# 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): August 5, 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              | NASDAO 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 5, 2020, 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, 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<br>Number | Description  |
|-------------------|--|
| <u>99.1</u>       | Press release issued by Checkpoint Therapeutics, Inc., dated August 5, 2020. |

# 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: August 5, 2020

**Checkpoint Therapeutics, Inc.** (Registrant)

/s/ James F. Oliviero James F. Oliviero Ву

President and Chief Executive Officer



#### Checkpoint Therapeutics Reports Second Quarter 2020 Financial Results and Recent Corporate Highlights

New York, NY – August 5, 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 second quarter ended June 30, 2020, and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "We continue to advance the development of cosibelimab, our potential best-in-class anti-PD-L1 antibody product candidate, towards the completion of its registration-enabling study in metastatic cutaneous squamous cell carcinoma ("mCSCC"). The trial is currently over 50% enrolled, with full enrollment anticipated around year-end. With a potential favorable safety profile and a plan to commercialize at a substantially lower price, we believe cosibelimab can be a market disruptive product in the \$25 billion PD-(L)1 class." Mr. Oliviero continued, "We look forward to presenting updated interim safety and efficacy data from our ongoing mCSCC trial at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020 that will supplement the encouraging data previously reported, which included a 50% objective response rate for cosibelimab by investigator assessment in the first 14 mCSCC patients, including one complete response."

#### **Recent Corporate Highlights:**

- In July 2020, Checkpoint announced that an abstract highlighting updated interim safety and efficacy data from the ongoing registration-enabling clinical trial of cosibelimab in patients with mCSCC was accepted for e-poster presentation at the ESMO Virtual Congress 2020, to be held September 19-21, 2020.
- In April 2020, Checkpoint announced that the U.S. Patent and Trademark Office issued a composition of matter patent for cosibelimab. U.S. Patent No. 10,590,199 specifically covers the antibody, cosibelimab, or a fragment thereof, providing protection through at least May 2038, exclusive of any additional patent-term extensions that might become available.

#### **Financial Results:**

- Cash Position: As of June 30, 2020, Checkpoint's cash and cash equivalents totaled \$21.9 million, compared to \$26.1 million as of December 31, 2019, a decrease of \$4.2 million year-to-date. Cash and cash equivalents as of June 30, 2020 does not include approximately \$5.0 million of net proceeds from the utilization of the Company's At-the-Market Issuance Sales Agreement during the third quarter of 2020.
- **R&D** Expenses: Research and development expenses for the second quarter of 2020 were \$3.0 million, compared to \$4.1 million for the second quarter of 2019, a decrease of \$1.1 million. Research and development expenses for the second quarters of 2020 and 2019 each included \$0.2 million of non-cash stock expenses.
- G&A Expenses: General and administrative expenses for the second quarter of 2020 were \$1.7 million, compared to \$1.8 million for the second quarter of 2019, a decrease of \$0.1 million. General and administrative expenses for the second quarters of 2020 and 2019 each included \$0.7 million of non-cash stock expenses.
- Net Loss: Net loss attributable to common stockholders for the second quarter of 2020 was \$4.6 million, or \$0.09 per share, compared to a net loss of \$4.8 million, or \$0.15 per share, in the second quarter of 2019.

#### **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; competi

#### **Company Contacts:**

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

|   | June 30, 2020<br>(Unaudited) |           | <b>December 31, 2019</b> |           |
|---|------------------------------|-----------|--------------------------|-----------|
| ASSETS  |                              |           |                          |           |
| Current Assets:   |                              |           |                          |           |
| Cash and cash equivalents   | \$                           | 21,924    | \$                       | 26,077    |
| Prepaid expenses and other assets   |                              | 719       |                          | 863       |
| Other receivables - related party   |                              | 42        |                          | 26        |
| Total current assets  |                              | 22,685    |                          | 26,966    |
| Total Assets  | \$                           | 22,685    | \$                       | 26,966    |
| LIABILITIES AND STOCKHOLDERS' EQUITY  |                              |           |                          |           |
| Current Liabilities:  |                              |           |                          |           |
| Accounts payable and accrued expenses   | \$                           | 6,674     | \$                       | 7,257     |
| Accounts payable and accrued expenses - related party   | •                            | 1,037     | ·                        | 862       |
| Total current liabilities   |                              | 7,711     |                          | 8,119     |
| Total Liabilities   |                              | 7,711     |                          | 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 June 30, 2020 and December 31, 2019    |                              | 1         |                          | 1         |
| Common shares, 50,980,004 and 47,004,764 shares issued and outstanding as of June 30, 2020 and December 31, |                              |           |                          |           |
| 2019, respectively  |                              | 5         |                          | 5         |
| Common stock issuable, 0 and 1,459,305 shares as of June 30, 2020 and December 31, 2019, respectively       |                              | -         |                          | 2,510     |
| Additional paid-in capital  |                              | 143,005   |                          | 136,442   |
| Accumulated deficit   |                              | (128,037) |                          | (120,111) |
| Total Stockholders' Equity  | -                            | 14,974    |                          | 18,847    |
| Total Liabilities and Stockholders' Equity  | \$                           | 22,685    | \$                       | 26,966    |

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

|  | For the three months ended June 30, |            |    | For the six months ended June 30, |    |            |    |            |
|--|-------------------------------------|------------|----|-----------------------------------|----|------------|----|------------|
|  |                                     | 2020       |    | 2019                              |    | 2020       |    | 2019       |
| Revenue - related party  | \$                                  | 42         | \$ | 1,051                             | \$ | 1,014      | \$ | 1,403      |
|  |                                     |            |    |                                   |    |            |    |            |
| Operating expenses:  |                                     |            |    |                                   |    |            |    |            |
| Research and development   |                                     | 3,029      |    | 4,120                             |    | 5,664      |    | 8,701      |
| General and administrative   |                                     | 1,687      |    | 1,758                             |    | 3,365      |    | 3,461      |
| Total operating expenses   |                                     | 4,716      |    | 5,878                             |    | 9,029      |    | 12,162     |
| Loss from operations   |                                     | (4,674)    |    | (4,827)                           |    | (8,015)    |    | (10,759)   |
|  |                                     |            |    |                                   |    |            |    |            |
| Other income   |                                     |            |    |                                   |    |            |    |            |
| Interest income  |                                     | 29         |    | 35                                |    | 89         |    | 77         |
| Total other income   |                                     | 29         |    | 35                                |    | 89         |    | 77         |
| Net Loss   | \$                                  | (4,645)    | \$ | (4,792)                           | \$ | (7,926)    | \$ | (10,682)   |
|  |                                     |            |    |                                   |    |            |    |            |
| Loss per Share:  |                                     |            |    |                                   |    |            |    |            |
| Basic and diluted net loss per common share outstanding                | \$                                  | (0.09)     | \$ | (0.15)                            | \$ | (0.15)     | \$ | (0.33)     |
|  |                                     |            |    |                                   |    |            |    |            |
| Basic and diluted weighted average number of common shares outstanding | _                                   | 51,802,451 | _  | 32,704,590                        |    | 51,338,963 | _  | 32,475,465 |