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): **December 20, 2018**

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. ☒

Item 8.01 Other Events.

On December 21, 2018, the Company issued a press release announcing the top-line results from the TRAXAR randomized Phase 2 clinical trial of TRC105 in advanced or metastatic renal cell carcinoma.

The TRAXAR trial evaluated the combination of TRC105 with Inlyta® (Axitinib) compared to single agent Inlyta in a total of 150 patients with advanced or metastatic renal cell carcinoma, following the failure of one prior VEGF TKI. The trial was designed to detect a three-month improvement in progression free survival (PFS), the primary endpoint, from the expected value of 4.8 months with single agent Inlyta. The combination of TRC105 and Inlyta did not meet the primary endpoint of improved median PFS versus single agent Inlyta.

The press release issued on December 21, 2018 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 December 21, 2018.

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: December 21, 2018

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

TRACON Pharmaceuticals Announces Top-line Data from Phase 2 TRAXAR Clinical Trial in Renal Cell Carcinoma

San Diego, CA – December 21, 2018 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration and fibrotic diseases, today announced that its Phase 2 TRAXAR trial evaluating TRC105 in combination with Inlyta (axitinib) in patients with advanced or metastatic renal cell carcinoma did not meet the primary endpoint of improving progression free survival (PFS) in the intent to treat population compared to Inlyta monotherapy.

Prespecified statistical analyses of PFS according to expression of two plasma biomarkers, TGFβ receptor III and osteopontin, also did not achieve statistical significance. The safety profile observed in TRAXAR was consistent with that observed in previously reported studies of TRC105 in combination with VEGF inhibitors.

TRACON will work with investigators to appropriately conclude the study in a manner consistent with the best interests of each patient. Data from this study will be analyzed and submitted for presentation at an upcoming scientific congress.

“We are disappointed that TRC105 in combination with Inlyta did not demonstrate clinically meaningful efficacy in patients with advanced or metastatic renal cell carcinoma. Importantly, data from TRAXAR, including analyses of an extensive biomarker panel, will contribute to our understanding of the role of endoglin inhibition in combination with VEGF inhibitors, and may inform our broad TRC105 clinical development program,” said Charles Theuer, M.D. Ph.D., President and CEO of TRACON. “We remain focused on the interim analysis to determine the final sample size of the Phase 3 TAPPAS trial of TRC105 and Votrient in angiosarcoma, which is expected in the first quarter of 2019.”

About the TRAXAR trial in Advanced or Metastatic Renal Cell Carcinoma

The TRAXAR trial compared treatment with TRC105 and Inlyta to treatment with single agent Inlyta in 150 patients with advanced or metastatic renal cell carcinoma with a clear cell component. Patients were randomized in equal numbers and the primary endpoint was progression free survival by RECIST 1.1. Key secondary endpoints included objective response rate, safety and tolerability.

About Carotuximab (TRC105)

TRC105 is a novel, clinical stage antibody to endoglin, a protein overexpressed on proliferating endothelial cells that is essential for angiogenesis, the process of new blood vessel formation. TRC105 is currently being studied in a pivotal Phase 3 trial in angiosarcoma and multiple Phase 2 clinical trials, in combination with VEGF inhibitors, as well as in a Phase 1 trial with Opdivo. TRC105 has received orphan designation for the treatment of soft tissue sarcoma in both the U.S. and EU. The ophthalmic formulation of TRC105, DE-122, is currently in a randomized Phase 2 trial for patients with wet AMD. For more information about the clinical trials, please visit TRACON’s website at www.traconpharma.com/clinical_trials.php.

About TRACON

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company's clinical-stage pipeline includes: TRC105, an endoglin antibody that is being developed for the treatment of multiple cancers; DE-122, the ophthalmic formulation of TRC105 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; and TRC253, a small molecule being developed for the treatment of prostate cancer. TRACON is actively seeking additional corporate partnerships whereby it leads regulatory and clinical development, and 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 its product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development milestones, and potential utility of TRACON's product candidates. 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; 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.

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