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): April 9, 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 (the "Company")

April 9, 2025

Item 2.01 Completion of Acquisition or Disposition of Assets.

On April 9, 2025, pursuant to the terms of an Asset Purchase Agreement, dated as of January 28, 2025 (the "Purchase Agreement"), between the Company and Ayala Pharmaceuticals, Inc., a Delaware corporation formerly known as Advaxis, Inc. ("Ayala"), the Company completed the previously announced acquisition of the *Lm*-based immune-oncology programs and related intellectual property assets (the "HER2 Assets") from Ayala.

The HER2 Assets include two Investigational New Drug filings with the U.S. Food and Drug Administration ("FDA"):

(i) ADXS-503 for Non-Small Cell Lung Cancer; and

(ii) ADXS-504 for Prostate Cancer.

The change in milestone payments and royalty consideration owed as it relates to the OST-HER2 program are as follows:

1. Elimination of $3,500,000 payment owed to Ayala upon the first filing of a Biologics Licensing Authorization approval for OST-HER2 with the FDA.

2. Elimination of a total of $16,500,000 in OST-HER2 related sales milestone payments owed to Ayala made up of the following payments:

    - $1,500,000 owed upon reaching cumulative sales of $20,000,000;
    - $5,000,000 owed upon reaching cumulative sales of $50,000,000; and
    - $10,000,000 owed upon reaching cumulative sales of $100,000,000.

3. The reduction in total royalty consideration owed on OST-HER2-related sales from 10% of net sales owed to Ayala to 1.5% of net sales owed under a license agreement with the Trustees of the University of Pennsylvania. The royalty consideration of 1.5% of net sales owed to University of Pennsylvania going forward will apply to sales related to:

    - OST-HER2-related sales;
    - ADXS-503-related sales;
    - ADXS-504-related sales; and
    - Sales related to any new immunotherapy drug candidates created from the *Lm* platform during the term of such license.

In consideration for the purchase of the HER2 Assets, the Company agreed to assume certain specified liabilities and to pay an aggregate purchase price of $8,000,000, which was paid as follows:

(i) $400,000 to Ayala ($150,000 of which was transferred upon signing of the Purchase Agreement and the remainder on the closing date);

(ii) $100,000 to a third party on behalf of Ayala on the closing date; and

(iii) $7,500,000 worth of shares of the Company's common stock, or 4,774,637 shares based on the volume-weighted average price of the Company's common stock over the 30 trading days immediately preceding the closing date (the "Consideration Shares").

Because the issuance of the Consideration Shares would require the Company to issue more than 19.99% of its outstanding common stock immediately prior to such issuance (the "NYSE Ownership Limitation"), the Company issued to Ayala (i) 2,164,215 shares of common stock (the "Initial Shares"), and (ii) a warrant to purchase 2,166,381 shares of common stock (the "Warrant" and the shares of common stock issuable thereunder, the "Warrant Shares"). Once the Company obtains stockholder approval in accordance with NYSE American LLC Company Guide Section 713, it will subsequently issue to Ayala the remaining 444,041 shares of common stock (the "Additional Consideration Shares"), except that, if at that time, the number of shares of common stock beneficially owned by Ayala would exceed 9.99% of the number of shares of common stock then outstanding, Ayala has the right to require the Company to issue, in lieu of such shares, a warrant to purchase 444,041 on substantially the same terms of the Warrant.

The Warrant is exercisable upon issuance at an exercise price per share of $0.001 (as adjusted from time to time in accordance with the terms thereof) and will expire three years from the date of issuance. The Warrant may not be exercised to the extent that the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. The holder may increase or decrease this percentage, but not in excess of 19.99%, unless and until the Company obtains stockholder approval as required by NYSE American LLC Company Guide Section 713.

In connection with the issuance of the Consideration Shares (including the Warrant Shares and the Additional Consideration Shares), the Company entered into a registration rights agreement with Ayala (the "Registration Rights Agreement"), requiring the Company to file one or more registration statements, as necessary, to register under the Securities Act of 1933, as amended (the "Securities Act"), the resale of such shares no later than 75 days after the closing of the transaction.

Ayala entered into a lock-up agreement, pursuant to which, and subject to the terms and conditions set forth therein, Ayala has agreed not to trade or transfer, subject to certain customary exceptions, any of the Consideration Shares (including the Warrant Shares) for a period of 180 days following the closing of the transaction.

The foregoing descriptions of the Warrant, the Purchase Agreement and the Registration Rights Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements, which are filed as Exhibits 4.1, 10.1 and 10.2, respectively, to this Current Report on Form 8-K and are incorporated by reference herein.

Item 3.02 Unregistered Sales of Equity Securities.

The information contained in Item 1.01 of this Current Report on Form 8-K is hereby incorporated by reference into this Item 3.02. The Consideration Shares (including the Additional Consideration Shares) and Warrant (including Warrant Shares) are being offered and sold by the Company to Ayala in reliance upon an exemption from the registration requirements of the Securities Act afforded by Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D promulgated thereunder.

Item 8.01 Other Events.

On April 9, 2025, the Company issued a press release announcing the acquisition of the HER2 Assets. The full text of the press release, a copy of which is attached hereto as Exhibit 99.1, is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on January 29, 2025).
10.1	Asset Purchase Agreement, dated as of January 28, 2025, between OS Therapies Incorporated and Ayala Pharmaceuticals, Inc. incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 29, 2025).*
10.2	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on January 29, 2025).
99.1	Press release, dated April 9, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplemental copies of any of the omitted schedules or exhibits upon request by the SEC.

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: April 15, 2025

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

Exhibit 99.1

OS Therapies Completes Acquisition of Advaxis Immunotherapies
Clinical, Pre-clinical and IP Assets from Ayala Pharmaceuticals

- *Company now listeria-based cancer immunotherapy world leader*
- *Expands clinical pipeline with 3 new cancer immunotherapy candidates*
- *8 pre-clinical immunotherapy candidates targeting 30+ cancers added*

NEW YORK--April 9, 2025-- OS Therapies (NYSE-A: OSTX) ("OS Therapies" or "the Company"), a clinical-stage immunotherapy and Antibody Drug Conjugate (ADC) biopharmaceutical company, today announced that it has completed the acquisition of the listeria-based cancer immunotherapy assets of Advaxis Immunotherapies from Ayala Pharmaceuticals. The Company is now positioned as the world leader in listeria-based cancer immunotherapies, poised to become a new commercial category of immunotherapy in oncology upon approval of the Company's lead asset OST-HER2 in the prevention of recurrence in fully-resected, lung metastatic osteosarcoma targeted for year-end 2025. New manufacturing-based intellectual property protects the listeria-based immunotherapy platform and cancer immunotherapy candidates into 2040.

"We are thrilled to have now consolidated all of the intellectual property for the listeria cancer immunotherapy platform into OS Therapies, positioning us to fully expand it in the years ahead and improve the standard of care across cancer treatment in the years ahead," said Paul Romness, CEO of OS Therapies. "We now have late-stage, mid-stage and early-stage cancer immunotherapy candidates, a rich pipeline of preclinical cancer immunotherapy candidates and a long IP runway to in order to fully leverage this powerful cancer immunotherapy platform."

A video explaining how the listeria platform works is available here.

Clinical-stage Cancer Immunotherapy Programs Acquired

1. OST-AXAL (previously AXAL/ADXS/HPV) for Human Papilloma Virus (HPV) associated cancers completed 1st (AIM2CERV) of 2 Phase 3 trials;
2. OST-503 (previously ADXS-503) for Non-Small Cell Lung Cancer (NSCLC) & Glioblastoma reported positive Phase 2 data in NSCLC;
3. OST-PSA (previously ADXS-504/ADXS31142) for Prostate Cancer.

Pre-clinical Cancer Immunotherapy Programs Acquired

8 un-named OST-HOT Listeria constructs designed for off-the shelf treatment of common cancers with shared hotspot mutations and cancer-testes antigen targets.

"The listeria cancer immunotherapy platform holds tremendous potential to improve the outcomes for cancer patients worldwide" said Dr. Robert Petit, Chief Medical & Scientific Officer of OS Therapies. "Immune-checkpoint inhibitors have revolutionized cancer treatment in settings where tumor antigens have generated a sufficient T cell response. However, in many cancers these treatments don't help because T cell responses against key tumor antigens have not developed. The OST Listeria platform specifically delivers relevant cancer targets directly to the immune system and generates new T cell responses that can be used to fight these cancers and help eliminate metastases. With OST-HER2 and the rest of the listeria platform, we have the potential to generate novel, more potent immune and targeted immune responses against solid tumors, metastatic disease and micro metastases from early-stage to late-stage cancers. I am thrilled to be able to guide the OST-HER2 asset through approval in osteosarcoma, and then fully explore that listeria platform's potential to improve treatment outcomes for cancer patients."

The global cancer immunotherapy market size was valued at $126 billion in 2023 and is projected to surpass around $296 billion by 2033, according to Nova One Advisor.

About OS Therapies

OS Therapies is a clinical stage oncology company focused on the identification, development, and commercialization of new class immunotherapy candidates for solid tumors, beginning with osteosarcoma. OST-HER2, the Company's lead asset, is the first in a new class of immunotherapy leveraging the immune-stimulatory effects of *Listeria* monocytogenes to initiate a strong immune response targeting to specific cancer antigens. The Company's lead asset OST-HER2 has received Rare Pediatric Disease Designation (RPDD) from the US Food & Drug Administration. OST-HER2 demonstrated positive data in a Phase 2b clinical trial of OST-HER2 in recurrent, fully resected, lung metastatic osteosarcoma and intends to submit a BLA Accelerated Approval request to the US FDA in the third quarter of 2025. Upon approval, the Company will become eligible to receive a Priority Review Voucher, currently valued at $150 million. OST-HER2 has completed a preclinical and clinical Phase 1 clinical study primarily in breast cancer patients. An animal OST-HER2 product candidate is indicated for the treatment of canine osteosarcoma and previously received conditional approval by the U.S. Department of Agriculture for the treatment of canine osteosarcoma.

In addition, OS Therapies is advancing its next-generation Antibody Drug Conjugate (ADC) and Drug Conjugates (DC), known as *tunable ADC* (tADC), which features tunable, tailored antibody-linker-payload candidates through its wholly-owned subsidiary OS Drug Candidates. This platform leverages the Company's proprietary silicone Si-Linker and Conditionally Active Payload (CAP) technology, enabling the delivery of multiple payloads per linker. For more information, please visit www.ostherapies.com.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of the federal securities laws. These forward-looking statements and terms such as "anticipate," "expect," "intend," "may," "will," "should" or other comparable terms involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. Those statements include statements regarding the intent, belief or current expectations of OS Therapies and members of its management, as well as the assumptions on which such statements are based. OS Therapies cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this news release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to the approval of OST-HER2 by the US FDA and grant of a priority review voucher and other risks and uncertainties described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's registration statement on Form S-1 filed with the Securities and Exchange Commission (the "SEC") on November 12, 2024, as amended on November 27, 2024, and other subsequent documents we file with the SEC, including but not limited to our Quarterly Reports on Form 10-Q. Any forward-looking statements contained in this press release speak only as of the date hereof, and, except as required by the federal securities laws, OS Therapies specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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