLC and Glioblastoma

OST-503 (formerly ADXS-503) is a next-generation immunotherapy candidate based on the Company's Lm vector platform. According to company disclosures, the asset is designed for use in NSCLC and potentially other solid tumors, such as glioblastoma. The development rationale is based on OST-503's immunotherapy mechanism potential ability to enhance or restore sensitivity to checkpoint inhibitors or other immune therapies in tumors that have become refractory, by delivering multiple neo-antigen targets and stimulating T-cell responses.

This program, similar to the Company's breast and HPV related cancers, provides OS Therapies with the potential to further expand the addressable market of its Lm technology platform, with the non-small cell lung cancer therapeutics market size estimated at \$21.45 billion in 2024 and projected to reach \$43.89 billion by 2030, growing at a CAGR of 12.71% (Source: Grand View Research's *Non-small Cell Lung Cancer Therapeutics Market [2025 - 2030]*, 2025).

The development rationale for this program is based on positive results on a Phase 2 study involving the use of OST-503 in NSCLC in frontline and metastatic disease when used in combination with Keytruda (Trial NCT03847519), results of which were included in the American Society Of Clinical Oncology (ASCO) Annual Meeting Poster). The study is described below.

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The study assessed the addition of ADXS-503/OST-503 to pembrolizumab (Keytruda®) in patients with metastatic NSCLC who had progressed on pembrolizumab or were receiving it in the first-line setting. Part B of the study investigated adding OST-503 to pembrolizumab after a patient's disease has progressed on pembrolizumab, and Part C investigates using OST-503 and pembrolizumab together in previously untreated patients

The treatment appeared to be well tolerated and induced antigen-specific T-cell responses and durable disease control in 46% of patients in Part B and 67% of patients in Part C. Overall, OST-503 appears to demonstrate favorable signals of immunogenicity and disease-control when combined with checkpoint inhibitor in the NSCLC setting, possibly inducing innate and adaptive immune responses that may restore or enhance sensitivity to checkpoint inhibitors.

OST-504 (OST-PSA): Prostate Cancer

OS Therapies acquired the prostate cancer program OST-504 (OST-PSA) in the Ayala transaction. In prostate cancer, the unmet medical need is significant. The disease affects ~1 in 8 men in their lifetime, is the most common cancer in men in the U.S. (other than skin cancer) and is the second leading cause of cancer death among men (Source: American Cancer Society). The global prostate cancer treatment market was estimated at \$17 billion in 2024 and is projected to reach \$31.99 billion by 2030, growing at a CAGR of 10.9% (Source: Grand View Research's *Prostate Cancer Therapeutics Market [2025 - 2030]*, 2025).

On September 2025, the Company announced that the last patient visit in its Phase 1b trial of OST-504 (in biochemically recurrent prostate cancer) has been completed, with clinical data expected in Q1 2026. Depending on results, the Company may determine the next phase of development (e.g., Phase 2 expansion, combination therapy, regulatory meetings). Integration of the data into broader strategy is a possibility, given the Company's priority is currently the lead asset in osteosarcoma.

OS Therapies believes the OST-504 construct has significant potential to be used in various prostate cancer settings. If the Company is successful in its regulatory efforts with OST-HER2, and if OST-504 demonstrates favorable safety and early efficacy signals, it could potentially become eligible for the FDA's new Platform Designation that could significantly accelerate OST-504's path to market.

OST-HER2—CANINE OSTEOSARCOMA

OS Therapies has formed a dedicated subsidiary, OS Animal Health, Inc. (OSAH), to lead the development and commercialization of OST-HER2 in the veterinary market for the treatment of canine osteosarcoma. The subsidiary is advancing plans to re-establish conditional approval from the U.S. Department of Agriculture (USDA), with a targeted submission of Q1 2026. This effort leverages an updated manufacturing process protected under a newly issued patent extending intellectual property coverage through 2040. OS Animal Health will operate as an independent entity, supported by separate funding and strategic partnerships tailored to the unique dynamics and regulatory requirements of the animal health sector.

In November 2025, OS Therapies announced plans to spin off OSAH into an independent public company to be listed on a U.S. national stock exchange, with completion of the spin-off and listing expected in the first half of 2026. The decision follows successful preliminary discussions with NYSE representatives and potential investors. Following the spin-off, OS Therapies shareholders will receive direct equity participation in the newly listed company.

The canine OST-HER2 program provides several strategic benefits to OS Therapies' broader OST-HER2 development efforts. OS Therapies leverages the concept of comparative oncology, the idea that naturally occurring cancers in dogs that mirror human disease can be used as a translational bridge to support human clinical trials. Given that canine osteosarcoma shares approximately 96% genetic homology with the human form of the disease, dogs serve as a highly relevant large-animal model for evaluating efficacy, safety, and immunologic responses that can guide OST-HER2 development in humans. Specifically, the concept of comparative oncology, as it relates to the Company's canine program, provides three key strategic advantages:

- *Translational value.* Positive outcomes in a naturally occurring large-animal model strengthen the case for human development and regulatory alignment.
- *Dual market potential.* Success in the veterinary indication enhances near-term commercial potential, while also strengthening human oncology credibility.
- *Regulatory leverage.* Biomarker and survival data from dogs may support human accelerated approval discussions, especially in rare pediatric osteosarcoma where surrogate endpoints are key.

Shelter Me: The Cancer Pioneers

OST-HER2 is also featured in the PBS documentary “Shelter Me: The Cancer Pioneers,” which offers a look into canine comparative oncology and covers developing treatments for rare forms of cancer. It is part of an Emmy Award-winning PBS series, Shelter Me, which celebrates the life-changing relationships between people and animals. The documentary premiered in May 2025 on PBS (and is available for streaming), won an Anthem Award in the for ‘Documentary or Film under Awareness Categories, Health’, and has been nominated for two Daytime Emmy Awards for Outstanding Daytime Special and Writing Team.

Canine Osteosarcoma

Canine osteosarcoma (OSA) is the most common primary bone cancer in dogs, representing approximately 80-98% of all malignant bone tumors in the species. Each year, an estimated 10,000 dogs in the U.S. are diagnosed with osteosarcoma, a rate roughly ten times higher than in humans. The disease predominantly affects the appendicular skeleton (limbs) of large and giant breeds, and at the time of diagnosis, 80% to 90% of dogs are believed to already have micrometastases, most commonly to the lungs. This metastatic spread contributes to the disease’s poor prognosis: approximately 80% of affected dogs die within two years of diagnosis, even with current standard-of-care treatments (Source: Morris Animal Foundation).

Because of its high prevalence, poor survival rates, and strong biological similarity to human osteosarcoma, canine osteosarcoma represents both a significant unmet need in veterinary oncology and a valuable comparative-oncology model for developing new human therapies.

According to Grand View Research, the global veterinary oncology market was valued at approximately \$1.57 billion and is projected to grow to \$3.1 billion by 2030. Within this market, OS Therapies estimates that the addressable opportunity for OST-HER2 in U.S. canine osteosarcoma alone exceeds \$150 million annually. Current treatment options—amputation, chemotherapy, and radiation therapy—are often invasive and provide limited survival benefits. In contrast, OST-HER2 offers the potential for a targeted, less invasive immunotherapeutic approach, designed to improve survival and quality of life for dogs affected by this aggressive and often fatal cancer.

Animal Studies

At the University of Pennsylvania, School of Veterinary Medicine’s Mason Immunotherapy Research Laboratory, researchers have investigated immunotherapeutic strategies in canine osteosarcoma and other spontaneous canine cancers. In the case of OST-HER2 and its predecessors, this work has helped validate safety/tolerability in the veterinary setting and identify potential biomarkers of immune activation applicable to human translation.

Preclinical Study (Post Resection) 2012-2015

From July 2012 to September 2015, a preclinical study (sometimes referred to as a Phase I animal study) evaluating ADXS-HER2, now known as OST-HER2, was conducted in 18 companion dogs with HER2-positive osteosarcoma. The study, sponsored by Advaxis (from whom OS Therapies later acquired the underlying patents), assessed OST-HER2 in dogs with minimal residual disease following standard therapy (amputation and chemotherapy).

Results demonstrated significant improvements in survival and reduction in metastatic progression compared to historical controls. Dogs treated with ADXS-HER2 achieved median survival of approximately 956 days, compared to 423 days in controls. One-, two- and three-year survival rates were 77.8%, 67%, and 56%, respectively, versus 55%, 28%, and 22% in the control group (Source: *Clinical Cancer Research, Vol. 22 (17): 4380-90, 2016*).

These findings provided strong proof of concept that HER2-targeted Listeria-based immunotherapy could generate durable anti-tumor immunity, significantly extend survival, and delay or prevent metastasis in canine osteosarcoma—a disease that closely mirrors human pediatric osteosarcoma, laying the foundation for subsequent regulatory submissions and translational human studies.

Proof-Of-Concept Data Limb Sparing (Pre-Resection) Study: Publication In Progress

On April 10, 2025, the Company announced positive proof-of-concept data for OST-HER2 in a limb-sparing study of dogs with unresected appendicular osteosarcoma. The combination of OST-HER2 with palliative radiation produced strong treatment responses after eight doses, accompanied by improvements in immune markers with additional dosing. The treatment resulted in clinical and radiographic arrest of primary tumor growth, delayed development of pulmonary metastases, and prolonged overall survival, exceeding 500 days in five of fifteen dogs. These findings demonstrate the potential of OST-HER2 to prevent or delay limb amputation and to serve as a frontline therapy in osteosarcoma, potentially reducing or eliminating the need for chemotherapy.

The results build on prior data supporting OST-HER2's conditional approval for increasing overall survival after amputation and highlight its potential role in both local tumor control and metastasis prevention. The data is currently being prepared for publication.

Additionally, the Company announced the publication of positive data demonstrating the correlation of innate and adaptive immune responses to OST-HER2, with prevention of metastasis and long-term survival benefits when used in the adjuvant setting following standard of care amputation and chemotherapy. The data show OST-HER2 induces strong innate and cytotoxic immune responses beginning at the first dose of three dose regimen, which correlate with prevention of metastasis and long-term survival in dogs with resected primary osteosarcoma (Source: *Molecular Therapy, Volume 33 (4): 1674-1686, 2025*).

Treatment with OST-HER2 was found to be safe and well tolerated in these studies. Taken together, the data support the potential of OST-HER2 to achieve progression free survival (PFS) of primary osteosarcoma, prevent or delay or metastatic disease, prolong PFS in metastatic disease, and significantly improve long term survival in patients with osteosarcoma.

Regulatory Pathway

Following completion of the initial study, Advaxis applied for the use of ADXS-HER2, now known as OST-HER2, in the treatment of canine osteosarcoma to the USDA. In December 2017, the USDA granted a conditional license for ADXS-HER2, authorizing its commercialization for use in dogs one year of age and older diagnosed with osteosarcoma.

As the current licensee of the ADXS-HER2 construct, OS Therapies held this conditional license following acquisition of the program. The Company later allowed the license to lapse in order to incorporate manufacturing process improvements designed to enhance performance. The Company is preparing to initiate regulatory correspondence with the USDA to re-apply for conditional licensure using data from the described studies as well as its updated manufacturing process, which includes key enhancements covered under a recently granted patent extending protection through 2040. The pathway to reactivation of conditional approval is expected to be clarified in Q1 2026, and thereafter the Company intends to complete the 'go-public' transaction to make OS Animal Health a standalone public company in Q2 2026. OS Therapies intends to launch OST-HER2 under conditional approval in 2026 if the agency agrees that no additional clinical studies are required and alignment is gained on manufacturing.

For full USDA licensure, additional data will be required to further describe OST-HER2's effects on metabolism and shedding in canines, as well as providing substantial evidence of safety, purity, potency, and effectiveness. To support full approval, OS Therapies plans to sponsor a confirmatory clinical trial at the University of Pennsylvania School of Veterinary Medicine, expected to begin in 2026.

TUNABLE ANTIBODY-DRUG CONJUGATE (tADC) PLATFORM

OS Therapies is also advancing a next-generation tunable Antibody Drug Conjugate (tADC) technology platform known as OST-tADC. This proprietary platform underpins OS Therapies' second major development engine and is designed to improve the therapeutic performance and safety of antibody-drug conjugates (ADCs) through precision linker chemistry and conditionally active payload release mechanisms.

The OST-tADC platform is built on OS Therapies' SiLinker™ technology, a silicon-based, pH-sensitive linker system and Conditionally Active Payloads (CAPs), which are engineered to be selectively activated within the acidic microenvironment of tumors. The SiLinker™ technology can release multiple therapeutic agents selectively within the tumor and tumor microenvironment, which experiences lower pH levels than the rest of the body. This approach aims to maximize the therapeutic effects while minimizing damage to healthy cells.

OST-tADC has demonstrated positive preclinical proof-of-concept data in models of ovarian cancer with its tADC candidate targeting folate receptor alpha, achieving potent tumor suppression with a favorable safety profile. The Company is initially assessing the use of its platform in ovarian and breast cancer, as well as other solid tumors, with Phase I trials for ovarian cancer expected to begin in 2027.

To further develop and strategically monetize the platform, OS Therapies has established a dedicated subsidiary, OS Drug Conjugates (OSDC), to house the OST-tADC technology and pursue collaborative growth opportunities. OS Therapies is positioning the tADC platform not only as an internal development engine, building its own portfolio of conjugate candidates, but also as a source of external value creation through licensing and joint-venture partnerships. This approach follows a well-established path within the conjugate therapeutics sector, where innovative linker or payload technologies are often partnered with larger ADC players to leverage complementary expertise and clinical infrastructure.

OS Therapies has initiated discussions with several clinical-stage ADC therapeutic companies in the U.S., China, and other jurisdictions to form joint ventures pairing those companies' clinical-stage assets with specific components of the OST-tADC platform. These joint ventures are envisioned as standalone public entities, with OS Therapies intending, if such transactions are completed successfully, to distribute stock dividends of these newly formed public JVs to existing OS Therapies shareholders.

From an investment perspective, the OST-tADC platform represents a second growth engine for OS Therapies beyond its lead immunotherapy program, providing a highly flexible, platform-based technology that enables the creation of novel ADC therapeutics, the pursuit of multiple licensing and joint-venture opportunities, and the expansion of a broader oncology pipeline, all without constraining the Company's own therapeutic development strategy.

Antibody Drug Conjugate (ADC) Market

The OST-tADC platform addresses key challenges of traditional ADC technology (tumor penetration, payload release specificity, bystander effect, and payload multiplicity), which could offer competitive advantages in the fast-growing ADC market. The global market for antibody-drug conjugates (ADCs) is projected to grow substantially, from an estimated \$10.8 billion in 2023 to approximately \$47.0 billion by 2029, reflecting a compound annual growth rate (CAGR) of 28.4% between 2024 and 2029 (Source: BBC Research's *Antibody-Drug Conjugates: Technologies and Global Markets*, 2024).

This rapid expansion is being driven by the rising global prevalence of cancer, a persistent unmet need in oncology, and significant advancements in ADC technologies and research. Continued innovation in next-generation payloads, expanding clinical indications, and combination therapy strategies are expected to sustain market momentum. Within this evolving market, competitive differentiation is increasingly driven by proprietary linker systems, optimized conjugation chemistry, and novel payload innovation, all of which form the technological foundation for next-generation and tunable ADC platforms such as OS Therapies' OST-tADC.

OST-tADC

Antibody-Drug Conjugates (ADCs) are an established class of targeted cancer therapies that combine the high specificity of monoclonal antibodies (mAbs) with the potent cytotoxic activity of small-molecule drugs. This hybrid design allows ADCs to selectively deliver powerful anti-tumor agents directly to cancer cells while minimizing exposure to normal tissues. The technology bridges biologics and chemotherapy, offering a precision approach that enhances efficacy and reduces systemic toxicity compared to conventional chemotherapeutic regimens.

Every ADC comprises three essential components: a monoclonal antibody (ligand), a linker, and a cytotoxic payload. The antibody directs the conjugate to cancer cells by binding to a surface antigen that is overexpressed on tumor cells but minimally present on normal tissue. Once bound, the ADC-antigen complex is internalized, allowing delivery of the payload directly into the cancer cell. The choice of antigen—such as HER2, CD30, or Trop-2—is critical to ensure selective targeting and efficient uptake. The design and balance of these three parts determine the drug’s specificity, potency, and safety.

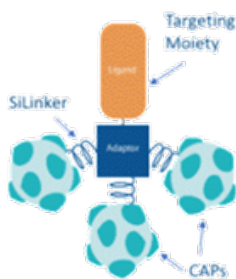
Since the first ADC approval (Mylotarg®) in 2000, more than a dozen ADCs have reached the market, and hundreds more are in development. The field has matured through successive generations of innovation, from early conjugates with unstable linkers and heterogeneous payload distribution, to highly engineered molecules with improved stability, controlled release, and optimized pharmacokinetics. The success of agents such as Enhertu® (Daiichi Sankyo/AstraZeneca), Adcetris® (Seagen), and Trodelvy® (Gilead) has validated ADCs as a major therapeutic modality and a rapidly expanding sector of oncology drug development.

OST-tADC Overview

tADCs improve on regular ADC technology by incorporating a modular system that allows fine adjustment of key molecular components such as the ligand (e.g., the monoclonal antibody), linker chemistry, payload type, and drug-to-antibody ratio. This flexibility is intended to optimize therapeutic performance for different tumor types and biological contexts, addressing common limitations of first- and second-generation ADCs such as off-target toxicity, limited tumor penetration, and unpredictable pharmacokinetics.

Figure 19
OST-tADC

An OST-tADC generally consists of three functional components: (1) the targeting moiety or ligand; (2) the linker (SiLinker™); and (3) the payload (CAP), as seen in Figure 19.



Targeting Moiety (Ligand). A targeting moiety is a specific molecule or structure, such as an antibody, peptide, or small molecule, which recognizes a specific antigen overexpressed on cancer cells. It is designed to bind to that particular target to deliver a therapeutic drug or diagnostic agent directly to that site, a principle central to targeted therapies. OST-tADCs utilize smaller targeting moieties, which enhance deeper tumor penetration and facilitate rapid clearance of tADCs from the body, reducing systemic toxicity.

Source: OS Therapies Inc.

A key advantage of the Company’s technology is that, while regular tADCs use antibodies as the ligand, the OST-tADC platform is compatible with different ligands, such as small molecules, peptides, and mRNA therapeutics, which allows the Company to expand the functionality and the oncology indications the platform can target.

Linker System. The linker connects the antibody and the cytotoxic payload, serving as a key determinant of when and where the drug is released. OS Therapies employs its patented SiLinkers™, silicon-based, pH-sensitive linkers that offer enhanced stability and precise control over payload activation. Unlike conventional ADC linkers, which typically rely on enzymatic or reductive cleavage and can release the payload prematurely in circulation, leading to dose-limiting toxicities, SiLinkers™ remain stable at physiological pH but rapidly cleave under acidic conditions. Because tumors and the tumor microenvironment are more acidic than normal tissues, this design ensures that the cytotoxic payload is activated primarily within targeted cancer cells, minimizing off-target effects and improving the therapeutic effect.

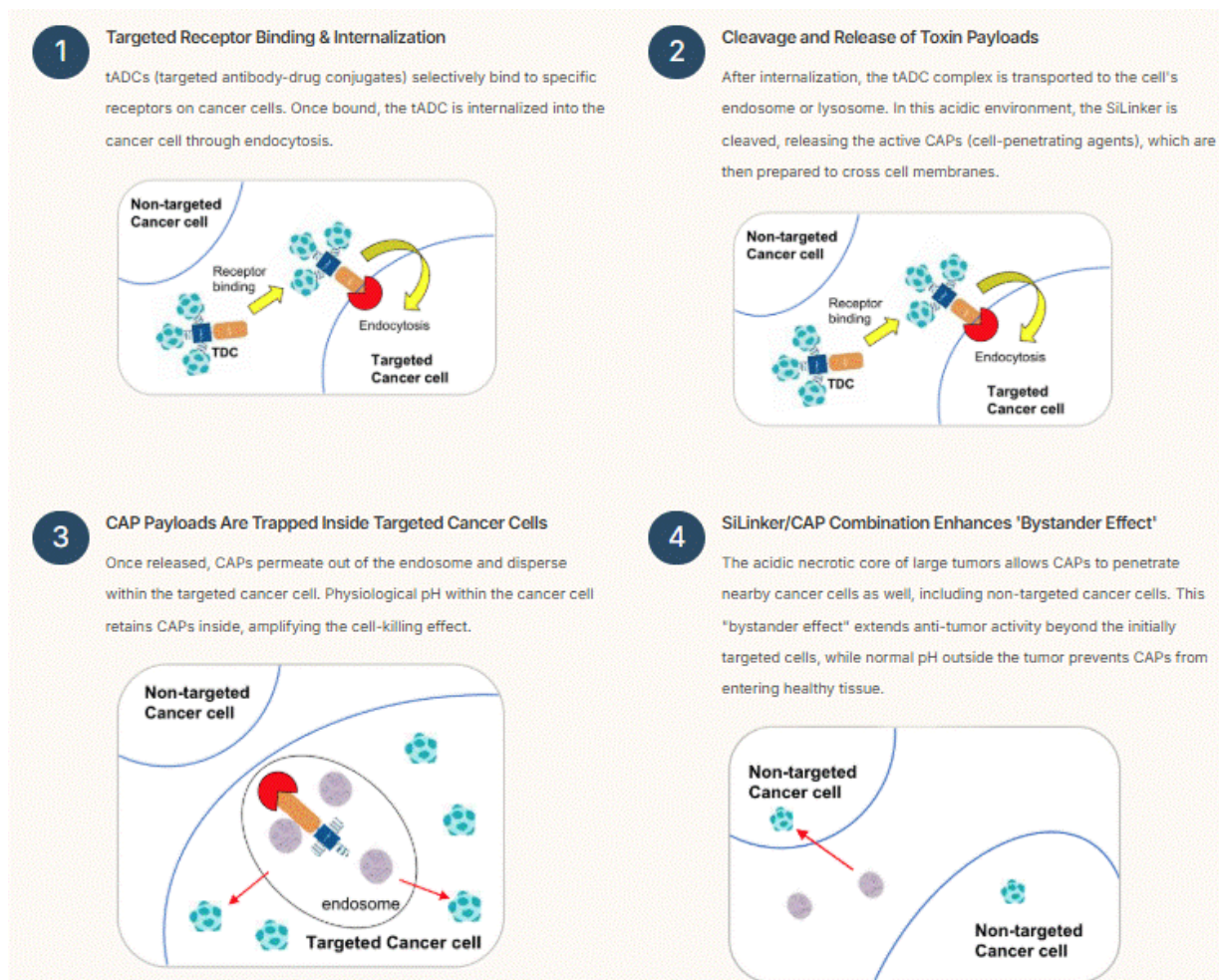
Payload (Cytotoxic Agent). The payload is an ultra-potent small molecule cytotoxin, far stronger than standard chemotherapy drugs. Because these agents are extremely toxic, precise control of delivery is vital to prevent systemic side effects. The Company's Conditionally Active Payloads (CAPs) only cross cell membranes and kill cancer cells under acidic conditions, trapping them within the tumor cells to maximize therapeutic effects. Since they do not enter normal cells, their use minimizes the risk to healthy tissues.

Together, these elements create a precision therapeutic designed to selectively kill cancer cells while sparing normal tissue, thus enhancing the therapeutic effect and safety when compared to earlier ADC generations.

OST-tADC Mechanism of Action

The OST-tADC platform operates through a series of carefully controlled steps designed to maximize tumor cell killing while minimizing off-target toxicity. OST-tADC mechanism of action (MOA) is illustrated in Figure 20, and detailed below.

Figure 20
OST-tADC MECHANISM OF ACTION



Source: OS Therapies Inc.

After intravenous administration, the antibody component binds to its specific antigen on the cancer cell surface. Following this binding, the conjugate is internalized and transported into the cell endosomes through receptor-mediated endocytosis, allowing the payload to reach intracellular compartments where it can exert its cytotoxic effect.

The SiLinker™ is engineered to remain stable under normal physiological conditions but to cleave in response to the lower pH found within tumors. Once the tADC complex reaches the endosome, the environmentally sensitive linker is cleaved, releasing the active cytotoxic payload. The active drug then diffuses into the cytoplasm, disrupting essential cellular processes, and inducing cell death. Because the activation process depends on the acidic environment unique to tumors, the payload remains largely inert in healthy tissue, reducing systemic toxicity. Furthermore, in response to the acidic nature of cancer cells, the released payloads can diffuse into adjacent tumor cells (even those with low antigen expression), creating a beneficial bystander effect, which extends the anti-tumor activity beyond the initially targeted cells

Competitive Advantages of OST-tADC vs. Other ADC Platforms

The ADC market has grown rapidly in recent years, driven by innovations from companies such as Seagen, Daiichi Sankyo, and AstraZeneca. However, despite commercial success, many approved ADCs still face limitations, including systemic toxicity, restricted tumor penetration, and the development of resistance to traditional cytotoxins. OS Therapies’ OST-tADC platform seeks to address these shortcomings through several distinct advantages.

First, the SiLinker™ technology offers superior pH sensitivity and stability, enabling precise control over when and where the payload is released. Traditional ADC linkers often rely on enzymatic or reductive cleavage, which can occur prematurely in circulation and cause dose-limiting toxicities. By contrast, SiLinker’s silicon-based chemistry maintains stability at physiological pH but rapidly cleaves under acidic conditions, ensuring that the cytotoxic payload activates only within the tumor microenvironment. The SiLinker™ system also supports the incorporation of multiple payloads on a single linker, offering opportunities to design multi-mechanistic conjugates capable of overcoming drug resistance or achieving synergistic effects (Figure 21).

Figure 21
OST-tADC SILICONE LINKER COMPETITIVE ADVANTAGE

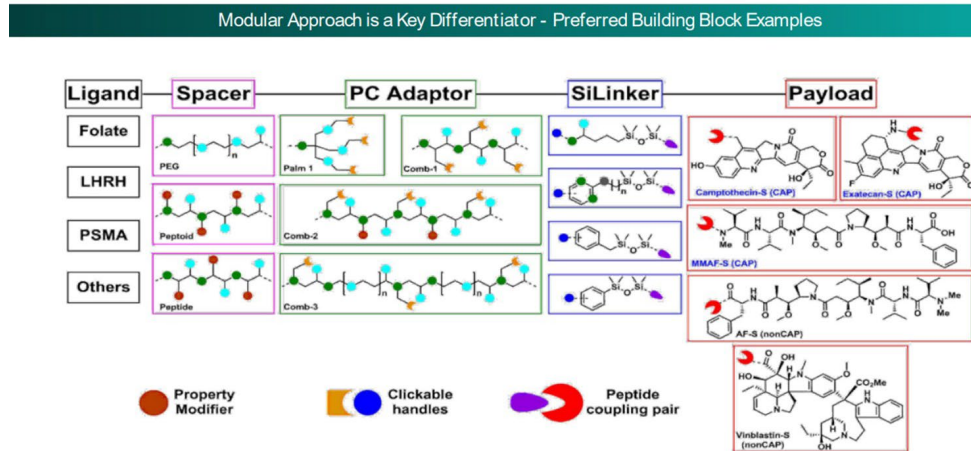
	Traditional VAL-QT LINKER	Traditional GGFLINKER	Next-Gen Silicone LINKER
%Payload at Released at Target Tumor Site	+	+	+++
Stability in Circulation	NO	Limited	YES
New IP for Old Payloads	NO	NO	YES
Premature Cathepsin Cleavage	YES – Ubiquitous	YES – Macrophages	NO
Myelosuppression	YES	NO	NO
Multiple Payloads per Linker	NO	NO	YES

Source: OS Therapies Inc.

Second, the use of CAPs provides a safety and efficacy edge. These payloads are inert until they encounter the tumor’s acidic conditions, reducing collateral damage to healthy tissues while allowing higher effective dosing within tumors. Improved control of linker stability and conditional activation reduces off-target toxicity, an improvement over first-generation ADCs that released highly potent toxins systemically.

Third, the OST-tADC platform offers a highly tunable framework (shown in Figure 22 [page 41]), allowing extensive customization beyond the limitations of conventional ADCs, which often have fixed antibody-to-drug ratios and restricted linker chemistries. OST-tADC can adjust multiple variables, including payload type, linker length, and drug-to-antibody ratio, to align with the unique biological characteristics of each tumor. Its modular design that also enables the attachment of multiple payloads to a single linker, opening the possibility of combining different mechanisms of action within a single molecule. This flexibility allows for precise optimization of drug load, payload selection, and linker configuration for each specific target or indication, enhancing both efficacy and therapeutic potential.

Figure 22
OST-tADC ADAPTABILITY



Source: OS Therapies Inc.

Finally, the smaller targeting moieties used in some OST-tADC designs improve tumor penetration and clearance profiles. This may give OS Therapies an edge in treating solid tumors, where dense stromal barriers often limit the efficacy of full-length antibody ADCs. Collectively, these advantages suggest that the OST-tADC platform could deliver a safer, more adaptable, and more potent next generation of conjugate therapeutics.

OST-tADC Development Activities

The OST-tADC program is currently in preclinical development, with its lead program targeting folate receptor alpha, a protein involved in cell signaling, replication, and division, which is overexpressed in several cancers, including ovarian and endometrial cancers. The lead compound, OST-tADC-FRA-H, utilizes a folate receptor alpha, a small molecule, as the targeting ligand, and contains six hexa-exatecan-payloads linked together with the Company's proprietary silicone linker technology, SiLinker™. The discovery and preclinical development of this compound are being conducted at Syngene International Limited, an integrated contract research organization (CRO) located in Bangalore, India.

In September 2024, OS Therapies announced positive preclinical data for OST-tADC-FRA-H, its first OST-tADC therapeutic candidate, in animal models of ovarian cancer. The studies demonstrated significant tumor growth inhibition in the KB and IGROV-1 mouse models, with no measurable systemic toxicity. These results provide compelling preclinical proof of concept that the Company's SiLinker™ platform can be leveraged to develop novel tADC-based therapeutics with the potential to improve the safety and efficacy of existing or emerging ADC combinations. In addition, the findings support the creation of new intellectual property, enhancing OS Therapies' competitive positioning and lifecycle management opportunities.

KB Tumor Growth Model. In this model, animals implanted with the KB tumor cell line received treatments of OST-tADC-FRA-H or vehicle control on Days 4, 8, and 12. By Day 20, animals treated with OST-tADC-FRA-H exhibited an average tumor volume of 10 mm³ compared to 1,000 mm³ in untreated controls. By Day 40, OST-tADC-FRA-H-treated animals showed no evidence of tumor growth, whereas control animals had succumbed to tumor progression.

IGROV-1 Tumor Growth Model. Animals implanted with the IGROV-1 tumor cell line were treated with either OST-tADC-FRA-H or vehicle control. By Day 50, OST-tADC-FRA-H-treated animals had an average tumor size of 40 mm³ compared to 400 mm³ in control animals.

Bodyweight Comparison. Animals treated with OST-tADC-FRA-H on Days 1 and 7 showed no loss in body weight, indicating that the treatment was well tolerated relative to controls.

The Company considers these results validation of both the SiLinkers™ chemistry and the broader tunable conjugate concept. Further preclinical studies are underway to expand the platform's applicability across different types of tumor and targets. The Company indicated plans to initiate an AI-driven based molecular modeling exercise to optimize linker and payload combinations and create new classes of next generation therapeutic candidates leveraging its unique SiLinkers™ platform. Pending positive results from its preclinical trials, OS Therapies plans to enter a clinical phase with a Phase I trial in ovarian cancer, likely pursuing an oncology-standard ADC regulatory pathway, guided by existing precedents in linker and payload chemistry.

Competition

The therapeutic landscape for osteosarcoma (OS) remains largely underserved, with limited innovation and poor outcomes in relapsed or metastatic disease. Standard-of-care treatments—comprising surgery, multi-agent chemotherapy (typically methotrexate, doxorubicin, and cisplatin), and limited use of targeted agents—have remained unchanged for over three decades. Five-year survival rates for metastatic or recurrent osteosarcoma remain below 30%, underscoring the significant unmet medical need and opportunity for differentiated therapies.

OS Therapies is one of the few biopharmaceutical companies focused specifically on developing novel immunotherapeutic approaches for osteosarcoma. While competition in osteosarcoma remains limited, several academic groups and smaller biotech companies are exploring new modalities, including:

- Immune checkpoint inhibitors (e.g., pembrolizumab, nivolumab), with modest activity to date and ongoing trials seeking biomarkers of response.
- Targeted therapies such as TKIs (e.g., regorafenib, cabozantinib, sorafenib), providing incremental benefits but lacking durable responses.
- Cell-based and vaccine approaches, including autologous dendritic cell vaccines and GD2-targeted therapies, which are primarily in early-stage or investigator-sponsored studies.
- Next-generation immunotherapies, with a limited number of industry-sponsored programs targeting neoantigens or tumor-specific antigens and few advancing beyond early clinical development.

As the Company continues to advance its pipeline candidates to achieve potential commercialization, OS Therapies might encounter competition from both major pharmaceutical companies active in the osteosarcoma space, as well as smaller biotechnology and pharmaceutical companies developing novel therapeutics. Global players such as Pfizer Inc., Novartis AG, Eli Lilly and Company, Bayer AG, Amgen Inc., and Merck & Co., Inc., among others, are listed among the key participants in osteosarcoma therapeutic development.

Specifically, Novartis is reportedly advancing precision oncology and cell-therapy platforms into bone sarcomas, including osteosarcoma, and Bayer and Eli Lilly are cited for their work in angiogenesis/VEGF or biomarker-driven therapies in bone-tumor settings. The large pharmaceutical companies involved in this market represent both potential competitors and potential partners for OS Therapies. Because some of the smaller biotech companies may focus on early-stage development, the landscape is ripe for collaborations (licensing, co-development) with larger pharma, especially once proof-of-concept data is generated. This dynamic may accelerate valuation inflection points for early-stage programs.

OS Therapies' competitive differentiation lies in its disease-specific focus, unique immunotherapeutic mechanism, and broad intellectual property protection surrounding Lm-based antigen delivery. The Company is well positioned to establish clinical and commercial leadership in a rare cancer space with high barriers to entry, minimal direct competition, and strong potential for regulatory incentives such as Orphan Drug Designation, Breakthrough Therapy status, and priority review pathways.

The list of companies presented in this section is not intended to be an exhaustive collection of OS Therapies' potential competitors. However, it is believed to be a sample of the type of competition that the Company may face as it strives to commercialize or license its technologies and product candidates.

AlaMab Therapeutics

AlaMab is a clinical stage biopharmaceutical company focused on commercializing novel monoclonal antibody therapeutics designed to inhibit tumor vasculature and metastatic progression, targeting indications with significant unmet treatment needs. AlaMab's portfolio was built upon two novel functional antibody drug candidates licensed from the University of Texas through the strategic investment of CSPC Pharmaceutical Group Ltd (HK: 1093). It is developing ALMB-0166 in Phase 2 for spinal cord injuries and other neurodegenerative diseases; and ALMB-0168, in Phase 1 trials for osteosarcoma and Phase 2 trials for breast cancer bone metastasis. ALMB-0168 has received Orphan Disease Drug and Rare Pediatric Disease designations from the FDA for its use in osteosarcoma. The company was founded in 2017 and is headquartered in Princeton, New Jersey.

Eisai Co Ltd/Merck & Co, Inc.

Eisai is a Japanese pharmaceutical company headquartered in Tokyo, with a subsidiary, Eisai Inc., in Nutley, New Jersey. It develops, manufactures, and markets pharmaceuticals, including prescription medicines and generics, focused on neurology and oncology. Its pipeline includes Lenvatinib (Lenvima), a multikinase inhibitor developed in collaboration with Merck & Co. Lenvima has been approved for thyroid cancer, hepatocellular carcinoma, and in combination with the anti PD-1 antibody Keytruda, for advanced renal cell carcinoma (RCC) and endometrial carcinoma. Lenvima is also being evaluated in multiple ongoing clinical trials across a wide range of tumor types under the "LEAP" (Lenvatinib And Pembrolizumab) program, including melanoma, non-small cell lung cancer (NSCLC), colorectal cancer, head & neck cancer, gastric cancer, esophageal cancer, hepatocellular carcinoma, and more.

Hansoh Pharmaceutical Group (via its oncology unit Hansoh BioMedical R&D Company)

Hansoh Pharmaceutical Group, an investment holding company, engages in the research, development, production, and sale of pharmaceutical products in the People's Republic of China. The company provides products for therapeutic areas, including anti-infection, central nervous system, oncology, and metabolic and other diseases, as well as autoimmune diseases. The company's pipeline includes HS-20093, an antibody-drug conjugate (ADC) being developed in conjunction with GlaxoSmithKline (for ex-China markets under the label GSK5764227). HS-20093 is in Phase 3 for osteosarcoma and other solid tumors, and has received U.S. FDA Breakthrough Designation in small-cell lung cancer and for late-line relapsed/refractory osteosarcoma, China's Breakthrough Therapy Designation by the NMPA in osteosarcoma, and PRIME (Priority Medicines) status by the EMA. The molecule is also being evaluated broadly in other solid tumors, including lung (both small-cell and non-small-cell), head & neck, and prostate cancers. The company was founded in 1995 and is headquartered in Shanghai, China. Hansoh Pharmaceutical Group, a subsidiary of Stellar Infinity Company Ltd, was founded in 1995 in Lianyungang, Jiangsu Province, China.

Lee's Pharmaceutical Holdings Limited

Lee's Pharmaceutical is a China-based research-driven biopharmaceutical company advancing Socazolimab, a humanized anti-PD-L1 antibody, in multiple solid tumor indications, including SCLC and osteosarcoma. The company holds the license for greater China from Sorrento Therapeutics (which filed for Chapter 11 on 2023). Socazolimab is being investigated in clinical trials for various cancers, including small cell lung cancer (SCLC), cervical cancer, osteosarcoma, and urothelial carcinoma. A Phase 3 trial is underway in China for first-line treatment of extensive-stage SCLC in combination with chemotherapy. Socazolimab has also been studied in high-grade osteosarcoma after adjuvant chemotherapy for maintenance purposes in a Phase I setting. Although Lee's Pharmaceuticals operations are in China, its osteosarcoma program could represent potential collaborator opportunities for large pharmaceutical companies pursuing immunotherapeutic strategies in rare cancers like osteosarcoma. The company was founded in 1994 and is headquartered in Shatin, Hong Kong.

MedPacto, Inc.

MedPacto is a South Korean drug discovery and development company involved in the discovery and development of therapeutics targeting cancer and autoimmune diseases. MedPacto's pipeline includes vactosertib, an oral small-molecule to modulate tumor-induced immunosuppression. The drug is being evaluated in solid tumors and sarcomas, including osteosarcoma, with early evidence suggesting potential synergy with checkpoint inhibitors. MedPacto's approach targets a key pathway involved in osteosarcoma metastasis and resistance, positioning it as a differentiated, mechanism-driven competitor in the immuno-oncology segment of the disease. Vactosertib has completed Phase 1 trials for osteosarcoma and is recruiting for a Phase 1b/2 for adolescents and adults with recurrent, refractory or progressive osteosarcoma. MedPacto, Inc. is based in Seoul, South Korea.

Zentalis Pharmaceuticals, Inc.

Zentalis is a clinical-stage biopharmaceutical company developing small-molecule therapies in oncology. Their lead agent, Azenosertib (ZN-c3), is a potentially first-in-class small molecule selective WEE1 inhibitor that disrupts DNA damage repair mechanisms in cancer cells. Zentalis is conducting trials on Azenosertib as a monotherapy for serous uterine cancer and serous ovarian cancer, both in Phase 2 studies. In addition, Zentalis is also developing Azenosertib in combination regimens with traditional chemotherapy, including a Phase 1/2 combination study of Azenosertib and Gemcitabine in osteosarcoma. Their Phase 1 trial in osteosarcoma reported increased Event-Free Survival (EFS) compared to historical controls, which supported advancement into further studies. Zentalis is headquartered in San Diego, California.

tADC Competitive Landscape

Since the approval of the first ADC, Mylotarg® (gemtuzumab ozogamicin), in 2000, the field has evolved from early conjugates with heterogeneous payload distribution and unstable linkers to precisely engineered molecules with optimized release kinetics, enhanced selectivity, and improved pharmacokinetics. The commercial success of Enhertu® (Daiichi Sankyo/AstraZeneca), Adcetris® (Seagen), and Trodelvy® (Gilead) has firmly established ADCs as a transformative class of oncology therapeutics and has fueled a rapidly expanding development pipeline.

The competitive landscape for next-generation antibody-drug conjugates (ADCs) is shaped by established leaders such as Daiichi Sankyo, with its DXd topoisomerase-I payload platform, and Seagen, known for its clinically validated vcMMAE linker-payload technology, alongside emerging innovators like Mersana Therapeutics and ImmunoGen. Each of these platforms differentiates itself through unique linker chemistries, payload engineering, and modular drug-antibody ratio (DAR) control, reflecting the field's shift toward increasingly sophisticated and application-specific conjugation technologies. As ADC science continues to mature, tunable ADC (tADC) approaches represent the logical next evolution, moving beyond fixed molecular architectures to highly adaptable systems that can be rapidly customized for new targets, payload classes, and combination strategies. This flexibility enhances both internal pipeline optionality and partnership-driven commercial opportunities.

Within this context, OS Therapies' tunable conjugate platforms position the Company to participate in the next wave of ADC innovation and address key limitations of current market leaders. Yet even the most successful ADCs still face challenges, such as systemic toxicity related to traditional cytotoxic payloads, limited tumor penetration in solid tumors, and the emergence of drug resistance. OS Therapies' OST-tADC platform is designed to mitigate these limitations by offering improved tunability, potentially superior therapeutic windows, and broader applicability across solid tumor targets where conventional ADCs may fall short.

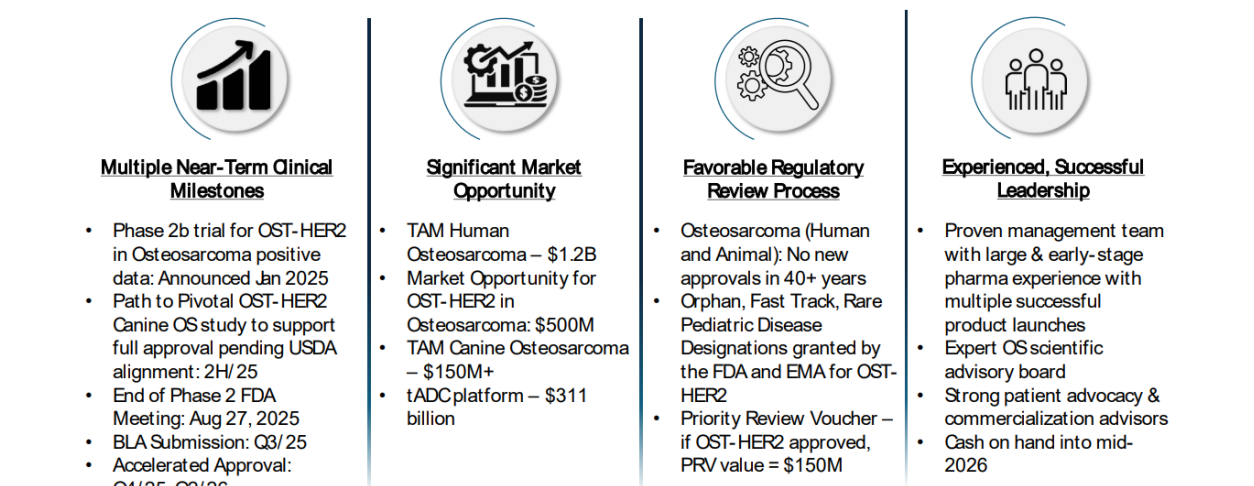
Investment Highlights

- OS Therapies is a clinical-stage immuno-oncology company addressing a major unmet need in osteosarcoma and solid tumors. The Company is developing and commercializing novel treatments for osteosarcoma and other HER2-expressing solid tumors across pediatric and adult populations, targeting a market with no new approved osteosarcoma therapies in over 40 years and significant unmet need.
- The Company has built a diversified pipeline around two novel technology platforms: OST-Lm, a bioengineered form of *Listeria monocytogenes* designed to drive robust immune responses against HER2-expressing cancer cells; and OST-tADC, a next-generation tunable antibody-drug conjugate platform featuring a patented silicone-based component that enhances both safety and efficacy.
- The lead OST-Lm program—OST-HER2—is an off-the-shelf immunotherapy targeting HER2-expressing cancers. OST-HER2 is in clinical development for osteosarcoma and breast cancer, and holds conditional approval for canine osteosarcoma.
 - The osteosarcoma program (lead indication in recurrent, resected lung-metastatic osteosarcoma) is the nearest to regulatory submission and has received the FDA’s rare pediatric disease designation, as well as orphan drug and fast track designations from the FDA and the European Medicines Agency (EMA).
 - A Phase 2b trial of OST-HER2 in osteosarcoma has completed its treatment phase, showing statistically significant benefits in 12-month Event-Free Survival (EFS) (35% vs. ~20% historical; primary endpoint) and a strong early overall survival benefit (OS) (75% two-year OS vs. ~40% historical), alongside a favorable safety profile.
 - OS Therapies believes that the demonstrated efficacy, favorable safety profile, and significant unmet clinical need in osteosarcoma support the potential for accelerated regulatory approval of OST-HER2, enabling advancement through the approval process without requiring a Phase 3 trial.
 - The Company is preparing a rolling BLA submission for Q1 2026 with a targeted FDA Accelerated Approval decision in Q3 2026. OS Therapies is also preparing conditional MAA submissions to the UK’s MHRA and the EMA in Q1 2026.
- OS Therapies is targeting the expansion of its Lm-platform into multiple high-value oncology indications through the development of additional product candidates: OST-AXAL (HPV-related cancers), OST-503 (NSCLC and glioblastoma), and OST-504/PSA (prostate cancer), along with additional preclinical programs targeting more than 30 solid tumor types.
- The Company also plans to create additional shareholder value through the proposed spin-off of its subsidiary, OS Animal Health (OSAH), which is developing OST-HER2 for canine osteosarcoma. OSAH plans to resubmit for USDA conditional approval in January 2026, with a potential commercial launch in 2026.
- OS Therapies is further advancing its proprietary OST-tADC platform, which is currently in preclinical development and is initially being evaluated for use in ovarian and breast cancers. The OST-tADC platform features patented pH-sensitive SiLinkers™ and CAP payloads, enabling precise payload release only in the tumor microenvironment, enhancing safety, reducing off-target toxicity, and enabling higher effective dosing.
 - The Company established a dedicated subsidiary, OS Drug Conjugates, to support internal development of the platform and pursue future licensing or partnership opportunities.

- OS Therapies is led by a management team with a strong track record of drug development, commercialization, and multiple M&A exits. The Company is developing several potential revenue streams for 2026 and 2027, including its canine osteosarcoma product (2026), the potential sale of a Priority Review Voucher, and the market introduction of OST-HER2 in osteosarcoma (2027).
 - In August 2025, the Company announced that its NYSE American listing (OSTX) was included in the Russell Microcap, Russell Microcap Value, and Russell Microcap Growth indexes.
- As of September 30, 2025, the Company reported cash of \$1.876 million; subsequent to quarter-end, OS Therapies received an additional \$1.5 million from the exercise of warrants.

Figure 23 provides a summary of the investment rationale for OS Therapies.

Figure 23
INVESTMENT RATIONALE



Source: OS Therapies Inc.

Historical Financial Results

Figures 24, 25, and 26 (pages 48-50) provide a summary of OS Therapies' most recent key financial statements for the quarter ended September 30, 2025.

Figure 24
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	For the three months ended September 30, 2025	For the three months ended September 30, 2024	For the nine months ended September 30, 2025	For the nine months ended September 30, 2024
OPERATING EXPENSES				
Research & Development	\$ 3,755,335	\$ 1,210,216	\$ 7,563,988	\$ 1,968,591
General & Administrative	3,124,260	1,227,177	9,153,821	1,878,831
Loss from Operations	<u>(6,879,595)</u>	<u>(2,437,393)</u>	<u>(16,717,809)</u>	<u>(3,847,422)</u>
OTHER INCOME/EXPENSE				
Interest Income	65	—	195	1
Interest Expense	—	(437,839)	—	(2,044,283)
Change in Fair Value of Warrant Liability	—	—	1,424,603	—
TOTAL OTHER INCOME/EXPENSE	<u>65</u>	<u>(437,839)</u>	<u>1,424,798</u>	<u>(2,044,282)</u>
NET LOSS	<u>(6,879,530)</u>	<u>(2,875,232)</u>	<u>(15,293,011)</u>	<u>(5,891,704)</u>
Cumulative Series A Preferred Stock Dividend Requirement	—	—	—	(31,250)
NET LOSS available to common shareholders	<u>\$ (6,879,530)</u>	<u>\$ (2,875,232)</u>	<u>\$ (15,293,011)</u>	<u>\$ (5,922,954)</u>
Weighted Average # of Shares	31,956,686	15,897,460	27,390,472	9,249,951
Basic & Diluted Loss per Common Share Outstanding	<u>\$ (0.21)</u>	<u>\$ (0.18)</u>	<u>\$ (0.57)</u>	<u>\$ (0.64)</u>

Source: OS Therapies Inc.

Figure 25
CONSOLIDATED BALANCE SHEETS
(unaudited)

	September 30, 2025	December 31, 2024
Current Assets		
Cash	\$ 1,876,626	\$ 5,533,527
Employee Advances	41,852	-
Prepaid Expenses	403,213	-
Total Current Assets	2,321,691	5,533,527
Long-Term Assets		
Fixed Assets (Net)	3,185	5,270
Patents (Net of Amortization)	6,628,375	-
TOTAL ASSETS	\$ 8,953,251	\$ 5,538,797
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts Payable	\$ 3,374,287	\$ 1,662,068
Accrued Expenses	395,450	521,010
Accrued Payroll and Payroll Taxes – Related Party	-	97,257
Accrued Payroll and Payroll Taxes	614	-
Preferred Dividends Payable	375,000	375,000
Warrant Liability	-	1,971,975
Total Current Liabilities	4,145,351	4,627,310
Long-Term Liabilities		
TEDCO Grant	100,000	100,000
Total Long-Term Liabilities	100,000	100,000
Total Liabilities	4,245,351	4,727,310
Commitments and contingencies (See Note 6)		
MEZZANINE EQUITY:		
Series A Convertible Preferred Stock, par value \$0.001, 2,500,000 shares authorized; 392,500 and 1,512,500 issued and outstanding, respectively	1,070,705	4,078,025
Total Mezzanine Equity	1,070,705	4,078,025
STOCKHOLDERS' EQUITY (DEFICIT)		
Common Stock A, par value \$0.001, 50,000,000 shares authorized; 33,269,981 and 20,869,908 issued and outstanding, respectively	33,270	20,870
Preferred Stock, par value \$0.001, 5,000,000 shares authorized; 0 and 0 issued and outstanding, respectively	-	-
Additional paid-in capital	57,329,311	35,144,967
Accumulated deficit	(53,725,386)	(38,432,375)
Total Stockholders' Equity (Deficit)	3,637,195	(3,266,538)
TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 8,953,251	\$ 5,538,797

Source: OS Therapies Inc.

Figure 26
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Nine Months Ended September 30, 2025 and 2024
(unaudited)

	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (15,293,011)	\$ (5,891,704)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and Amortization expense	238,147	1,390
Amortization of Debt Discounts Issuance and Warrants	-	1,425,679
Change in value of Warrant Liabilities	(1,424,603)	-
Commitment Shares issued for Equity Line of Credit	568,235	-
Common Shares issuance for services	595,841	-
Stock-based Compensation	2,661,397	-
Adjustments to reconcile net loss to net cash used in operating activities:		
Prepaid Expenses	697,500	(35,000)
Employee Advances	(41,852)	(77,500)
Accounts Payable	1,712,219	(943,434)
Accrued Expenses	(125,560)	133,900
Accrued Interest on Convertible Notes	-	613,605
Accrued Payroll and payroll taxes	(96,643)	(134,654)
<i>Net cash used in operating activities</i>	<u>(10,508,330)</u>	<u>(4,907,718)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent License Acquisition	(466,423)	-
<i>Net cash used in investing activities</i>	<u>(466,423)</u>	<u>-</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Sale of Preferred Stock and related Warrants	1,053,582	-
Common Stock Issuance for Warrant Exercise	6,264,270	-
Short-Term Borrowings	-	250,000
Short-Term Loan Repayments	-	(250,000)
Initial Public Offering (Net of Fees)	-	5,225,840
Net Proceeds from Conversion of Debt A, B, C, D, E & F	-	1,501,000
<i>Net cash provided by financing activities</i>	<u>7,317,852</u>	<u>6,726,840</u>
Net change in cash	(3,656,901)	1,819,122
Cash – beginning of period	5,533,527	38,982
Cash – end of period	<u>\$ 1,876,626</u>	<u>\$ 1,858,104</u>
Cash paid for interest	<u>\$ -</u>	<u>\$ -</u>
NON CASH INVESTING AND FINANCING ACTIVITIES		
Discount on Notes Payable – redemption premium	-	750,500
Dividends Payable	-	31,250
Mezzanine Equity Conversion (Net of Costs)	3,730,121	-
Conversion of Preferred Stock to Common Stock	-	1,302
Amortization of deferred offering costs	-	751,050
Conversion of Convertible Notes into Common Stock	-	24,757,252
Conversion of Warrants into Common Stock	-	116
Issuance of Common Stock to Investor Advisor - Settlement	-	320
Common Stock issued for Patent Purchase	6,398,015	-
Reclassification of Warrants Liability to equity	878,153	-
Shares issued for prepaid services	<u>\$ 1,100,713</u>	<u>\$ -</u>

Source: OS Therapies Inc.

Recent Events

01/05/2026— OS Therapies Inc. (“OS Therapies” or “the Company”) outlined key H1 2026 milestones centered on regulatory filings for its lead program, OST-HER2, in metastatic osteosarcoma, including a U.S. FDA Biologics License Application submission targeted for the end of January 2026 under the Accelerated Approval pathway. The Company also expects to release Phase 2b biomarker data during the week of the 2026 J.P. Morgan Healthcare Conference, and to submit conditional approval applications in the U.K. (end of February 2026) and EU (March 2026). After these filings, OS Therapies anticipates multiple meetings with the FDA, MHRA, and EMA to support review and align on endpoints, confirmatory trial design, and post-authorization monitoring. Separately, it expects an early-January SEC confidential filing tied to a go-public transaction for OS Animal Health, plus Q1 2026 data from OST-504 (prostate cancer) and a planned End of Phase 2 FDA meeting in Q2 2026 for OST-503 (NSCLC with Keytruda).

12/15/2025—Reported a successful Type C meeting with the U.S. FDA for its Phase 2b trial of OST-HER2 in fully resected pulmonary metastatic osteosarcoma. The FDA confirmed that single-arm studies in ultra-rare diseases could support a BLA under the Accelerated Approval pathway and provided feedback on confirmatory study design and biomarker strategy, including the potential use of canine data. OS Therapies reiterated its plan to submit a BLA by the end of January 2026.

12/09/2025—Reported a successful pre-MAA meeting with the UK MHRA for its Phase 2b trial of OST-HER2 in fully resected pulmonary metastatic osteosarcoma, gaining alignment on non-clinical, CMC, and post-marketing confirmatory study plans. The MHRA also supported the Company’s strategy to use immune-response biomarkers as a surrogate efficacy endpoint, and OS Therapies reiterated its plan to submit a conditional MAA to the MHRA by the end of January 2026.

12/05/2025—Announced that the U.S. Food & Drug Administration (FDA) granted the Company waiver of the application fee for its planned BLA submission for OST-HER2. Additionally, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) granted Union Marketing Authorization eligibility for OST-HER2 and requested an accelerated Marketing Authorization Application (MAA) submission for the metastatic osteosarcoma program by February 28, 2026.

11/25/2025—Announced that the WHO International Nonproprietary Names (INN) Expert Committee has approved “daznelimgene lisbac” as the non-proprietary name for its HER2-targeted *Listeria monocytogenes* cancer immunotherapy candidate, OST-HER2. INNs provide globally unique identifiers for active pharmaceutical ingredients to ensure clear identification and safe prescribing. OS Therapies will begin transitioning to the use of daznelimgene lisbac alongside OST-HER2 in upcoming communications.

11/20/2025—Announced plans to spin off its wholly owned subsidiary, OS Animal Health, Inc. (OSAH), into an independent public company to be listed on a U.S. national stock exchange. The Company anticipates completing the spin-off and public listing in the first half of 2026. The announcement follows successful preliminary discussions with NYSE representatives and potential investors. Upon completion of the spin-off, OS Therapies shareholders are expected to receive direct equity participation in the newly listed company.

11/17/2025—Reported third quarter 2025 financial results ended September 30, 2025, and provided a business update.

10/22/2025—Announced additional overall and Event Free Survival data generated from the sub-group analysis of its Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, pulmonary metastatic osteosarcoma. The Company previously announced statistically significant positive final 2-year overall survival data on October 10, 2025. Results of the sub-group analysis indicated that patients with a lung-only second or greater metastatic event had a 2-year overall survival of 80.0%, and 1-year Event Free Survival of 50%; and patients with a lung-only first metastatic event had a 2-year overall survival of 73.8% (vs. 30% Natural History Comparator) and 1-year Event Free Survival of 28.6%.

10/17/2025—Announced that the FDA granted a second Type C Meeting, following its successful End of Phase 2 Meeting for OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma (“the Pulmonary Metastatic Osteosarcoma Program”). The primary purpose of the meeting, scheduled for December 11, 2025, is to gain alignment on the clinical efficacy data endpoints to support a Biologics License Application (BLA) under the Accelerated Approval Program. Concurrently, the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) granted a pre-Marketing Authorization Application (MAA) Meeting for the OST-HER2 metastatic osteosarcoma program.

10/10/2025—Announced statistically significant positive final 2-year overall survival data from the Company’s Phase 2b osteosarcoma trial. 75% of OST-HER2 treated patients (27 out of 36 evaluable patients; 5 patients were lost to follow-up) achieved 2-year overall survival as measured from most recent pulmonary resection, compared with 40% of historical control. Subgroup analyses showed that 100% of patients who achieved 12-month EFS achieved 2-year overall survival whereas 59% of patients who did not achieve EFS achieved 2-year overall survival.

10/09/2025—Announced a positive regulatory update following an October 6, 2025 meeting with its EMA rapporteur, the Dutch Medicines Evaluation Board (MEB). During the meeting, OS Therapies and the Dutch Rapporteur aligned on key areas, including safety, non-clinical, and chemistry, manufacturing, and controls (CMC) data in support of the Company’s ongoing OST-HER2 Phase 2b Osteosarcoma Trial. The Rapporteur advised that the overall survival results, demonstrating statistically significant, final two-year data, may serve as an appropriate primary endpoint for consideration of conditional marketing authorization (CMA). Additionally, the Company reported that the UK MHRA granted OS Therapies an expedited Market Access Scientific Advice Meeting, an important milestone in the MAA submission and approval process.

10/07/2025—Announced its participation in the following upcoming October 2025 conferences and events: Cell and Gene Meeting on the Mesa, October 6-8, 2025, in Phoenix, AZ; Roth Annual Healthcare Opportunities Conference, October 9, 2025 in New York City, NY; FDA/The Osteosarcoma Institute (OSI) Workshop: Advancing Osteosarcoma Drug Development - Connecting Research and Regulatory Pathways for Improved Outcomes, October 10, 2025 in Washington, DC; BIOFuture 2025, October 13-15, 2025 in New York City, NY; 52nd Daytime Emmy Awards (where *Shelter Me: Cancer Pioneers* is nominated for 2 Emmys), October 17, 2025, in Pasadena, CA; Maxim Growth Summit: Maxim Group Healthcare Conference, October 22, 2025, in New York City, NY; and BIO - Europe, November 3-5, 2025, in Vienna, Austria.

09/30/2025—Provided a regulatory update on its plans for filing marketing authorizations in the U.S. and the UK for its Pulmonary Metastatic Osteosarcoma Program. The Company has updated its regulatory filing sequence to prioritize the MHRA conditional MAA final module submission to immediately precede its BLA final module submission under the Accelerated Approval Program. The Company expects to complete the MHRA conditional MAA submission in December 2025, with the FDA’s BLA Accelerated Approval submission expected in January 2026.

09/19/2025—Announced that it has been invited to participate in the “Beyond the Cure: The Brave New World of Revolutionary Cancer Therapeutics” Spotlight Panel at BioFuture 2025 taking place at Cure in New York City on October 13, 2025. Additionally, the Company is positioned to commence submission of a BLA in the fourth quarter of 2025. If approved prior to September 30, 2026, the Company will become eligible to receive a Priority Review Voucher (PRV) that it intends to sell to support its clinical development programs.

09/12/2025—Announced that the last patient enrolled in its OST-504 (previously ADXS-504) Phase 1b clinical trial in subjects with biochemically recurrent prostate cancer previously treated with radical prostatectomy (RP) or radiation therapy (external beam or brachytherapy) who are not currently receiving androgen ablation therapy has completed their last patient visit. A total of 7 patients enrolled in the study.

09/03/2025—Announced that it will participate in the following upcoming investor conferences: Cantor Global Healthcare Conference 2025 being held September 3-5, 2025 in New York City, NY; H.C. Wainwright 27th Annual Global Investment Conference being held September 8-10, 2025 in New York City, NY; and Lake Street Capital Markets 9th Annual Best Ideas Growth (BIG9) Conference being held on September 11, 2025 in New York City, NY.

09/02/2025—Provided a detailed update regarding the Company’s Pulmonary Metastatic Osteosarcoma Program, following an End of Phase 2 Meeting with the FDA, where both parties achieved alignment in several areas crucial for a successful BLA submission. The Company remains on track to begin rolling BLA submission in September 2025. Additionally, the Company received confirmation from FDA that it is eligible for a Prescription Drug User Fee Act (PDUFA) small business fee waiver, with a final decision on the PDUFA fee waiver anticipated by the end of Q3 2025.

09/02/2025—Announced that it completed a warrant inducement and exchange offer with the holders of all remaining outstanding warrants with an exercise price \$1.12 per share issued in connection with a private placement with an initial closing date of December 31, 2024. The Company completed the Warrant Exchange on substantially similar terms to the previously announced warrant exercise inducement and exchange offer on July 14, 2025. The Warrant Exchange raised approximately \$3.7 million in gross proceeds, which the Company intends to use primarily to accelerate commercial preparations for its Pulmonary Metastatic Osteosarcoma program. The Company now has funding into 2027.

08/25/2025—Announced that it terminated its Equity Purchase Agreement with Square Gate Capital Master Fund, LLC—Series 3, effective August 26, 2025. The recent success of its warrant exercise inducement and exchange offering provided the Company with \$4.2 million in gross proceeds to fund operations into mid-year 2026, through the Priority Review Voucher sunset date of September 30, 2026.

08/19/2025—Reported second quarter 2025 financial results ended June 30, 2025, and provided a business update.

08/07/2025—Announced statistically significant positive updated interim 2-year overall survival data from the Company’s Phase 2b Osteosarcoma Trial. 66.6% (18 out of 27) of OST-HER2 treated patients achieved 2-year overall survival compared with 40% of historical control. Additionally, the FDA issued a BLA number for OST-HER2 to receive a BLA submission following the Company’s pending August 27, 2025, End of Phase 2 Meeting. Concurrent with this announcement, the Company announced that its NYSE American listing is included in the Russell Microcap, Russell Microcap Value, and Russell Microcap Growth indexes.

08/07/2025—Announced that it held a successful Scientific Advice Meeting with the MHRA in July and has submitted an invited Innovative Licensing and Access Pathway (ILAP) application to begin the regulatory process towards approval of OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma. MHRA suggested synchronizing its MAA process with the FDA BLA Accelerated Approval Program. In addition, a European Medicines Agency rapporteur, the Netherlands Medicines Evaluation Board (MEB), granted the Company a SAM meeting to begin the requisite processes towards a European Union-wide Marketing Authorization via the Centralized Procedure.

07/14/2025—Announced that it has closed its previously announced warrant exercise inducement and exchange offer. The Company raised a total of \$4.2 million in gross proceeds from the offering. The Company intends to use the net proceeds primarily to support its clinical development programs, including its U.S. and international regulatory and pre-commercial efforts aimed at securing accelerated marketing authorizations for its Pulmonary Metastatic Osteosarcoma Program.

07/03/2025—Announced it was granted an End of Phase 2 Meeting by the FDA to review the OST-HER2 Pulmonary Metastatic Osteosarcoma Program. The Company expects the meeting to occur in the third quarter of 2025. The End of Phase 2 Meeting marks a pivotal point in the drug development process, and a significant milestone towards market access.

06/30/2025—Announced positive 1-year Event-Free Survival (EFS), overall survival, and safety clinical trial data updates from the 40-patient treatment arm of its Phase 2b Osteosarcoma Trial. Results, presented by Principal Investigator Dr. Damon Reed at the MIB Factor Osteosarcoma Conference held in Salt Lake City, Utah on Saturday June 28, 2025, indicated that 35% (14 out of 40) of OST-HER2-treated patients achieved 1-year Event-Free Survival (EFS) compared with 20% of patients from equivalent data from peer-reviewed publication.

06/23/2025—Announced a warrant exercise inducement and exchange offer for holders of its five-year warrants (exercise price \$1.12 per share) issued from a PIPE financing that closed on December 31, 2024. Under the offer, holders can exercise their existing warrants now in exchange for receiving new five-year warrants to buy the same number of shares, but at a higher exercise price of \$3.00 per share. The New Warrants otherwise have substantially the same terms as the Old Warrants. If all Old Warrants are exercised, the Company would raise about \$8 million in gross proceeds before expenses. So far, \$1.76 million has already been received, which extends the Company’s cash runway into the second half of 2026.

06/10/2025—Selected EVERSANA®, a leading provider of global commercial services to the life sciences industry, to support the U.S. commercialization of OST-HER2, a novel immunotherapy for recurrent, fully resected, pediatric lung metastatic osteosarcoma. Through the use of EVERSANA’s end-to-end EVERSANA ONCOLOGY Commercialization model, which includes market access, medical affairs, field deployment, patient services, and stakeholder engagement, the Company expects to accelerate awareness and access to OST-HER2 among healthcare providers treating osteosarcoma, as well as the potential to treat additional HER2-positive cancers.

06/06/2025—Announced it has submitted a request for Regenerative Medicine Advanced Therapy (RMAT) Designation to U.S. FDA for OST-HER2 in the prevention of metastases in recurrent, fully-resected, lung metastatic pediatric osteosarcoma. RMAT designations are granted to sponsors with regenerative medicine therapies for serious or life-threatening conditions and provides sponsors with various benefits, including eligibility for an accelerated BLA review.

05/16/2025—Reported first quarter 2025 financial results ended March 31, 2025, and provided a business update.

05/15/2025—Announced the launch of OS Animal Health, Inc., a wholly owned subsidiary focused on commercializing OST-HER2 for the treatment of canine osteosarcoma. The newly formed subsidiary is focused on re-establishing USDA conditional approval for OST-HER2 in canine osteosarcoma, with a targeted submission in the second half of 2025. OS Animal Health will operate independently from the parent company, with separate funding aligned to the needs of the animal health market.

05/07/2025—Announced the issuance of U.S. Patent #12,230,738 protecting proprietary commercial manufacturing methods for the Company’s *Listeria monocytogenes (Lm)* cancer immunotherapy platform technology into 2040. Phase 3-stage OST-AXAL for HPV, Phase 2-stage OST-503 for NSCLC & GBM, Phase 1-stage OST-504 for Prostate cancer, 8 pre-clinical stage immunotherapy candidates are also protected under this patent. The patent also covers OST-HER2’s use in canine osteosarcoma.

04/10/2025—Announced positive data in the prevention or delay of amputation during the treatment of primary osteosarcoma for OST-HER2 combined palliative radiation in dogs with unresected appendicular osteosarcoma. The treatment led to clinical and radiographic arrest of the primary tumor and prolonged time to metastasis in dogs without surgery or chemotherapy.

04/09/2025—Announced that it has completed the acquisition of the listeria-based cancer immunotherapy assets of Advaxis Immunotherapies from Ayala Pharmaceuticals. The Company is now positioned as the world leader in listeria-based cancer immunotherapies, expanding its clinical pipeline with 3 new cancer immunotherapy candidates and 8 pre-clinical immunotherapy candidates targeting 30+ cancers.

04/02/2025—Announced that the Company will be hosting an Analyst Day at the New York Stock Exchange in Lower Manhattan that will start at 10:00 am on Monday, April 7, 2025. The Company intends to focus the Analyst Day discussion on its OST-HER2 program for human recurrent, fully resected lung metastatic osteosarcoma, for canine osteosarcoma, and OST-HER2 data in breast cancer, and other human solid tumors. Additionally, the Company will review the pipeline of assets being acquired from Ayala Pharmaceuticals.

03/31/2025—Reported full-year 2024 financial results ended December 31, 2024, and provided a business update.

03/31/2025—Provided a regulatory update for its OST-HER2 *Listeria monocytogenes* (Lm) immunotherapeutic cancer biologic drug candidate in the prevention or delay of fully-resected, recurrent, lung metastatic osteosarcoma. The Company initiated regulatory correspondence with the FDA and the MHRA in the first quarter of 2025, and intends to initiate regulatory interaction with EMA in the second quarter of 2025.

03/25/2025—Announced that OST-HER2 is featured in the upcoming movie *Shelter Me: The Cancer Pioneers*. The movie offers a look into canine comparative oncology, a field that compares treatment of cancers in dogs to those in people. The movie will premiere on April 3, 2025, at AMC Century City in Los Angeles and will be available to stream through the PBS app and on PBS.org starting in May 2025.

03/21/2025—Announced that Paul Romness, the Company’s Chief Executive Officer, and Gerald Commissiong, the Company’s Chief Business Officer, will be accepting meetings with registered investors at The Jones Healthcare and Technology Innovation Conference. The conference is being held on April 8-9, 2025, at the Venetian Resort in Las Vegas.

03/13/2025—Announced that it has been awarded a presentation slot at the MIB Agents Factor Osteosarcoma Conference to be held June 26-28, 2025, in Salt Lake City, Utah. Key data will be presented from the Company’s Phase 2b clinical trial of OST-HER2 in the prevention of recurrent, fully resected, lung metastatic osteosarcoma.

02/24/2025—Announced the formation of subsidiary OS Drug Conjugates (OSDC). The formation of OSDC coincides with formal strategic options initiatives to create value from the Company’s tunable antibody drug conjugates (tADC) & other tunable drug conjugates (tDC) platforms. The Company has initiated discussions with clinical-stage ADC therapeutics companies in the U.S., China, and other jurisdictions to form joint ventures (JVs), eventually spinning the JVs into standalone public companies. If successful, OS Therapies intends to provide stock dividends of the public JVs to shareholders.

02/20/2025—Announced that it received a Notice of Allowance from the U.S. Patent & Trademark Office (USPTO) that a patent will be issued covering the manufacturing methods required for the OST-HER2 commercial product. The USPTO granted a Patent Term Adjustment of 572 days, providing market exclusivity for the OST-HER2 commercial drug product into 2040.

02/14/2025—Announced that it has entered into agreements for the commercial manufacture of OST-HER2. The Company is currently organizing additional data in relation to the recently completed treatment phase of its Phase 2b Osteosarcoma Trial in preparation for a meeting with the FDA.

01/29/2025—Announced it has entered into an asset purchase agreement to acquire the *Listeria monocytogenes*-based immuno-oncology programs and related intellectual property (IP) assets from Ayala Pharmaceuticals. The assets being acquired include a Phase 2 lung cancer and a Phase 1 prostate cancer program, in addition to the gaining direct ownership of the underlying IP related to OS Therapies’ lead asset OST-HER2 for osteosarcoma and other HER2-related indications. Under the terms of the agreement, OS Therapies has agreed to pay \$0.5 million in cash and issue \$7.5 million worth of OS Therapies’ common shares to Ayala.

01/15/2025—Announced positive data from a Phase 2b clinical trial ([NCT04974008](#)) of OST-HER2 (OST31-164) in the rare pediatric-designated indication of prevention of recurrent, fully resected, lung metastatic osteosarcoma. The data demonstrates statistically significant results in the primary endpoint of the study, 12-month EFS, in OST-HER2-treated patients when compared with the leading published historical comparable control group. The data also shows a strong trend in favor of OST-HER2-treated patients in overall survival at the 1-year and 2-year interim timepoints of the ongoing 3-year overall survival secondary endpoint. Notably, all patients who achieved the primary 12-month EFS endpoint remain alive.

01/02/2025—Announced that its Chair & CEO Paul Romness has accepted an invitation to attend the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, CA, taking place on January 13-16, 2025. This conference is the largest and most informative health care investment symposium in the industry, which connects global industry leaders, emerging fast-growth companies, innovative technology creators, and members of the investment community.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Crystal Research Associates, LLC (“CRA”) with the assistance of OS Therapies Inc. (“OS Therapies” or “the Company”) based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in OS Therapies’ SEC statements on forms filed from time to time.

The content of this report concerning OS Therapies has been compiled primarily from information available to the public released by the Company through news releases and other filings. OS Therapies is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by OS Therapies or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its agreement, CRA has been compensated by the Company in cash of fifty thousand dollars and one hundred thousand options for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about OS Therapies’ business, as described below and more fully detailed in the Company’s recent filings. Investors should not interpret the order in which considerations are presented in this document or other filings as an indication of their relative importance. In addition, the risks and uncertainties covered in the accompanying sections are not the only risks the Company faces. Additional risks and uncertainties not presently known to OS Therapies or that it currently believes to be immaterial may also adversely affect the Company’s business and are outlined in the Company’s recent filings. If any such risks and uncertainties develop into an actual event, OS Therapies’ business, financial condition, and results of operations could be materially and adversely affected.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved in investing in the Company, as well as for copies of this report, please contact OS Therapies by calling (410) 849-9067.

RISK FACTORS

The following is a risk factor summary for OS Therapies as it appears on the Company’s 10-K filing dated March 31, 2025. The full details of the Company’s risk factors can be found at <https://ir.ostherapies.com/sec-filings/annual-reports##document-253-0001213900-25-026238-2>

Risks Related to the Company’s Financial Position and Need for Additional Capital

- OS Therapies is a clinical stage biopharmaceutical company and has not generated any revenue to date from drug sales and may never become profitable.
- The Company has incurred significant operating losses in recent periods and anticipates that it will incur continued losses for the foreseeable future.
- If OS Therapies is unable to raise capital when needed or on attractive terms, it would be forced to delay, scale back, or discontinue some of its product candidate development programs or commercialization efforts.
- OS Therapies’ independent registered public accounting firm has expressed substantial doubt about its ability to continue as a going concern.

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- The Company's ability to utilize its net operating loss carry forwards and certain other tax attributes may be limited.

Risks Related to Drug Development and Regulatory Approval

- OS Therapies depends heavily on the success of its core product candidates, OST-HER2 and OST-tADC. The Company may not be able to obtain regulatory permission to conduct future clinical studies or may not be able to obtain regulatory approval for, or successfully commercialize, any of its current or future product candidates.
- If OS Therapies experiences delays or difficulties in the enrollment of patients in clinical trials, its receipt of necessary regulatory approvals could be delayed or prevented.
- If the Company is not able to obtain, or if there are delays in obtaining, required regulatory approvals both for its current or future product candidates, OS Therapies will not be able to commercialize, or will be delayed in commercializing, its current or future product candidates, and its ability to generate revenue will be materially impaired.
- OS Therapies' current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their future testing in clinical studies or delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- The Company may not be able to obtain or maintain orphan drug designation or exclusivity for any product candidates and, even if it does, that exclusivity may not prevent the FDA or the EMA from approving other competing products.
- Even if OS Therapies receives regulatory approval for any of its current or future product candidates, it will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expenses. Additionally, the Company's current or future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and OS Therapies may be subject to penalties if it fails to comply with regulatory requirements or experience unanticipated problems with its drugs.
- Even if OS Therapies receives marketing approval for its current or future product candidates in the U.S., the Company may never receive regulatory approval to market its current or future product candidates outside of the U.S.
- Manufacturing OS Therapies' current or future product candidates is complex, and the Company may encounter difficulties in production. If it encounters such difficulties, OS Therapies' ability to provide supply of its current or future product candidates for pre-clinical studies and clinical trials or for commercial purposes could be delayed or stopped.
- The Company's future growth may depend, in part, on its ability to penetrate foreign markets, where it would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect OS Therapies' business.

Risks Related to Intellectual Property

- If OS Therapies or those from whom it in-licenses patents are unable to obtain and maintain patent and other intellectual property protection for the Company's technology and product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, OS Therapies' competitors could develop and commercialize technology and drugs similar or identical, and the Company's ability to successfully commercialize its technology and drugs may be impaired.

- If the Company's trademarks and trade names for its products or company name are not adequately protected in one or more countries where it intends to market its products, OS Therapies may delay the launch of product brand names, use different trademarks or trade names in different countries, or face other potentially adverse consequences to building its product brand recognition.
- If OS Therapies is unable to adequately protect and enforce its trade secrets, the Company's business and competitive position would be harmed.
- OS Therapies may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce its intellectual property rights, which could be expensive, time-consuming, and unsuccessful.
- The Company may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.
- If OS Therapies fails to comply with its obligations in any agreements under which it may license intellectual property rights from third parties or otherwise experiences disruptions to the business relationships with its licensors, the Company could lose license rights that are important to its business.
- Any in-license patent covering OS Therapies' current or future product candidates or other valuable technology could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad, including the USPTO and the EPO.

Risks Related to Management and OS Therapies' Operations

- In OS Therapies' industry in particular, the Company's future success depends on its ability to retain key scientific employees and to attract, retain, and motivate qualified personnel.
- The Company's internal computer systems, or those of its third-party clinical research organizations (CROs), or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of OS Therapies' current or future product candidates' development programs.
- OS Therapies will incur increased costs as a result of operating as a public company, and its management will be required to devote substantial time to new compliance initiatives.

Glossary

Antibody-Drug Conjugate (ADC)—A targeted therapy that links a monoclonal antibody to a cytotoxic drug, delivering the therapeutic payload directly to cancer cells expressing a specific antigen.

Antigen-Presenting Cells (APCs)—Immune cells, including dendritic cells, macrophages, and B cells, that process and present antigens to T cells to initiate an immune response.

Biologics License Application—A formal application a company submits to the U.S. FDA asking for permission to market a biologic (like a vaccine, monoclonal antibody, or cell/gene therapy) in the U.S. A BLA typically includes evidence on safety and effectiveness, details on manufacturing and quality controls (to show the product can be made consistently), and proposed labeling.

Checkpoint Inhibitors—A class of immunotherapies that block proteins used by cancer cells to evade the immune system, enabling T cells to attack tumors more effectively.

Comparative Oncology—A research field that studies naturally occurring cancers in animals, especially dogs, to inform and accelerate human cancer drug development.

Conditionally Active Payloads (CAPs)—Cytotoxic agents are designed to remain inactive until triggered by specific conditions in the tumor microenvironment, improving safety and precision.

Event-Free Survival (EFS)—A clinical endpoint measuring the time from treatment initiation until disease progression, relapse, a major medical event, or death.

Fast Track Designation—A U.S. FDA program that expedites the development and review of drugs for serious conditions with unmet medical needs.

Folate receptor alpha (FR α)—Folate receptor alpha (FR α) is a cell-surface protein that binds folate (vitamin B9) with high affinity and helps transport it into cells. While it is present at low levels in most normal tissues, FR α is overexpressed in several cancers, including ovarian, endometrial, lung, and certain breast cancers.

Human epidermal growth factor receptor 2 (HER2)—A protein receptor (human epidermal growth factor receptor 2) involved in cell growth. Overexpression of HER2 is associated with several cancers, including breast, gastric, and some pediatric tumors.

Linker—The chemical component in an ADC that connects the antibody to its drug payload and determines when and where the payload is released.

Listeria monocytogenes—A species of bacteria that can be engineered for therapeutic use. In immuno-oncology, attenuated strains are used as vectors to stimulate immune responses against cancer.

Marketing Authorization Application (MAA)—The formal application submitted to the European Medicines Agency (EMA) and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) to obtain approval to market a medicine in their respective regions.

Micrometastatic—Referring to very small, often undetectable clusters of cancer cells that have spread from the primary tumor to other parts of the body.

Monoclonal Antibodies (mAbs)—Laboratory-produced antibodies engineered to bind specific targets (antigens), commonly used in diagnostics, immunotherapy, and targeted cancer treatment.

Orphan Drug—A designation granted to therapies intended for rare diseases, providing incentives such as market exclusivity and tax credits.

Osteosarcoma—A rare and aggressive malignant bone tumor that most commonly affects children, adolescents, and young adults. It often arises in long bones and has a high risk of metastasis.

Overall Survival (OS)—A clinical endpoint measuring the length of time from treatment start until death from any cause.

Phagocytosis—A process by which certain immune cells (such as macrophages and neutrophils) engulf, internalize, and break down microorganisms, dead cells, or other particles to help protect the body and clear cellular debris.

Phagosome—A membrane-bound vesicle formed within immune cells after engulfing pathogens or particles, playing a key role in antigen processing and immune activation.

Priority Review Voucher (PRV)—A voucher awarded by the FDA that allows a company to receive priority review for a future drug application. PRVs can be used or sold.

Project Orbis—An FDA initiative enabling concurrent review of oncology products among international regulatory partners to expedite global patient access.

Rare Pediatric Disease—A serious or life-threatening condition primarily affecting individuals aged 18 or younger, with a U.S. prevalence below 200,000.

Tumor-associated antigens (TAAs)—Proteins (or protein fragments) found at higher levels on cancer cells than on normal cells. Because the immune system can recognize TAAs as “targets,” they’re often used in cancer vaccines and other immunotherapies to help direct an immune response toward tumor cells.

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About Our Firm: For the past decade, Crystal Research Associates, LLC (www.crystalra.com) has successfully articulated the exceptional stories of small- and mid-cap companies to the Wall Street investor community. Our methods are well-established and diverse, from compiling and disseminating objective, factual information for both institutional and retail investor audiences to capitalizing on our expansive line of targeted distribution channels, which include industry-leading financial data and information providers. Our distribution efforts are accompanied by the use of prominent social media channels and by strategic and targeted appearances on national news programs and print media.

Crystal Research Associates is led by Wall Street veterans, Jeffrey Kraws and Karen Goldfarb. Together, Kraws and Goldfarb have built a unique business model, capitalizing on decades of experience as an award-winning sell-side analyst team to produce institutional-quality industry and market research in a manner that is easily understood by investors and consumers. Our firm's approach has been proven successful over the years as our products are published and available on Bloomberg, Thomson Reuters/First Call, Capital IQ, FactSet, Yahoo! Finance, and scores of other popular forums.

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