**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 14, 2019**

**TRACON Pharmaceuticals, Inc.**
(Exact name of registrant as specified in its charter)

| **Delaware** | **001-36818** | **34-2037594** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **4350 La Jolla Village Drive, Suite 800 San Diego, California** | **92122** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

**Registrant's telephone number, including area code: (858) 550-0780**

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))

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. ☒

Securities registered pursuant to Section 12(b) of the Securities Act:

| Title of each class | Trading symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.001 per share | TCON | The NASDAQ Stock Market LLC |

**Item 2.02 Results of Operations and Financial Condition.**

On May 14, 2019, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2019. A copy of this press release is furnished as Exhibit 99.1 hereto.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued by TRACON Pharmaceuticals, Inc. on May 14, 2019 announcing its financial results for the quarter ended March 31, 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.

**TRACON Pharmaceuticals, Inc.**

Dated: May 14, 2019

By: /s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
*President and Chief Executive Officer*

**TRACON Pharmaceuticals Reports First Quarter 2019 Financial Results and Provides Corporate Update**

**San Diego, CA – May 14, 2019**– TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, and through our license to Santen Pharmaceutical Co. Ltd., wet age-related macular degeneration, today announced financial results for the first quarter ended March 31, 2019.

**Recent Corporate Highlights**

- In April, we announced termination of further enrollment into company sponsored trials of TRC105 due to lack of efficacy in the Phase 3 TAPPAS trial evaluating TRC105 in combination with Votrient® (pazopanib) in patients with advanced or metastatic angiosarcoma.

"While we were disappointed in the outcome of the TAPPAS interim analysis, we have several other active clinical programs and look forward to developing multiple bispecific antibodies through our broad and long term partnership with I-Mab Biopharma," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We are poised to initiate first-in-human dosing of the CD73 antibody TJ004309 and look forward to 2020 when we expect to begin clinical development of the first of up to five bispecific antibodies. We also continue to evaluate companies with first-in-class or best-in-class clinical stage assets who would benefit from accessing our product development platform, which we believe offers a rapid and capital-efficient U.S. drug development solution."

**Expected Upcoming Milestones**

- Dosing of the first patient in a Phase 1 study of TJ004309 as a single agent and in combination with Tecentriq® (atezolizumab), a PD-L1 checkpoint inhibitor marketed by Roche, in patients with advanced solid tumors is expected mid-2019.
- Publication of TRC253 Phase 1 data in patients with metastatic castrate resistant prostate cancer is expected in the second quarter of 2019.
- Top-line data from the randomized Phase 2 AVANTE trial of DE-122 in patients with wet age-related macular degeneration (AMD) are expected in the first half of 2020.

**First Quarter 2019 Financial Results**

- Cash, cash equivalents and short-term investments were $32.1 million at March 31, 2019, compared to $39.1 million at December 31, 2018. We expect our current cash, cash equivalents and short-term investments to fund operations into the third quarter of 2020.
- Collaboration revenue was $0 for the first quarter of 2019 compared to $3.0 million for the first quarter of 2018. The decrease was due to the $3.0 million non-refundable upfront payment received in connection with our prior agreement with Ambrx, which was recorded as revenue in the first quarter of 2018.

- Research and development expenses for the first quarter of 2019 were $5.2 million compared to $9.4 million for the first quarter of 2018. The decrease was primarily attributable to lower manufacturing expenses for TRC105 in the first quarter of 2019 as compared to the 2018 period.

- General and administrative expenses for the first quarter of 2019 were $1.9 million compared to $1.8 million for the first quarter of 2018.

- Net loss for the first quarter of 2019 was $7.2 million compared to $8.4 million for the first quarter of 2018.

**Investor Conference Call**

The Company will hold a conference call today at 4:30 p.m. EST / 1:30 p.m. PST to provide an update on corporate activities and to discuss the financial results of its first quarter 2019. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 9290299. A live webcast of the conference call will be available online from the Investor/Events and Presentation page of the Company's website at www.traconpharma.com.

After the live webcast, a replay will remain available on TRACON's website for 60 days.

**About DE-122 (carotuximab)**

DE-122, a novel ophthalmic formulation of carotuximab, is active in preclinical choroidal neovascularization (CNV) models and designed to enhance the effect of approved VEGF inhibitors used to treat wet AMD. DE-122 is being investigated in the Phase 2 randomized AVANTE trial assessing the efficacy and safety of intravitreal injections in combination with Lucentis® (ranibizumab) compared to Lucentis monotherapy in patients with wet AMD.

**About TRC253**

TRC253 is a novel, orally bioavailable small molecule that is a potent, high affinity competitive inhibitor of the androgen receptor (AR) and AR mutations, including the F877L mutation. The AR F877L mutation results in an alteration in the AR ligand binding domain that confers resistance to therapies for prostate cancer. Therapies targeting the AR have demonstrated clinical efficacy by extending time to disease progression, and in some cases, the survival of patients with metastatic castration-resistant prostate cancer. However, resistance to these agents is often observed and several molecular mechanisms of resistance have been identified, including gene amplification, overexpression, alternative splicing, and point mutation of the AR. TRC253 is currently being studied in a Phase 1/2 clinical trial in prostate cancer. For more information about the clinical trial, please visit TRACON's website at www.traconpharma.com/clinical_trials.php

**About TJ004309**

TJ004309 is a novel, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to adenosine, which is highly

immunosuppressive. TJ004309 is currently being studied in a Phase 1 trial to assess safety and preliminary efficacy as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq in patients with advanced solid tumors.

**About TRACON**

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company's clinical-stage pipeline includes: DE-122, the ophthalmic formulation of carotuximab that is being developed in wet AMD through a collaboration with Santen Pharmaceutical Company Ltd.; TRC102, a small molecule being developed for the treatment of lung cancer and glioblastoma; TRC253, a small molecule being developed for the treatment of prostate cancer; and TJ004309, a CD73 antibody being developed for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it shares in the cost and risk of clinical development and commercialization of new product candidates. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States. To learn more about TRACON and its product candidates, visit TRACON's website at www.traconpharma.com.

**Forward-Looking Statements**

Statements made in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding TRACON's plans to further develop product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development milestones, estimated cash runway, potential utility of product candidates, potential events under collaboration and license agreements, and TRACON's business development strategy. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON or others will be able to complete or initiate clinical trials on TRACON's expected timelines, if at all; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials or initiate additional trials of TRACON's product candidates; the fact that TRACON's collaboration agreements are subject to early termination; whether and when any bispecific antibodies are developed under TRACON's collaboration with I-Mab; potential changes in regulatory requirements in the United States and foreign countries; TRACON's reliance on third parties for the development of its product candidates, including the conduct of its clinical trials and manufacture of its product candidates; whether TRACON will be able to obtain additional financing; the possibility of unexpected expenses or other uses of TRACON's cash resources; and other risks described in TRACON's filings with the Securities and Exchange Commission under the heading "Risk Factors". All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. TRACON undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

**TRACON Pharmaceuticals, Inc.**
**Unaudited Condensed Consolidated Statements of Operations**
**(in thousands, except share and per share data)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2019** | **2018** |
| Collaboration revenue | $- | $3,000 |
| Operating expenses: | | |
| Research and development | 5,214 | 9,438 |
| General and administrative | 1,949 | 1,751 |
| Total operating expenses | 7,163 | 11,189 |
| Loss from operations | (7,163) | (8,189) |
| Total other expense | (50) | (175) |
| Net loss | $(7,213) | $(8,364) |
| Net loss per share, basic and diluted | $(0.24) | $(0.46) |
| Weighted-average common shares outstanding, basic and diluted | 29,892,007 | 18,214,787 |

**TRACON Pharmaceuticals, Inc.**
**Condensed Consolidated Balance Sheets**
**(in thousands)**

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| **Assets** | **(Unaudited)** | |
| Current assets: | | |
| Cash and cash equivalents | $22,085 | $25,136 |
| Short-term investments | 9,984 | 13,968 |
| Prepaid and other assets | 1,019 | 1,499 |
| Total current assets | 33,088 | 40,603 |
| Property and equipment, net | 38 | 45 |
| Other assets | 1,061 | - |
| Total assets | $34,187 | $40,648 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $11,034 | $10,947 |
| Accrued compensation and related expenses | 714 | 1,464 |
| Long-term debt, current portion | 1,806 | 1,084 |
| Total current liabilities | 13,554 | 13,495 |
| Other long-term liabilities | 1,124 | 368 |
| Long-term debt, less current portion | 4,704 | 5,343 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock | 30 | 30 |
| Additional paid-in capital | 161,648 | 161,072 |
| Accumulated deficit | (146,873) | (139,660) |
| Total stockholders' equity | 14,805 | 21,442 |
| Total liabilities and stockholders' equity | $34,187 | $40,648 |


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