**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): June 24, 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 June 24, 2024, Checkpoint Therapeutics, Inc. issued a press release to announce it has reached alignment with the Food and Drug Administration on its biologics license application resubmission strategy for cosibelimab.

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 June 24, 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: June 24, 2024

Checkpoint Therapeutics, Inc.
(Registrant)

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

**Exhibit 99.1**

**Checkpoint Therapeutics Announces Alignment with FDA Enabling Upcoming Cosibelimab BLA Resubmission**

**Waltham, MA – June 24, 2024** – Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced it has reached alignment with the Food and Drug Administration ("FDA") on its biologics license application ("BLA") resubmission strategy for cosibelimab. Accordingly, Checkpoint plans to move forward with a mid-year BLA resubmission seeking the U.S. marketing approval for 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.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "We're pleased to have reached alignment with the FDA on our BLA resubmission strategy to potentially address all approvability deficiencies outlined in the complete response letter ("CRL") received last December. We're eager to resubmit our BLA and to potentially bring a new and potentially differentiated immunotherapy treatment option to patients with advanced 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 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 cSCC. 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 reaching alignment with the FDA on our cosibelimab BLA resubmission strategy, our ability to address in a BLA resubmission all approvability deficiencies outlined in the CRL received last December, our ability to work with our third-party CMO and the U.S. 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 resubmission and regulatory review timelines, and 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 our third-party CMO will not pass regulatory inspections or re-inspections, 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.

**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