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

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

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# FORM 8-K

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**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of the**
**Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **August 8, 2019**

# Checkpoint Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

| **Delaware** | **001-38128** | **47-2568632** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (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.
☐ 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.

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 August 8, 2019, Checkpoint Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the second quarter ended June 30, 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 |
|---|---|
| 99.1 | Press release issued by Checkpoint Therapeutics, Inc., dated August 8, 2019. |

**SIGNATURES**

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.

**CHECKPOINT THERAPEUTICS, INC.**
(Registrant)

Date: August 8, 2019

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

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(Back To Top)

# Section 2: EX-99.1 (EXHIBIT 99.1)

**Exhibit 99.1**


**Checkpoint Therapeutics Reports Second Quarter 2019 Financial Results and Recent Corporate Highlights**

**New York, NY – August 8, 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 second quarter ended June 30, 2019.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, “During the second quarter, we continued to advance our lead clinical programs toward key interim data readouts expected in the second half of 2019. We look forward to reporting additional clinical data for CK-101, our novel, oral, third-generation epidermal growth factor receptor (“EGFR”) inhibitor, before year-end, with the goal of commencing a Phase 3 clinical trial in first-line EGFR mutation-positive non-small cell lung cancer (“NSCLC”) in 2020. In May, we announced positive interim clinical results for cosibelimab (formerly CK-301), our fully human anti-PD-L1 antibody, showing anti-tumor activity across multiple advanced cancers. The initial data are encouraging and potentially differentiate cosibelimab from other drugs in this class as a result of its dual mechanism of action through engaging both T-cells and NK cells. We intend to announce updated clinical data on cosibelimab later this year.”

**Financial Results:**

- **Cash Position**: As of June 30, 2019, Checkpoint’s cash and cash equivalents totaled $13.2 million. On a non-GAAP basis, pro-forma cash and cash equivalents as of June 30, 2019 (excluding third quarter 2019 operations) totaled approximately $16.2 million, after giving effect to approximately $3.0 million of net proceeds from the utilization of the Company’s At-the-Market Issuance Sales Agreement (the "ATM") during the third quarter of 2019. Checkpoint believes that its cash and cash equivalents and projected licensing revenue, along with the additional capital raised in the third quarter of 2019, will be sufficient to fund its anticipated operating cash requirements for at least 12 months.

- **R&D Expenses**: Research and development expenses for the second quarter of 2019 were $4.1 million, compared to $5.5 million for the second quarter of 2018, a decrease of $1.4 million. Research and development expenses for the second quarter of 2019 included $0.2 million of non-cash stock expenses, compared to a credit of $0.4 million in stock compensation expense for the second quarter of 2018. The Company expects that, for the balance of 2019, research and development expenses will continue to remain lower than the comparable periods in 2018.

- **G&A Expenses**: General and administrative expenses for the second quarter of 2019 were $1.8 million, compared to $1.4 million for the second quarter of 2018, an increase of $0.4 million. General and administrative expenses for the second quarter of 2019 included $0.7 million of non-cash stock expenses, compared to $0.5 million for the second quarter of 2018.

- **Net Loss**: Net loss attributable to common stockholders for the second quarter of 2019 was $4.8 million, or $0.15 per share, compared to a net loss of $6.6 million, or $0.23 per share, for the second quarter of 2018. The net loss for the second quarter of 2019 included $0.9 million of non-cash stock expenses, compared to $0.1 million for the second quarter of 2018.

**Recent Corporate Highlights:**

- 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 potentially 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.

- In July 2019, Checkpoint announced that it was added to the Russell 2000® Index.

**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 epidermal growth factor receptor ("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)

| | June 30, 2019 (Unaudited) | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 13,205 | $ 21,995 |
| Prepaid expenses and other assets | 967 | 1,372 |
| Other receivables - related party | 1,051 | 1,532 |
| Total current assets | 15,223 | 24,899 |
| **Total Assets** | **$ 15,223** | **$ 24,899** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | $ 7,093 | $ 12,317 |
| Accounts payable and accrued expenses - related party | 921 | 776 |
| Total current liabilities | 8,014 | 13,093 |
| **Total Liabilities** | **8,014** | **13,093** |
| | | |
| **Commitments and Contingencies** | | |
| | | |
| **Stockholders' Equity** | | |
| Common Stock ($0.0001 par value), 60,000,000 shares authorized | | |
| Class A common shares, 7,000,000 shares issued and outstanding as of June 30, 2019 and December 31, 2018 | 1 | 1 |
| Common shares, 29,960,034 and 27,076,154 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively | 3 | 3 |
| Common stock issuable, 0 and 960,428 shares as of June 30, 2019 and December 31, 2018, respectively | - | 1,748 |
| Additional paid-in capital | 113,284 | 105,451 |
| Accumulated deficit | (106,079) | (95,397) |
| Total Stockholders’ Equity | 7,209 | 11,806 |
| **Total Liabilities and Stockholders’ Equity** | **$ 15,223** | **$ 24,899** |

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

| | For the three months ended June 30, | | For the six months ended June 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Revenue - related party | $ 1,051 | $ 127 | $ 1,403 | $ 470 |
| Operating expenses: | | | | |
| Research and development | 4,120 | 5,453 | 8,701 | 12,385 |
| General and administrative | 1,758 | 1,352 | 3,461 | 3,546 |
| Total operating expenses | 5,878 | 6,805 | 12,162 | 15,931 |
| Loss from operations | (4,827) | (6,678) | (10,759) | (15,461) |
| Other income | | | | |
| Interest income | 35 | 39 | 77 | 57 |
| Total other income | 35 | 39 | 77 | 57 |
| **Net Loss** | **$ (4,792)** | **$ (6,639)** | **$ (10,682)** | **$ (15,404)** |
| **Loss per Share:** | | | | |
| Basic and diluted net loss per common share outstanding | $ (0.15) | $ (0.23) | $ (0.33) | $ (0.57) |
| Basic and diluted weighted average number of common shares outstanding | 32,704,590 | 29,044,962 | 32,475,465 | 26,910,116 |

(Back To Top)