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): **February 25, 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 February 25, 2021, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter and year ended December 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 February 25, 2021 announcing its financial results for the quarter and year ended December 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.

Date: February 25, 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 Fourth Quarter and Year-End 2020 Financial Results and Provides Corporate Update

San Diego, CA – February 25, 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 fourth quarter and year ended December 31, 2020. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

"We ended 2020 on a high note by enrolling the first patient in the ENVASARC pivotal trial within one year of licensing envafolimab and raising additional capital at market price that further extends our cash runway into the second half of 2022," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We are focused on enrolling the ENVASARC trial expeditiously and expect the availability of interim data later this year, final data in 2022, and assuming positive clinical data and regulatory approval, to potentially commercialize envafolimab in 2023, in order to address a high unmet need for patients with UPS or MFS."

Recent Corporate Highlights

Envafolimab

- As of February 5, 2021, TRACON had initiated 16 clinical sites and enrolled multiple patients at multiple sites in the pivotal ENVASARC trial of single agent envafolimab and envafolimab combined with Yervoy.

- In January 2021, TRACON announced that its partners Alphamab Oncology and 3D Medicines received notification their New Drug Application for envafolimab, submitted in November 2020 in China, was granted priority review by the Center for Drug Evaluation of the National Medical Products Administration in the indication of MSI-H/dMMR cancer.

- In December 2020, TRACON announced the dosing of the first patient in the pivotal ENVASARC trial.

TRC102

- In November 2020, TRACON announced the publication of clinical data in the journal *Cancer Cell*, that provided molecular insight into TRC102's mechanism of action and patient populations most likely to respond to treatment. The article, entitled, "*Molecular Features of Cancers Exhibiting Exceptional Responses to Treatment,*" highlighted the clinical features and tumor biology of an exceptional responder patient treated with TRC102. TRC102 is a small molecule inhibitor of DNA base inhibitor repair being studied in Phase 1 and Phase 2 trials sponsored by the National Cancer Institute.

Corporate

- In December 2020, TRACON announced financings of approximately $13.8 million in the aggregate with multiple new and existing healthcare focused institutional investors through registered direct offerings of its common stock. The financings were completed at market price, and TRACON expects the net proceeds will extend its cash runway into the second half of 2022.

Expected Key Upcoming Milestones

- Independent Data Monitoring Committee review of ENVASARC safety data in 1H 2021.
- Submit envafolimab response data to the FDA for orphan drug designation in sarcoma in 1H 2021.
- Data presentation on TJ004309 Phase 1 results in 1H 2021.
- Interim ENVASARC efficacy and safety data in 2H 2021.
- Data presentation on TRC102 Phase 2 results in 2H 2021.
- Request FDA breakthrough therapy designation for envafolimab in 2H 2021.
- Decision on envafolimab NDA in China for MSI-H/dMMR cancer.

Fourth Quarter 2020 Financial Results

- Cash, cash equivalents and short-term investments were $36.1 million at December 31, 2020, compared to $16.4 million at December 31, 2019. 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 fourth quarter of 2020 were $2.2 million, compared to $1.9 million for the fourth quarter of 2019.
- General and administrative expenses for the fourth quarter of 2020 were $2.0 million, compared to $1.9 million for the fourth quarter of 2019.
- Net loss for the fourth quarter of 2020 was $4.3 million, compared to $4.0 million for the fourth quarter of 2019.

Conference Call Details

Thursday, February 25, at 4:30 PM Eastern Time / 1:30 PM Pacific Time	
Domestic:	**855-779-9066**
International:	**631-485-4859**
Conference ID:	**5681569**

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, as well as in a Phase 2 pivotal trial as a single agent in MSI-H/dMMR advanced solid tumor patients and a Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China sponsored by TRACON's corporate partners, Alphamab Oncology and 3D Medicines. 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 KEYNOTE-164.

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 US 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 December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$2,197	$1,913	$8,198	$14,530
General and administrative	1,980	1,899	8,025	7,766
Total operating expenses	4,177	3,812	16,223	22,296
Loss from operations	(4,177)	(3,812)	(16,223)	(22,296)
Total other expense	(134)	(124)	(552)	(378)
Net loss	$(4,311)	$(3,936)	$(16,775)	$(22,674)
Net loss per share, basic and diluted	$(0.31)	$(1.25)	$(1.87)	$(7.47)
Weighted-average common shares outstanding, basic and diluted	13,800,771	3,159,740	8,984,148	3,034,299

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$32,131	$16,412
Short-term investments	3,999	-
Prepaid and other assets	784	848
Total current assets	36,914	17,260
Property and equipment, net	16	23
Other assets	508	838
Total assets	$37,438	$18,121
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$6,235	$7,875
Accrued compensation and related expenses	1,590	1,355
Long-term debt, current portion	2,718	2,604
Total current liabilities	10,543	11,834
Other long-term liabilities	432	850
Long-term debt, less current portion	1,391	2,739
Commitments and contingencies		
Stockholders' equity:		
Common stock	15	4
Additional paid-in capital	204,166	165,028
Accumulated deficit	(179,109)	(162,334)
Total stockholders' equity	25,072	2,698
Total liabilities and stockholders' equity	$37,438	$18,121

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