

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): August 12, 2024

Checkpoint Therapeutics, Inc.

(Exact Name of Registrant as Specified in charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-38128
(Commission File Number)

47-2568632
(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 August 12, 2024, Checkpoint Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the second quarter ended June 30, 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 August 12, 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: August 12, 2024

Checkpoint Therapeutics, Inc.
(Registrant)

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



Checkpoint Therapeutics Reports Second Quarter 2024 Financial Results and Recent Corporate Updates

Waltham, MA – August 12, 2024 – Checkpoint Therapeutics, Inc. (“Checkpoint”) (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced financial results for the second quarter ended June 30, 2024, and recent corporate updates.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, “We’ve made significant recent progress as we seek approval of cosibelimab as a potential new treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma (“cSCC”) who are not candidates for curative surgery or curative radiation. We are pleased to have reached alignment with the U.S. Food and Drug Administration (“FDA”) on our strategy to potentially address the deficiencies identified in the complete response letter (“CRL”) received last December. Shortly thereafter, we resubmitted our Biologics License Application (“BLA”), which was accepted by the FDA for review as a complete response to the CRL. We look forward to working with the FDA in advance of the Prescription Drug User Fee Act (“PDUFA”) goal date of December 28, 2024, to potentially deliver this important therapeutic option to cutaneous squamous cell carcinoma patients and their families.”

Recent Corporate Updates:

- Checkpoint submitted a BLA to the FDA in January 2023 seeking approval of cosibelimab as a potential new treatment for patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or curative radiation. In December 2023, the FDA issued a CRL for the cosibelimab BLA. The CRL only cited findings that arose during a multi-sponsor inspection of Checkpoint’s third-party contract manufacturing organization (“CMO”) as approvability issues to address in a BLA resubmission. The CRL did not state any concerns about the clinical data package, safety, or labeling for the approvability of cosibelimab.
- In June 2024, Checkpoint reached alignment with the FDA on its BLA resubmission strategy for cosibelimab and resubmitted the BLA shortly thereafter.
- In July 2024, Checkpoint announced that the FDA accepted for review the resubmission of its BLA for cosibelimab as a complete response to the CRL issued in December 2023 and set a PDUFA goal date of December 28, 2024.
- Also in July 2024, Checkpoint announced a collaboration to explore the combined therapeutic potential of cosibelimab, its anti-PD-L1 antibody with dual mechanism of action, with GC Cell’s Immucell-LC, an innovative autologous Cytokine Induced Killer T cell therapy composed of cytotoxic T lymphocytes and natural killer T cells.
- Also in July 2024, Checkpoint completed a registered direct offering priced At-the-Market under Nasdaq rules and a concurrent private placement of warrants to purchase Checkpoint common stock, for total gross proceeds of approximately \$12.0 million.

Financial Results:

- **Cash Position:** As of June 30, 2024, Checkpoint’s cash and cash equivalents totaled \$5.0 million, compared to \$11.2 million at March 31, 2024 and \$4.9 million at December 31, 2023, a decrease of \$6.2 million for the quarter and an increase of \$0.1 million, year-to-date. After the end of the second quarter, Checkpoint raised gross proceeds of approximately \$12.0 million in a registered direct offering completed in July 2024.
- **R&D Expenses:** Research and development expenses for the second quarter of 2024 were \$4.5 million, compared to \$13.9 million for the second quarter of 2023, a decrease of \$9.4 million. Research and development expenses for the second quarter of 2024 included \$0.6 million of non-cash stock expenses, compared to \$0.2 million for the second quarter of 2023.
- **G&A Expenses:** General and administrative expenses for the second quarter of 2024 were \$2.2 million, compared to \$2.3 million for the second quarter of 2023, a decrease of \$0.1 million. General and administrative expenses for the second quarter of 2024 included \$0.6 million of non-cash stock expenses, compared to \$0.8 million for the second quarter of 2023.
- **Net Loss:** Net loss attributable to common stockholders for the second quarter of 2024 was \$6.7 million, or \$0.18 per share, compared to a net loss of \$16.5 million, or \$1.05 per share, in the second quarter of 2023. Net loss for the second quarter of 2024 included \$1.2 million of non-cash stock expenses, compared to \$1.0 million for the second quarter of 2023.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. is a clinical-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint is evaluating its lead antibody product candidate, cosibelimab, a potential differentiated anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, as a potential new treatment for patients with selected recurrent or metastatic cancers, including metastatic and locally advanced cSCC. Checkpoint is also evaluating its lead small-molecule, targeted anti-cancer agent, olafertinib, 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 our resubmission of our BLA for cosibelimab and review thereof, our belief that the BLA resubmission potentially addresses all the issues in the CRL, our belief about the comprehensive nature of our BLA resubmission and reaching alignment with the FDA on our cosibelimab BLA resubmission strategy, our ability to work with our third-party CMO and the FDA to adequately address the issues raised in the CRL and execute on a pathway forward for the potential marketing approval of cosibelimab, the adequacy of the responses to the inspection

issues submitted to FDA by our third-party CMO, our projections of regulatory review timelines, the commercial potential of cosibelimab, if approved, and the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies and the dual mechanism of action of cosibelimab translating into potential enhanced efficacy. Factors that could cause our actual results to differ materially include the following: the risks and uncertainties associated with the regulatory review process; uncertainties regarding the timeline of FDA review of the resubmitted BLA; any inability to successfully work with the FDA to find a satisfactory solution to address any concerns in a timely manner or at all during the review process for the BLA, including any inability to provide the FDA with data, analysis or other information sufficient to support an approval of the BLA; our, and our third party CMO's, ability to adequately address the issues raised in the CRL; issues associated with any facility inspection or re-inspection of our third party CMO or otherwise during the review process for the BLA; the risk that our third-party CMO will not meet deadlines, and/or comply with applicable regulations; whether the FDA accepts the data and results as included in the BLA resubmission at levels consistent with the published results, or at all; our ability to execute a partnering or other relationship to enable the commercialization of cosibelimab, if approved, on acceptable terms, if at all; the risk that topline and interim data remains subject to audit and verification procedures that may result in the final data being materially different from the topline or interim data we previously published; the risk that safety issues or trends will be observed in the clinical trial when the full safety dataset is available and analyzed; the risk that a positive primary endpoint does not translate to all, or any, secondary endpoints being met; risks that regulatory authorities will not accept an application for approval of cosibelimab based on data from the Phase 1 clinical trial; the risk that the clinical results from the Phase 1 clinical trial will not support regulatory approval of cosibelimab to treat cSCC or, if approved, that cosibelimab will not be commercially successful; 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, including the risk that the evolving and unpredictable Russia/Ukraine conflict and COVID-19 pandemic delay achievement of those milestones. 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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CHECKPOINT THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)

	June 30, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 4,951	\$ 4,928
Prepaid expenses and other current assets	678	450
Other receivables - related party	41	-
Total current assets	5,670	5,378
Total Assets	\$ 5,670	\$ 5,378
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 18,115	\$ 15,485
Accounts payable and accrued expenses - related party	3,179	2,815
Common stock warrant liabilities	125	125
Total current liabilities	21,419	18,425
Total Liabilities	21,419	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 June 30, 2024 and December 31, 2023, respectively		
Class A common shares, 700,000 shares issued and outstanding as of June 30, 2024 and December 31, 2023	-	-
Common shares, 41,631,500 and 27,042,035 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	4	3
Common stock issuable, 0 and 1,492,915 shares as of June 30, 2024 and December 31, 2023, respectively	-	3,419
Additional paid-in capital	316,195	297,864

Accumulated deficit								(331,948)	(314,333)
Total Stockholders' Equity (Deficit)								(15,749)	(13,047)
Total Liabilities and Stockholders' Equity (Deficit)								\$ 5,670	\$ 5,378

CHECKPOINT THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(Unaudited)

	<u>For the three months ended June 30,</u>				<u>For the six months ended June 30,</u>			
	<u>2024</u>		<u>2023</u>		<u>2024</u>		<u>2023</u>	
Revenue - related party	\$	41	\$	31	\$	41	\$	66
Operating expenses:								
Research and development		4,480		13,945		12,977		29,771
General and administrative		2,234		2,281		4,685		4,573
Total operating expenses		<u>6,714</u>		<u>16,226</u>		<u>17,662</u>		<u>34,344</u>
Loss from operations		<u>(6,673)</u>		<u>(16,195)</u>		<u>(17,621)</u>		<u>(34,278)</u>
Other income (expense)								
Interest income		3		31		7		74
(Loss) gain on common stock warrant liabilities		-		(357)				7,209
Foreign currency exchange loss		-		-		(1)		-
Total other income (expense)		<u>3</u>		<u>(326)</u>		<u>6</u>		<u>7,283</u>
Net Loss	\$	(6,670)	\$	(16,521)	\$	(17,615)	\$	(26,995)
Loss per Share:								
Basic and diluted net loss per common share outstanding	\$	(0.18)	\$	(1.05)	\$	(0.51)	\$	(1.97)
Basic and diluted weighted average number of common shares outstanding		<u>36,526,268</u>		<u>15,700,324</u>		<u>34,728,623</u>		<u>13,735,646</u>