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): **September 19, 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 8.01 Other Events.

On September 21, 2020, the Company issued a press release announcing the presentation of positive clinical data for envafolimab at the 2020 Chinese Society of Clinical Oncology (CSCO) Virtual Scientific Program by the Company's partners 3D Medicines and Alphamab Oncology.

The pivotal Phase 2 trial enrolled 103 patients with MSI-H colorectal (CRC), gastric cancer (GC) or other advanced solid tumors, in an open label format with efficacy endpoints, including the primary endpoint of confirmed objective response rate (ORR) determined by independent central review. MSI-H/dMMR status was assessed centrally for CRC and GC and locally for other tumors. The trial was conducted at clinical sites in China. Key highlights include:

- The confirmed ORR in 103 patients with CRC who failed fluoropyrimidine and oxaliplatin or irinotecan (n=65), GC (n=18) or another advanced tumors (n=20) was 43% (95% CI: 33%, 53%). Duration of response (DOR) was greater than or equal to 12 months in 92% of patients and overall survival (OS) was greater than or equal to 12 months in 75% of patients.
- The confirmed ORR in 65 patients with CRC who failed a fluoropyrimidine and oxaliplatin or irinotecan was 43% (95% CI: 31%, 56%). DOR was greater than or equal 12 months in 88% of patients and OS was $\geq$ 12 months in 73% of patients.
- The confirmed ORR in 41 patients with CRC who failed a fluoropyrimidine and oxaliplatin and irinotecan was 32% (95% CI: 18%, 48%). DOR was greater than or equal 12 months in 75% of patients and OS was $\geq$ 12 months in 65% of patients.
- Envafolimab was well tolerated with a safety profile similar to that observed in Phase 1, 2 and 3 trials that have enrolled more than 700 patients in China, Japan and the United States, and was similar to that of approved PD-(L)1 checkpoint inhibitors except that envafolimab did not cause infusion-related reactions.

The press release issued on September 21, 2020, is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by TRACON Pharmaceuticals, Inc. on September 21, 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: September 21, 2020

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

TRACON Pharmaceuticals Highlights Updated Envafolimab Clinical Results in MSI-H/dMMR Colorectal Cancer

TRACON's Pivotal ENVASARC Trial of envafolimab in the Sarcoma Subtypes of UPS and MFS Expected to Initiate Dosing in 4Q 2020

San Diego, CA – September 21, 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 highlighted updated clinical data from the pivotal trial of envafolimab in MSI-H/dMMR cancer patients that were recently presented by the Company's corporate partners, 3D Medicines and Alphamab Oncology.

In a presentation highlighting updated clinical results at the Chinese Society of Clinical Oncology (CSCO) 2020 Virtual Scientific Program entitled, "Subcutaneous Injection of PD-L1 Antibody Envafolimab (KN035) in Advanced Tumors with Mismatch-Repair Deficiency," single agent envafolimab was shown to have a 32% confirmed objective response rate (ORR) by central radiographic review of 41 patients with MSI-H/dMMR colorectal cancer (CRC) who failed a fluoropyrimidine, oxaliplatin and irinotecan, and had at least two on-study tumor assessments. Duration of response (DOR) was greater than or equal to 12 months in 75% of patients and overall survival (OS) was greater than or equal to 12 months in 65% of patients. The ORR in the overall population (N=103) was 43%, DOR was greater than or equal to 12 months in 92% of patients and OS was greater than or equal to 12 months in 75% of patients. Envafolimab demonstrated good tolerability and safety and there continued to be no infusion-related reactions.

Earlier data from this trial were presented by 3D Medicines and Alphamab Oncology at ASCO 2020, in a presentation entitled, "Envafolimab (KN035) in Advanced Tumors with Mismatch-Repair Deficiency," at which time single agent envafolimab was shown to have a 28% confirmed ORR by central radiographic review in 39 patients with MSI-H/dMMR CRC who failed a fluoropyrimidine, oxaliplatin and irinotecan, and had at least two on-study tumor assessments. The trial enrolled 103 patients with MSI-H CRC, GC or with dMMR in other advanced solid tumors at clinical sites in China, in an open label format with efficacy endpoints, including the primary endpoint of confirmed ORR determined by independent central review. MSI-H/dMMR status was assessed centrally for CRC and GC and locally for other tumors.

The confirmed ORR in MSI-H/dMMR colorectal cancer patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan reported at CSCO 2020 of 32% is similar to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR colorectal cancer patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan, and the 27.9% confirmed ORR reported for Keytruda in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan seen in cohort A of the pivotal KEYNOTE-164 trial.

"The CSCO 2020 data provide further clinical evidence that envafolimab's activity is similar to that of Opdivo and Keytruda in MSI-H/dMMR cancer. Also impressive is the durability of response at 12 months," said James Freddo, M.D., TRACON Chief Medical Officer. "Given the 4% ORR reported in the pivotal study of Votrient, the only approved therapy for refractory UPS and MFS, and the demonstrated efficacy of immune checkpoint

inhibitors in these populations, we believe the clinical results of our ENVASARC pivotal trial, if positive, could position envafolimab as a transformative new standard of care for sarcoma patients. Moreover, the elimination of PD-L1 associated infusion-related reactions observed to date and the convenience provided by envafolimab as the only subcutaneously administered PD-L1 inhibitor currently being studied in registrational trials, could provide significant benefits for clinicians and their patients."

About ENVASARC

Key elements for the planned ENVASARC pivotal trial include:

- Multi-center, open-label, randomized, non-comparative, parallel cohort study at approximately 25 top cancer centers in the United States.
- Eligible patients will have undifferentiated pleomorphic sarcoma (UPS) or myxofibrosarcoma (MFS) and received one or two prior cancer therapies, but no prior immune checkpoint inhibitor therapy.
- Planned total enrollment of 160 patients, 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.
- Primary endpoint of confirmed ORR with duration of response a key secondary endpoint.
- Open-label format with blinded independent central review of efficacy endpoint data.

About Envafolimab

Envafolimab (KN035), a novel, single-domain antibody against PD-L1, is the first subcutaneously administered PD-(L)1 inhibitor to be studied in registrational trials. Envafolimab is currently dosing in a Phase 2 registration trial as a single agent in MSI-H/dMMR advanced solid tumor patients and a Phase 3 registration trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China. 3D Medicines and Alphamab Oncology, TRACON's corporate partners for this program, plan to submit a BLA to the NMPA in China for envafolimab in 2020 based on the ORR in MSI-H/dMMR advanced solid tumor patients. The confirmed ORR in MSI-H/dMMR colorectal cancer patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan reported at CSCO 2020 was 32%, which was similar to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR colorectal cancer patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan and the 27.9% 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 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 subcutaneous PD-L1 single-domain antibody being developed for the treatment of sarcoma with the goal of initiating a registrational trial in the U.S. in the fourth quarter of 2020; TRC253, a Phase 3 ready small molecule drug candidate for the treatment of prostate cancer; TRC102, a Phase 2 small molecule drug candidate in development for the treatment of lung cancer; and TJ004309, a Phase 1 CD73 antibody in 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 partners’ plans to further develop product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development and regulatory milestones and timing thereof, 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 or other pandemics; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that interim data from clinical trials may not be consistent with future or final data from the same trials; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials, initiate additional trials or seek regulatory approval 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; 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.

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