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 5, 2021**

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 5, 2021, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2021. 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 5, 2021 announcing its financial results for the quarter ended March 31, 2021.

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.

Date: May 5, 2021

TRACON Pharmaceuticals, Inc.

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

Exhibit 99.1

TRACON Pharmaceuticals Reports First Quarter 2021 Financial Results and Provides Corporate Update

San Diego, CA – May 5, 2021 – 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, 2021. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

"We continue to be pleased with the pace of enrollment in the pivotal ENVASARC trial and remain on track to deliver interim data in the 2nd half of this year and final data in 2022," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We have now initiated 22 sites and have enrolled more than 20 patients which has triggered the initial Data Monitoring Committee review of safety data from each cohort, which we expect later this quarter."

Recent Corporate Highlights

Envafolimab

- In April, we resubmitted our Orphan Drug Designation application to the FDA in response to a request for preclinical or clinical evidence of activity for envafolimab in sarcoma. We expect correspondence from the FDA this quarter based on the amended application.

- As of May 5, we have initiated 22 U.S. clinical sites and enrolled more than 20 patients in the pivotal ENVASARC trial of single agent envafolimab and envafolimab combined with Yervoy, which has triggered the initial Data Monitoring Committee review of safety data from each cohort.

Expected Key Upcoming Milestones

- Orphan Drug Designation for envafolimab in soft tissue sarcoma from FDA in 1H 2021.

- Independent Data Monitoring Committee review of ENVASARC safety data in 1H 2021.

- American Society of Clinical Oncology (ASCO) presentation of ENVASARC pivotal trial design in 1H 2021.

- ASCO presentation of TJ004309 Phase 1 data in 1H 2021.

- Interim ENVASARC efficacy and safety data in 2H 2021.

- Request FDA breakthrough therapy designation or Fast Track designation for envafolimab in 2H 2021.

- Decision on the envafolimab New Drug Application (NDA) in MSI-H/dMMR cancer that is under priority review by the Chinese National Medical Products Administration (NMPA).

First Quarter 2021 Financial Results

- Cash, cash equivalents and short-term investments were $30.4 million at March 31, 2021, compared to $36.1 million at December 31, 2020. The Company expects that its current cash, cash equivalents and short-term investments will fund operations into the second half of 2022.

- Research and development expenses for the first quarter of 2021 were $2.3 million, compared to $2.0 million for the first quarter of 2020.

- General and administrative expenses for the first quarter of 2021 were $2.7 million, compared to $1.9 million for the first quarter of 2020.

- Net loss for the first quarter of 2021 was $5.1 million, compared to $4.0 million for the first quarter of 2020.

Conference Call Details

Wednesday, May 5, at 4:30 PM Eastern Time / 1:30 PM Pacific Time	
Domestic:	**855-779-9066**
International:	**631-485-4859**
Conference ID:	**8852857**

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 (KN035), a novel, single-domain antibody against PD-L1, is the first subcutaneously injected PD-(L)1 inhibitor to be studied in pivotal trials. Envafolimab is currently being studied in the ENVASARC Phase 2 pivotal trial in the U.S. sponsored by TRACON, has been studied in a completed Phase 2 pivotal trial as a single agent in MSI-H/dMMR advanced solid tumor patients in China and is being studied in an ongoing Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China, with both Chinese trials sponsored by 3D Medicines. TRACON's partners Alphamab Oncology and 3D Medicines submitted an NDA to the NMPA in China for envafolimab in MSI-H/dMMR cancer that was accepted for review in December 2020 and granted priority review in January 2021. In the Phase 2 MSI-H/dMMR advanced solid tumor trial, the confirmed objective response rate (ORR) by blinded independent central review in MSI-H/dMMR colorectal cancer (CRC) patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan was 32%, which was similar to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan and the 33% confirmed ORR reported for Keytruda in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan in cohort A of the KEYNOTE-164 clinical trial.

About ENVASARC (NCT04480502)

The ENVASARC pivotal trial is a multi-center, open label, randomized, non-comparative, parallel cohort study at approximately 25 top cancer centers in the United States that began dosing in December 2020. TRACON expects the trial to enroll 160 patients with UPS or MFS who have progressed following one or two lines of prior treatment and have not received an immune checkpoint inhibitor, with 80 patients enrolled into cohort A of treatment with single agent envafolimab and 80 patients enrolled in cohort B of treatment with envafolimab and Yervoy. The primary endpoint is ORR by blinded independent central review with duration of response a key secondary endpoint.

About TRC102

TRC102 (methoxyamine) is a novel, small molecule inhibitor of the DNA base excision repair pathway, which is a pathway that causes resistance to alkylating and antimetabolite chemotherapeutics. TRC102 is currently being studied in multiple Phase 1 and Phase 2 clinical trials sponsored by the National Cancer Institute through a Cooperative Research and Development Agreement (CRADA) and has orphan drug designation from the U.S. FDA in malignant glioma, including glioblastoma.

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 an ongoing 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, CRO independent, product development platform. The Company’s clinical-stage pipeline includes: Envafolimab, a PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; TRC253, a Phase 3 ready small molecule drug candidate for the treatment of prostate cancer; TRC102, a Phase 2 small molecule drug candidate 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 and its collaboration partners’ plans to further develop product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development, regulatory and commercial milestones and timing thereof, estimated cash runway, potential utility of product candidates, potential events 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 and regulatory approval of novel pharmaceutical products; 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; 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,	
	2021	**2020**
Operating expenses:		
Research and development	$2,284	$1,998
General and administrative	2,671	1,886
Total operating expenses	4,955	3,884
Loss from operations	(4,955)	(3,884)
Total other expense	(109)	(137)
Net loss	$(5,064)	$(4,021)
Net loss per share, basic and diluted	$(0.33)	$(0.78)
Weighted-average common shares outstanding, basic and diluted	15,479,304	5,171,351

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$26,408	$32,131
Short-term investments	4,000	3,999
Prepaid and other assets	809	784
Total current assets	31,217	36,914
Property and equipment, net	18	16
Other assets	419	508
Total assets	$31,654	$37,438
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$6,798	$6,235
Accrued compensation and related expenses	743	1,590
Long-term debt, current portion	2,739	2,718
Total current liabilities	10,280	10,543
Other long-term liabilities	319	432
Long-term debt, less current portion	698	1,391
Commitments and contingencies		
Stockholders' equity:		
Common stock	15	15
Additional paid-in capital	204,515	204,166
Accumulated deficit	(184,173)	(179,109)
Total stockholders' equity	20,357	25,072
Total liabilities and stockholders' equity	$31,654	$37,438

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