UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): December 13, 2024

Checkpoint Therapeutics, Inc.

(Exact Name of Registrant as Specified in charter)

Delaware	**001-38128**	**47-2568632**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

95 Sawyer Road, Suite 110,
Waltham, MA 02453
(Address of Principal Executive Offices)

(781) 652-4500
(Registrant's telephone number, including area code)

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:

☐ 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-2b 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 Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	CKPT	Nasdaq Capital Market

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. ☐

Item 8.01. Other Events.

On December 13, 2024, Checkpoint Therapeutics, Inc. issued a press release to announce that the U.S. Food and Drug Administration has approved UNLOXCYT™ (cosibelimab-ipdl) for the treatment of adults with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation.

A copy of such press release is being furnished as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit Number	**Description**
99.1	Press release issued by Checkpoint Therapeutics, Inc., dated December 13, 2024.
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL)

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.

Date: December 16, 2024

Checkpoint Therapeutics, Inc.
(Registrant)

By /s/ James F. Oliviero
James F. Oliviero
President and Chief Executive Officer

Exhibit 99.1

Checkpoint Therapeutics Announces FDA Approval of UNLOXCYT™ (cosibelimab-ipdl)

UNLOXCYT is the first and only FDA-approved anti-PD-L1 treatment for advanced cutaneous squamous cell carcinoma

Waltham, MA – December 13, 2024 – Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), today announced that the U.S. Food and Drug Administration ("FDA") has approved UNLOXCYT™ (cosibelimab-ipdl) for the treatment of adults with metastatic cutaneous squamous cell carcinoma ("cSCC") or locally advanced cSCC who are not candidates for curative surgery or curative radiation. UNLOXCYT is the first and only programmed death ligand-1 ("PD-L1") blocking antibody to receive FDA marketing approval for this indication.

The recommended commercial dosage of UNLOXCYT is 1,200 mg administered as an intravenous infusion over 60 minutes every three weeks.

"Today's FDA approval of UNLOXCYT – the first marketing approval for our company – is a significant milestone both for Checkpoint and for patients with advanced cSCC," said James Oliviero, President and Chief Executive Officer of Checkpoint. "This approval marks Checkpoint's transformation to a commercial-stage company, with the opportunity to compete in a U.S. market estimated to exceed $1 billion annually, where we believe UNLOXCYT offers a differentiated treatment option versus available therapies by binding to PD-L1, rather than programmed death receptor-1 ("PD-1"), to release the inhibitory effects of PD-L1 on the anti-tumor immune response. Additionally, UNLOXCYT has demonstrated the ability to induce antibody-dependent cell-mediated cytotoxicity ("ADCC"), another potential differentiating feature of the drug compared to existing marketed therapies for patients with cSCC."

"cSCC is the second most common form of skin cancer, and those diagnosed with advanced disease that has recurred or metastasized face a poor prognosis. cSCC remains a disease with a significant need for more effective and tolerable treatment options, particularly for patients with concomitant hematological malignancies, solid organ transplant recipients, or a history of autoimmune disorders," stated Emily Ruiz, M.D., M.P.H., Academic Director of the Mohs and Dermatologic Surgery Center at Brigham and Women's Hospital, Director of the High-Risk Skin Cancer Clinic at Dana Farber Cancer Center, and Associate Professor of Dermatology at Harvard Medical School. "UNLOXCYT is the first FDA-approved PD-L1–blocking antibody to demonstrate clinically meaningful objective response rates with durable responses in advanced cSCC. With its dual mechanisms of action and compelling safety profile, this promising drug will provide U.S. oncologists with an important new immunotherapy option for the treatment of cSCC."

FDA approval for UNLOXCYT was granted based on clinically meaningful objective response rates and duration of response data, as assessed by an independent central review committee, from Study CK-301-101 (NCT03212404), a multicenter, multicohort, open-label study of UNLOXCYT in adults with advanced solid tumor cancers, including cSCC.

"We are excited about the approval of UNLOXCYT and are currently developing a commercial launch plan. We want to thank the patients, physicians, nurses, and clinical coordinators for their support and participation in our clinical program, and the FDA for their collaboration throughout this process," concluded Mr. Oliviero.

About Cutaneous Squamous Cell Carcinoma

Cutaneous squamous cell carcinoma ("cSCC") is the second most common type of skin cancer in the United States, with an estimated annual incidence of approximately 1.8 million cases according to the Skin Cancer Foundation. Important risk factors for cSCC include chronic ultraviolet exposure and immunosuppressive conditions. While most cases are localized tumors amenable to curative resection, each year approximately 40,000 cases become advanced and an estimated 15,000 people in the United States die from this disease. In addition to being a life-threatening disease, cSCC causes significant functional morbidities and cosmetic deformities based on tumors commonly arising in the head and neck region and invading blood vessels, nerves and vital organs such as the eye or ear. The immune-suppressed population in particular represents a challenging target in the treatment of advanced cSCC, as patients present with a more aggressive disease and with a higher risk of developing immune-related toxicities from checkpoint inhibitor treatment.

About UNLOXCYT™ (cosibelimab-ipdl)

UNLOXCYT is a human immunoglobulin G1 ("IgG1") monoclonal antibody that binds PD-L1 and blocks the interaction between PD-L1 and its T cell receptors, PD-1 and B7.1. This interaction releases the inhibitory effects of PD-L1 on the anti-tumor immune response. UNLOXCYT has also been shown to induce ADCC.

INDICATION and IMPORANT SAFETY INFORMATION

INDICATION

UNLOXCYT (cosibelimab-ipdl) is indicated for the treatment of adults with metastatic cutaneous squamous cell carcinoma ("cSCC") or locally advanced cSCC who are not candidates for curative surgery or curative radiation.

IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions listed herein may not include all possible severe and fatal immune-mediated adverse reactions. Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue, and occur at any time after starting a PD-1/PD-L1–blocking antibody, including UNLOXCYT. While immune-mediated adverse reactions usually manifest during treatment, they can also manifest after discontinuation of PD-1/PD-L1–blocking antibodies. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously.

- Monitor closely for signs and symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue UNLOXCYT depending on the severity of the adverse reaction (see Dosage and Administration in Prescribing Information). In general, if UNLOXCYT requires interruption or discontinuation, administer systemic corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids.

Immune-Mediated Pneumonitis

- UNLOXCYT can cause immune-mediated pneumonitis. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 1% (3/223, Grade 2) of patients receiving UNLOXCYT.

Immune-Mediated Colitis

- UNLOXCYT can cause immune-mediated colitis, which may present with diarrhea, abdominal pain, and lower gastrointestinal bleeding. Cytomegalovirus infection/reactivation has occurred in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1–blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 0.4% (1/223, Grade 1) of patients receiving UNLOXCYT.

Immune-Mediated Hepatitis

- UNLOXCYT can cause immune-mediated hepatitis.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- UNLOXCYT can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity. Adrenal insufficiency occurred in 0.9% (2/223) of patients receiving UNLOXCYT, including Grade 2 in 0.4% (1/223) of patients.

Hypophysitis

- UNLOXCYT can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity.

Thyroid Disorders

- UNLOXCYT can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity. Hypothyroidism occurred in 10% (22/223) of patients receiving UNLOXCYT, including Grade 2 in 5% (10/223) of patients. Hyperthyroidism occurred in 5% (12/223) of patients receiving UNLOXCYT, including Grade 2 in 0.4% (1/223) of patients.

Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis

- UNLOXCYT can cause type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity.

Immune-Mediated Nephritis with Renal Dysfunction

- UNLOXCYT can cause immune-mediated nephritis.

Immune-Mediated Dermatologic Adverse Reactions

- UNLOXCYT can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), have occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue UNLOXCYT depending on severity. Immune-mediated dermatologic adverse reactions occurred in 7% (15/223) of patients receiving UNLOXCYT, including Grade 3 in 0.9% (2/223) of patients and Grade 2 in 4% (9/223) of patients.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred in <1% of the 223 patients who received UNLOXCYT or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.
  - Cardiac/Vascular: Myocarditis, pericarditis, vasculitis.
  - Nervous System: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barre syndrome, nerve paresis, autoimmune neuropathy.
  - Ocular: Uveitis, iritis, other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

- Gastrointestinal: Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis.
- Musculoskeletal and Connective Tissue: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica.
- Endocrine: Hypoparathyroidism.
- Other (Hematologic/Immune): Autoimmune hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

- UNLOXCYT can cause severe or life-threatening infusion-related reactions. Infusion-related infusion reactions were reported in 11% (24/223) of patients, including Grade 2 in 5.8% (13/223) of patients receiving UNLOXCYT.
- Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue UNLOXCYT based on severity of reaction. Consider premedication with an antipyretic and/or an antihistamine for patients who have had previous systemic reactions to infusions of therapeutic proteins.

Complications of Allogeneic HSCT

- Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1–blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1–blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

- Based on its mechanism of action, UNLOXCYT can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus, resulting in fetal death. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with UNLOXCYT and for 4 months after the last dose.

Common Adverse Reactions

The most common adverse reactions (≥10%) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.

Please see full Prescribing Information.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. ("Checkpoint") is a commercial-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint has received approval from the U.S. FDA for UNLOXCYT™ (cosibelimab-ipdl) for the treatment of adults with metastatic cSCC or locally advanced cSCC who are not candidates for curative surgery or curative radiation. Additionally, Checkpoint is evaluating its lead investigational small-molecule, targeted anti-cancer agent, olafertinib (formerly CK-101), a third-generation epidermal growth factor receptor ("EGFR") inhibitor, as a potential new treatment for patients with EGFR mutation-positive non-small cell lung cancer. Checkpoint is headquartered in Waltham, MA and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, visit www.checkpointtx.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended, that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding expectations for the timing and commercial launch and availability of UNLOXCYT™ (cosibelimab-ipdl) for the treatment of adults with metastatic cutaneous squamous cell carcinoma ("cSCC") or locally advanced cSCC who are not candidates for curative surgery or curative radiation; the commercial potential of UNLOXCYT; and anticipated healthcare professional and patient acceptance and use of UNLOXCYT for the FDA-approved indication. In addition to the risk factors identified from time to time in our reports filed with the Securities and Exchange Commission, factors that could cause our actual results to differ materially include the following: our ability to establish and maintain a commercial infrastructure or to partner or license UNLOXCYT to a third-party with a commercial infrastructure; our, or our partner or licensee's, ability to successfully launch, market and sell UNLOXCYT or future products, if approved; failure to obtain and maintain requisite regulatory approvals; the potential for variation from our projections and estimates about the potential market for UNLOXCYT; the risk that UNLOXCYT will not be commercially successful; our ability to meet post-approval compliance obligations (on topics including but not limited to product quality, product distribution and supply chain, pharmacovigilance, and sales and marketing); potential regulatory challenges to our plans to seek marketing approval for UNLOXCYT in additional geographies, outside of the U.S.; risks related to our chemistry, manufacturing and controls and contract manufacturing relationships; risks related to our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks related to our need for substantial additional funds; other uncertainties inherent in research and development; our dependence on third-party suppliers; government regulation; patent and intellectual property matters; competition; unfavorable market or other economic conditions; and our ability to achieve the milestones we project. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K, and in our other filings with the U.S. Securities and Exchange Commission. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

Any forward-looking statements set forth in this press release speak only as of the date of this press release. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law. This press release and prior releases are available at www.checkpointtx.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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