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): **November 13, 2023**

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 November 13, 2023, Checkpoint Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 30, 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 November 13, 2023.
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.

Checkpoint Therapeutics, Inc.
(Registrant)

Date: November 13, 2023

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

Checkpoint Therapeutics Reports Third Quarter 2023 Financial Results and Recent Corporate Highlights

Biologics License Application for cosibelimab under review by U.S. FDA; PDUFA goal date of January 3, 2024

Recent publication of cosibelimab pivotal trial results in the Journal for ImmunoTherapy of Cancer

Waltham, MA – November 13, 2023 – Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced financial results for the third quarter ended September 30, 2023, and recent corporate highlights.

"The January 3, 2024, action date for our Biologics License Application ("BLA") for cosibelimab is fast-approaching, and we continue to work closely with the U.S. Food and Drug Administration ("FDA") in completing their review," said James Oliviero, President and Chief Executive Officer of Checkpoint. "During the third quarter, pivotal trial results for cosibelimab in metastatic cutaneous squamous cell carcinoma ("cSCC") were published in the peer-reviewed *Journal for ImmunoTherapy of Cancer*, which further supports the efficacy and safety of cosibelimab. We also reported longer-term data from our pivotal trials in both locally advanced and metastatic cSCC that demonstrate a deepening of response over time with substantially higher complete response rates. We firmly believe that cosibelimab's clinical profile, which includes a unique dual mechanism of action and favorable safety profile, should position the product, upon its potential launch next year, as the preferred immunotherapy of oncologists, particularly for the large number of difficult-to-treat cSCC patients who continue to suffer poor outcomes with currently available treatments."

Recent Corporate Highlights:

- Checkpoint submitted a BLA to the FDA seeking approval of cosibelimab in January 2023. In March 2023, Checkpoint announced the FDA accepted the BLA filing for cosibelimab and set a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024. The FDA has indicated that an advisory committee meeting to discuss the application is not planned.
- 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 with cosibelimab treatment over time, resulting in substantially higher complete response rates than previously reported. Furthermore, responses continue to remain durable over time.

- Also in July 2023, Checkpoint completed a registered direct offering priced at-the-market under Nasdaq rules for total gross proceeds of $10 million.
- In October 2023, Checkpoint announced the exercise of previously issued warrants for $11.13 million in gross proceeds.
- Also 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" (doi:10.1136/jitc-2023-007637), describes safety and efficacy results from 78 patients with metastatic cSCC enrolled at clinical sites in eight countries.

Financial Results:

- **Cash Position**: As of September 30, 2023, Checkpoint's cash and cash equivalents totaled $1.8 million, compared to $7.4 million at June 30, 2023 and $12.1 million at December 31, 2022, a decrease of $5.6 million for the quarter and a decrease of $10.3 million for the first nine months of 2023. Subsequent to the end of the third quarter, Checkpoint raised approximately $11.13 million of gross proceeds from the exercise of previously issued warrants.
- **R&D Expenses**: Research and development expenses for the third quarter of 2023 were $5.5 million, compared to $8.9 million for the third quarter of 2022, a decrease of $3.4 million. Research and development expenses for the third quarters of 2023 and 2022 both included $0.3 million of non-cash stock expenses.
- **G&A Expenses**: General and administrative expenses for the third quarter of 2023 were $2.2 million, compared to $1.8 million for the third quarter of 2022, an increase of $0.4 million. General and administrative expenses for the third quarter of 2023 included $0.6 million of non-cash stock expenses, compared to $0.5 million for the third quarter of 2022.
- **Net Loss**: Net loss attributable to common stockholders for the third quarter of 2023 was $5.7 million, or $0.29 per share, compared to a net loss of $10.6 million, or $1.20 per share, in the third quarter of 2022. Net loss for the third quarter of 2023 included $0.9 million of non-cash stock expenses, compared to $0.8 million for the third quarter of 2022.

About Checkpoint Therapeutics
Checkpoint Therapeutics, Inc. ("Checkpoint") 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, in an ongoing open-label, multi-regional, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including cohorts in metastatic and locally advanced cSCC intended to support one or more applications for marketing approval. Based on positive topline and interim results in metastatic and locally advanced cSCC, respectively, Checkpoint submitted a BLA for these indications in January 2023, which application is filed and under review with a PDUFA goal date of January 3, 2024. Checkpoint is 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 the FDA review of the BLA for the approval of cosibelimab for the treatment of patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation and the commercial potential of cosibelimab if the BLA is approved, statements relating to the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies, the two-fold mechanism of action of cosibelimab translating into potential enhanced efficacy, and our projections of publication and

regulatory review timelines. 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.

Company Contact:
Jaclyn Jaffe
Checkpoint Therapeutics, Inc.
(781) 652-4500
ir@checkpointtx.com

Investor Relations Contact:
Ashley R. Robinson
Managing Director, LifeSci Advisors, LLC
(617) 430-7577
arr@lifesciadvisors.com

Media Relations Contact:
Katie Kennedy
Gregory FCA
610-731-1045
Checkpoint@gregoryfca.com

CHECKPOINT THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,772	$ 12,068
Prepaid expenses and other current assets	415	1,149
Other receivables - related party	31	73
Total current assets	2,218	13,290
Total Assets	**$ 2,218**	**$ 13,290**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 16,390	$ 20,297
Accounts payable and accrued expenses - related party	2,880	1,306
Common stock warrant liabilities	1,991	11,170
Total current liabilities	21,261	32,773
Total Liabilities	**21,261**	**32,773**
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Common Stock ($0.0001 par value), 80,000,000 and 50,000,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively		
Class A common shares, 700,000 shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common shares, 21,702,547 and 9,586,683 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	2	1
Common stock issuable, 0 and 368,907 shares as of September 30, 2023 and December 31, 2022, respectively	-	1,885
Additional paid-in capital	276,160	241,117
Accumulated deficit	(295,205)	(262,486)
Total Stockholders' (Deficit) Equity	(19,043)	(19,483)
Total Liabilities and Stockholders' (Deficit) Equity	**$ 2,218**	**$ 13,290**

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue - related party	$ 31	$ 48	$ 97	$ 118
Operating expenses:				
Research and development	5,496	8,866	35,267	35,589
General and administrative	2,236	1,846	6,809	6,218
Total operating expenses	7,732	10,712	42,076	41,807
Loss from operations	(7,701)	(10,664)	(41,979)	(41,689)
Other income				
Interest income	7	52	81	87
Gain on common stock warrant liabilities	1,970	-	9,179	-
Total other income	1,977	52	9,260	87
Net Loss	**$ (5,724)**	**$ (10,612)**	**$ (32,719)**	**$ (41,602)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$ (0.29)	$ (1.20)	$ (2.07)	$ (4.78)
Basic and diluted weighted average number of common shares outstanding	19,988,079	8,856,750	15,842,693	8,705,529