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): **September 17, 2020**

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.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(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 September 17, 2020, Checkpoint Therapeutics, Inc. issued a press release announcing updated interim results from its registration-enabling Phase 1 clinical trial of anti-PD-L1 antibody cosibelimab in patients with metastatic cutaneous squamous cell carcinoma. A copy of such press release is being filed as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed herewith:

Exhibit Number	Description
99.1	Press release issued by Checkpoint Therapeutics, Inc., dated September 17, 2020.

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: September 17, 2020

Checkpoint Therapeutics, Inc.
(Registrant)

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

Exhibit 99.1

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

- *51.4% objective response rate and 13.5% complete response rate in half the planned pivotal cohort*
- *Interim results presented at ESMO Virtual Congress 2020*
- *On track to report full top-line results in mid-2021*
- *Potentially favorable safety profile compared to anti-PD-1 therapies*
- *Market-disruptive pricing planned in $25 billion PD-(L)1 market*

New York, NY – September 17, 2020 – Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced updated interim results from the ongoing global, open-label, multicohort, Phase 1 clinical trial of its anti-PD-L1 antibody, cosibelimab, in patients with advanced cancers, including the registration-enabling cohort of patients with metastatic cutaneous squamous cell carcinoma ("mCSCC"). Cosibelimab demonstrated a 51.4% objective response rate ("ORR") and 13.5% complete response rate, which is nearly double the complete response rate observed at the time of previous analysis. This trial, upon successfully meeting the pre-defined endpoints, is intended to support marketing approval application submissions for cosibelimab worldwide. The interim results were presented in an e-poster at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020.

"These exciting new interim results demonstrate the potential best-in-class efficacy and safety profile of cosibelimab. Importantly, the observed ORR and complete response rate in approximately half of the planned pivotal cohort of patients continue to trend higher than the response rates that supported the regulatory approvals of the two currently available anti-PD-1s in mCSCC, which we believe is attributable to cosibelimab's two-fold mechanism of action of engaging both T-cells and natural killers cells to augment its efficacy. These interim results also continue to demonstrate the potential favorable safety profile of cosibelimab versus available anti-PD-1 therapies, with lower observed rates of severe adverse events," said James F. Oliviero, President and Chief Executive Officer of Checkpoint.

"With U.S. patients paying up to 20% of the cost of a drug as coinsurance, many insured patients are responsible for out-of-pocket costs of up to $2,000 per infusion for anti-PD-1 therapy," continued Mr. Oliviero. "Upon approval of cosibelimab, our planned market-disruptive pricing strategy should substantially lower these burdensome out-of-pocket costs, while also enabling more patients to have access to a potentially life-saving immunotherapy cancer treatment that they might not otherwise be able to afford."

"The interim data presented at ESMO is highly encouraging and further confirms the safety and efficacy results seen previously in mCSCC patients treated with cosibelimab," said Professor Philip Clingan, Medical Oncologist at Southern Medical Day Care Centre in Australia and co-principal investigator of the trial. "Cosibelimab's well-tolerated safety profile and early achievement of complete responses seen to date have provided a real benefit to our patients. We look forward to the full cohort results next year and advancing this important treatment option forward."

Summary of Data Presented at ESMO:
The mCSCC cohort of the ongoing trial is evaluating cosibelimab in patients with cutaneous squamous cell carcinoma with nodal and/or distant metastatic disease, with a target enrollment of approximately 75 patients and a primary endpoint of ORR as assessed by independent central review using Response Evaluation Criteria in Solid Tumors (RECIST) 1.1. Patients receive cosibelimab administered as a fixed dose of 800 mg every two weeks or 1200 mg every three weeks until confirmed and worsening disease progression or clinical deterioration, followed by post-treatment follow-up.

As of the interim analysis, 37 mCSCC patients were enrolled and evaluable for efficacy by investigator assessment with at least one post-baseline tumor assessment or discontinued treatment prior. Key efficacy results were as follows:

- 51.4% ORR (95% CI: 34.4, 68.1) per RECIST 1.1.
    - 13.5% of patients achieved a complete response (all confirmed) and 37.8% of patients achieved a partial response (2 pending confirmation at the next scan).
- Median duration of response has not yet been reached, with 84.2% of responses ongoing, with the longest response duration at 24 months (ongoing) at the time of analysis.
- Responses were durable, with 91.7% of eligible responses having a duration of over 6 months.

Tumor response assessments by investigator assessment are summarized in the table below.

Tumor Response by RECIST 1.1	**mCSCC (n=37)**
Best overall response, n (%)	
Complete response	5 (13.5)
Partial response[1]	14 (37.8)
Stable disease	4 (10.8)
Progressive disease	10 (27.0)
Not evaluated/done[2]	4 (10.8)
Objective response rate, % (95% CI)	**51.4 (34.4, 68.1)**
Response ongoing, n (%)	16 (84.2)
Median duration of response, months (min, max)	Not reached (0.3, 24.0)
Patients with duration of response ≥ 6 months, n (%)[3]	11 (91.7)
Median observed time to response, months (range)	1.8 (1.6, 7.7)

Objective response rate = best overall response of complete response or partial response divided by the number of evaluable patients.[1]Two partial responses pending confirmation at next scan. [2]Represents patients who discontinued study without a post-baseline tumor assessment.[3]Proportion excludes 7 patients with ongoing response duration <6 months at time of data analysis.

At the time of analysis, 114 patients with advanced cancers had been treated with cosibelimab and were evaluable for safety. Cosibelimab appeared to be safe and well-tolerated with a potentially favorable safety profile as compared to currently available anti-PD-1 therapies. The most common treatment-related adverse events ("TRAEs") included fatigue (n=17, 14.9%) and rash (n=16, 14.0%), with only 3 patients (2.6%) discontinuing treatment due to a TRAE. Grade ≥3 TRAEs occurred in only 6 patients (5.3%), most commonly anemia and fatigue (each n=2, 1.8%, grade 3 only).

The trial continues to enroll patients, and full top-line results are expected in mid-2021.

A copy of the e-poster presentation is available on the Publications page of the Pipeline section of Checkpoint's website, www.checkpointtx.com.

Additional information on the meeting can be found on the ESMO website, www.esmo.org.

About Cutaneous Squamous Cell Carcinoma
Cutaneous squamous cell carcinoma ("CSCC") is the second most common human cancer in the United States, with an estimated annual incidence of 700,000 cases. While most cases are localized tumors amenable to curative resection, approximately 8% of patients will experience a local recurrence, 5% of patients will develop nodal metastases, and an estimated 2% of patients will die from their disease. Ten-year survival rates are less than 20% for patients with regional lymph-node involvement. For those patients who develop distant metastases, the median survival time is estimated to be less than two years. 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 intended to support one or more applications for marketing approval. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, 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 New York City and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.checkpointtx.com.

Forward-Looking Statements
This press release may contain "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. Such statements include, but are not limited to, any statements relating to our plans to submit one or more Biologics License Applications and seek approvals for cosibelimab, statements regarding the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies, statements relating to the half-life and functional Fc domain of cosibelimab translating into potential enhanced efficacy, statements relating to the timing of the completion of enrollment and full top-line results, statements relating to how long we believe our cash will fund our operations, any statements relating to our growth strategy, product development programs and commercial prospects, and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks that regulatory authorities will not accept an application for approval of cosibelimab based on data from the ongoing Phase 1 study; risks relating to our growth strategy and commercial prospects; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our Securities and Exchange Commission filings. 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.

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