



Corporate Presentation

September 2026

NYSE American: OSTX

Safe Harbor Statement



This document contains forward-looking statements. In addition, from time to time, we or our representatives may make forward-looking statements orally or in writing. We base these forward-looking statements on our expectations and projections about future events, which we derive from the information currently available to us. Such forward-looking statements relate to future events or our future performance, including: our financial performance and projections; our growth in revenue and earnings; and our business prospects and opportunities. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as “may,” “should,” “expects,” “anticipates,” “contemplates,” “estimates,” “believes,” “plans,” “projected,” “predicts,” “potential,” or “hopes” or the negative of these or similar terms. In evaluating these forward-looking statements, you should consider various factors, including: our ability to change the direction of the Company; our ability to keep pace with new technology and changing market needs; and the competitive environment of our business. These and other factors may cause our actual results to differ materially from any forward-looking statement. Forward-looking statements are only predictions. The forward-looking events discussed in this document and other statements made from time to time by us or our representatives, may not occur, and actual events and results may differ materially and are subject to risks, uncertainties and assumptions about us. We are not obligated to publicly update or revise any forward-looking statement, whether as a result of uncertainties and assumptions, the forward-looking events discussed in this document and other statements made from time to time by us or our representatives might not occur.

Risks Related To Our Business

Our business is subject to a number of risks you should be aware of before making an investment decision. These risks include the following:

- Our success is primarily dependent on the successful development, regulatory approval and commercialization of our lead product candidates which are in the early stages of development
- Our approach to the discovery and development of innovative products is novel, and unproven and may not result in marketable products
- We have no source of predictable revenue, have incurred significant losses since inception, may never become profitable and may incur substantial and increasing net losses for the foreseeable future as we continue the development of, and seek regulatory approvals for our product candidates
- If clinical trials of our product candidates fail to demonstrate safety and efficacy, we may be unable to obtain regulatory approvals to commercialize our product candidates
- We are subject to regulatory approval processes that are lengthy, time-consuming and unpredictable. We may not obtain approval for any of our product candidates from the FDA or foreign regulatory authorities
- Even if we obtain regulatory approval, the market may not be receptive to our product candidates
- We may not be able to establish collaborative partnerships with other pharmaceutical companies, through which we expect to complete development of, obtain marketing approval for and, if approved, manufacture and market our product candidates
- We may encounter difficulties satisfying the requirements of clinical trial protocols, including patient enrollment
- We may face competition from other companies in our field or claims from third parties alleging infringement of their intellectual property

Investment Highlights



Over \$300 million has been invested in listeria platform to date, mostly by Advaxis/Ayala (OS acquired all listeria-based assets in April 2025)

Platforms

- OST-HER2: Listeria monocytogenes (Lm):
 - Ultra Orphan Lead Clinical Program in Osteosarcoma (OS) with follow-on applications in breast cancer and other solid tumor cancers
 - The total addressable market (or "TAM") for these assets and follow-on applications are \$258B TAM

OST-Lm platform represents new cancer immunotherapy category: cervical cancer, non-small cell lung, GBM, prostate, etc.

- OST-tADC:
 - Next-gen Tunable Drug Conjugate (or "tADC")
 - Unique Patented Silicone linker improves safety and efficacy

Near-Term Catalytic Milestones

Meetings with FDA/MHRA/EMA & subsequent BLA & MAA submissions for OST-HER2 in Human Osteosarcoma – Q2/26 – Q3/26

- Q4 2026: FINAL 3-year OS data
- Q4 2026: Phase 3 trial initiation (UK only)
- Q4 2026: FDA BLA, MHRA/EMA CMAA submissions

FDA Accelerated Approval– Q4 2026 – Q1/27

Priority Review Voucher (or "PRV") – Upon FDA Accelerated Approval

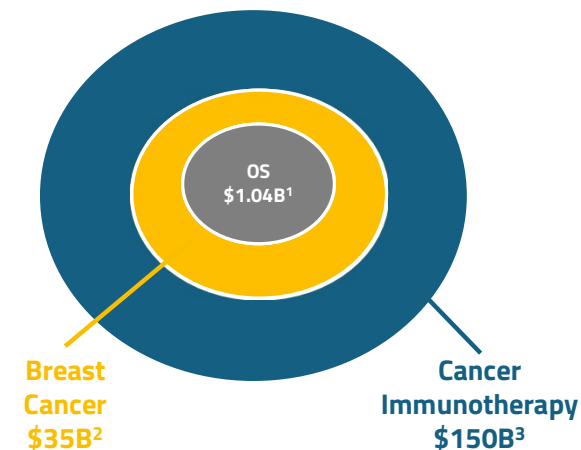
- A recent sale \$220M (BMS buyer, July 2026)
- Rare Pediatric Disease Designation (RPDD) granted by FDA
- Orphan Designation & Fast Track Designation granted by the FDA & EMA

Total Addressable Market

Human Osteosarcoma: currently valued at \$0.81 billion

OST-HER2 peak osteosarcoma sales expected to exceed \$1.5B in annual global revenues

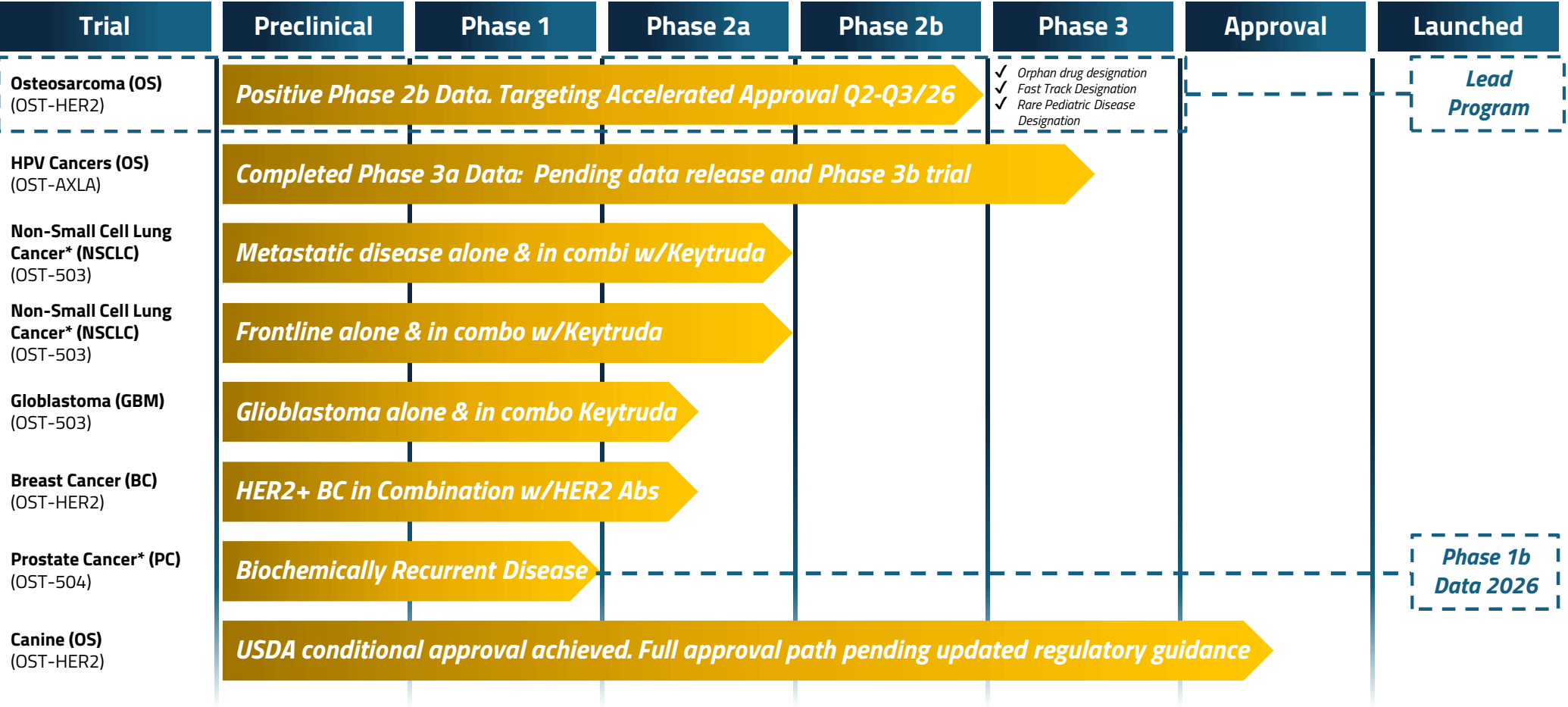
Cancer Immunotherapy:



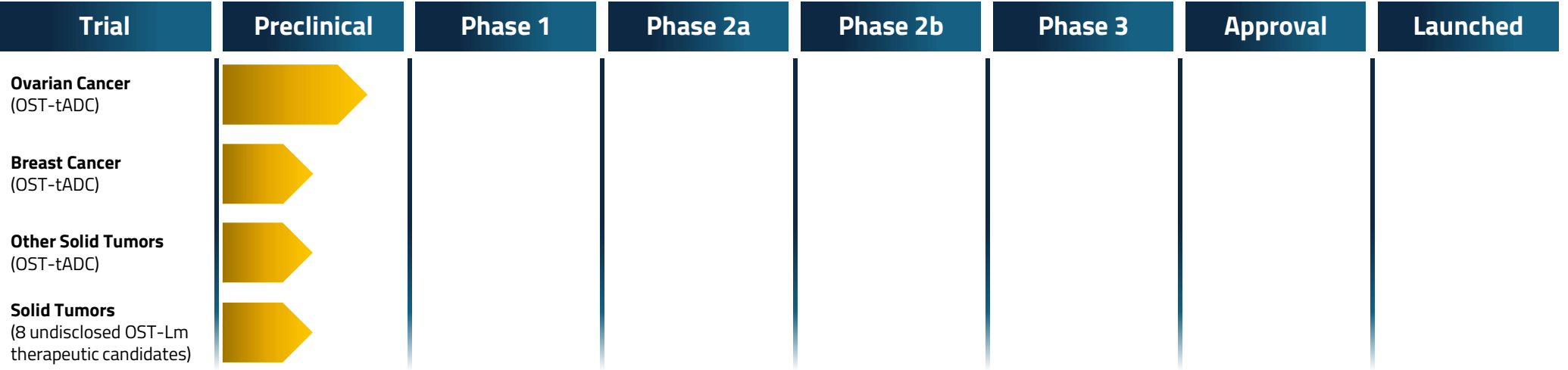
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- https://www.databridgemarketresearch.com/reports/global-osteosarcoma-drug-market?srltid=AfmBOoq2MDXhcErgt54L7LfW2enl_YWZk32_h9rHwXagX4P62ImMplKu
- <https://www.mordorintelligence.com/industry-reports/breast-cancer-therapeutics-market>
- <https://www.novaoneadvisor.com/report/cancer-immunotherapy-market>

Clinical-Stage Pipeline (Listeria Platform)



Preclinical Pipeline –Silicone Linker tADC Platform



Management Team - 100+ Years of Experience



Paul Romness, MHP
President & CEO - OS Therapies

- 25 years of experience in the biopharma
 - Johnson & Johnson
 - Amgen
 - Boehringer Ingelheim
- 9 major product launches:
 - Oncology, surgery, HIV, FSD, COPD, IPF, CV & diabetes
- Masters of Health Policy from George Washington University Medical Center & B.S. in Finance from American University



Robert Petit, PhD
Chief Medical & Scientific Officer
Founding Scientist: OST-HER2

- Inventor & Founding Scientist behind OS Therapies' clinical-stage listeria cancer vaccine platform
- Large Pharma Experience: BMS, & Pharmacia
- Small Pharma Experience: MGI Pharma (Acquired by Otsuka), Advaxis, SARS Therapeutics, RGP Biotech & Orionis Biosciences
- MD from Ohio State University College of Medicine & BS in Life Science from Indiana State University
- Research interests: Oncology & Virology



Gerald Commissiong
Chief Business Officer

- 15 years of experience in biopharma
- Small Pharma Experience: Amarantus Bioscience Holdings, Avant Diagnostics and Todos Medical
- Specializes in M&A, Capital Raising, Strategic Planning and Investor Relations
- Therapeutic areas: Oncology, Neurology, Immunology and Regenerative Medicine
- Biotechnology, Pharmaceuticals, Natural Products, Medical Devices, Diagnostics
- BS in Management Science & Engineering from Stanford University



Jutta Wanner, PhD
Advisor
Founding Scientist: OST-tADC

- Inventor & Founding Scientist behind OS Therapies' tunable Drug Conjugate (tDC) platform (tADC, tSMDC and tmRNADC)
- Large Pharma Experience: Roche
- Small Pharma Experience: BlinkBio
- PhD from the University of Kansas w/ postdoc training at The Scripps Research Institute in San Diego
- Research interests: Oncology & Virology

Paul Romness was inspired to launch OS Therapies following the Osteosarcoma diagnosis of a close family friend

Dr. Craig Eagle
Strategic Advisor



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Dr. Craig Eagle currently serves as Guardant Health's Chief Medical Officer. Prior to joining Guardant Health, Dr. Eagle served as Vice President of Medical Affairs Oncology for Genentech, where he oversaw the medical programs across the oncology portfolio and developed innovative cancer trials and strategies in personalized health care. Prior to Genentech, Dr. Eagle held several leadership roles at Pfizer, including oncology business lead for the United Kingdom and Canada, global lead for Oncology Strategic Alliances and Partnerships, and global head of the Oncology Therapeutic Area Global Medical and Outcomes Group, where he oversaw the U.S. oncology business, an extensive clinical trial program, health outcomes assessments, and scientific collaborations.

Dr. Bob Langer is one of nine Institute Professors at the Massachusetts Institute of Technology (MIT). His pioneering work includes isolating the first angiogenesis inhibitors (with Dr. Judah Folkman) leading to new treatments for cancer and blindness. He also created the first nanoparticles and microparticles for delivering large molecules, including nucleic acids, and helped establish the field of tissue engineering. more than 40 ventures, including Moderna. Dr. Langer chaired the FDA's Science Board, the agency's highest advisory board and received the U.S. National Medal of Science and the National Medal of Technology and Innovation (one of only three living individuals to receive both).

Dr. Robert Langer
Strategic Advisor



Scientific Advisory Board for Osteosarcoma



Peter M. Anderson, MD



Department Of Pediatric
Hematology, Oncology And
Blood & Marrow
Transplantation

Meenakshi Hedge, MD



Assistant Professor,
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Section Of Hematology -
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Alejandro S. Cordero, MD



Pediatric Malignancies - Cancer
Genetics - Associate Professor
Of Pediatrics

Brenda Weigel, MD



University of Minnesota
Masonic Children's Hospital

Professor, Division Of Pediatric
Hematology And Oncology -
Masonic Cancer Center

Felafsa M. Wodajo, MD



Orthopedics Surgery -
Musculoskeletal Oncology

Advisory Boards, Media and Partnerships



OS Patient Advocacy

Miriam Cohen
Mother of OS Angel



Mac Tichenor
Father of OS Angel



Serena Subada
Osteosarcoma Patient

OST-HER2 Trial Participant

Olivia Egge
Osteosarcoma Patient



Tony Trent
Father of OS Angel



Antibody Drug Conjugates (ADCs)

Dr. Jutta Wanner
Founding Scientist



Dr. Borys Shor
President & CEO



Dr. Colin Goddard
Founding Scientist



Commercialization

Chris Benecchi
Chief Business Officer



Scott Styles
Managing Partner

STYLES STRATEGY
Austin, TX - Washington, DC

Edward Robb, DVM
Chief Strategy Officer



Recent Features and Partnerships



ShelterMe
The Cancer Pioneers



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<https://www.youtube.com/watch?v=8wWeaGKT3Ak>

<https://www.youtube.com/watch?v=z2YLhT3bb1Q>

OST-HER2: Osteosarcoma + Other Cancers

Osteosarcoma (Bone Cancer)



No Treatments Available to Prevent or Delay Subsequent Recurrences

Global Death Rate Upon Recurrence/Metastasis is 80-90%

Crompton et al: Survival after recurrence of osteosarcoma: A 20-year experience at a single institution. August 2005: Pediatric Blood & Cancer.
<https://onlinelibrary.wiley.com/doi/abs/10.1002/pbc.20580>

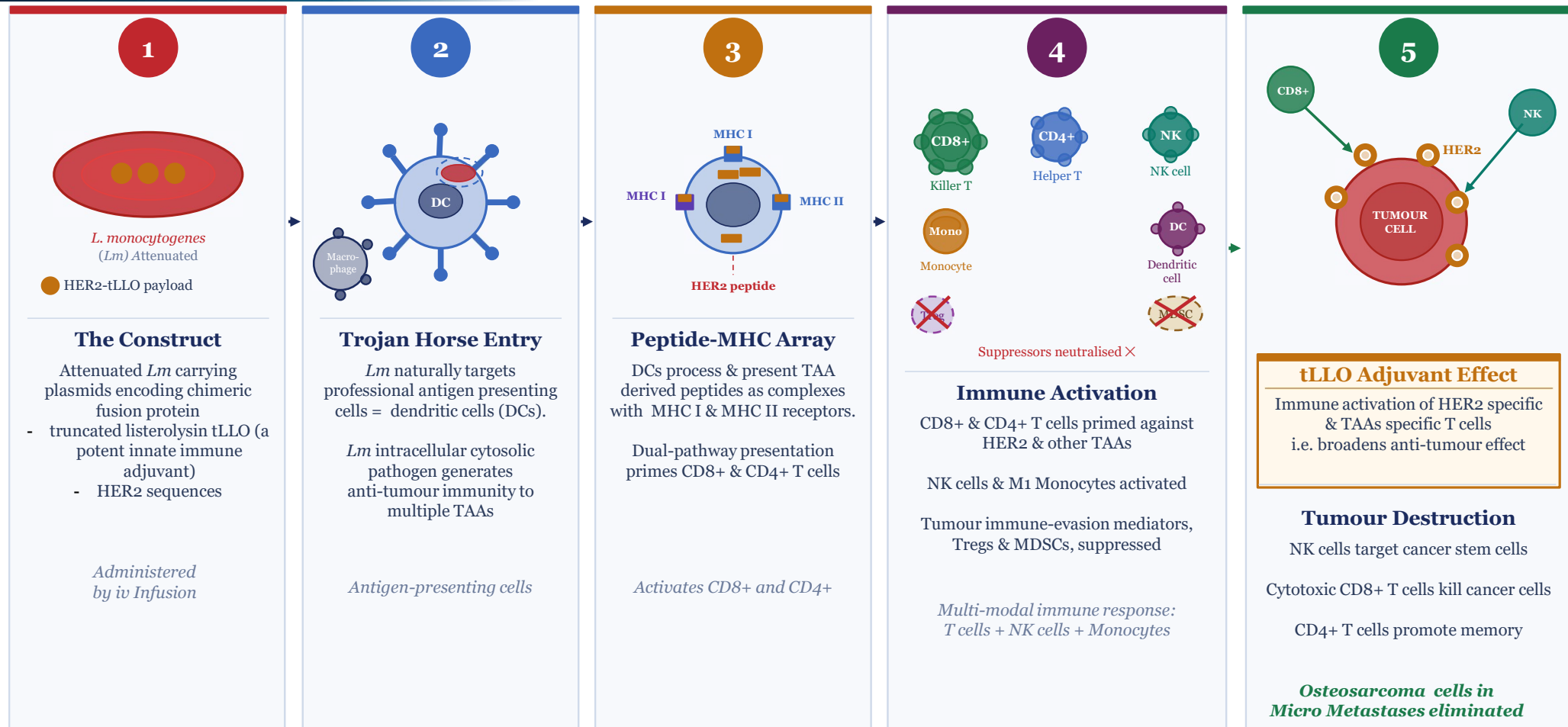
Osteosarcoma ("Bone Cancer") is a solid tumor of the bone:

- 1,000 cases/year in US; 20,000 globally
- Most Cases Present In Patients 15-20 Years Of Age
- No New Treatments In Over 40 Years
- METS (Lung) In ~40-50%+ Of Patients: 400 to 500 patients
- High Lung METS Recurrence: Survival Rate: ~ 40% @ 2 years, 90% @ 5 years
- Time To Mortality Upon METS Recurrence: ~12 Months
- Only Treatment for Recurrent METS: Lung METS Surgery
 - No drug therapy used (chemotherapy/Keytruda/Herceptin etc all failed)
- Objective = Prevent Recurrence - Increase Overall Survival

Standard of Care (or "SOC"):

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

Mechanism of Action: Immune Activation



OST-HER2 Open Label Phase 2b Trial



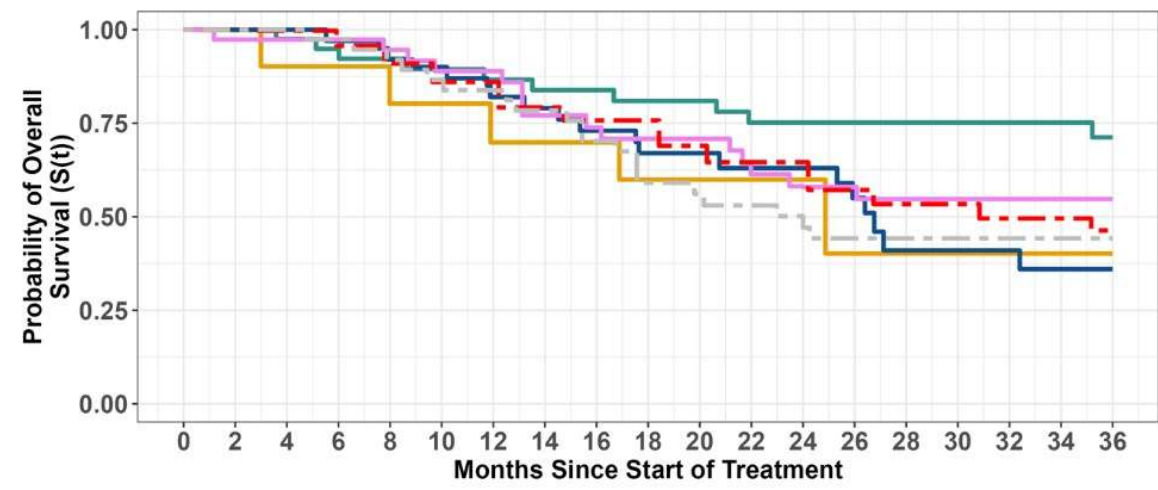
Enrollment Criteria

- 12-39 years old
- Recurred, resected metastatic (METS) Osteosarcoma
- 39 evaluable patients at 21 centers, single treatment arm – FULL TREATMENT ARM COMPLETE
- 52 Weeks on Study: Dosed 16 times every 3 weeks for 48 weeks with 4-week follow-up final visit
- Primary Endpoint: 12-month Event Free Survival (EFS) vs. Children's Oncology Group (COG) publication
- Secondary Endpoint: Overall Survival (OS)
- Exploratory Endpoint #1: 12-month EFS vs. Natural History Case Matched Database
- Exploratory Endpoint #2: OS vs. Leaving Publication

Exploratory Endpoint - Natural History Case Matched Database: Only Database Currently Available in US

- Patient Advocacy Group Collected under IRB (n=55)
- Many didn't meet the stringent enrollment criteria outlined above or had missing key data points (n=46)
- Only 9 evaluable subjects

OST-HER2: Interim 3-Year Overall Survival Data vs. Historical Control



Study	Population	Number of patients
OST31-164-01	Recurrent, Completely Resected, Pulmonary	41
CHEN	Recurrent, Completely Resected, Pulmonary	10
ARNDT	Recurrent, Completely Resected, Pulmonary	41
HINGORANI	Recurrent, Completely Resected, Pulmonary	39
KEMPF-BIELACK	Recurrent, Completely Resected	339
JANEWAY	Recurrent, Completely Resected	38

71.2% Overall Survival for OST-HER2 vs. 45.8% for historical control ($p=0.002$)

OST-HER2 Clinical Data in Recurrent, Resected Metastatic Osteosarcoma

	OST-HER2 Treated Group (n=41)	Published Historical Control (n=42)	P-Value
Primary Endpoint:12-month EFS	35% (n = 40 evaluable, 1 lost to follow-up)	20%	0.0196
Interim Secondary Endpoint: 3-year OS	71.8% (n = 35 evaluable, 5 lost to follow-up)	45.8%	0.002

Milestones to Accelerated Approval (US) & Conditional Approval (UK/EMA)	Timeline – Strategy: Overall Survival + Biomarkers
US FDA BEST Biomarker Qualification Program Meeting	Q3-2026
US FDA Ph 2b 2.5 year Statistical Methods Meeting (RMAT & Rolling Review Decision follow)	Q3-2026
MHRA Ph 2b 2.5 year Statistical Methods Meeting	Q3-2026
Complete UK MHRA MAA Submission	Q4-2026
Complete EMA MAA Submission	Q4-2026
Complete FDA BLA Submission	Q4-2026
FDA Pre-BLA Meeting	Q4-2026
UK MHRA CMAA Approval	Q4-2026
US FDA BLA Accelerated Approval	Q4-2026 / Q1-2027
EMA CMAA Approval	Q4-2026 / Q1-2027

OST-HER2 Regulatory Strategy



Next Steps

- Continued monitoring of overall survival for continued separation
- U.K. MHRA and EMA have accepted historical control as comparator
- FDA risk/benefit analysis being updated based upon recent Type C Meeting to include pending final 3-year OS data
- U.K. MHRA has requested, and Company accepted, for MHRA to lead on Project Orbis approval pathway
- **To Date, 100% success rate for U.K. Project Orbis-driven submissions leading to U.S. FDA approval**
- U.K. MHRA also has access to national cancer database data that is making available to Company as part of Orbis in support of international regulatory filings
- Conditional Marketing Authorisation Application (CMAA) in U.K. to drive U.S. and European regulatory alignment following MHRA taking lead on Project Orbis
- Key manufacturing milestone to start confirmatory Ph 3 trial (required prior to grant of BLA and CMAAs) pending late October 2026
- Ph 3 trial expected to start November 2026 to allow for U.K. approval in December 2026 with Phase 2 material (MHRA waived the Ph 3 material requirement)
- U.S. Pre-BLA meeting expect to occur after start of Ph 3 trial
- MHRA/FDA/EMA early market access expected Q4 2026 – Q1 2027 (PRV immediately after U.S. approval)
- Commercial Drug Product available for launch in H2 2027

OST-HER2 Additional Cancer Clinical Targets



Solid Tumor Treatment Potential – Combined \$20B +TAM

HER2+ Solid Tumors¹

Bladder, Breast Cancer, other HER2+ solid tumors

OST-HER2 plus trastuzumab may prevent development of trastuzumab resistance in HER2+ solid tumors like Bladder, Breast, others

[https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(07\)70190-0/abstract](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(07)70190-0/abstract)

Esophageal²

Rationale: **OST-HER2 + trastuzumab may prevent development of trastuzumab resistance** in HER2+ gastroesophageal cancer and extend utility of trastuzumab after first progression

<https://link.springer.com/article/10.1186/s13045-019-0737-2>

Colorectal³

Rationale: 2-3% are HER2+, ICI have not been active in CRC except in DNA Mismatch Repair where there is high T cell infiltration Trastuzumab and lapatinib – 30% response rate in HER2 + CRC

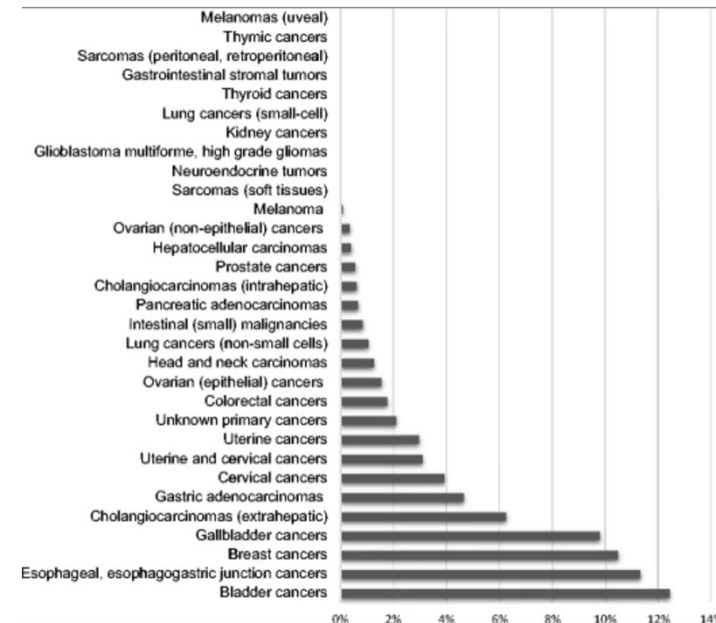
Increasing T cell infiltration with OST31-164 may improve activity of ICI in CRC, especially HER2+ CRC

<https://ascopubs.org/doi/full/10.1200/PO.19.00154>

1. <https://finance.yahoo.com/news/her2-positive-breast-cancer-treatment-123000015.htm>
2. <https://www.marketresearchfuture.com/reports/esophageal-cancer-market-3280>
3. <https://www.delveinsight.com/report-store/colorectal-cancer-crc-market>

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HER2 positivity across cancers: analysis of 37,992 samples by IHC. IHC 3+ was considered HER2 IHC positive



Yan, M., Schwaederle, M., Arguello, D. et al. HER2 expression status in diverse cancers: review of results from 37,992 patients. *Cancer Metastasis Rev* 34, 157– 164 (2015). <https://doi.org/10.1007/s10555-015-9552-6>

Yan, M., Schwaederle, M., Arguello, D. et al. HER2 expression status in diverse cancers: review of results from 37,992 patients. *Cancer Metastasis Rev* 34, 157– 164 (2015). <https://doi.org/10.1007/s10555-015-9552-6>

OST-Lm Platform Additional Immunotherapy Candidates



Solid Tumor Treatment Potential – Combined \$35B TAM

OST-AXAL (HPV Cancers)

- AIM2SERV™ Trial Completed: 1st of 2 Phase 3 clinical trials needed for approval
- Phase 3a trial completed
- Phase 3b trial

OST-503 (NSCLC & Glioblastoma)

- Positive NSCLC data in frontline in combination with Keytruda and Keytruda salvage
- Positive NSCLC data in metastatic disease

OST-504

- Positive interim Phase 1b/2a prostate cancer data in castration resistant population
- Single site study at Columbia: enrollment paused with potential to restart enrollment

Key Takeaways



Catalyst Rich Advanced OST-HER2 Cancer Therapeutic Platform



Multiple Near-Term Clinical Milestones

- Phase 2b trial for OST-HER2 in Osteosarcoma positive data: Announced Jan 2025.
- May 2026: 2.5-year OS data (ASCO)
- H2 2026: 3-year OS data
- Type B Pre-BLA FDA Meeting: Q2/26
- FDA/MHRA/EMA Approval Submissions: Q1-Q2 2026
 - Approval: Q3/26-Q4/26
- PDUFA date expected in Q3/2027, enabling full US launch
- OS Animal Health Spinoff: Commercialization of OST-HER2 for canine osteosarcoma: 1H/26



Significant Market Opportunity

- TAM Human Osteosarcoma – \$1.04B
- Market Opportunity for OST-HER2 in Osteosarcoma: \$600M+
- TAM Canine Osteosarcoma – \$150M+
- tADC platform – \$311 billion



Favorable Regulatory Review Process

- Osteosarcoma (Human and Animal): No new approvals in 40+ years
- Orphan, Fast Track, Rare Pediatric Disease Designations granted by the FDA and EMA for OST-HER2
- Priority Review Voucher – if OST-HER2 approved, PRV value = ~\$200M



Experienced, Successful Leadership

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

Thank You!

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