
**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): **November 4, 2020**

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 November 4, 2020, Checkpoint Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 30, 2020. 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
99.1	Press release issued by Checkpoint Therapeutics, Inc., dated November 4, 2020.
104	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: November 4, 2020

Checkpoint Therapeutics, Inc.
(Registrant)

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



Checkpoint Therapeutics Reports Third Quarter 2020 Financial Results and Recent Corporate Highlights

New York, NY – November 4, 2020 – Checkpoint Therapeutics, Inc. (“Checkpoint”) (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers, today announced financial results for the third quarter ended September 30, 2020, and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, “We are excited to have presented updated positive interim results from the ongoing registration-enabling clinical trial of cosibelimab for the treatment of metastatic cutaneous squamous cell carcinoma (“mCSCC”) at the European Society for Medical Oncology (“ESMO”) Virtual Congress 2020. These compelling data underscore cosibelimab’s potential to be best-in-class. We expect to complete enrollment of the registration-enabling cohort in mCSCC in early 2021 and anticipate reporting top-line results in the second half of the year. Based on our planned pricing strategy, we believe cosibelimab can be a market-disruptive product in the \$25 billion PD-(L)1 class. Importantly, in order to support the continued development of cosibelimab, as well as our broader oncology pipeline, we expanded our cash runway through the successful completion of a \$20.5 million financing during the third quarter.”

Recent Corporate Highlights:

- In September 2020, Checkpoint announced updated positive interim results from the ongoing global, open-label, multicohort, Phase 1 clinical trial of its anti-PD-L1 antibody, cosibelimab, in patients with advanced cancers, including the registration-enabling cohort of patients with mCSCC. Cosibelimab demonstrated a 51.4% objective response rate (“ORR”) and 13.5% complete response rate, which is nearly double the complete response rate observed at the time of previous analysis. These interim data were presented at the ESMO Virtual Congress 2020.
- In September 2020, Checkpoint closed on gross total of approximately \$20.5 million in an underwritten public offering of its common stock before deducting underwriting discounts and commissions and other offering-related expenses.
- Earlier this month, Checkpoint announced the expansion of a long-term manufacturing partnership for cosibelimab with Samsung Biologics. Building upon an existing contract manufacturing agreement entered into in 2017, Samsung Biologics will provide additional commercial-scale drug substance manufacturing for cosibelimab.

Financial Results:

- **Cash Position:** As of September 30, 2020, Checkpoint’s cash and cash equivalents totaled \$42.0 million, compared to \$26.1 million as of December 31, 2019, an increase of \$15.9 million year-to-date.
 - **R&D Expenses:** Research and development expenses for the third quarter of 2020 were \$2.5 million, compared to \$3.9 million for the third quarter of 2019, a decrease of \$1.4 million. Research and development expenses for the third quarters of 2020 and 2019 each included \$0.2 million of non-cash stock expenses.
 - **G&A Expenses:** General and administrative expenses for the third quarter of 2020 were \$2.4 million, compared to \$1.6 million for the third quarter of 2019, an increase of \$0.8 million. General and administrative expenses for the third quarter of 2020 included \$1.3 million of non-cash stock expenses, compared to \$0.7 million in stock compensation expense for the third quarter of 2019.
 - **Net Loss:** Net loss attributable to common stockholders for the third quarter of 2020 was \$4.9 million, or \$0.09 per share, compared to a net loss of \$5.2 million, or \$0.15 per share, in the third quarter of 2019.
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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-1 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 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 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; 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.

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

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
	<u>(Unaudited)</u>	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 42,029	\$ 26,077
Prepaid expenses and other assets	588	863
Other receivables - related party	28	26
Total current assets	42,645	26,966
Total Assets	\$ 42,645	\$ 26,966
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,665	\$ 7,257
Accounts payable and accrued expenses - related party	755	862
Total current liabilities	6,420	8,119
Total Liabilities	6,420	8,119
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 September 30, 2020 and December 31, 2019	1	1
Common shares, 60,883,303 and 47,004,764 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	6	5
Common stock issuable, 0 and 1,459,305 shares as of September 30, 2020 and December 31, 2019, respectively	-	2,510
Additional paid-in capital	169,185	136,442
Accumulated deficit	(132,967)	(120,111)
Total Stockholders' Equity	36,225	18,847
Total Liabilities and Stockholders' Equity	\$ 42,645	\$ 26,966

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

	For the three months ended September		For the nine months ended September	
	30,		30,	
	2020	2019	2020	2019
Revenue - related party	\$ 28	\$ 280	\$ 1,042	\$ 1,683
Operating expenses:				
Research and development	2,543	3,894	8,207	12,595
General and administrative	2,429	1,620	5,794	5,081
Total operating expenses	4,972	5,514	14,001	17,676
Loss from operations	(4,944)	(5,234)	(12,959)	(15,993)
Other income				
Interest income	14	28	103	105
Total other income	14	28	103	105
Net Loss	\$ (4,930)	\$ (5,206)	\$ (12,856)	\$ (15,888)
Loss per Share:				
Basic and diluted net loss per common share outstanding	\$ (0.09)	\$ (0.15)	\$ (0.24)	\$ (0.48)
Basic and diluted weighted average number of common shares outstanding	56,405,734	34,561,844	53,040,215	33,178,567