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): March 28, 2025

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 2.02. Results of Operations and Financial Condition.

On March 28, 2025, Checkpoint Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the fiscal year ended December 31, 2024. A copy of such press release is being furnished as Exhibit 99.1 to this report.

The information, including Exhibit 99.1, in this Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall otherwise be expressly set forth by specific reference in such filing.

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 March 28, 2025.
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: March 28, 2025

Checkpoint Therapeutics, Inc.
(Registrant)

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

Checkpoint Therapeutics Reports Full-Year 2024 Financial Results and Recent Corporate Updates

UNLOXCYT™ (cosibelimab-ipdl) approved by U.S. FDA as first and only anti-PD-L1 treatment for advanced cutaneous squamous cell carcinoma

Waltham, MA – March 28, 2025 – Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a commercial-stage immunotherapy and targeted oncology company, today announced financial results for the fiscal year ended December 31, 2024, and recent corporate updates.

Recent Corporate Updates:

- In March 2025, Checkpoint announced that it entered into an Agreement and Plan of Merger (the "Merger Agreement") with Sun Pharmaceutical Industries, Inc. ("Sun Pharma"), and a wholly owned subsidiary of Sun Pharma, with Checkpoint continuing as the surviving corporation of the transaction and a wholly owned subsidiary of Sun Pharma (the "Merger"). The total transaction value of the Merger, including the upfront cash payment and the maximum value of the contingent value right ("CVR"), is up to approximately $416 million, and the Merger is expected to be completed in the second quarter of 2025. The transaction is subject to customary closing conditions, including required regulatory approvals and approval by the holders of a majority of the voting power of outstanding shares of Checkpoint common stock, and by the holders of a majority of the shares of Checkpoint common stock that are not held by Fortress Biotech, Inc. or by certain other affiliates of Checkpoint.

- In December 2024, Checkpoint announced that the U.S. Food and Drug Administration ("FDA") 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.

- In September 2024, Checkpoint presented longer-term data from its pivotal trial of cosibelimab in locally advanced and metastatic cSCC during the European Society for Medical Oncology ("ESMO") Congress 2024. Longer-term results for cosibelimab presented at the ESMO Congress demonstrate a deepening of response over time, with higher objective response and complete response rates than initially observed at the primary analyses. A copy of the ESMO poster can be found on the Publications page of Checkpoint's website.

Financial Results:

- **Cash Position**: As of December 31, 2024, Checkpoint's cash and cash equivalents totaled $6.6 million, compared to $4.9 million at December 31, 2023, an increase of $1.7 million. Subsequent to the end of the fiscal year, Checkpoint received approximately $38.1 million in cash proceeds through the exercise of existing warrants.

- **R&D Expenses**: Research and development expenses for the year ended December 31, 2024, were $36.2 million, compared to $43.6 million for the year ended December 31, 2023, a decrease of $7.4 million. Research and development expenses for the year ended December 31, 2024, included $12.9 million of non-cash stock expenses, compared to $4.6 million in non-cash stock expenses for the year ended December 31, 2023.

- **G&A Expenses**: General and administrative expenses for the year ended December 31, 2024, were $20.1 million, compared to $8.7 million for the year ended December 31, 2023, an increase of $11.4 million. General and administrative expenses for the year ended December 31, 2024, included $11.0 million of non-cash stock expenses, compared to $2.7 million in non-cash stock expenses for the year ended December 31, 2023.

- **Net Loss**: Net loss attributable to common stockholders for the year ended December 31, 2024, was $56.2 million, or $1.42 per share, compared to a net loss of $51.8 million, or $3.17 per share, for the year ended December 31, 2023.

About UNLOXCYT™ (cosibelimab-ipdl)

UNLOXCYT is a human immunoglobulin G1 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 antibody-dependent cell-mediated cytotoxicity.

INDICATION and IMPORANT SAFETY INFORMATION

INDICATION

UNLOXCYT (cosibelimab-ipdl) is indicated for the treatment of adults with metastatic 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. 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 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, express or implied, statements regarding the Merger and related matters, including the benefits of and timeline for closing the Merger, any payments under the CVRs, prospective performance and opportunities, post-closing operations and the outlook for the companies' businesses; projections of or targets for revenues, costs, income (or loss), earnings per share, capital expenditures, dividends, capital structure, net financials and other financial measures; expectations for the timing and commercial launch and availability of 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; the commercial potential of UNLOXCYT; anticipated healthcare professional and patient acceptance and use of UNLOXCYT for the FDA-approved indication; and assumptions underlying or relating to such statements.

Factors that may affect future results and may cause these forward-looking statements to be inaccurate include, but are not limited to: uncertainties as to the timing of completion of the Merger; uncertainties as to whether Checkpoint's stockholders will vote to approve the transaction; the possibility that competing offers will be made; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction (or only grant approval subject to adverse conditions or limitations); the possibility that the proposed transaction may not be completed in the time frame expected by Checkpoint, or at all; failure to realize the anticipated benefits of the proposed transaction in the time frame expected, or at all; the effects of the transaction on relationships with employees, other business partners or governmental entities; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed transaction; significant or unexpected costs, charges or expenses resulting from the proposed transaction; negative effects of this announcement or the consummation of the proposed acquisition on Checkpoint's common stock and/or Checkpoint's operating results; the difficulty of predicting the timing or outcome of regulatory approvals or actions; the risks related to non-achievement of the CVR milestone and that holders of the CVRs will not receive payments in respect of the CVRs; other business effects, including the effects of industry, economic or political conditions outside of the companies' control; transaction costs; actual or contingent liabilities; risk of litigation and/or regulatory actions related to the proposed acquisition; adverse impacts on business, operating results or financial condition in the future due to pandemics, epidemics or outbreaks, and their impact on Checkpoint's business, operations, supply chain, patient enrollment and retention, clinical trials, strategy, goals and anticipated milestones; government-mandated or market-driven price decreases for Checkpoint's products; the existence or introduction of competing products; reliance on information technology; Checkpoint's ability to successfully market current and new products; Checkpoint's and its collaborators' ability to continue to conduct research and clinical programs; and exposure to product liability and legal proceedings and investigations. Further risks and uncertainties that could cause actual results to differ materially from the results anticipated by the forward-looking statements are detailed from time to time in Checkpoint's periodic reports filed with the SEC, including the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and the definitive proxy statement to be filed by Checkpoint with the SEC in connection with the proposed transaction. These filings, when available, are available on the investor relations section of Checkpoint's website at https://ir.checkpointtx.com or on the SEC's website at https://www.sec.gov.

Any forward-looking statements set forth in this press release speak only as of the date of this press release, are made based on current beliefs and judgments, and are not predictions of actual performance. New risks and uncertainties arise from time to time, and it is impossible for us to predict these events or how they may affect us. We caution that a number of important factors, including those described in this document, could cause actual results to differ materially from those contemplated in any forward-looking statements. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. 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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CHECKPOINT THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)

	December 31, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,604	$ 4,928
Prepaid expenses and other assets	867	450
Total current assets	7,471	5,378
Total Assets	**$ 7,471**	**$ 5,378**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 17,465	$ 15,485
Accounts payable and accrued expenses - related party	2,433	2,815
Common stock warrant liabilities	198	125
Total current liabilities	20,096	18,425
Total Liabilities	**20,096**	**18,425**
Commitments and Contingencies		
Stockholders' Equity (Deficit)		
Common Stock ($0.0001 par value), 175,000,000 and 80,000,000 shares authorized as of December 31, 2024 and 2023, respectively		
Class A common shares, 700,000 shares issued and outstanding as of December 31, 2024 and December 31, 2023	-	-
Common shares, 53,640,422 and 27,042,035 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	5	3
Common stock issuable, 2,386,808 and 1,492,915 shares as of December 31, 2024 and December 31, 2023, respectively	7,638	3,419
Additional paid-in capital	350,305	297,864
Accumulated deficit	(370,573)	(314,333)
Total Stockholders' Equity (Deficit)	(12,625)	(13,047)
Total Liabilities and Stockholders' Equity (Deficit)	**$ 7,471**	**$ 5,378**

CHECKPOINT THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)
(Unaudited)

	For the year ended December 31,	
	2024	2023
Revenue - related party	$ 41	$ 103
Operating expenses:		
Research and development	36,152	43,566
General and administrative	20,063	8,685
Total operating expenses	56,215	52,251
Loss from operations	(56,174)	(52,148)
Other income (loss):		
Interest income	11	84
Gain (loss) on common stock warrant liabilities	(73)	217
Foreign currency exchange loss	(4)	-
Total other income (loss)	(66)	301
Net Loss	**$ (56,240)**	**$ (51,847)**
Loss per Share:		
Basic and diluted net loss per Class A common share and common share outstanding	$ (1.42)	$ (3.17)
Basic and diluted weighted average number of Class A common shares and common shares outstanding	39,674,444	18,742,494