

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 27, 2016

CHECKPOINT THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

000-55506

(Commission
File Number)

47-2568632

(IRS Employer
Identification No.)

2 Gansevoort Street, 9th Floor, New York, New York

(Address of Principal Executive Offices)

10014

(Zip Code)

Registrant's Telephone Number, Including Area Code: **(781) 652-4500**

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))
-

Item 4.01. Changes in Registrant's Certifying Accountant.

- (a) Previous independent registered public accounting firm.

On September 27, 2016, Checkpoint Therapeutics, Inc. (the "Company") dismissed EisnerAmper LLP ("EisnerAmper") as the Company's independent registered public accounting firm. The Company's Audit Committee participated in and approved this decision.

The reports of EisnerAmper on the consolidated financial statements of the Company for the fiscal year ended December 31, 2015 and the fiscal period from November 10, 2014 (inception) to December 31, 2014, did not contain an adverse opinion or a disclaimer of opinion, nor were such reports qualified or modified as to uncertainty, audit scope, or accounting principles.

During the Company's fiscal year ended December 31, 2015 and the fiscal period from November 10, 2014 (inception) to December 31, 2014, and through September 27, 2016, the Company did not have any disagreements with EisnerAmper on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of EisnerAmper, would have caused it to make reference to the subject matter of the disagreements in connection with its reports on the consolidated financial statements for such time periods.

During the Company's fiscal year ended December 31, 2015 and the fiscal period from November 10, 2014 (inception) to December 31, 2014, and through September 27, 2016, no "reportable events" as defined in Item 304(a)(1)(v) of Regulation S-K have occurred.

EisnerAmper has indicated to the Company that it concurs with the foregoing statements contained in the second, third and fourth paragraphs above as they relate to EisnerAmper and has furnished a letter to the Securities and Exchange Commission to this effect. A copy of the letter from EisnerAmper is attached to this Form 8-K as Exhibit 16.1.

The Company will retain BDO USA, LLP ("BDO") as its new independent registered public accounting firm and will file an additional Current Report on Form 8-K when it formally engages BDO.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(c) On September 27, 2016, the Company and Mr. James F. Oliviero III entered into an amendment (the "Amendment") to Mr. Oliviero's Executive Employment Agreement, dated October 13, 2015. Pursuant to the Amendment, Mr. Oliviero opted to voluntarily delay the vest of 83,333 shares of Company common stock, \$0.0001 par value, on October 13, 2016 until October 13, 2017. The foregoing summary of the Amendment is qualified in its entirety by the copy of such agreement filed as Exhibit 10.1 hereto and incorporated by reference.

Item 8.01. Other Events.

On October 3, 2016, the Company issued a press release announcing that the first patient had been dosed in a Phase 1/2 clinical study of CK-101, its novel, oral, third-generation epidermal growth factor receptor inhibitor product candidate. The Phase 1 dose escalation portion of the study will evaluate the safety and tolerability of ascending doses of CK-101 in patients with advanced solid tumors to determine the maximum tolerated dose and/or recommended Phase 2 dose of CK-101. A copy of the press release is being filed as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 10.1 | Amendment No. 1, dated September 27, 2016, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III. |
| 16.1 | Letter from EisnerAmper LLP to the Securities and Exchange Commission dated October 3, 2016. |
| 99.1 | Press Release, dated October 3, 2016. |

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 thereunto duly authorized.

CHECKPOINT THERAPEUTICS, INC.

Date: October 3, 2016

/s/ James F. Oliviero

Name: James F. Oliviero

Title: President and Chief Executive Officer

INDEX TO EXHIBITS

| Exhibit Number | Description |
|---------------------------|--|
| 10.1 | Amendment No. 1, dated September 27, 2016, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III. |
| 16.1 | Letter from EisnerAmper LLP to the Securities and Exchange Commission dated October 3, 2016. |
| 99.1 | Press Release, dated October 3, 2016. |

AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

Amendment (this "Amendment") dated as of September 27, 2016 to the Executive Employment Agreement (the "Agreement") dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. (the "Company" or "Checkpoint") and James F. Oliviero III ("Oliviero"). All capitalized terms not otherwise defined herein shall have the meanings given to them in the Agreement.

WHEREAS, on October 13, 2015, Oliviero received a grant of 1,000,000 restricted shares of Checkpoint common stock, \$0.0001 par value, and pursuant to the Agreement 333,333 of such shares (the "Shares") are set to vest over time in four equal annual installments beginning on the Effective Date;

WHEREAS, on September 27, 2016, Oliviero and the Company agreed to amend the vesting schedule in the Agreement;

WHEREAS, the Company believes that it is in its best interest to amend the vesting schedule in the Agreement; and

WHEREAS, the Company and Oliviero have agreed to amend the Agreement.

NOW THEREFORE, in consideration of the foregoing and of the mutual covenants hereinafter set forth, the parties agree as follows:

1. Amendments.

Section 3.4.3 of the Agreement with regard to the Shares shall be amended by deleting the phrase "One-third of the Shares will vest over time in four equal annual installments beginning on the Effective Date. One-third of the Shares will vest in three equal parts based on the Company's achievement of fully-diluted Market Capitalization of \$250,000,000, \$500,000,000, and \$750,000,000 respectively. For purposes of this Agreement, "**Market Capitalization**" shall be determined by multiplying the total shares of the Company's common stock that are outstanding (including common stock issuable upon conversion, exchange or exercise of any derivative security, including without limitation, options, warrants, convertible equity or debt or restricted equity) by the last reported closing price of the Company's common stock on a nationally recognized exchange or in the over-the-counter market. The final third will vest in two equal installments as follows: (i) one installment will vest upon the earlier of (A) the Company's first Corporate Development Transaction (as defined below) or (B) the first FDA approval of a Company product or medical device, and (ii) the second installment will vest upon the earlier of (A) the Company's second Corporate Development Transaction (as defined below) or (B) a second FDA approval of a Company product or medical device" and inserting the following:

The Shares will vest over time pursuant to the following schedule:

| <u>Vesting Date</u> | <u>Number of Shares Vested</u> |
|--|--------------------------------|
| October 13, 2017 | 166,667 |
| October 13, 2018 | 83,333 |
| October 13, 2019 | 83,333 |
| The first date that the Company achieves a fully-diluted Market Capitalization (as defined in the Employment Agreement) of \$250,000,000 | 111,111 |
| The first date that the Company achieves a fully-diluted Market Capitalization (as defined in the Employment Agreement) of \$500,000,000 | 111,111 |
| The first date that the Company achieves a fully-diluted Market Capitalization (as defined in the Employment Agreement) of \$750,000,000 | 111,111 |
| The earlier to occur of: (A) the Company's first Corporate Development Transaction (as defined in the Employment Agreement) or (B) the first FDA approval of a Company product or medical device | 166,667 |
| The earlier to occur of: (A) the Company's second Corporate Development Transaction (as defined in the Employment Agreement) or (B) a second FDA approval of a Company product or medical device | 166,667 |

For purposes of this Agreement, "**Market Capitalization**" shall be determined by multiplying the total shares of the Company's common stock that are outstanding (including common stock issuable upon conversion, exchange or exercise of any derivative security, including without limitation, options, warrants, convertible equity or debt or restricted equity) by the last reported closing price of the Company's common stock on a nationally recognized exchange or in the over-the-counter market.

2. Effect on the Agreement.

(a) Upon the effectiveness of this Amendment, each reference in the Agreement to "this Agreement" "hereunder", "hereof", "herein" or words of like import shall mean and be a reference to the Agreement as amended hereby.

(b) Except as expressly amended, the Agreement and all other documents and agreements executed and/or delivered in connection therewith, shall remain in full force and effect.

3. Governing Law.

This Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns and shall be governed by and construed in accordance with the laws of the State of New York without regard to its conflict of laws principles.

4. Counterparts.

This Amendment may be executed by the parties hereto in one or more counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same agreement.

IN WITNESS WHEREOF, Checkpoint Therapeutics, Inc. and James F. Oliviero III have executed this Amendment to the Executive Employment Agreement as of the date first written above.

CHECKPOINT THERAPEUTICS, INC.

By: /s/ Michael S. Weiss
Michael S. Weiss
Executive Chairman

/s/ James F. Oliviero III
James F. Oliviero III

Securities and Exchange Commission
Washington, D.C. 20549

Ladies and Gentlemen:

We were previously principal accountants for Checkpoint Therapeutics, Inc. and, under the date of March 23, 2016, except for Note 6 as to which the date is April 26, 2016 and Note 3 and Note 9 as to which the date is July 11, 2016, we reported on the consolidated financial statements of Checkpoint Therapeutics, Inc. as of and for the year ended December 31, 2015 and the fiscal period from November 10, 2014 (inception) to December 31, 2014. On September 27, 2016, we were dismissed. We have read Checkpoint Therapeutics Inc.'s statements included under Item 4.01 of its Form 8-K dated October 3, 2016, and we agree with such statements.

Very truly yours,

/s/ EisnerAmper LLP



Checkpoint Therapeutics Initiates Phase 1/2 Study of CK-101 – A Novel Third-Generation EGFR Inhibitor

New York, NY – October 3, 2016 – Checkpoint Therapeutics, Inc. (“Checkpoint”), a Fortress Biotech (NASDAQ: FBIO) company, today announced that the first patient has been dosed in a Phase 1/2 clinical study of CK-101, its novel, oral, third-generation epidermal growth factor receptor (“EGFR”) inhibitor product candidate.

The Phase 1 dose escalation portion of the study will evaluate the safety and tolerability of ascending doses of CK-101 in patients with advanced solid tumors to determine the maximum tolerated dose and/or recommended Phase 2 dose of CK-101. The Phase 2 portion of the study is planned to evaluate the safety and efficacy of the recommended Phase 2 dose of CK-101 in patients with EGFR T790M mutation-positive non-small cell lung cancer.

“This is a very exciting time for Checkpoint, with the initiation of our first clinical program for a product candidate in our portfolio,” said James F. Oliviero, III, President and CEO of Checkpoint Therapeutics. “We believe there is a need for additional treatment options for non-small cell lung cancer patients with the EGFR T790M mutation. We look forward to moving the CK-101 clinical program forward, with the goal of developing CK-101 both as a monotherapy and in combination with our portfolio of immuno-oncology agents.”

Checkpoint holds an exclusive worldwide license (except with respect to certain Asian countries) to CK-101 (also known as RX518), which it acquired from NeuPharma, Inc. in 2015.

About the CK-101-101 Study

Study CK-101-101 is a first-in-human, two-part, open-label, safety, pharmacokinetic, and efficacy study of CK-101 administered daily as a single-agent in ascending doses in patients with advanced solid tumor cancer, followed by a Phase 2 portion at the recommended Phase 2 dose in previously treated non-small cell lung cancer patients who have documented evidence of the EGFR T790M mutation and have failed treatment with a first-line EGFR inhibitor. The Phase 2 portion of the study is expected to enroll approximately 60 patients, and the primary endpoint is objective response rate.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. (“Checkpoint”), a Fortress Biotech company, is an innovative, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel, non-chemotherapy, immune-enhanced combination treatments for patients with solid tumor cancers. Checkpoint aims to acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently, Checkpoint is developing a portfolio of fully human immuno-oncology targeted antibodies generated in the laboratory of Dr. Wayne Marasco, MD, PhD, a professor in the Department of Cancer Immunology and AIDS at the Dana-Farber Cancer Institute (“Dana-Farber”). The portfolio of antibodies Checkpoint licensed from Dana-Farber includes antibodies targeting Programmed death-ligand 1 (“PD-L1”), Glucocorticoid-induced TNFR related protein (“GITR”) and carbonic anhydrase IX (“CAIX”). Checkpoint plans to develop these novel immuno-oncology and checkpoint inhibitor antibodies on their own and in combination with each other, as data suggests that combinations of these targets may work synergistically together. Checkpoint has also licensed and is developing three oral, small molecule, targeted anti-cancer agents, consisting of an inhibitor of epidermal growth factor receptor (“EGFR”) mutations, an inhibitor of the bromodomain and extra-terminal (“BET”) protein, BRD4, and an inhibitor of poly (ADP-ribose) polymerase (“PARP”). Checkpoint will also seek to add additional immuno-oncology drugs and other targeted therapies in order to create wholly-owned proprietary combinations that leverage the immune system and complimentary mechanisms. Checkpoint is headquartered in New York City. For more information, visit www.checkpointtx.com.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress plans to develop and commercialize products both within Fortress and through subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress will leverage its biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies achieve their goals. Additionally, Fortress will provide funding and management services to each of the Fortress Companies and, from time to time, Fortress and the Fortress Companies will seek licensing, 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. 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 price. Factors that could cause actual results to differ materially from those currently anticipated are: the risk that Checkpoint will not be able to advance its research programs; risks related to the timing of starting and completing of clinical trials; risks inherent in research and development activities; risks related to its growth strategy; its ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; its dependence on third-party suppliers; its ability to attract, integrate, and retain key personnel; the early stage of products under development; its need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in Checkpoint’s public filings and reports. Checkpoint expressly disclaims 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.

Contact:

Jaelyn Jaffe
Checkpoint Therapeutics, Inc.
781-652-4500; ir@checkpointtx.com
