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 13, 2020**

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))

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

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 13, 2020, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2020. 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 13, 2020 announcing its financial results for the quarter ended March 31, 2020.

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 13, 2020

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 2020 Financial Results and Provides Corporate Update

San Diego, CA – May 13, 2020 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted cancer therapeutics and utilizing a cost efficient, CRO-independent product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the U.S., today announced financial results for the first quarter ended March 31, 2020.

Recent Corporate Highlights

- In May, TRACON completed a Type B meeting with the FDA to discuss the pivotal ENVASARC trial design for the potential registration of envafolimab in multiple soft tissue sarcoma subtypes. The FDA agreed with the trial design to enroll separate noncomparative cohorts of 80 patients each with undifferentiated pleomorphic sarcoma (UPS) or myxofibrosarcoma (MFS), with the first cohort receiving single-agent envafolimab and the second cohort receiving envafolimab plus Yervoy (ipilimumab), with the primary endpoint being objective response rate by RECIST by blinded independent radiographic review in each cohort. TRACON expects to initiate dosing of ENVASARC in the second half of 2020, provide interim clinical trial data in 2021, final clinical trial data in 2022, and provided the drug is approved by the US FDA, commercialize envafolimab in 2023.

- In April, TRACON amended its agreement with Aspire Capital Fund, LLC (Aspire Capital) to lower the minimum price of shares sold to be considered at the market purchases for Nasdaq purposes to $1.89 per share. Under the amended agreement, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of our common stock at our request from time to time until June 2022, $14.2 million of which remained available for sale as of March 31, 2020.

- In April, TRACON retained global rights to TRC253 by virtue of Janssen Pharmaceutica N.V.'s decision not to exercise its option to reacquire global rights to TRC253 following a review of the Phase 2 data in prostate cancer patients with acquired resistance to Xtandi or Erleada. TRACON has initiated an out-licensing process to identify a corporate partner to develop and commercialize TRC253 in an earlier line of treatment in China, where the androgen receptor inhibitors Xtandi and Erleada are not widely accessible.

- In April, TRACON entered into a deferral agreement with Silicon Valley Bank to defer principal payments for six months, which is expected to extend TRACON's cash runway further into the first quarter of 2021.

- In March, TRACON's licensee Santen announced the discontinuation of DE-122 development based on top-line data from the Phase 2a AVANTE clinical study that indicated the combination of DE-122 and Lucentis did not improve visual acuity when compared to single-agent Lucentis.

"We are pleased the FDA agreed with our pivotal ENVASARC trial design and endpoints as we believe it can enable a fast to market strategy to provide envafolimab as expeditiously as possible to sarcoma patients in need of a new therapy," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We look forward to the presentation of envafolimab clinical data by our corporate partner, 3D Medicines, at ASCO, enrolling the first

ENVASARC patient in the second half of this year, and potentially becoming a commercial stage company in three years."

Expected Upcoming Milestones

- Receive orphan drug designation for envafolimab in soft tissue sarcoma in the second half of 2020.
- Enroll the first patient in ENVASARC, a pivotal trial in the sarcoma subtypes of UPS and MFS, during the second half of 2020.
- Report top-line data from the Phase 1 dose escalation study of TJ4309, a CD73 antibody, as a single agent and in combination with Tecentriq (a PD-L1 antibody being supplied by Roche), in the second half of 2020.

First Quarter 2020 Financial Results

- Cash and cash equivalents were $14.1 million at March 31, 2020, compared to $16.4 million at December 31, 2019. We expect our current cash and cash equivalents to fund operations into the first quarter of 2021. We believe our cash runway could extend into the third quarter of 2021 if we were to fully utilize the $14.2 million that remains available under the Aspire Capital agreement.
- Research and development expenses for the first quarter of 2020 were $2.0 million, compared to $5.2 million for the first quarter of 2019. The decrease was primarily attributable to lower manufacturing expenses and clinical trial expenses due to the discontinuation of the Phase 3 TRC105 program and lower manufacturing expenses for TRC253.
- General and administrative expenses for the first quarter of 2020 and 2019 were $1.9 million.
- Net loss for the first quarter of 2020 was $4.0 million, compared to $7.2 million for the first quarter of 2019.

Investor Conference Call

The Company will hold a conference call today at 4:30 p.m. EDT / 1:30 p.m. PDT to provide an update on corporate activities and to discuss the financial results of its first quarter 2020. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 6453397. 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 Envafolimab

Envafolimab is a novel, single-domain antibody against PD-L1 that is administered by subcutaneous injection without the need for an adjuvant. Envafolimab is currently dosing in Phase 1 trials in the U.S. and Japan and is

being studied in China in a Phase 2 registration trial as a single agent in MSI-H tumor patients, and in combination with gemcitabine and oxaliplatin in a Phase 3 registration trial in biliary tract cancer. Subject to positive data from the MSI-H registrational trial, 3D Medicines plans to file a BLA in China for envafolimab in 2020 based on overall response rate in MSI-H patients. The filing would be based on the principle that the response rate required for approval in China is similar to the response rates seen with Keytruda and Opdivo in MSI-H patients from separate clinical trials per the U.S. product package inserts.

About TRC253

TRC253 is a novel, orally bioavailable small molecule drug 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 recently completed a Phase 1/2 clinical trial in prostate cancer conducted by TRACON. TRACON believes TRC253 can be developed and commercialized successfully in China and is actively seeking a strategic collaboration.

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 utilizing a capital efficient product development platform. The Company’s clinical-stage pipeline includes: Envafolimab, a subcutaneous PD-L1 single-domain antibody being developed for the treatment of sarcoma with the goal of starting a registrational trial in the U.S. in the second half of 2020; TRC253, a small molecule drug candidate being developed of the treatment of prostate cancer; TRC102, a small molecule drug candidate being developed for the treatment of lung cancer; and TJ004309, a CD73 antibody in Phase 1 development for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads U.S. regulatory and clinical development and shares in the cost and risk of clinical development and leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the U.S. To learn more about TRACON and its product pipeline, 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 and timing thereof, estimated cash runway, potential access to future capital, potential utility of product candidates, potential events, payments and actions under collaboration and license agreements, and TRACON's business development strategy and goals to enter into additional collaborations. 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, including due to risks associated with the COVID-19 pandemic; 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 TRACON will be able to enter into additional collaboration agreements on favorable terms or at all; whether and when any bispecific antibodies are developed under TRACON's collaboration with I-Mab; uncertainty with respect to the outcome of TRACON's disputes 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, including being able to meet the conditions for sales of common stock under TRACON's agreement with Aspire Capital; 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,	
	2020	**2019**
Operating expenses:		
Research and development	$1,998	$5,214
General and administrative	1,886	1,949
Total operating expenses	3,884	7,163
Loss from operations	(3,884)	(7,163
Total other income (expense)	(137)	(50)
Net loss	$(4,021)	$(7,213)
Net loss per share, basic and diluted	$(0.78)	$(2.41)
Weighted-average common shares outstanding, basic and diluted	5,171,351	2,989,251

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

	March 31, 2020	December 31, 2019
Assets	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$14,134	$16,412
Prepaid and other assets	835	848
Total current assets	14,969	17,260
Property and equipment, net	19	23
Other assets	760	838
Total assets	$15,748	$18,121
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$6,911	$7,875
Accrued compensation and related expenses	594	1,355
Long-term debt, current portion	1,267	2,604
Total current liabilities	8,772	11,834
Other long-term liabilities	754	850
Long-term debt, less current portion	3,438	2,739
Commitments and contingencies		
Stockholders' equity:		
Common stock	5	4
Additional paid-in capital	169,134	165,028
Accumulated deficit	(166,355)	(162,334)
Total stockholders' equity	2,784	2,698
Total liabilities and stockholders' equity	$15,748	$18,121

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