

Market Data

OS Therapies, Inc.	
NYSE American: OSTX	
Fiscal Year	December
Industry	Biopharma
Recent Price	\$2.51
Market Cap	\$52.5M
Shares Out.	20.9M
Float	1.6M
Cash (mrq) ¹	\$0.1M
<i>Price data as of August 1, 2024</i>	
<i>¹ does not include proceeds from \$6.4M July 2024 IPO</i>	
ostherapies.com	

Strong support from OS community



Company Overview

OS Therapies, a clinical stage biopharmaceutical company, is at the forefront of developing innovative treatments for Osteosarcoma (OS), breast cancer and other solid tumors. With a dedicated focus on addressing the unmet need for new cancer treatments in children and young adults, the company is making significant strides in tackling the complexities of OS, a rare but aggressive bone cancer predominantly affecting individuals under 40 years of age.

The company's primary initiative revolves around its lead product candidate, OST-HER2 (OST31-164), which is poised to revolutionize the treatment landscape for OS, breast cancer, and other HER2 expressing cancers. This innovative immunotherapy leverages a genetically modified strain of *Listeria monocytogenes* to specifically target cancer cells that express HER2 p, a promising approach in the fight against cancer that is complementary to HER2 antibody therapy such as Herceptin®. Notably, OST-HER2 is distinct in the current landscape, as there have been no new treatments approved by the FDA for OS in over 40 years.

In addition to OST-HER2, OS Therapies is expanding its impact with the OST-Tunable Antibody Drug Conjugate (OST-tADC) platform. This cutting-edge technology represents a next-generation approach in antibody-drug conjugates (ADCs), featuring tunable pH-sensitive silicone linkers (SiLinkers™) and the potential to deliver a range of payloads, including antibodies, chemotherapeutics, and mRNA treatments. The OST-tADC platform is being developed to target solid tumors.

Investment Highlights

Multiple near-term milestones

- Phase 2b trial for OST-HER2 with data expected in 4Q24
- US FDA Breakthrough designation for OST-HER2 in osteosarcoma in 2H24
- Full approval in canine osteosarcoma in 2H24

Next-generation ADC – OST tADC

- Unique, patented, and innovative suite of assets
- Potential to generate multiple therapeutic candidates with completely “tunable” targeted drug conjugation technology
- Compatible with antibody-based small molecule, improves intracellular delivery, provides capacity for multiple payloads within cassettes, and offers precise payload release
- Global market for ADCs is anticipated to reach \$7.5 billion by 2025

Large market opportunity

- TAM for human osteosarcoma is \$1.72 billion
- Breast cancer market: \$28 billion
- Multiple other indications with blockbuster potential

Several early potential revenue streams

- Out-License Canine Osteosarcoma - \$15+M
- Out-License Human Osteosarcoma - \$100+M
- Out-License OST-tADC SiLinkers™ - \$20-80M
- Priority Review Voucher - \$100-110M

Industry leading team

- Strong track record of drug development, commercialization, and multiple M&A exits

Oncology Pipeline

Program	Indication	Pre-Clinical	Phase I	Phase II	Phase III	Approval
OST-HER2 (OST31-164)	Canine Osteo	USDA Provisionally Approved				
	Human Osteo	Phase IIIb: 2021-2024				
	Breast	Phase II Ready				
	Esophageal, Other Solid Tumors					
OST-tADC	Ovarian					
	Pancreatic, Lung, GI, Osteo					

Value Proposition

OS Therapies stands out in the biopharma landscape with its dedicated mission to develop novel treatments for Osteosarcoma (OS) and other solid tumors. Through its innovative product candidates, OST-HER2 and OST-tADC, the company is not only addressing a significant gap in pediatric and young adult cancer care but also expanding its therapeutic reach to a broader range of solid tumors. As it advances through clinical stages, OS Therapies could significantly alter the trajectory of cancer treatment for a demographic long in need of breakthrough therapies.

OS Therapies is on the verge of major clinical milestones and is poised to potentially generate revenues from multiple streams: out-licensing deals for canine OS (\$15+M), human OS (\$100+M), and OST-tADC SiLinkers™ (\$20-80M) represent near-term revenue potential. A priority review voucher, valued at between \$100-110M adds another layer of potential revenue.

OS Therapies presents a compelling investment opportunity characterized by its innovative approach to cancer treatment, significant near-term clinical milestones, large market potential, diverse revenue streams, and a seasoned leadership team. For investors looking to capitalize on groundbreaking advancements in biopharmaceuticals, particularly in cancer therapy, OS Therapies offers a balanced mix of innovation, market potential, and proven leadership.

Multiple Upcoming Milestones

Canine Osteosarcoma Full Approval (2H24)

- Conditional approval granted by US FDA
- Full approval pending 3-week listeria shedding trial
- Out-License opportunity upon approval

OST-HER2 Osteosarcoma Phase 2b Clinical Trial Topline Data (2H24)

- If data positive, potential for accelerated approval based on:
 - Co-primary endpoint: 1-year event free survival (EFS)
 - Interim co-primary endpoint: 1-year overall survival (OS)
- If accelerated approval pathway opens, potential to sell PRV rights based on granted RPDD

US FDA Breakthrough Therapy Designation (2H24)

- Breakthrough request submitted to US FDA in 2Q24 (promising initial feedback, dialogue ongoing)
- Rare Pediatric Disease Designation granted in 2021
 - Fast Track Designation granted in 2018
 - Orphan Drug Designation granted in 2018