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): **January 19, 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 January 19, 2018, TRACON Pharmaceuticals, Inc. (“TRACON”) announced positive initial clinical data from its ongoing Phase 1b/2 study of TRC105 and Nexavar® (sorafenib) in patients with advanced hepatocellular carcinoma (HCC).

Initial data announced from the ongoing open-label, non-randomized study included:

- Partial responses by RECIST 1.1 occurred in 2 of 8 (25%) evaluable patients and a reduction of 50% or greater in alpha fetoprotein (AFP) concentration occurred in 3 of 8 (38%) evaluable patients. Reduction in AFP, a tumor marker expressed in patients with HCC, in early treatment may help identify a favorable response to treatment and was observed in both cases of partial response.
- Hybrid dosing consisting of four weekly doses of TRC105 at 10 mg/kg followed by every other week dosing at 15 mg/kg thereafter was tolerable when given with the standard Nexavar dose of 400 mg twice daily.
- Adverse events typical of each drug did not increase in frequency or severity when the drugs were administered concurrently.

In addition, TRACON confirmed that completion of the enrollment of approximately 33 patients is expected by the end of 2018.

A copy of a press release regarding the interim data is attached as Exhibit 99.1 hereto.

This report contains forward-looking statements, including statements regarding TRACON’s plans and timing with respect to on-going clinical trials, and other development plans and potential benefits of TRACON’s product candidates. These forward-looking statements are based on management's expectations and assumptions as of the date of this report and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include, but are not limited to, the fact that initial clinical trial results or results from prior studies may not be consistent with subsequent results, TRACON’s and others’ ability to identify and enroll patients in on-going and planned clinical trials, potential delays in completing on-going clinical trials, whether TRACON’s product candidates will be shown to be safe and effective in subsequent studies, and TRACON’s and others’ ability and willingness to fund additional clinical development of TRACON’s product candidates. For a further description of these and other risks facing TRACON, please see the risk factors described in TRACON’s filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements speak only as of the date of this report and TRACON undertakes no obligation to update or revise these statements, except as may be required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by TRACON Pharmaceuticals, Inc. dated January 19, 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: January 19, 2018

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

Exhibit 99.1

TRACON Pharmaceuticals Announces Positive Data from Ongoing Phase 1b/2 Trial of TRC105 in Hepatocellular Carcinoma Patients

Two Partial Responses (25%) by RECIST and Three > 50% Reductions of Alpha Fetoprotein in Eight Evaluable Patients (38%) Treated to Date with Combination of TRC105 and Nexavar®

Data Presented at ASCO 2018 Gastrointestinal Cancers Symposium

San Diego, CA – January 19, 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 positive initial clinical data from its ongoing Phase 1b/2 study of TRC105 and Nexavar® (sorafenib) in patients with advanced hepatocellular carcinoma (HCC) were presented in a poster presentation at the 2018 ASCO Gastrointestinal Cancers Symposium in San Francisco, California.

Initial data from the ongoing open-label, non-randomized study were presented by Dr. Kanwal Raghav from the University of Texas MD Anderson Cancer Center:

- Partial responses by RECIST 1.1 occurred in 2 of 8 (25%) evaluable patients and a reduction of 50% or greater in alpha fetoprotein (AFP) concentration occurred in 3 of 8 (38%) evaluable patients. Reduction in AFP, a tumor marker expressed in patients with HCC, in early treatment may help identify a favorable response to treatment and was observed in both cases of partial response.
- Hybrid dosing consisting of four weekly doses of TRC105 at 10 mg/kg followed by every other week dosing at 15 mg/kg thereafter was tolerable when given with the standard Nexavar dose of 400 mg twice daily.
- Adverse events typical of each drug did not increase in frequency or severity when the drugs were administered concurrently.
- The trial is ongoing, with the completion of the enrollment of approximately 33 patients expected by the end of 2018.

“We continue to be encouraged with the safety and activity of TRC105 in combination with Nexavar in patients with HCC, a tumor type with limited treatment options,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “Importantly, the initial data from the current trial are consistent with the 33% partial response rate by RECIST 1.1 reported in the completed Phase 1/2 study published by the National Cancer Institute in 2017. We expect to complete enrollment of the current multicenter study by the end of 2018, and will discuss a potential registration-enabling study of the combination of TRC105 and Nexavar in HCC with regulatory authorities shortly thereafter.”

The poster is available on TRACON’s website at: www.traconpharma.com/publications.php

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. 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, ophthalmic and fibrotic 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. To learn more about TRACON and its product candidates, visit TRACON's website at www.traconpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding TRACON's plans and timing with respect to on-going clinical trials, and other development plans and potential benefits of TRACON's product candidates. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include, but are not limited to, the fact that initial clinical trial results or results from prior studies may not be consistent with subsequent results, TRACON's and others' ability to identify and enroll patients in on-going and planned clinical trials, potential delays in completing on-going clinical trials, whether TRACON's product candidates will be shown to be safe and effective in subsequent studies, and TRACON's and others' ability and willingness to fund additional clinical development of TRACON's product candidates. For a further description of these and other risks facing TRACON, please see the risk factors described in TRACON's filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements speak only as of the date of this press release and TRACON undertakes no obligation to update or revise these statements, except as may be required by law.

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