



OS THERAPIES

NYSE American: OSTX



ABOUT US

OS Therapies is a development-stage biotechnology company focused on the treatment of osteosarcoma, HER2+ solid tumors and other cancers

With two platform technologies, we seek to transform the way cancer is treated by improving patient survival outcomes while improving quality of life by reducing side effects due to reduced need for systemic chemo.

OST-HER2

Lysteria monocytogenes

OST-tADC

Next-Generation ADC –
(Tunable Drug Conjugate)

VALUE CREATION IN 2025 AND BEYOND

- **Unique development pipeline** with lead asset OST-HER2 for Human & Canine Osteosarcoma (OS) & other HER2+ Solid Tumors, and HPV, NSCLC/GBM & Prostate cancer clinical-stage pipeline candidates
- **Proprietary technologies licensed** from U. Penn. (*listeria monocytogenes/Lm*) & Scripps/BlinkBio (tADC)
- **Disciplined focus on IP** – exclusive WW patent licenses and Company-owned IP w/ coverage into 2040
- **Industry leading team** – strong track record of drug development, commercialization & M&A exits
- **Clear Milestones:** OST-HER2 accelerated approval (AA) by US FDA by YE-2025 in refractory metastatic OS. Thereafter, expand OST-HER2 into metastatic & frontline OS and other HER2+ cancers + pipeline development in HPV, NSCLC & GBM and Prostate cancer
- **Priority Review Voucher (PRV)** –AA for OST-HER2 in refractory metastatic OS, PRV sale worth >\$150M

OS THERAPIES PIPELINE

Trial	Preclinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Approval	Launched
Osteosarcoma (OS) (OST-HER2)	Positive Phase 2b Data. Targeting Accelerated Approval Q2-Q3/26				<ul style="list-style-type: none"> ✓ Orphan drug designation ✓ Fast Track Designation ✓ Rare Pediatric Disease Designation 		Lead Program
HPV Cancers (OS) (OST-AXLA)	Completed Phase 3a Data: Pending data release and Phase 3b trial						
Non-Small Cell Lung Cancer* (NSCLC) (OST-503)	Metastatic disease alone & in combi w/Keytruda						
Non-Small Cell Lung Cancer* (NSCLC) (OST-503)	Frontline alone & in combo w/Keytruda						
Glioblastoma (GBM) (OST-503)	Glioblastoma alone & in combo Keytruda						
Breast Cancer (BC) (OST-HER2)	HER2+ BC in Combination w/HER2 Abs						
Prostate Cancer* (PC) (OST-PSA)	Biochemically Recurrent Disease						Phase 1b Data Q4/25
Canine (OS) (OST-HER2)	USDA conditional approval achieved. Full approval path pending updated regulatory guidance						



INVESTMENT HIGHLIGHTS

- 2025 Milestones:**
- 1) FDA Type C Meeting December 11, 2025 to align around endpoints for Accelerated Approval,
 - 2) UK MHRA Pre-MAA Meeting December 2025 to align Conditional Approval endpoints
 - 3) EMA Scientific Advice Meeting December 2025 to align around Conditional Approval endpoints
 - 4) UK MHRA MAA Filing Dec 2025, US FDA BLA Filing Jan 2026, EMA MAA Filing Q1/26
- Cash flow positive:** 2026
- Next Generation ADC:** pH-Sensitive Silicon SiLinkers™ & Multiple CAPed Payloads
- Large value markets:** TAM - Human OS: \$1.2B, Canine OS: \$150M, HER2+ Cancers: \$36B+, Cancer Immunotherapy: \$126B+
- High need market:** No approved alternatives for OS, incomplete responses in HER2+ and other cancers
- Pending Revenue Streams:** Priority Review Voucher sale >\$150M, Canine OS - \$15M+/year, Human OS – \$0.5B-\$1B/year

LEAD PRODUCT OVERVIEW: OST-HER2, OFF-THE-SHELF IMMUNOTHERAPY

- Positive OS and EFS data from Phase 2b OS clinical trial w/ forthcoming biomarker data
- Delivered into the immune system by attenuated bioengineered *Lm* vector
- Significant comparative oncology proof-of-concept in Phase I & III canine study (p-value = .0007)
- Granted: Fast Track Designation + Orphan Designation + Rare Pediatric Disease Designation
- Completed Phase 1 with positive safety data primarily in breast cancer
- Expansion into HER2+ cancers after osteosarcoma

LEAD PRODUCT OVERVIEW: OST-tADC, NEXT GENERATION TUNABLE ADC

OST-tADC: Interchangeable Ligands, Linkers, and Payloads – Tunable Drug Conjugate

- “Plug & Play” – Targeting Ligands, pH sensitive Silinkers™ (silicon linkers), and multiple CAPed (Conditionally Active) Payloads
- A platform technology with extensive flexibility and multiple licensing opportunities – without limiting OS Therapies therapeutic development
- Platform is currently in pre-clinical studies and working toward 2-Week & GLP toxicity trials
- Selection of lead candidate for IND-enabling in 2026

OSTEOSARCOMA NOT-FOR-PROFIT INVESTORS/SHAREHOLDERS

OST-HER2: *Listeria monocytogenes*

Ultra Orphan Lead Clinical Program in Osteosarcoma with follow-on application in Breast Cancer



OST-tADC: Next-gen Tunable Drug Conjugate (tADC)

Unique Patented Silicone linker improves safety & efficacy

