
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): **March 15, 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.

Item 2.02. Results of Operations and Financial Condition.

On March 15, 2019, Checkpoint Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the year ended December 31, 2018. 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 March 15, 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: March 15, 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 Full-Year 2018 Financial Results and Recent Corporate Highlights

New York, NY – March 15, 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 full year ended December 31, 2018.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, “During 2018, we continued to advance our lead clinical programs, CK-101, a third-generation epithelial growth factor receptor (“EGFR”) tyrosine kinase inhibitor (“TKI”), and CK-301, a fully human anti-PD-L1 antibody, and presented our first interim clinical data for CK-101 in an oral presentation at the World Conference on Lung Cancer. We look forward to presenting our first interim safety and efficacy data from the ongoing CK-301 study in the second quarter as we continue to enroll potential registration-enabling expansion cohorts in endometrial and colorectal cancers, and plan to initiate a registration trial for CK-101 by year-end.”

- **Cash Position:** As of December 31, 2018, Checkpoint’s cash and cash equivalents totaled \$22.0 million, compared to \$19.2 million at December 31, 2017, an increase of \$2.8 million.
- **R&D Expenses:** Research and development expenses for the year ended December 31, 2018 were \$33.7 million, compared to \$19.1 million for the year ended December 31, 2017, an increase of \$14.6 million.
- **G&A Expenses:** General and administrative expenses for the year ended December 31, 2018 were \$6.6 million, compared to \$5.4 million for the year ended December 31, 2017, an increase of \$1.2 million.
- **Net Loss:** Net loss attributable to common stock holders for the year ended December 31, 2018 was \$36.4 million, or \$1.27 per share, compared to a net loss of \$22.7 million, or \$1.00 per share, for the year ended December 31, 2017.

2018 and Recent Corporate Highlights:

- In March 2018, Checkpoint completed an underwritten public offering that raised net proceeds of \$20.8 million.
- Also in March 2018, Checkpoint completed the dose escalation portion of the ongoing Phase 1 trial of CK-301, a fully human anti-PD-L1 antibody, in selected recurrent or metastatic cancers, and initiated the first dose expansion cohort, which is evaluating an 800 mg dose of CK-301 administered every two weeks.
- In April 2018, preclinical data were presented on Checkpoint’s BET inhibitor, CK-103, at the American Association for Cancer Research (AACR) Annual Meeting. CK-103 demonstrated combinatorial effects in an *in vivo* model with anti-PD-1 antibodies, which may support the development of CK-103 as an anti-cancer agent alone and in combination with CK-301.

- In September 2018, Checkpoint announced interim safety and efficacy data from its Phase 1/2 clinical trial of CK-101, a third-generation EGFR TKI being evaluated in advanced NSCLC. The data were presented in an oral presentation at the International Association for the Study of Lung Cancer (“IASLC”) 19th World Conference on Lung Cancer in Toronto. CK-101 was well tolerated across multiple dose groups and safe. Durable anti-tumor activity was observed, particularly in treatment-naïve EGFR mutation-positive NSCLC patients.
- In October 2018, Checkpoint appointed Christian Béchon to its Board of Directors.
- In January 2019, Checkpoint announced that the ongoing multi-center clinical trial of anti-PD-L1 antibody CK-301 was expanded to enroll patients in three endometrial and colorectal cohorts intended to support requests for accelerated approval and BLA submissions to the FDA. The ongoing trial is also enrolling cohorts of patients with 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.

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, CK-301, 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. 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 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.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 21,995	\$ 19,225
Prepaid expenses and other assets	1,372	1,857
Other receivables - related party	1,532	331
Total current assets	24,899	21,413
Total Assets	\$ 24,899	\$ 21,413
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 12,317	\$ 5,762
Accounts payable and accrued expenses - related party	776	610
Total current liabilities	13,093	6,372
Total Liabilities	13,093	6,372
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 December 31, 2018 and December 31, 2017	1	1
Common shares, 27,076,154 and 18,512,429 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	3	2
Common stock issuable, 960,428 and 591,836 shares as of December 31, 2018 and December 31, 2017, respectively	1,748	2,296
Additional paid-in capital	105,451	71,772
Accumulated deficit	(95,397)	(59,030)
Total Stockholders' Equity	11,806	15,041
Total Liabilities and Stockholders' Equity	\$ 24,899	\$ 21,413

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

	For the year ended December 31,	
	2018	2017
Revenue - related party	\$ 3,506	\$ 1,725
Operating expenses:		
Research and development	33,654	19,081
General and administrative	6,592	5,419
Total operating expenses	40,246	24,500
Loss from operations	(36,740)	(22,775)
Other income		
Interest income	148	98
Other income	225	-
Total other income	373	98
Net Loss	\$ (36,367)	\$ (22,677)
Loss per Share:		
Basic and diluted net loss per common share outstanding	\$ (1.27)	\$ (1.00)
Basic and diluted weighted average number of common shares outstanding	28,553,711	22,618,931

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