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): February 27, 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 March 2, 2023, Checkpoint Therapeutics, Inc. (the "Company") issued a press release announcing the U.S. Food and Drug Administration's acceptance for filing of a Biologics License Application for cosibelimab, its investigational anti-PD-L1 antibody, as a treatment for patients with metastatic cutaneous squamous cell carcinoma ("cSCC") or locally advanced cSCC who are not candidates for curative surgery or radiation.

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 March 2, 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: March 2, 2023

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

Checkpoint Therapeutics Announces FDA Filing Acceptance of Biologics License Application for Cosibelimab in Metastatic or Locally Advanced Cutaneous Squamous Cell Carcinoma

Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024
FDA indicates that it does not currently plan to hold an advisory committee meeting

Waltham, MA – March 2, 2023 – 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 filing the Biologics License Application ("BLA") for cosibelimab, Checkpoint's investigational anti-PD-L1 antibody, as a treatment for patients with metastatic cutaneous squamous cell carcinoma ("cSCC") or locally advanced cSCC who are not candidates for curative surgery or radiation. The FDA has set a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024. In its BLA filing acceptance letter, the FDA indicated that no potential filing review issues have been identified, and that an advisory committee meeting to discuss the application is not currently planned.

"The filing acceptance of our BLA is a major milestone for Checkpoint and our promising cosibelimab development program," said James Oliviero, President and Chief Executive Officer of Checkpoint. "We look forward to continuing to work closely with the FDA as we endeavor to bring cosibelimab to patients in need as quickly as possible. I would like to thank the patients and physicians who participated in the cosibelimab clinical studies, as well as our team for their hard work and dedication in achieving this important milestone."

Mr. Oliviero continued, "According to U.S. prescription claims data, in 2021, approximately 11,000 cSCC patients were treated with systemic therapies. As PD-1 inhibitors comprised less than half of patient prescriptions, cSCC remains a disease with a high need for more effective and tolerable treatment options, particularly for the significant number of cSCC patients with immunosuppressive conditions or autoimmune diseases. With its unique mechanism of action and compelling safety profile, we believe cosibelimab, if approved, would be uniquely positioned to provide an important new treatment option for cSCC patients that are currently underserved by available therapies."

The BLA submission is supported by the positive results from Checkpoint's registration-enabling clinical trial evaluating cosibelimab in patients with metastatic and locally advanced cSCC. In January 2022, Checkpoint announced that the metastatic cSCC cohort met its primary endpoint, with cosibelimab demonstrating a confirmed objective response rate ("ORR") of 47.4% (95% CI: 36.0, 59.1) based on independent central review of 78 patients enrolled in the cohort using Response Evaluation Criteria in Solid Tumors version 1.1 ("RECIST 1.1") criteria. The pivotal results were subsequently presented at the June 2022 American Society of Clinical Oncology ("ASCO") Annual Meeting. Also in June 2022, Checkpoint announced positive interim results from its locally advanced cSCC cohort, with cosibelimab demonstrating a confirmed ORR of 54.8% (95% CI: 36.0, 72.7) based on independent central review of 31 patients enrolled in the cohort. Based upon subsequent interactions with the FDA, the BLA under review includes both the metastatic and locally advanced cSCC indications.

About Cutaneous Squamous Cell Carcinoma (cSCC)
cSCC is the second most common type of skin cancer in the United States, with an estimated annual incidence of approximately 1.8 million cases according to the Skin Cancer Foundation. Important risk factors for cSCC include chronic ultraviolet exposure and immunosuppressive conditions. While most cases are localized tumors amenable to curative resection, approximately 40,000 cases will become advanced, and an estimated 15,000 people will die from this disease each year. In addition to being a life-threatening disease, cSCC causes significant functional morbidities and cosmetic deformities based on tumors commonly arising in the head and neck region and invading blood vessels, nerves and vital organs such as the eye or ear. The immune-suppressed population represents a challenging target in the treatment of advanced cSCC, as they present with a more aggressive disease and with a higher risk of developing immune-related toxicities from checkpoint inhibitor treatment.

About Cosibelimab
Cosibelimab is a potential best-in-class, high affinity, fully-human monoclonal antibody of IgG1 subtype that directly binds to programmed death ligand-1 ("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 >99% target tumor occupancy to reactivate an antitumor immune response and the additional benefit of a functional Fc domain capable of inducing antibody-dependent cell-mediated cytotoxicity ("ADCC") for potential enhanced efficacy in certain tumor types.

About Checkpoint Therapeutics
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 Biologics License Application ("BLA") for cosibelimab for the treatment of patients with metastatic cutaneous squamous cell carcinoma ("cSCC") 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 approve 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; 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 for the fiscal year ended December 31, 2021, 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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