UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 14, 2025

OS THERAPIES INCORPORATED
(Exact name of registrant as specified in its charter)

Delaware	001-42195	82-5118368
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

115 Pullman Crossing Road, Suite 103 Grasonville, Maryland	21638
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (410) 297-7793

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☒ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	OSTX	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

CURRENT REPORT ON FORM 8-K

OS Therapies Incorporated

October 14, 2025

Item 7.01. Regulation FD Disclosure.

On October 17, 2025, OS Therapies Incorporated (the "Company") posted an investor presentation to its website at ir.ostherapies.com. The information on the Company's website is not incorporated by reference into this Current Report on Form 8-K. The Company expects to use the investor presentation, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others. A copy of this investor presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 is being furnished pursuant to Item 7.01 of Form 8-K. In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as may be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

Annual Meeting Adjournment

On October 14, 2025 at 10:00 a.m., Eastern time, the Company convened its 2025 annual meeting of stockholders (the "Annual Meeting") virtually. The proposals submitted to the Company's stockholders for approval at the Annual Meeting are described in the definitive proxy statement filed with the Securities and Exchange Commission (the "SEC") on August 25, 2025 (the "Proxy Statement"). Based on the preliminary tabulation of votes received, the Issuance Proposal, the Charter Amendment Proposal and the Auditor Ratification Proposal (each as defined in the Proxy Statement) received the requisite votes for approval. However, the Company adjourned the Annual Meeting in order to allow additional time to solicit proxies. The adjourned Annual Meeting will reconvene at 10:00 a.m., Eastern time, on October 21, 2025. The reconvened Annual Meeting will still be held in a virtual meeting format accessible at *https://meeting.vstocktransfer.com/OSTHERAPIESOCT25*. The close of business on August 20, 2025 will continue to be the record date for the determination of stockholders of the Company entitled to vote at the reconvened Annual Meeting.

Stockholders may vote at the reconvened Annual Meeting or by submitting a proxy for the reconvened Annual Meeting. Stockholders of the Company who have previously submitted their proxy or otherwise voted and who do not want to change their vote do not need to take any action. During the period of the adjournment, the Company will continue to solicit votes from its stockholders with respect to the proposals for the Annual Meeting.

The Company encourages all stockholders of record as of the close of business on August 20, 2025, who have not yet voted, to do so by October 20, 2025 at 11:59 p.m., Eastern time. Notwithstanding the foregoing, any votes properly received before the close of the reconvened Annual Meeting on October 21, 2025 will be accepted. Proxies previously submitted in respect of the Annual Meeting will be voted at the reconvened Annual Meeting unless properly revoked.

Additional Information and Where to Find It

This document may be deemed to be solicitation material in respect of the Annual Meeting to be reconvened on October 21, 2025. The Company previously filed the Proxy Statement on August 25, 2025. BEFORE MAKING ANY VOTING DECISIONS, STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS FILED BY THE COMPANY WITH THE SEC, BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT THE RECONVENED ANNUAL MEETING. The Proxy Statement has been made available to stockholders who are entitled to vote at the Annual Meeting. No changes have been made in the proposals to be voted on by stockholders at the Annual Meeting. The Company's Proxy Statement and any other materials filed by the Company with the SEC can be obtained free of charge at the SEC's website at www.sec.gov.

Participants in the Solicitation

The Company and its directors and executive officers and other employees may be deemed to be participants in the solicitation of proxies in respect of the reconvened Annual Meeting.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Investor Presentation – OS Therapies Incorporated.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OS THERAPIES INCORPORATED

Dated: October 17, 2025

By: /s/ Paul A. Romness, MPH
Name: Paul A. Romness, MPH
Title: President and Chief Executive Officer

Exhibit 99.1


OS THERAPIES
OS THERAPIES
Corporate Presentation
October 2025
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 – 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

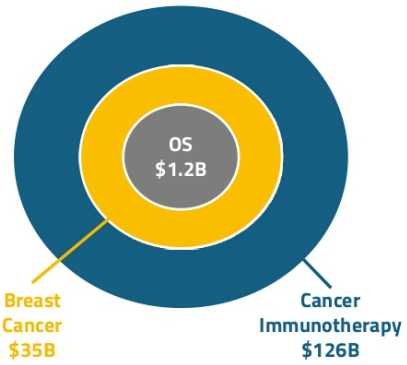
Total Addressable Market

Human Osteosarcoma: $1.2B

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

Canine Osteosarcoma: $150M+

Cancer Immunotherapy:

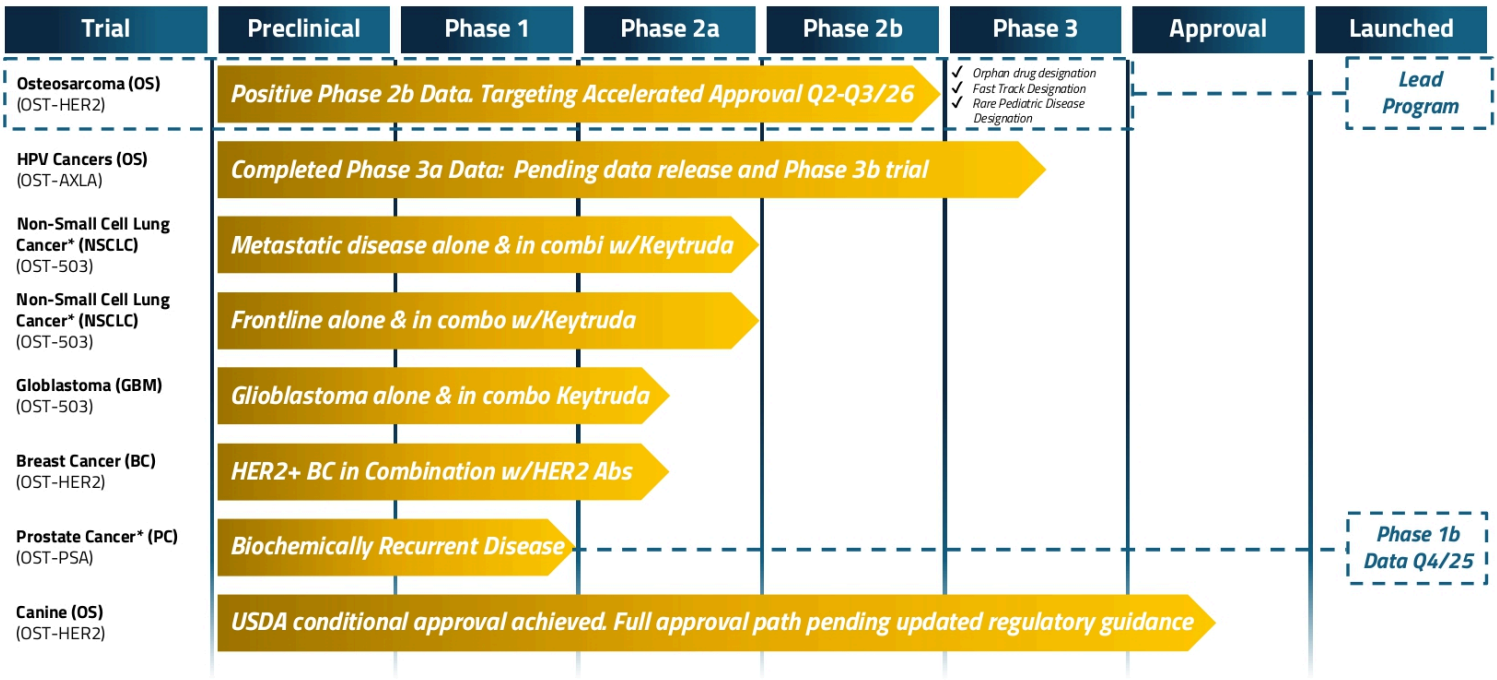


Market and Financial Summary

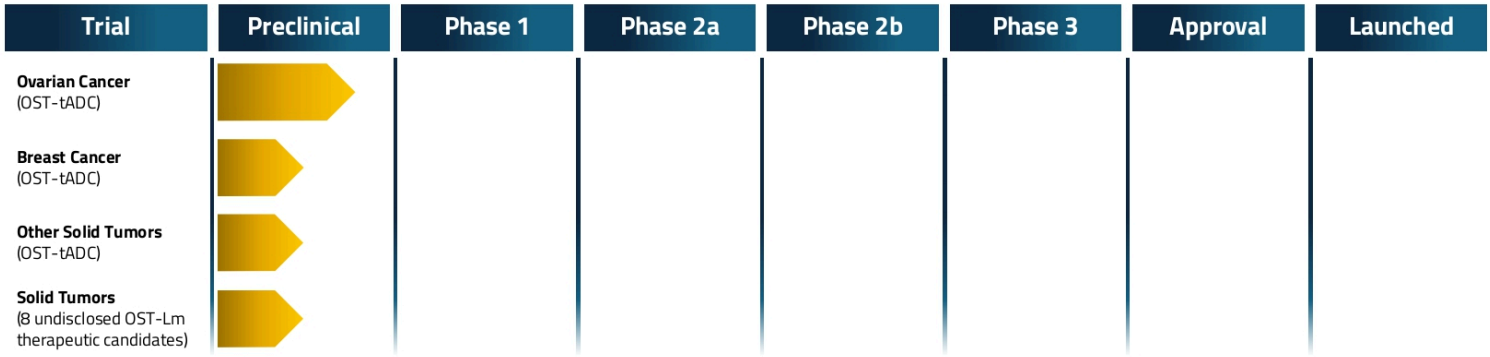
Stock Price: [$1.87]	Shares Outstanding: [~34M]	Market Cap: [$60M]	Cash: [~$4M]	Monthly Cash Burn: [~$300K]

Timing of Accelerated FDA Approval and PRV: April-September 2026	Estimated PRV Sale Proceeds: [~$160M]

Clinical-Stage Pipeline (Listeria Platform)



Preclinical Pipeline (Listeria & ADC Platform)5

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

Scientific Advisory Board for Osteosarcoma

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Peter M. Anderson, MD

Cleveland Clinic

Department Of Pediatric Hematology, Oncology And Blood & Marrow Transplantation

Meenakshi Hedge, MD

Texas Children's Hospital

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

Nabil M. Ahmed, MD

Texas Children's Hospital

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

Alejandro S. Cordero, MD

UCSF Health

Pediatric Malignancies - Cancer Genetics - Associate Professor Of Pediatrics

Brenda Weigel, MD

M HEALTH University of Minnesota Masonic Children's Hospital

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

Felafsa M. Wodajo, MD

Inova

Orthopedics Surgery - Musculoskeletal Oncology

Commercialization and Partnerships

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OS Patient Advocacy

Miriam Cohen
Mother of OS Angel
OSTEOSARCOMA COLLABORATIVE

Serena Subada
Osteosarcoma Patient
OST-HER2 Trial Participant

Mac Tichenor
Father of OS Angel
OSTEOSARCOMA INSTITUTE

Olivia Egge
Osteosarcoma Patient
OS THERAPIES

Tony Trent
Father of OS Angel
TYLER TRENT FOUNDATION

Antibody Drug Conjugates (ADCs)

Dr. Jutta Wanner
Founding Scientist
BlinkBio OS THERAPIES

Dr. Borys Shor
President & CEO
Manhattan BIOSOLUTIONS

Dr. Colin Goddard
Founding Scientist
BlinkBio OS THERAPIES

Commercialization

Chris Benecchi
Chief Business Officer
Sage Therapeutics

Scott Styles
Managing Partner
STYLES STRATEGY
Austin, TX - Washington, DC

Edward Robb, DVM
Chief Strategy Officer
ANIVIVE

Recent Features and Partnerships

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

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

Johnson & Johnson INNOVATION | JLABS

Osteosarcoma (Bone Cancer)

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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

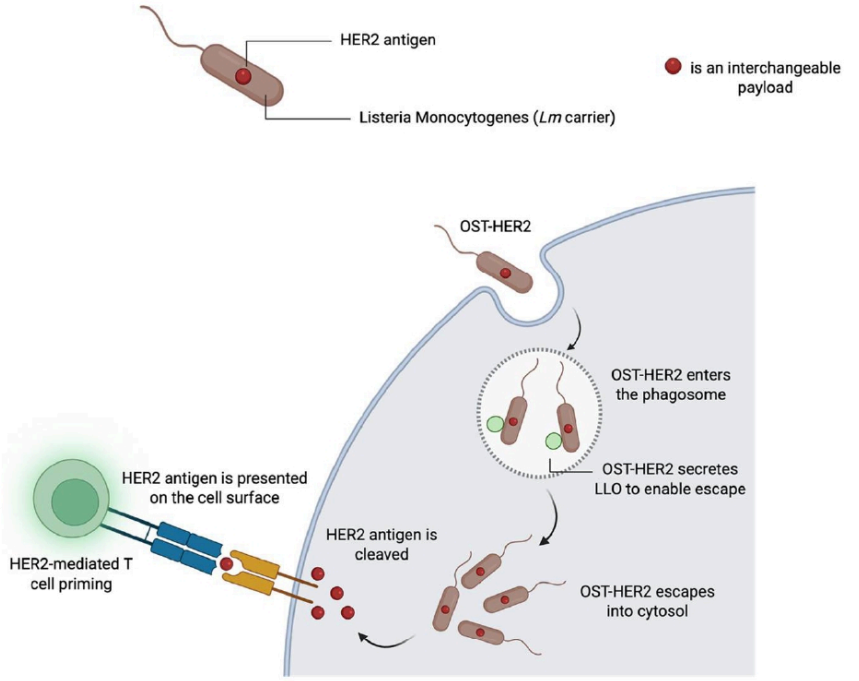
Osteosarcoma ("Bone Cancer") is a solid tumor of the bone:

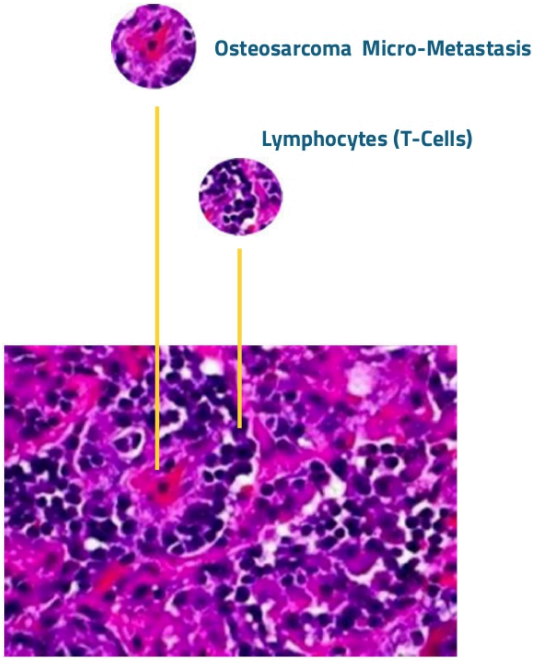
- 1,000 cases/year in US; 20,000 globally
- Most Cases Present In Patients 15-20 Years Of Age
- No New Treatments In Over 40 Years
- METS (Lung) In ~40-50%+ Of Patients: 400 to 500 patients
- High Lung METS Recurrence: Fatality Rate: ~ 90% @ 5 years, 40% @ 2 years
- Time To Mortality Upon METS Recurrence: ~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 with10% treatment-associated mortality
- Secondary OS / Recurrent Disease: None

OST-HER2 leverages antigen presentation to drive attack on metastases





OST-HER2 Open Label Phase 2b Trial

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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	**1st 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
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)	December 2025
US FDA BLA Filing for Approval (3-6 month review after filing)	January 2026
EMA MAA Filing for Approval (3-6 month review after filing)	Q1/2026

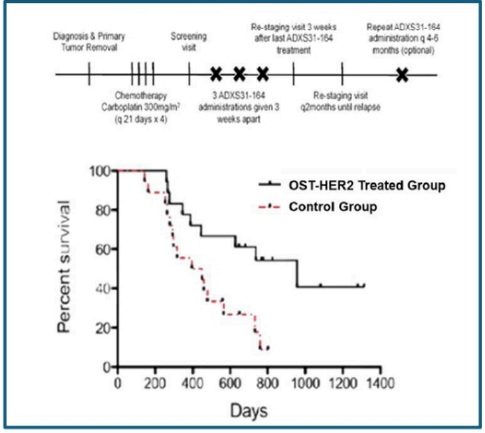
OST-HER2 Canine Osteosarcoma Program

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

Design



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

3: Immunological responses and clinical outcomes in dogs with osteosarcoma receiving standard therapy and a Listeria vaccine expressing HER2, Mason, Nicola J. et al, Molecular Therapy, Volume 0, Issue 0

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: $1x10^9$ CFU

Secondary

- Efficacy signals
  - One patient left hospice care following treatment

Animal Data: Inhibition of Growth of Breast Cancer Tumors

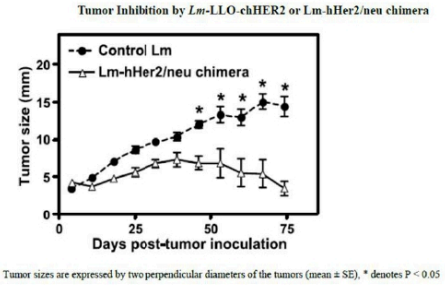
Mouse Models of Breast Cancer

- 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.

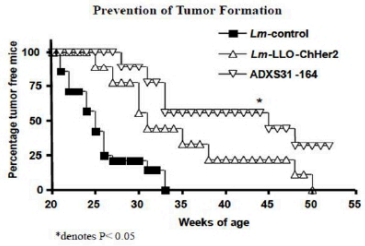
The NT-2 tumor cell line was derived from a spontaneous mammary tumor in a rat HER2/neu transgenic FVB/N mouse and therefore expresses rat HER2.

Treatment Model



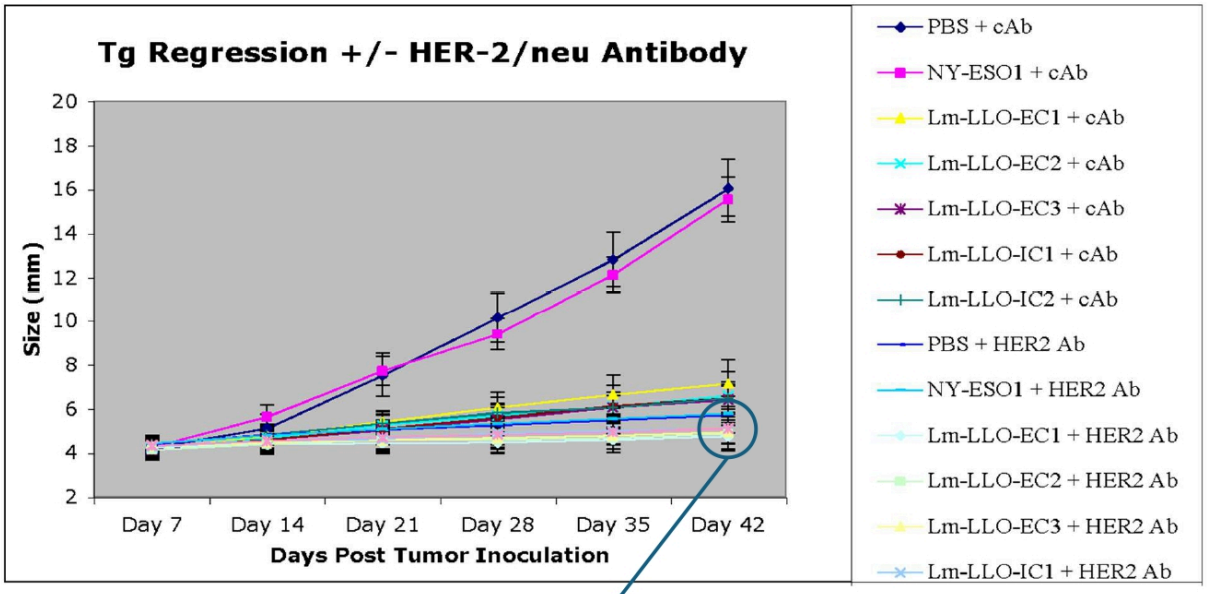
Tumor sizes are expressed by two perpendicular diameters of the tumors (mean ± SE). * denotes P < 0.05

Prevention Model



*denotes P< 0.05

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

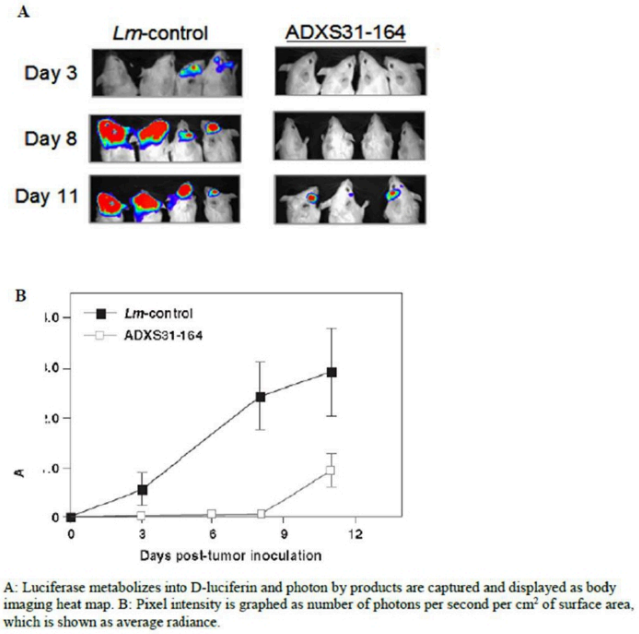
Suppression of Growth of Metastatic Breast Cancer in the Brain

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 cm² 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

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

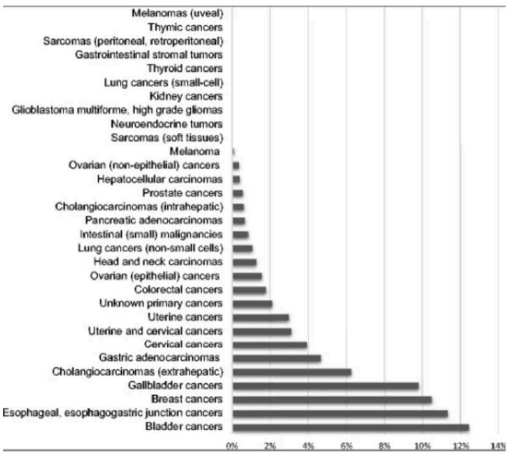
Colorectal

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

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

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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


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OST-tADC Linker Platform
tADCs / tSM-DCs /tmRNA-DCs
NYSE American: OSTX
20

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 SiLinkersTM (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
- Phase 1 trials for ovarian cancer are expected to begin in 2025

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

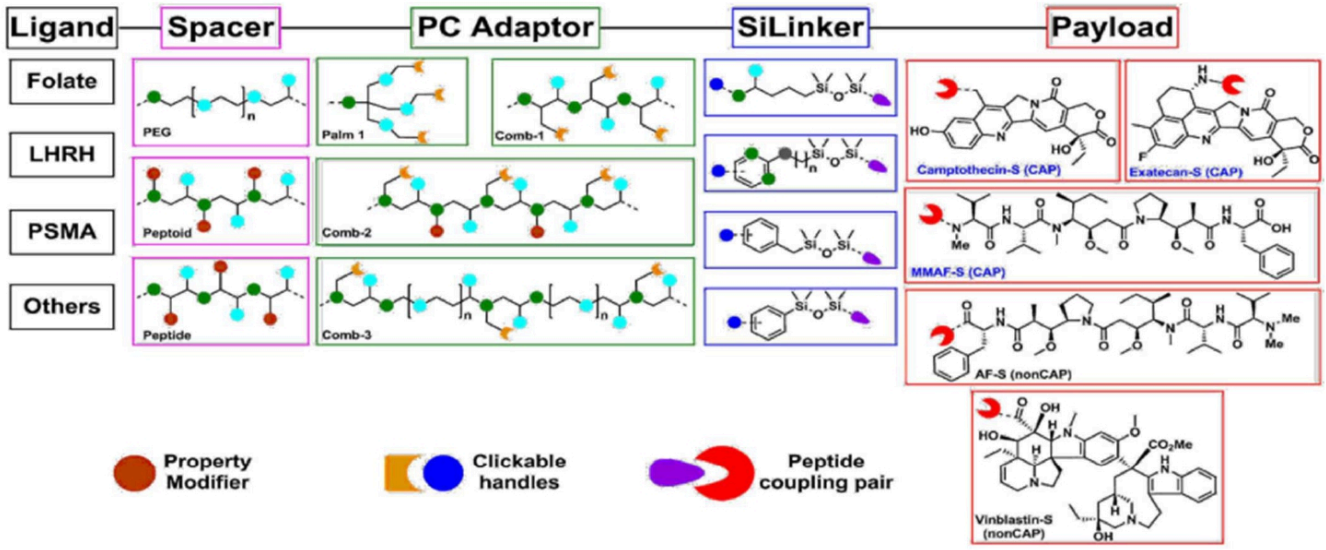
OS Therapies Forms Subsidiary OS Drug Conjugates and Initiates Review of Strategic Options for its tunable ADC & Drug Conjugates Platforms

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

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

OS THERAPIES

Modular Approach is a Key Differentiator - Preferred Building Block Examples



CHEMICAL MODIFIERS ALLOW TUNABLE SiLINKERS CLEAVAGE

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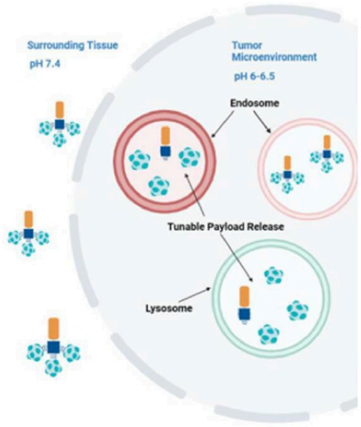
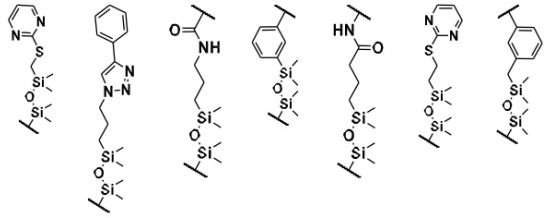
Payload Release can be Tuned to Occur Either in Endosome or Lysosome



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

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Patented OST SiLinker Pioneering Next-Gen ADCs

	Traditional VAL-CIT LINKER	Traditional GGFG LINKER	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 Cathespin Cleavage	YES – Ubiquitous	YES – Macrophages	**NO**
Myelosuppresion	YES	NO	**NO**
Multiple Payloads per Linker	NO	NO	**YES**


OS THERAPIES
Corporate Overview

Management Team - 100+ Years of Experience

OS THERAPIES

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	**$30B+** Epoetin Alfa	**$30B+** Herceptin	**$20B+** Yervoy
$20B+ Spiriva	**$25B+** Retuxin	**$20B+** Pradaxa	**$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
- Path to Pivotal OST-HER2 Canine OS study to support full approval pending USDA alignment: 2H/25
- End of Phase 2 FDA Meeting: Aug 27, 2025
- BLA Submission: Q3/25
- Accelerated Approval: Q4/25-Q2/26

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


OS THERAPIES
Thank You!
Paul Romness
President & CEO
par@ostherapies.com
(703) 541-9811
Investor Relations
Harrison Seidner, PhD
WaterSeid Partners
OSTX@waterseid.com
Public Relations
Stephanie Chen
Elev8 New Media
stephanie@elev8newmedia.com