# 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): **April 21, 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.
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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 April 21, 2020, Checkpoint Therapeutics, Inc. issued a press release announcing that the U.S. Patent and Trademark Office has issued a composition of matter patent for anti-PD-L1 antibody cosibelimab. A copy of such press release is being filed as Exhibit 99.1 to this report and incorporated herein by reference.

**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 April 21, 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: April 21, 2020

**Checkpoint Therapeutics, Inc.**
(Registrant)

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

**Exhibit 99.1**


**Checkpoint Therapeutics Announces Issuance of U.S. Composition of Matter Patent for Anti-PD-L1 Antibody Cosibelimab**

- *U.S. patent protection through at least May 2038*
- *Registration-enabling study of cosibelimab in cutaneous squamous cell carcinoma over one-third enrolled*

**New York, NY – April 21, 2020** – Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced that the U.S. Patent and Trademark Office has issued a composition of matter patent for cosibelimab (formerly referred to as CK-301), Checkpoint's high affinity, fully-human IgG1 monoclonal antibody 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. U.S. Patent No. 10,590,199 specifically covers the antibody, cosibelimab, or a fragment thereof, providing protection through at least May 2038, exclusive of any additional patent-term extensions that might become available.

Cosibelimab is currently being studied in an ongoing, multicenter, registration-enabling Phase 1 clinical trial intended to support a potential Biologics License Application ("BLA") submission for the initial indication of metastatic cutaneous squamous cell carcinoma ("CSCC"). Earlier this year, Checkpoint announced that the U.S. Food and Drug Administration had confirmed the registration submission pathway for cosibelimab in CSCC based on the ongoing clinical trial, which is over one-third enrolled. Cosibelimab is potentially differentiated from currently marketed PD-1 and PD-L1 antibodies with a half-life that supports sustained >99% tumor target occupancy and the additional benefit of a functional Fc domain capable of inducing antibody-dependent cell-mediated cytotoxicity ("ADCC") for possible enhanced efficacy in certain tumor types.

"This important issued U.S. patent for cosibelimab affords broad, foundational composition of matter protection for our antibody," said James F. Oliviero, President and CEO of Checkpoint. "We intend to continue expanding and fortifying our intellectual property portfolio for cosibelimab in the U.S. and internationally as we advance toward the completion of our clinical development program in CSCC, which initial indication for cosibelimab offers a $1-2 billion potential market opportunity."

**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 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. PD-L1 is an immune-inhibitory checkpoint molecule expressed on epithelial and vascular endothelial cells, as well as by a number of immune cells, and is utilized by tumor cells as an immune escape mechanism. 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 with a half-life that supports sustained >99% target tumor occupancy 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 potentially differentiated anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts intended to support one or more Biologics License Application submissions. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, CK-101, a third-generation epidermal growth factor receptor ("EGFR") inhibitor, in a Phase 1 clinical trial for the treatment of patients with EGFR mutation-positive non-small cell lung cancer ("NSCLC"). 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 BLAs 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 how long we believe our cash will fund our operations, any statements relating to our growth strategy and product development programs, 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; 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 SEC 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.

**Company Contacts:**
Jaclyn Jaffe and William Begien
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:**
Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com