
**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 6, 2021**

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, 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 (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))

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 2.02. Results of Operations and Financial Condition.

On May 6, 2021, 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, 2021. 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> 104	<u>Press release issued by Checkpoint Therapeutics, Inc., dated May 6, 2021.</u> Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 6, 2021

Checkpoint Therapeutics, Inc.
(Registrant)

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



Checkpoint Therapeutics Reports First Quarter 2021 Financial Results and Recent Corporate Highlights

New York, NY – May 6, 2021 – Checkpoint Therapeutics, Inc. (“Checkpoint”) (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced financial results for the first quarter ended March 31, 2021, and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, stated, “During the first quarter of 2021, we continued to advance the development of our two lead drug candidates while also enhancing our cash position. Enrollment in our registration-enabling study for cosibelimab in metastatic cutaneous squamous cell carcinoma (“mCSCC”) is nearly complete and the study remains on track to report top-line results by year-end. With a successful study, we anticipate submitting our first application for marketing approval for cosibelimab next year.”

Mr. Oliviero continued, “Additionally, our collaboration partner in Asia for olafertinib (CK-101), Neupharma Inc., continues to enroll patients as planned into a Phase 3, registration-enabling study in first-line, EGFR mutation-positive locally advanced or metastatic non-small cell lung cancer (“NSCLC”). We intend to meet with the FDA to discuss the ongoing Phase 3 study design and its potential use to support a New Drug Application submission in the United States.”

Recent Corporate Highlights:

- In March 2021, Checkpoint announced the formation of a Scientific Advisory Board comprised of industry thought leaders. Members include Wayne A. Marasco, M.D., Ph.D., Roy S. Herbst, M.D., Ph.D., F. Stephen Hodi, Jr., M.D., Bruce E. Johnson, M.D., David Miller, M.D., Ph.D., and Emily Ruiz, M.D., M.P.H.
- During the first quarter of 2021, Checkpoint raised \$23.9 million of net proceeds from the utilization of the Company’s At-the-Market Issuance Sales Agreement at an average price of \$3.50.

Financial Results:

- **Cash Position:** As of March 31, 2021, Checkpoint’s cash and cash equivalents totaled \$60.0 million, compared to \$40.8 million at December 31, 2020, an increase of \$19.2 million.
- **R&D Expenses:** Research and development expenses for the first quarter of 2021 were \$4.2 million, compared to \$2.6 million for the first quarter of 2020, an increase of \$1.6 million. Research and development expenses for the first quarter of 2021 included \$0.2 million of non-cash stock expenses, compared to \$0.1 million in the first quarter of 2020.

-
- **G&A Expenses:** General and administrative expenses for the first quarter of 2021 were \$2.4 million, compared to \$1.7 million for the first quarter of 2020, an increase of \$0.7 million. General and administrative expenses for the first quarter of 2021 included \$1.2 million of non-cash stock expenses, compared to \$0.5 million for the first quarter of 2020.
 - **Net Loss:** Net loss attributable to common stockholders for the first quarter of 2021 was \$6.5 million, or \$0.09 per share, compared to a net loss of \$3.3 million, or \$0.06 per share, in the first quarter of 2020. Net loss for the first quarter of 2021 included \$1.4 million of non-cash stock expenses, compared to \$0.6 million for the first quarter of 2020.

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 potential best-in-class anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing global, open-label, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma intended to support one or more applications for marketing approval. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, CK-101, a third-generation epidermal growth factor receptor (“EGFR”) inhibitor, as a potential new treatment for patients with EGFR mutation-positive non-small cell lung cancer. 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 Biologics License Applications 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-L1 therapies, statements relating to the half-life and functional Fc domain of cosibelimab translating into potential enhanced efficacy, statements relating to the timing of the completion of enrollment and full top-line results, statements relating to how long we believe our cash will fund our operations, any statements relating to our growth strategy, product development programs and commercial prospects, 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 and commercial prospects; 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 Securities and Exchange Commission 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, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Company Contacts:

Jaclyn Jaffe and Bill 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:

Eddie Kraft
 Affect
 (212) 398-9680
ekraft@affect.com

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

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
	<u>(Unaudited)</u>	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 60,033	\$ 40,772
Prepaid expenses and other assets	1,329	1,804
Other receivables - related party	68	20
Total current assets	<u>61,430</u>	<u>42,596</u>
Total Assets	\$ 61,430	\$ 42,596
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 6,076	\$ 6,367
Accounts payable and accrued expenses - related party	1,179	850
Total current liabilities	<u>7,255</u>	<u>7,217</u>
Total Liabilities	7,255	7,217
Commitments and Contingencies		
Stockholders' Equity		
Common Stock (\$0.0001 par value), 95,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of March 31, 2021 and December 31, 2020	1	1
Common shares, 72,163,822 and 62,420,439 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	7	6
Common stock issuable, 0 and 1,742,449 shares as of March 31, 2021 and December 31, 2020, respectively	-	4,617
Additional paid-in capital	203,864	173,947
Accumulated deficit	(149,697)	(143,192)
Total Stockholders' Equity	<u>54,175</u>	<u>35,379</u>
Total Liabilities and Stockholders' Equity	\$ 61,430	\$ 42,596

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

	<u>For the three months ended</u>	
	<u>March 31,</u>	
	<u>2021</u>	<u>2020</u>
Revenue - related party	\$ 68	\$ 972
Operating expenses:		
Research and development	4,213	2,635
General and administrative	2,373	1,678
Total operating expenses	<u>6,586</u>	<u>4,313</u>
Loss from operations	<u>(6,518)</u>	<u>(3,341)</u>

Other income		
Interest income	13	60
Total other income	13	60
Net Loss	\$ (6,505)	\$ (3,281)
Loss per Share:		
Basic and diluted net loss per common share outstanding	\$ (0.09)	\$ (0.06)
Basic and diluted weighted average number of common shares outstanding	70,303,387	50,875,476
