



Corporate Presentation

December 2025

NYSE American: OSTX

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 – December '25 – March '26

Regulatory pathway for OST-HER2 in Canine Osteosarcoma & spinoff– Q4/25 – Q1/26

FDA Accelerated Approval– Q2/Q3 2026

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

- Most recent sale \$160M (Abeona, June 2026)
- Rare Pediatric Disease Designation (RPDD) granted by FDA
- Orphan Designation & Fast Track Designation granted by the FDA & EMA

Total Addressable Market

Human Osteosarcoma: \$1.2B

Expected US topline revenue for OST-HER2 in osteosarcoma: \$500M+

Canine Osteosarcoma: \$150M+

Market and Financial Summary

Stock Price:
[\$1.87]

Shares Outstanding:
[~34M]

Market Cap:
[\$60M]

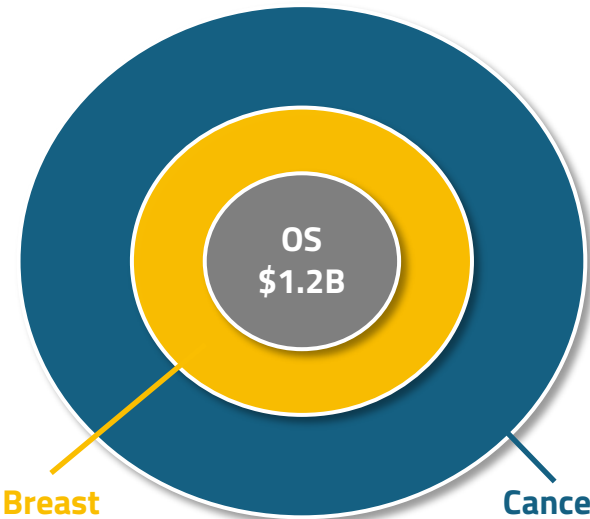
Cash:
[~\$4M]

Monthly Cash Burn:
[~\$300K]

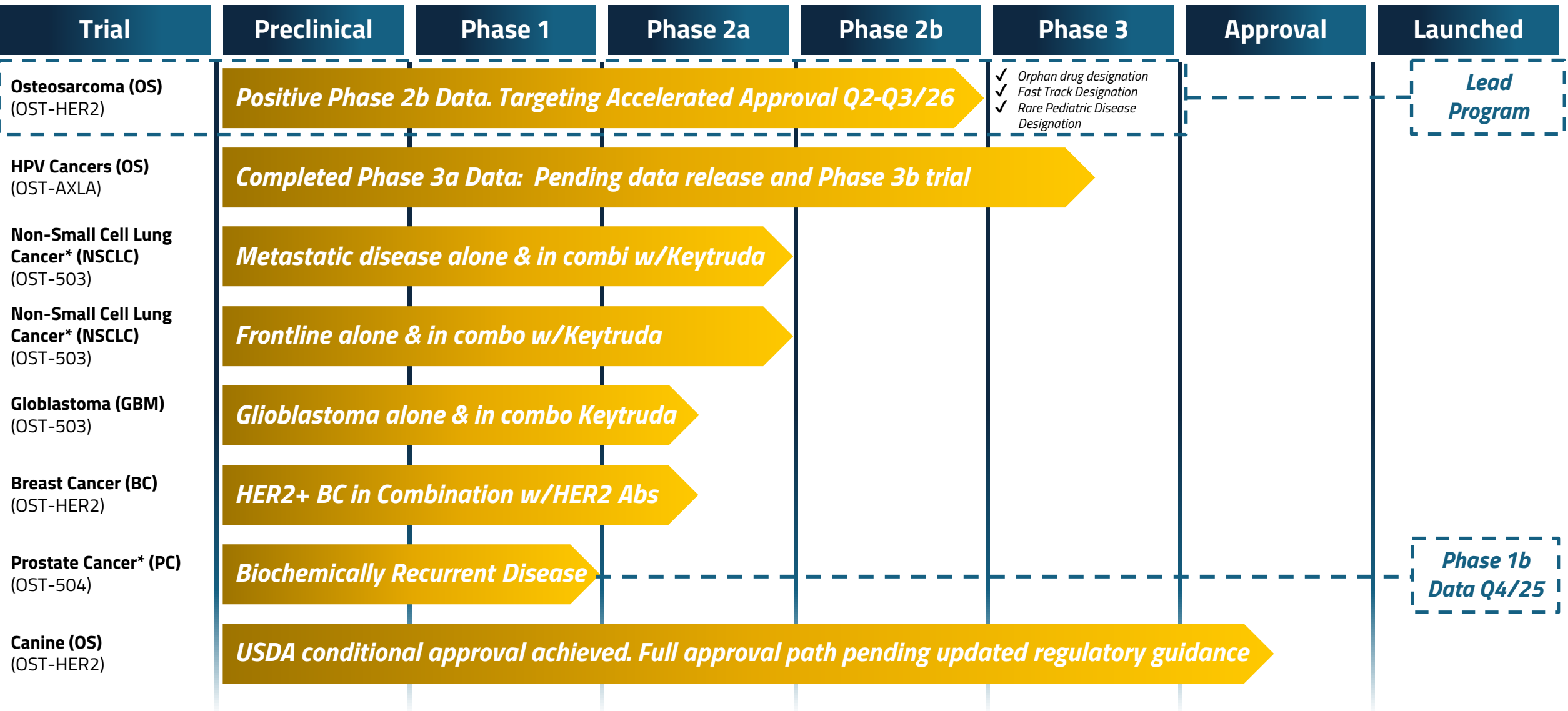
Timing of Accelerated FDA Approval and PRV:
April-September 2026

Estimated PRV Sale Proceeds:
[~\$160M]

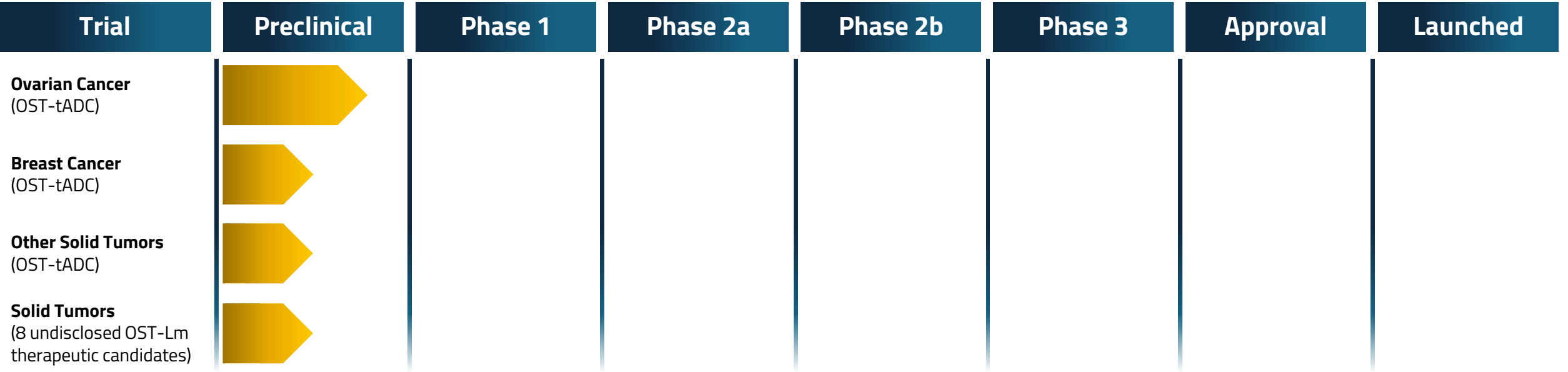
Cancer Immunotherapy:



Clinical-Stage Pipeline (Listeria Platform)



Preclinical Pipeline (Listeria & ADC Platform)5





OST-HER2: Human & Canine Osteosarcoma + Other Human Cancers

Scientific Advisory Board for Osteosarcoma

Peter M. Anderson, MD



Department Of Pediatric
Hematology, Oncology And
Blood & Marrow
Transplantation

Meenakshi Hedge, MD



Assistant Professor,
Department Of Pediatrics,
Section Of Hematology -
Oncology, Baylor College Of
Medicine

Nabil M. Ahmed, MD



Associate Professor,
Department Of Pediatrics,
Section Of Hematology-
Oncology, Baylor College Of
Medicine

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

Commercialization and Partnerships



OS Patient Advocacy

Miriam Cohen
Mother of OS Angel



Serena Subada
Osteosarcoma Patient

OST-HER2 Trial Participant

Mac Tichenor
Father of OS Angel



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

60
MINUTES



ShelterMe
— The Cancer Pioneers —

Johnson & Johnson

INNOVATION | JLABS

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>

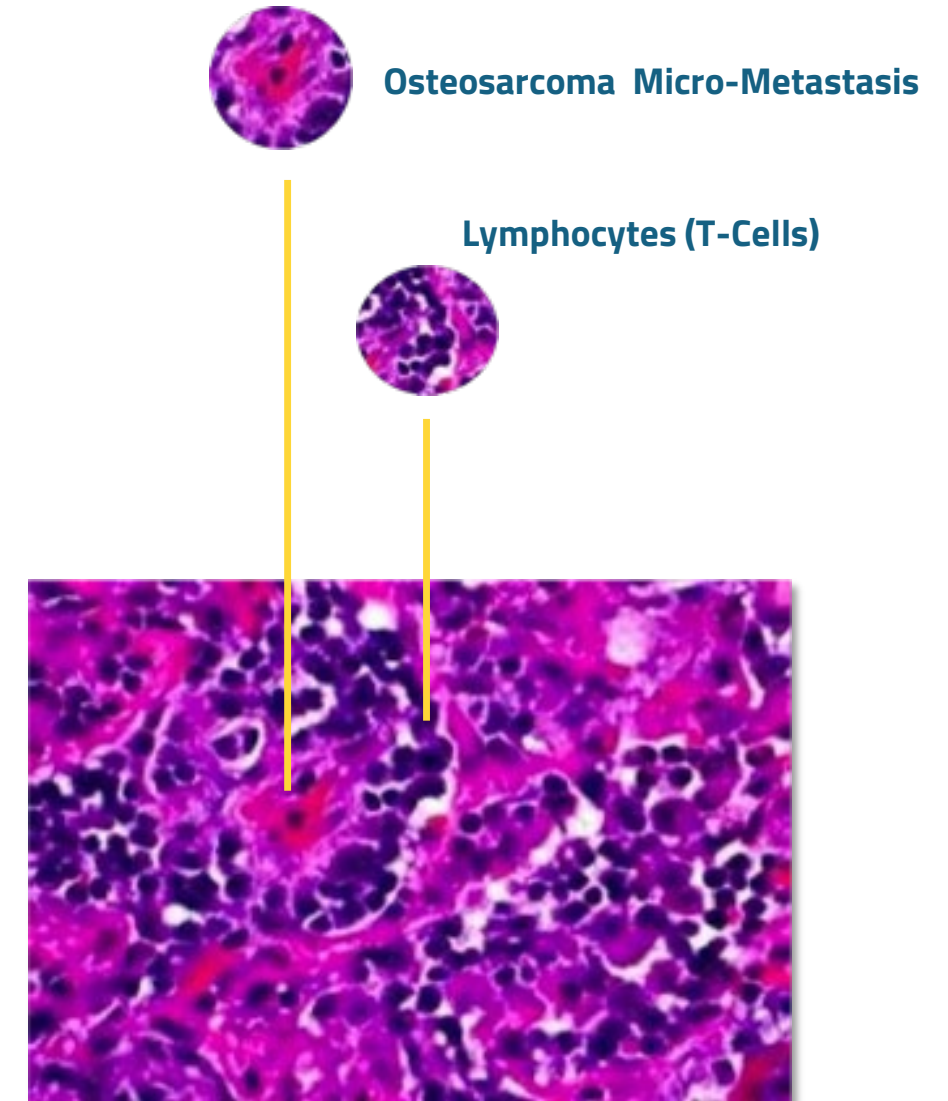
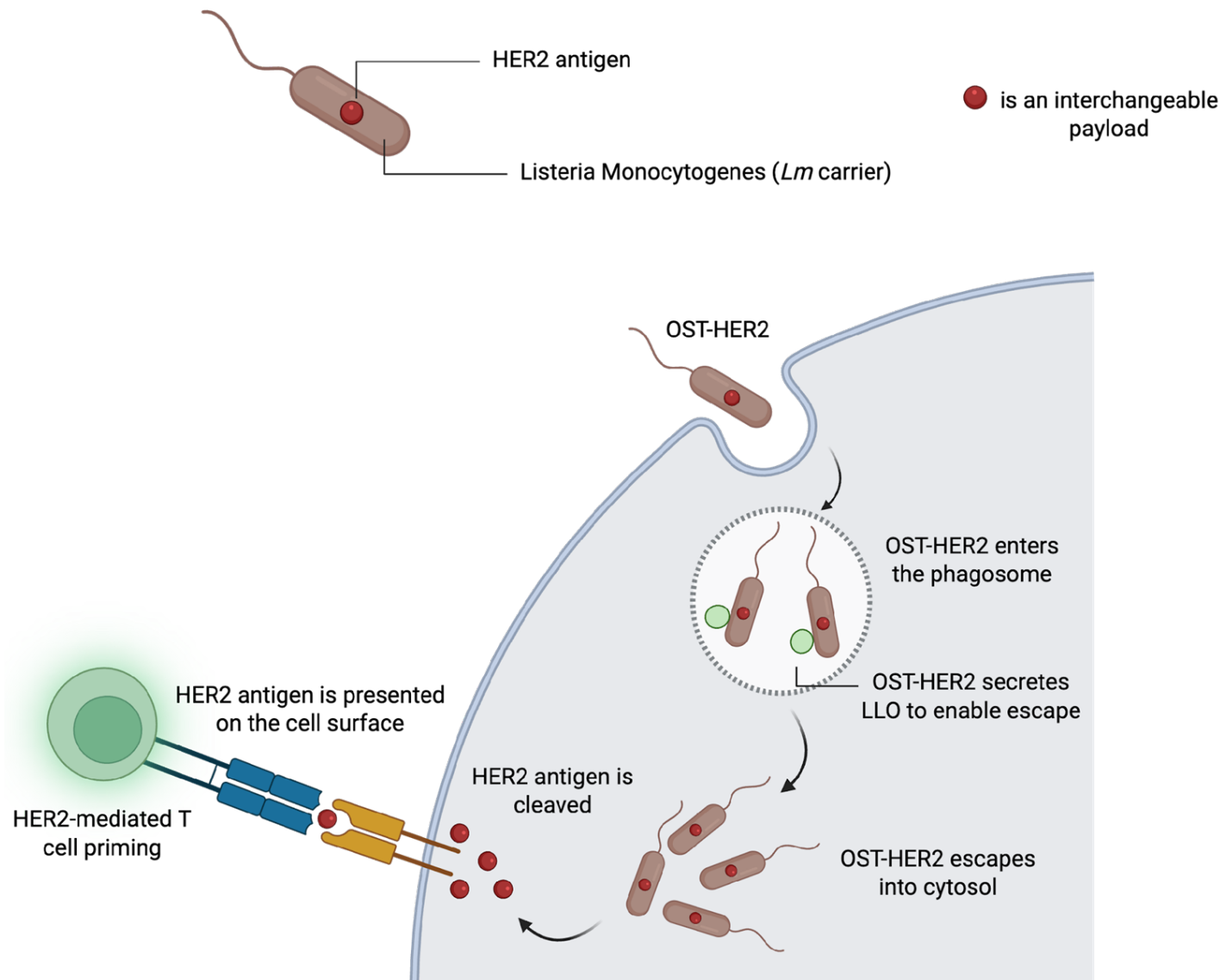
Osteosarcoma ("Bone Cancer") is a solid tumor of the bone:

- 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: Fatality Rate: ~ 90% @ 5 years, 40% @ 2 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

OST-HER2 leverages antigen presentation to drive attack on metastases



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 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
Secondary Endpoint: 2-year OS	75% (n = 36 evaluable, 5 lost to follow-up)	40%	<0.0001
Subgroup: OS in =>12month EFS	100%		
Subgroup: OS in < 12 month EFS	59%		
	Female	Male	P-Value
Primary Endpoint:12mo EFS	47%	20%	0.0604
	2+ Resections	1 st Resection	
Primary Endpoint: 12mo EFS	55%	25%	0.0848
	Within 2+ Resection: On study	Within 2+ Resections: Prior to Study	P-Value
Primary Endpoint: 12mo EFS	55%	27%	0.1945

Milestones to Accelerated Approval (US) & Conditional Approval (UK/EMA)	Timeline – Strategy: Overall Survival + Biomarkers
EMA SAM Meeting (2-year overall survival + pending biomarker correlation)	✓ December 2, 2025
UK MHRA Pre-MAA Meeting (2-year overall survival biomarker correlation)	✓ December 8, 2025
US FDA Type C Meeting (2-year overall survival + pending biomarker correlation)	December 11, 2025
UK MHRA MAA Filing for Approval (2-3 month review after filing)	End of January 2026
US FDA BLA Filing for Approval (3-6 month review after filing)	End of January 2026
EMA MAA Filing for Approval (3-6 month review after filing)	End of February 2026

OS Animal Health: Canine Spinoff

University of Pennsylvania Veterinary School (UPenn Vet)

Positive proof-of-concept data post-resection: Published

- Able to distinguish responders with biomarkers
- Treatment response, as measured by immune markers, can improve with more doses
 - New study planned to evaluate continued dosing

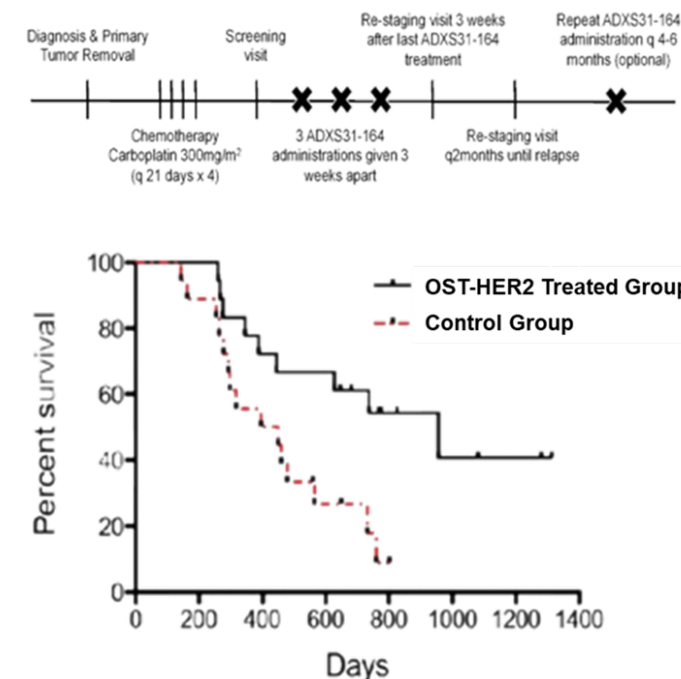
Positive proof-of-concept data limb sparing (pre-resection): Publication in progress

- Strong treatment response w/ 8 doses
- Immune markers improved with more doses

Regulatory Pathway

- Preparing for Meeting with USDA to review new manufacturing process for reactivation of conditional approval (Q4/2025, subject to gov't shutdown)
- Company intends to launch under conditional approval in 2026
- Company will sponsor confirmatory trial at UPenn Vet to support full approval, expected in 2026

Design



OST-HER2 Breast Cancer Treatment

Positive Preclinical & Phase 1 Results > Anticipate 2025 Phase 2 Trial – \$30B TAM

Preclinical Studies

- In nonclinical studies, OST31-164 was found to cause regression of tumors in both a spontaneous HER2-expressing tumor model and in a metastatic breast cancer model in mice
- The reduction in tumor growth with OST31-164 was directly associated with the induction of HER2-specific immune responses
- HER2-specific CD8 T-cell responses are elicited by OST31-164

Phase 1 Trial Endpoints Met

Study Design

- Late stage advanced/metastatic HER2 expressing solid tumors (n=12)

Primary

- Dose limiting toxicity for OST31-164
 - Determined therapeutic dose: 1×10^9 CFU

Secondary

- Efficacy signals
 - One patient left hospice care following treatment

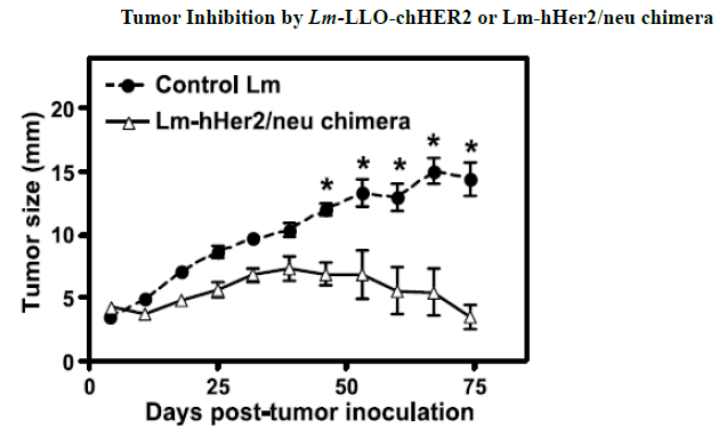
Mouse Models of Breast Cancer

- The first figure on the right is a treatment model
- The second figure on the right is a prevention model

The first figure shows Lm-LLO-chHER2 (OST-HER2 component) Anti-tumor activity against a foreign antigen of an established tumor in female FVB/N mice.

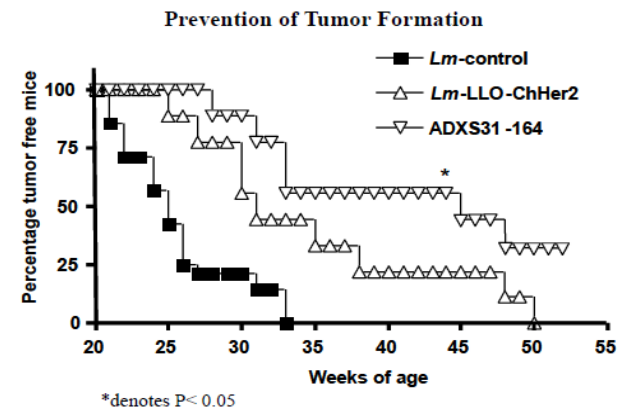
The NT-2 tumor cell line was derived from a spontaneous mammary tumor in a rat HER2/neu transgenic FVB/N mouse and therefore expresses rat HER2.

Treatment Model

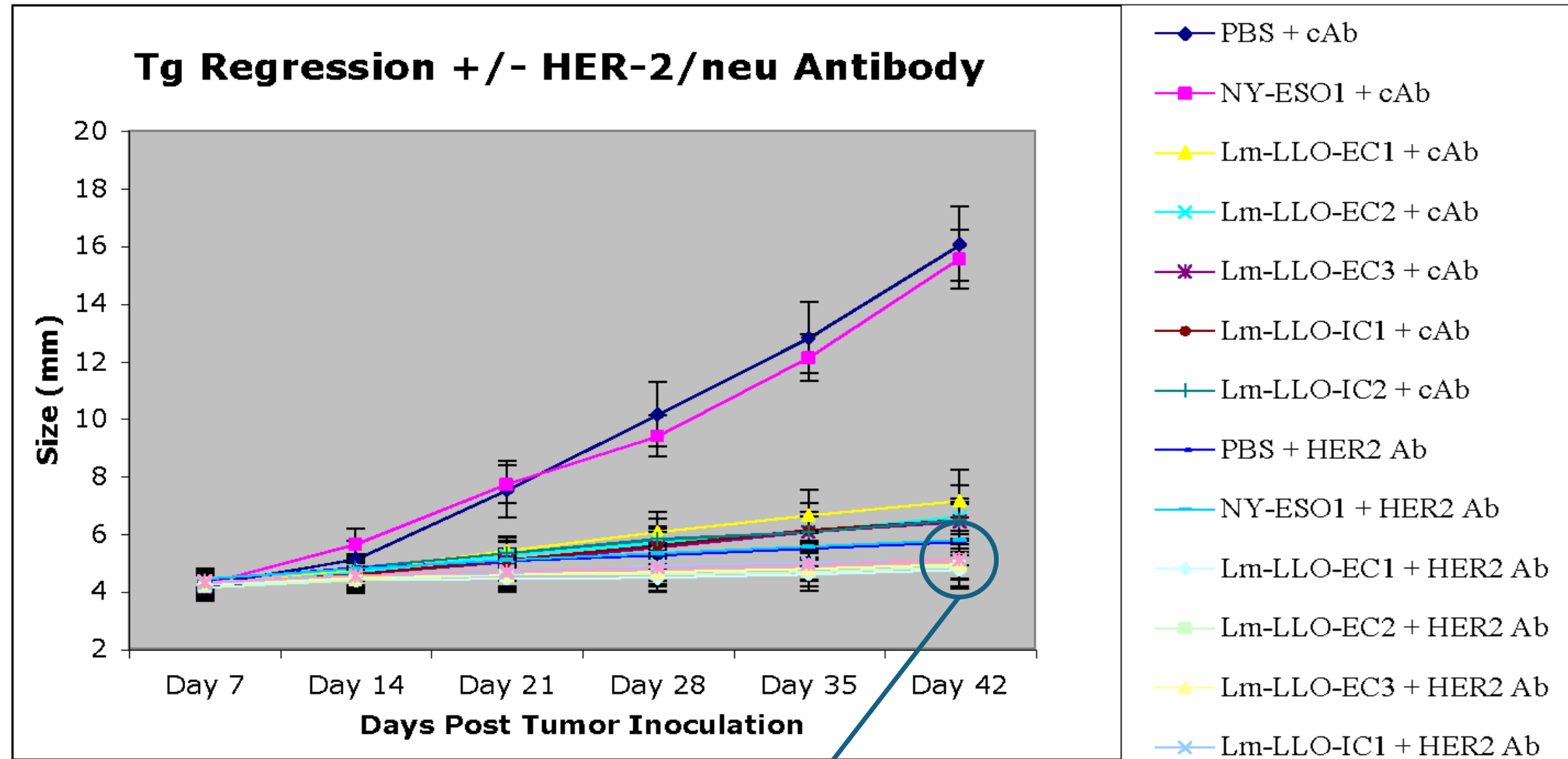


Tumor sizes are expressed by two perpendicular diameters of the tumors (mean $\pm$ SE), * denotes $P < 0.05$

Prevention Model



OST-HER2+ HER-2/neu Ab Combo Shows Stronger Efficacy Than HER-2/neu Ab Alone



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

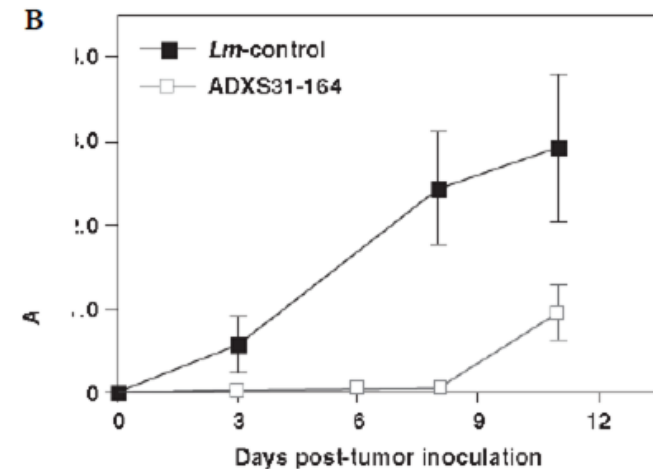
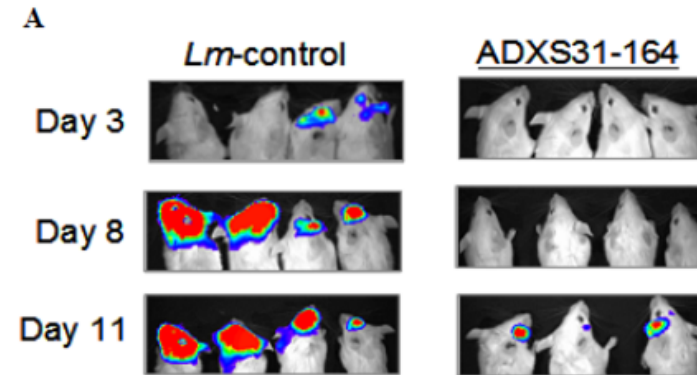
Suppression of Growth of Metastatic Breast Cancer in the Brain

To determine whether OST- could inhibit the growth of a metastatic breast cancer in the brain, BALB/c mice (n=4 animals/ group) were administered 5×10^8 CFU of OST-HER2 or Lm control by intraperitoneal injection once a week for three weeks.

After the third injection, mouse breast carcinoma EMT6 cells stably transfected with luciferase (EMT6-Luc) were injected into the brains of anesthetized mice (5000cells/mouse).

Tumor growth was detected in all control animals but none of the OST-HER2 treated animals.

Delay of Breast Cancer Growth in the Brain



A: Luciferase metabolizes into D-luciferin and photon by products are captured and displayed as body imaging heat map. B: Pixel intensity is graphed as number of photons per second per cm^2 of surface area, which is shown as average radiance.

OST-HER2 Additional Cancer Clinical Targets

Solid Tumor Treatment Potential – Combined \$35B TAM

HER2+ Solid Tumors

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://doi.org/10.1016/S1470-2045\(07\)70190-0](https://doi.org/10.1016/S1470-2045(07)70190-0)

Esophageal

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

<https://dx.doi.org/10.1186%2Fs13045-019-0737-2>

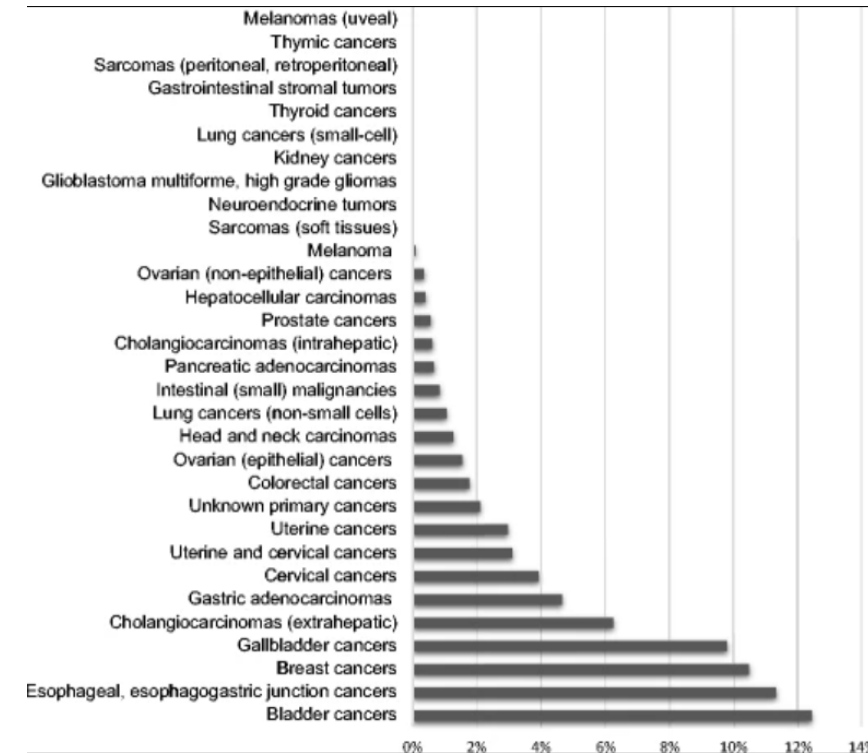
Colorectal

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>

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>

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

OST-tADC Linker Platform

tADCs / tSM-DCs / tmRNA-DCs

OST-tADC Product Overview

Potential to Displace Legacy Cancer Chemo Treatment

Interchangeable Ligands, Linkers, and Payloads: Tunable Drug Conjugate

- “Plug & Play” - Targeting Ligands, pH sensitive SiLinkers™ (silicon linkers), and multiple CAPed (Conditionally Active) Payloads
- Antibodies (ADC), small molecules (SM-DC) and mRNA therapeutics (mRNA-DC)

OST-tADC Program

- A platform technology with extensive flexibility and multiple licensing opportunities – without limiting OS Therapies therapeutic development
- Currently in pre-clinical studies and working toward 2-Week & GLP toxicity trials

BIOTECH

ASCO: Replacing chemotherapy with ADCs? AbbVie rebuilds next-gen assets after Rova-T flop

By Gabrielle Masson

Jun 4, 2024 11:26am

AbbVie ASCO 2024 ASCO antibody drug conjugates

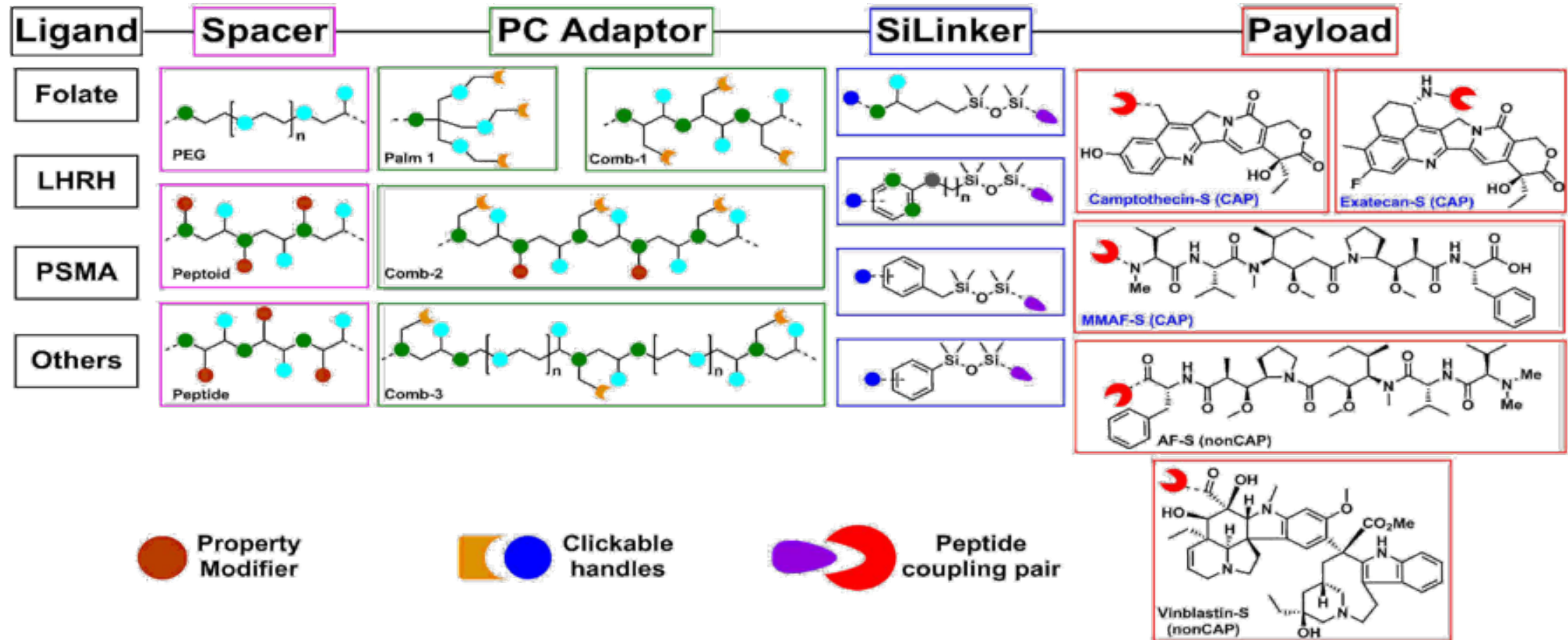


OS Therapies Forms Subsidiary OS Drug Conjugates and Initiates Review of Strategic Options for its tunable ADC & Drug Conjugates Platforms

February 24, 2025, 7:25 AM Eastern Standard Time

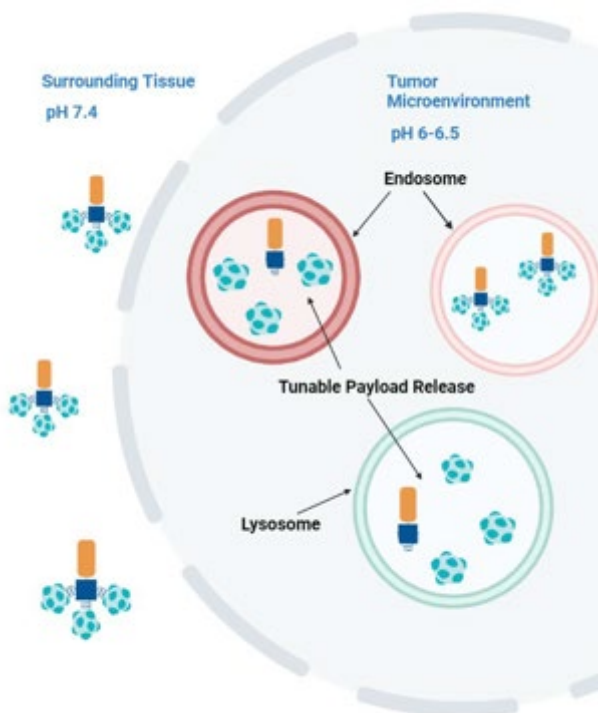
OST-tADC PLATFORM IS “PLUG AND PLAY” AND “ADAPTABLE”

Modular Approach is a Key Differentiator - Preferred Building Block Examples



CHEMICAL MODIFIERS ALLOW TUNABLE SiLINKERS CLEAVAGE

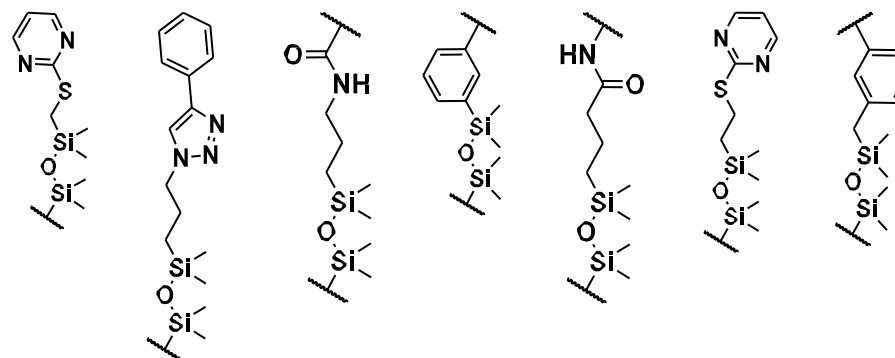
Payload Release can be Tuned to Occur Either in Endosome or Lysosome



Key Points:

- Proximal functional groups influence the hydrolysis rate of the silicone linkers
- We have demonstrated that rapid hydrolysis with the pyrimidine system in vitro translated to rapid linker cleavage in cells

Linkers which cleave more rapidly under slightly acidic conditions are ideal for small OST-TDC approach



Stable SiLinkers can be used in ADCs to raise the Drug-to-Antibody Ratio (DAR) to between 6 and 24 payloads per ADC

	Pyrimidine	Amide	Phenyl	Carboxamide	Homologous Pyrimidine	Triazole	Benzyl
pH 7.4 $t_{1/2}$ (mins)	>600	6080	6170	>7920	9850	9134	>11520
pH 5 $t_{1/2}$ (mins)	2	77	307	95	480	445	1550

LCMS Hydrolysis studies were carried out in 50 mM HEPES buffer (pH 7.4 or pH 5) at 37 °C

tADC Patented Silicon Linkers Design

Patented OST SiLinker Pioneering Next-Gen ADCs

	<u>Traditional VAL-CIT LINKER</u>	<u>Traditional GGFG LINKER</u>	<u>Next-Gen Silicone LINKER</u>
% Payload at Released at Target Tumor Site	+	+	+++
Stability in Circulation	NO	Limited	YES
New IP for Old Payloads	NO	NO	YES
Premature Cathespin Cleavage	YES – Ubiquitous	YES – Macrophages	NO
Myelosuppresion	YES	NO	NO
Multiple Payloads per Linker	NO	NO	YES

Corporate Overview

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, Todos Medical
- Specializes in M&A, Capital Raising, Strategic Planning and Investor Relations
- Therapeutic areas: Oncology, Neurology, Immunology and Regenerative Medicine
- 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

Deep Pharmaceutical Experience And Successful Track Records

100+ Years Combined Experience

> 20 Product Launches

> 10 Licensing Deals

Global Sales

\$35B+

Revlimid

\$20B+

Spiriva

\$30B+

Epoetin Alfa

\$25B+

Retuxin

\$30B+

Herceptin

\$20B+

Pradaxa

\$20B+

Yervoy

\$8B+

Jardiance

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
- OS Animal Health Spinoff: Commercialization of OST-HER2 for canine osteosarcoma: 1H/26
- Type C FDA Meeting: December 11, 2025
- FDA/MHRA/EMA Approval Submissions: Q1/26
 - Approval: Q2/26-Q3/26



Significant Market Opportunity

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



Favorable Regulatory Review Process

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



Experienced, Successful Leadership

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

Thank You!

Paul Romness
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