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 22, 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 2.02. Results of Operations and Financial Condition.

On March 22, 2024, 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, 2023. 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 22, 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: March 22, 2024

Checkpoint Therapeutics, Inc.
(Registrant)

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

Checkpoint Therapeutics Reports Full-Year 2023 Financial Results and Recent Corporate Highlights

Waltham, MA – March 22, 2024 – Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced financial results for the full-year ended December 31, 2023, and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "We continue to work closely with our third-party contract manufacturing organization to expeditiously resolve the deficiencies noted in the complete response letter ("CRL") we received last December, and are targeting a Biologics License Application ("BLA") resubmission for cosibelimab by mid-year to potentially obtain marketing approval before the end of 2024. Simultaneously, we continue to execute on a select number of key long lead time commercial launch preparation activities to shorten our launch timeline in anticipation of a potential approval. We remain highly confident in the clinical data and safety package in support of cosibelimab. We look forward to providing additional updates in the second quarter."

2023 and Recent Corporate Highlights:

- Checkpoint submitted a BLA to the FDA seeking approval of cosibelimab in January 2023 and the FDA accepted the BLA for filing in March 2023. 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 as approvability issues to address in a resubmission. The CRL did not state any concerns about the clinical data package, safety, or labeling for the approvability of cosibelimab. Checkpoint intends to address the feedback in a BLA resubmission to potentially enable marketing approval in 2024.

- In December 2023, Checkpoint announced that the U.S. Patent and Trademark Office ("USPTO") issued a new patent (U.S. Patent No. 11,834,505) covering a method of treating various cancers, including cutaneous squamous cell carcinoma ("cSCC"), through the administration of cosibelimab. Checkpoint secured U.S. patent protection for cosibelimab through at least May 2038.

- In October 2023, Checkpoint announced the publication of results from the multicenter, multiregional, pivotal trial evaluating cosibelimab in patients with metastatic cSCC in the *Journal for ImmunoTherapy of Cancer (JITC)*, the peer-reviewed, online journal of the Society of Immunotherapy of Cancer. The paper, entitled, "Efficacy and Safety of Cosibelimab, an Anti–PD-L1 Antibody, in Metastatic Cutaneous Squamous Cell Carcinoma", describes safety and efficacy results from 78 patients with metastatic cSCC enrolled at clinical sites in eight countries.

- In July 2023, Checkpoint announced new, longer-term data for cosibelimab from its pivotal studies in locally advanced and metastatic cSCC. These results demonstrate a deepening of response over time, resulting in higher complete response rates than previously reported (55% objective response rate; 26% complete response rate in locally advanced cSCC and 50% objective response rate; 13% complete response rate in metastatic cSCC). Furthermore, responses continue to remain durable over time.

- In June 2023, Checkpoint announced that new pharmacokinetic ("PK") modeling data on cosibelimab supporting the extension to an every-three-week dosing regimen were presented at the Population Approach Group Europe 2023 Annual Meeting. Results support comparability of the cosibelimab 800 mg every-two-week and 1200 mg every-three-week dosing regimens.

- Throughout 2023 and in January 2024, Checkpoint completed multiple registered direct offerings priced At-the-Market under Nasdaq rules and concurrent private placements of two series of warrants to purchase Checkpoint common stock, for total gross proceeds of approximately $47.6 million. Additionally, in October 2023, Checkpoint announced entry into a definitive agreement for the immediate exercise of warrants for $11.1 million in gross proceeds.

- In March 2024, Checkpoint announced the appointment of accomplished life sciences executive, Amit Sharma, M.D., FACP, FASN, FNKF, currently Vice President of Clinical Development and Therapeutic Head for Nephrology and Hematology at Alexion, AstraZeneca Rare Disease, as a non-executive director to Checkpoint's Board of Directors.

Financial Results:

- **Cash Position**: As of December 31, 2023, Checkpoint's cash and cash equivalents totaled $4.9 million, compared to $12.1 million at December 31, 2022, a decrease of $7.2 million. This cash position is not reflective of the registered direct offering that closed in January 2024 for total gross proceeds of approximately $14.0 million.

- **R&D Expenses**: Research and development expenses for the year ended December 31, 2023, were $43.6 million, compared to $49.8 million for the year ended December 31, 2022, a decrease of $6.2 million. Research and development expenses for the year ended December 31, 2023 included $4.6 million of non-cash stock expenses, compared to $2.8 million in non-cash stock expenses for the year ended December 31, 2022.

- **G&A Expenses**: General and administrative expenses for both the years ended December 31, 2023 and December 31, 2022, were $8.7 million. General and administrative expenses for the year ended December 31, 2023 included $2.7 million of non-cash stock expenses, compared to $2.5 million in non-cash stock expenses for the year ended December 31, 2022.

- **Net Loss**: Net loss attributable to common stockholders for the year ended December 31, 2023, was $51.8 million, or $3.17 per share, compared to a net loss of $62.6 million, or $7.09 per share, for the year ended December 31, 2022.

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 best-in-class 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 cutaneous squamous cell carcinoma. Checkpoint is also evaluating its lead 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 our ability to work with our third-party contract manufacturer and the U.S. Food and Drug Administration to address the issues raised in the complete response letter and execute on a pathway forward for the potential approval of cosibelimab for the treatment of patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or radiation and our projections of resubmission and regulatory review timelines, statements related to our ability to shorten our launch timeline in anticipation of a potential approval, and statements relating to the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies and the two-fold mechanism of action of cosibelimab translating into potential enhanced efficacy. Factors that could cause our actual results to differ materially include the following: 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.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,928	$ 12,068
Prepaid expenses and other assets	450	1,149
Other receivables - related party	-	73
Total current assets	5,378	13,290
Total Assets	**$ 5,378**	**$ 13,290**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 15,485	$ 20,297
Accounts payable and accrued expenses - related party	2,815	1,306

Common stock warrant liabilities	125	11,170
Total current liabilities	18,425	32,773
Total Liabilities	**18,425**	**32,773**
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Common Stock ($0.0001 par value), 80,000,000 and 50,000,000 shares authorized as of December 31, 2023 and 2022, respectively		
Class A common shares, 700,000 shares issued and outstanding as of December 31, 2023 and December 31, 2022	-	-
Common shares, 27,042,035 and 9,586,683 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	3	1
Common stock issuable, 1,492,915 and 368,907 shares as of December 31, 2023 and December 31, 2022, respectively	3,419	1,885
Additional paid-in capital	297,864	241,117
Accumulated deficit	(314,333)	(262,486)
Total Stockholders' (Deficit) Equity	(13,047)	(19,483)
Total Liabilities and Stockholders' (Deficit) Equity	**$ 5,378**	**$ 13,290**

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

	For the year ended December 31,	
	2023	**2022**
Revenue - related party	$ 103	$ 192
Operating expenses:		
Research and development	43,566	49,825
General and administrative	8,685	8,700
Total operating expenses	52,251	58,525
Loss from operations	(52,148)	(58,333)
Other income (loss):		
Interest income	84	160
Gain (loss) on common stock warrant liabilities	217	(4,451)
Total other income	301	(4,291)
Net Loss	**$ (51,847)**	**$ (62,624)**
Loss per Share:		
Basic and diluted net loss per common share outstanding	$ (3.17)	$ (7.09)
Basic and diluted weighted average number of common shares outstanding	18,742,494	8,835,521