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 15, 2023**

Checkpoint Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38128**	**47-2568632**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

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-2(b) 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 Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value 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 18, 2023, Checkpoint Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has issued a complete response letter ("CRL") for cosibelimab. The CRL only cites findings that arose during a multi-sponsor inspection of the Company's third-party contract manufacturing organization as approvability issues to address in a resubmission.

A copy of the Company's press release is furnished herewith as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Checkpoint Therapeutics, Inc., dated December 18, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

Date: December 18, 2023

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

U.S. Food and Drug Administration Issues Complete Response Letter for Cosibelimab Solely Due to Inspection Findings at Third-Party Manufacturer

FDA did not state any concerns about the clinical data package, safety, or labeling for the approvability of cosibelimab

Waltham, MA – December 18, 2023 – Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), today announced that the U.S. Food and Drug Administration ("FDA") has issued a complete response letter ("CRL") for the cosibelimab biologic license application ("BLA") for the treatment of patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or radiation. The CRL only cites 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.

"As the only deficiencies relate to the FDA's inspection of our third-party contract manufacturing organization, we believe we can address the feedback in a resubmission to enable marketing approval in 2024," said James Oliviero, President and Chief Executive Officer of Checkpoint. "We are committed to working closely with our third-party manufacturer and the FDA on our resubmission in order to make cosibelimab available to patients living with cSCC."

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 FDA to address the issues raised in the CRL and execute on a quick pathway forward for the approval of cosibelimab in 2024 for the treatment of patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation, and our projections of resubmission 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.

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