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 16, 2022**

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-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 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 16, 2022, Checkpoint Therapeutics, Inc. issued a press release announcing positive interim efficacy results from its registration-enabling clinical trial evaluating its anti-PD-L1 antibody, cosibelimab, in patients with locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or radiation. 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 16, 2022.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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 16, 2022

Checkpoint Therapeutics, Inc.
(Registrant)

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

Checkpoint Therapeutics Announces Positive Interim Results from Registration-Enabling Trial of Cosibelimab in Locally Advanced Cutaneous Squamous Cell Carcinoma

- *Objective response rate of 54.8% in patients with locally advanced cSCC, a potential 2nd indication for cosibelimab*
- *Previously met primary endpoint in patients with metastatic cSCC; BLA submission on track for later this year*
- *Company to continue discussions with the FDA on the potential addition of the locally advanced indication to its planned BLA submission*

Waltham, MA – June 16, 2022 – Checkpoint Therapeutics, Inc. (Checkpoint) (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced positive interim efficacy results from its registration-enabling clinical trial evaluating its anti-PD-L1 antibody, cosibelimab, in patients with locally advanced cutaneous squamous cell carcinoma (cSCC) who are not candidates for curative surgery or radiation. The design of the interim analysis incorporated recent feedback from the U.S. Food and Drug Administration (FDA) and is intended to potentially support the approval of cosibelimab in this indication. As of the March 2022 data cutoff, the objective response rate (ORR) determined by independent central review (ICR) in 31 patients was 54.8% (95% CI: 36.0, 72.7), substantially exceeding a clinically meaningful lower bound of the 95% two-sided confidence interval of 25%.

Based on these positive results, Checkpoint intends to continue discussions with the FDA on the potential addition of locally advanced cSCC as a second indication in the planned Biologics License Application (BLA) targeted for submission later this year. Checkpoint previously reported positive top-line data from a cohort of 78 patients with metastatic cSCC in its pivotal trial of cosibelimab.

“These exciting positive interim results in this cohort of patients suggest a potential second indication for cosibelimab in locally advanced cSCC, which, when added to the potential labeling in the metastatic cSCC setting, could double the market opportunity at launch for cosibelimab globally. Locally advanced cSCC occurs when tumors become large or have grown deep into underlying tissues, muscles, or nerves, destroying nearby healthy tissue, but have not yet spread metastatically to the lymph nodes or other distant locations of the body," said James Oliviero, President and Chief Executive Officer of Checkpoint.

“We believe the data generated to date continue to show cosibelimab as a differentiated and potentially best-in-class anti-PD-L1 antibody, leveraging a two-fold mechanism of action to deliver robust efficacy with a potentially more favorable safety profile due to its binding to PD-L1 rather than PD-1, an attribute reported in scientific literature as associated with lower rates of severe or worse adverse events as compared to anti-PD-1 therapy,” continued Oliviero. “Based on this compelling clinical profile, our planned market-disruptive pricing, and our patent protection through at least 2038, we believe cosibelimab has the opportunity to gain meaningful market share in the $32 billion and growing anti-PD-(L)1 class, while significantly lowering the barrier of high out-of-pocket costs patients endure worldwide to access existing premium-priced cancer therapies."

Cosibelimab was licensed by Checkpoint in 2015 from the Dana-Farber Cancer Institute.

About Cutaneous Squamous Cell Carcinoma

Cutaneous squamous cell carcinoma (cSCC) is the second most common type of skin cancer in the United States, with an estimated annual incidence of approximately 1 million cases according to the Skin Cancer Foundation. 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 their disease. 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.

About Cosibelimab

Cosibelimab (formerly referred to as CK-301) 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 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 global, open-label, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma (cSCC) intended to support one or more applications for marketing approval. Following positive topline results in metastatic cSCC, Checkpoint intends to submit a Biologics License Application for this indication later this year. Additionally, the global, randomized Phase 3 (CONTERNO) trial of cosibelimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with non-squamous non-small cell lung cancer is ongoing. 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 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 projections of publication and regulatory submission timelines. Factors that could cause our actual results to differ materially include the following: our ability to successfully deliver the complete dataset from the clinical trial and complete BLA and MAA submissions on schedule as planned; the risk that topline or interim data from our clinical trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints are analyzed; the risk that topline or interim data remains subject to audit and verification procedures that may result in the final data being materially different from the topline 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; the risk that the interim results are not sufficient for inclusion in the initial planned BLA or, if approved, that cosibelimab will not be commercially successful; 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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