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): July 25, 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 8.01. Other Events.

On July 25, 2024, Checkpoint Therapeutics, Inc. issued a press release to announce that the U.S. Food and Drug Administration ("FDA") accepted Checkpoint's resubmission of its Biologics License Application for cosibelimab, its anti-programmed death ligand-1 antibody, as a potential new treatment for adults with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation. The FDA has set a Prescription Drug User Fee Act goal date of December 28, 2024.

A copy of such press release is being furnished as Exhibit 99.1 to this report.

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 July 25, 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: July 25, 2024

Checkpoint Therapeutics, Inc.
(Registrant)

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

Exhibit 99.1

Checkpoint Therapeutics Announces FDA Acceptance of BLA Resubmission of Cosibelimab for the Treatment of Advanced Cutaneous Squamous Cell Carcinoma

- PDUFA goal date of December 28, 2024 set by FDA

Waltham, MA – July 25, 2024 – Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced that the U.S. Food and Drug Administration ("FDA") has accepted for review Checkpoint's resubmission of its Biologics License Application ("BLA") for cosibelimab, its anti-programmed death ligand-1 ("PD-L1") antibody, as a potential new treatment for adults with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or curative radiation. The resubmission has been accepted as a complete response to the FDA's December 2023 complete response letter ("CRL") and the FDA has set a Prescription Drug User Fee Act ("PDUFA") goal date of December 28, 2024.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "We are pleased that the FDA has accepted our BLA resubmission as a complete response after we aligned on our BLA resubmission strategy. We look forward to working closely with the FDA to finalize the review and to the potential opportunity to deliver cosibelimab's unique dual mechanism of action to patients suffering from cSCC."

In December 2023, the FDA issued a CRL for the cosibelimab BLA, which 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.

About Cosibelimab

Cosibelimab is a potential differentiated, high affinity, fully-human monoclonal antibody of IgG1 subtype that directly binds to PD-L1 and blocks the PD-L1 interaction with the programmed death receptor-1 ("PD-1") and B7.1 receptors. Cosibelimab's primary mechanism of action is based on the inhibition of the interaction between PD-L1 and its receptors PD-1 and B7.1, which removes the suppressive effects of PD-L1 on anti-tumor CD8+ T-cells to restore the cytotoxic T cell response. Cosibelimab is potentially differentiated from the currently marketed PD-1 and PD-L1 antibodies through sustained high tumor target occupancy of PD-L1 to reactivate an antitumor immune response and the additional potential benefit of a functional Fc domain capable of inducing antibody-dependent cellular cytotoxicity ("ADCC") for potential enhanced efficacy.

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 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; any facility inspection or re-inspection required for our third party CMO or otherwise during the review process for the BLA; 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 relationship for the commercialization of cosibelimab, if approved, on acceptable terms, if at all; the risk that our third-party CMO will not meet deadlines, and/or comply with applicable regulations; 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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