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 6, 2018**

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.

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 6, 2018, Checkpoint Therapeutics, Inc. (the "Company") issued a press release announcing safety and efficacy data from the Company's Phase 1/2 Clinical Trial of EGFR Inhibitor CK-101. A copy of such press release is being furnished as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

Exhibit Number	Description
99.1	Press release issued by Checkpoint Therapeutics, Inc., dated September 6, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CHECKPOINT THERAPEUTICS, INC.
(Registrant)

Date: September 6, 2018

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

Exhibit 99.1

Checkpoint Therapeutics Announces Encouraging Safety and Efficacy Data from Phase 1/2 Clinical Trial of EGFR Inhibitor CK-101

6 of 8 pts (75%) ORR in treatment-naïve EGFR mutation-positive NSCLC patients

Well-tolerated with unremarkable safety profile; No DLTs or related SAEs

Phase 3 trial in treatment-naïve EGFR mutation-positive NSCLC patients targeted to commence in 2019

New York, NY – September 6, 2018 – Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), a clinical-stage immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers, today announced positive preliminary safety and efficacy data from an ongoing Phase 1/2 clinical trial of CK-101 (also known as RX518), a third-generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) being evaluated in advanced non-small cell lung cancer (NSCLC). The data will be presented on Monday, Sept. 24, at 10:30 a.m. ET in a late-breaking oral presentation at the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer in Toronto.

"These preliminary data demonstrate CK-101 is well-tolerated at the doses tested while also demonstrating encouraging anti-tumor activity, particularly in treatment-naïve EGFR mutation-positive lung cancer patients," said Melissa L. Johnson, M.D., Associate Director, Lung Cancer Research, Sarah Cannon Research Institute at Tennessee Oncology, PLLC, and study chair of the Phase 1/2 trial.

"The data to date demonstrate CK-101's potential to be a highly effective mutant-selective EGFR inhibitor with the potential for a differentiated safety profile," said James F. Oliviero, President and Chief Executive Officer of Checkpoint Therapeutics. "We look forward to continuing to advance CK-101 towards a pivotal Phase 3 trial next year, positioning CK-101 to potentially be only the second third-generation EGFR inhibitor to enter the market."

The first-in-human, multicenter trial is evaluating CK-101 in NSCLC patients with EGFR mutations and other advanced malignancies (NCT02926768). Following dose escalation ranging from 100 mg to 1,200 mg/day in patients with any solid tumor where targeted EGFR was deemed reasonable, a first dose-expansion cohort was enrolled at 400 mg twice daily in patients with a confirmed diagnosis of either (1) EGFR mutation-positive advanced or metastatic NSCLC without prior exposure to EGFR-TKI therapy, or (2) T790M-positive advanced or metastatic NSCLC with disease progression on previous EGFR-TKI therapy. There was no limit on the number of prior lines of systemic therapy patients received prior to entering the study.

Key Data from the Abstract

As of June 2018, 37 patients had been treated with CK-101 in dose escalation and dose-expansion cohorts and were evaluable for safety.

- No dose limiting toxicities (DLTs) or treatment-related serious adverse events (SAEs) were reported.
- The most common drug-related treatment-emergent adverse events (>10%) included nausea (16%), diarrhea (14%), lacrimation increased (14%) and vomiting (11%).

In dose-expansion, 19 EGFR mutation-positive NSCLC patients were treated with CK-101 at a dose of 400 mg twice daily and were evaluable for response (RECIST v1.1). Eight patients achieved a partial response (7 confirmed, 1 pending). Additional efficacy findings include:

- In eight treatment-naïve patients, six patients (75%) achieved a partial response.
- In six patients with brain metastases present at baseline, three patients achieved a partial response.
- Higher drug exposures were associated with a higher response rate with a confirmed objective response rate (ORR) of 55% (6/11) in patients achieving a maximum serum concentration (Cmax) greater than 400 ng/mL.
- 100% (19/19) disease control rate was observed, with 84% (16/19) of patients experiencing target lesion reduction versus baseline.
- Median duration of response and progression-free survival were not reached as of the data cutoff.

Enrollment in the trial is ongoing to identify the optimal dose to maximize therapeutic effect.

Oral Presentation

Details of the oral presentation at the IASLC 19th World Conference on Lung Cancer are as follows:

Title: CK-101 (RX518), a Third Generation Mutant-Selective Inhibitor of EGFR in NSCLC: Results of an Ongoing Phase I/II Trial
Date / Time: Monday, Sept. 24, 2018 at 10:30am
Session: Novel Therapies in ROS1, HER2 and EGFR
Presenter: Melissa L. Johnson, M.D., Associate Director, Lung Cancer Research, Sarah Cannon Research Institute at Tennessee Oncology, Nashville, Tenn.

The full abstract can be found on theconference website and is also available on the Publications page in the Pipeline section of Checkpoint's website,www.checkpointtx.com.

About CK-101

CK-101 (also known as RX518) is an oral, third-generation, irreversible kinase inhibitor against selective mutations in the EGFR gene. Activating mutations in the tyrosine kinase domain of EGFR, such as L858R and exon 19 deletion, are found in approximately 20 percent of patients with advanced non-small cell lung cancer (NSCLC).

Compared to chemotherapy, first-generation EGFR inhibitors significantly improved objective response rate and progression-free survival in previously untreated NSCLC patients carrying EGFR mutations. However, tumor progression could develop due to resistance mutations, often within months of treatment with first-generation EGFR inhibitors. The EGFR T790M "gatekeeper" mutation is the most common resistance mutation found in patients treated with first-generation EGFR inhibitors. The mutation decreases the affinity of first-generation inhibitors to EGFR kinase domain, rendering the drugs ineffective. Second-generation EGFR inhibitors have improved potency against the T790M mutation, but have not provided meaningful benefits in NSCLC patients due to toxicity from also inhibiting wild-type EGFR. Third-generation EGFR inhibitors are designed to be highly selective against both EGFR-TKI-sensitizing and resistance mutations, with minimal activity on wild-type EGFR, thereby improving tolerability and safety profiles.

Checkpoint Therapeutics is developing CK-101 for the treatment of NSCLC patients carrying the susceptible EGFR mutations. These include the EGFR T790M mutation in second-line NSCLC patients, as well as the EGFR L858R and exon 19 deletion mutations in first-line NSCLC patients.

Checkpoint holds an exclusive worldwide license (except with respect to certain Asian countries) to CK-101, which it acquired from NeuPharma, Inc., in 2015.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. ("Checkpoint") is a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, CK-101, in a Phase 1/2 clinical trial for the treatment of patients with EGFR mutation-positive non-small cell lung cancer (NSCLC). In addition, Checkpoint is currently evaluating its lead antibody product candidate, CK-301, an anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in a Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers. Checkpoint plans to develop CK-301 as a treatment for patients with NSCLC and other solid tumors. Checkpoint, a Fortress Biotech company, is headquartered in New York City. For more information, visit www.checkpointtx.com.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") (NASDAQ: FBIO) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensing arrangements, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit www.fortressbiotech.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 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 relating to our growth strategy; our ability to identify doses of CK-101 that increase drug exposure at safe levels; our ability to commence a Phase 3 trial for CK-101 in 2019; 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.

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