

Section 1: 8-K (FORM 8-K)

**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): **May 9, 2019**

Checkpoint Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38128
(Commission File Number)

47-2568632
(IRS Employer Identification No.)

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

Securities registered pursuant to Section 12(b) of the 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

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2019, Checkpoint Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the first quarter ended March 31, 2019. 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
<u>99.1</u>	<u>Press release issued by Checkpoint Therapeutics, Inc., dated May 9, 2019.</u>

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: May 9, 2019

Checkpoint Therapeutics, Inc.
(Registrant)

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

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Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1



Checkpoint Therapeutics Reports First Quarter 2019 Financial Results and Recent Corporate Highlights

New York, NY – May 9, 2019 – 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 financial results and recent corporate highlights for the first quarter ended March 31, 2019.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, “We continue to make substantial progress with our lead clinical programs, both of which have recently produced data demonstrating unequivocal activity in patients with multiple forms of cancer, including lung cancer and skin cancer. We presented data late last year in an oral presentation at the World Conference on Lung Cancer demonstrating that CK-101, our novel, oral, third-generation EGFR inhibitor, was active in patients with treatment-naïve and relapsed/refractory EGFR mutation-positive lung cancer. EGFR mutation-positive lung cancer represents approximately 20% of the 228,000 newly-diagnosed lung cancer patients in the US, and there is currently only one third-generation EGFR inhibitor approved for these patients. Our plan is to commence a phase 3 trial in first-line EGFR mutation-positive non-small cell lung cancer later this year.”

Mr. Oliviero continued, “We are also excited by our progress with our anti-PD-L1 program. We announced earlier this year that we advanced cosibelimab (“cosi”, formerly CK-301), our high affinity, fully-human anti-PD-L1 antibody, into potentially pivotal cohorts in several solid tumor indications. This was supported by the positive interim clinical results we announced earlier this month showing anti-tumor activity across multiple advanced cancers. We believe the early data for cosi are very exciting and may show differentiation from other drugs in this class as a result of cosi’s dual mechanism of action through the engagement of both T-cells and NK cells.”

Financial Results:

- **Cash Position:** As of March 31, 2019, Checkpoint’s cash and cash equivalents totaled \$14.1 million. The Company believes its cash and cash equivalents and projected licensing revenue will be sufficient to fund its anticipated operating cash requirements for at least 12 months.
 - **R&D Expenses:** Research and development expenses for the first quarter of 2019 were \$4.6 million, compared to \$6.9 million for the first quarter of 2018, a decrease of \$2.3 million. Research and development expenses for the first quarter of 2019 included \$0.2 million of non-cash stock expenses, compared to \$0.7 million for the first quarter of 2018. The Company expects research and development expenses throughout the rest of 2019 to continue to remain lower than the comparable periods in 2018.
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- **G&A Expenses:** General and administrative expenses for the first quarter of 2019 were \$1.7 million, compared to \$2.2 million for the first quarter of 2018, a decrease of \$0.5 million. General and administrative expenses for the first quarter of 2019 included \$0.6 million of non-cash stock expenses, compared to \$1.1 million for the first quarter of 2018.
- **Net Loss:** Net loss attributable to common stockholders for the first quarter of 2019 was \$5.9 million, or \$0.18 per share, compared to a net loss of \$8.8 million, or \$0.35 per share, for the first quarter of 2018. The net loss for the first quarter of 2019 included \$0.8 million of non-cash stock expenses, compared to \$1.8 million for the first quarter of 2018.

Recent Corporate Highlights:

- In January 2019, Checkpoint announced that the ongoing multi-center clinical trial of anti-PD-L1 antibody cosibelimab was expanded to enroll patients in three endometrial and colorectal cohorts intended to support potential requests for accelerated approval and Biologics License Application (“BLA”) submissions to the U.S. Food and Drug Administration (“FDA”). The ongoing trial is also enrolling cohorts of patients with non-small cell lung cancer (“NSCLC”) and cutaneous squamous cell carcinoma.
- In March 2019, Checkpoint announced two new patent issuances by the U.S. Patent and Trademark Office and the European Patent Office for CK-101. The patents cover CK-101 in the U.S. and Europe through at least August 2034, not including any potential patent term extensions.
- In May 2019, Checkpoint announced positive interim safety and efficacy data from its ongoing multicenter Phase 1 clinical trial of cosibelimab. Cosibelimab is a 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. 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 potential enhanced efficacy in certain tumor types. Cosibelimab appeared to be safe and well-tolerated with no dose-limiting toxicities. Objective responses and target lesion reductions were observed across diverse tumor types, particularly in NSCLC and cutaneous squamous cell carcinoma.

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, a third-generation EGFR inhibitor, 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, cosibelimab, an 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. 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 accelerated approvals for cosibelimab, statements regarding the potential differentiation of cosibelimab, 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 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.

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CHECKPOINT THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
	<u>(Unaudited)</u>	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 14,147	\$ 21,995
Prepaid expenses and other assets	1,064	1,372
Other receivables - related party	77	1,532
Total current assets	15,288	24,899
Total Assets	\$ 15,288	\$ 24,899
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 7,407	\$ 12,317
Accounts payable and accrued expenses - related party	803	776
Total current liabilities	8,210	13,093
Total Liabilities	8,210	13,093
Commitments and Contingencies		
Stockholders' Equity		
Common Stock (\$0.0001 par value), 60,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of March 31, 2019 and December 31, 2018	1	1
Common shares, 28,881,756 and 27,076,154 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	3	3
Common stock issuable, 0 and 960,428 shares as of March 31, 2019 and December 31, 2018, respectively	-	1,748
Additional paid-in capital	108,361	105,451
Accumulated deficit	(101,287)	(95,397)
Total Stockholders' Equity	7,078	11,806
Total Liabilities and Stockholders' Equity	\$ 15,288	\$ 24,899

CHECKPOINT THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)
(in thousands, except share and per share amounts)

	For the three months ended March 31,	
	2019	2018
Revenue - related party	\$ 352	\$ 343
Operating expenses:		
Research and development	4,581	6,932
General and administrative	1,703	2,194
Total operating expenses	<u>6,284</u>	<u>9,126</u>
Loss from operations	<u>(5,932)</u>	<u>(8,783)</u>
Other income		
Interest income	42	18
Total other income	<u>42</u>	<u>18</u>
Net Loss	<u>\$ (5,890)</u>	<u>\$ (8,765)</u>
Loss per Share:		
Basic and diluted net loss per common share outstanding	<u>\$ (0.18)</u>	<u>\$ (0.35)</u>
Basic and diluted weighted average number of common shares outstanding	<u>32,243,796</u>	<u>24,751,550</u>

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