

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): **November 11, 2016**

**TRACON Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction  
of incorporation)

**001-36818**

(Commission File Number)

**34-2037594**

(IRS Employer Identification No.)

**8910 University Center Lane, Suite 700**  
**San Diego, California**

(Address of principal executive offices)

**92122**

(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))
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**Item 8.01 Other Events.**

On November 11, 2016, TRACON Pharmaceuticals, Inc. (TRACON) issued a press release announcing updated results from the on-going Phase 1b/2 clinical trial of TRC105 in combination with Votrient® (pazopanib) in soft tissue sarcoma. The press release issued on November 11, 2016 is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On November 13, 2016, TRACON issued a press release announcing preclinical data from two separate liver fibrosis models in a poster presentation entitled “Endoglin Antibody Reduces the NAFLD Activity Score in the STAM Model of NASH and Reduces Liver Fibrosis Following Carbon Tetrachloride Treatment.” The press release issued on November 13, 2016 is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by TRACON Pharmaceuticals, Inc. dated November 11, 2016.
99.2	Press release issued by TRACON Pharmaceuticals, Inc. dated November 13, 2016.

## 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: November 14, 2016

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

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by TRACON Pharmaceuticals, Inc. dated November 11, 2016.
99.2	Press release issued by TRACON Pharmaceuticals, Inc. dated November 13, 2016.

## TRACON Pharmaceuticals Announces Presentation of Updated Data from Phase 1b/2 Study of TRC105 and Votrient® in Patients with Angiosarcoma

### *Combination Treatment Continues to Demonstrate Encouraging Signs of Activity*

**San Diego, CA – November 11, 2016** – 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 presented updated data from the Company's Phase 1b/2 study of TRC105 and Votrient (pazopanib) at the Connective Tissue Oncology Society (CTOS) annual meeting taking place in Lisbon, Portugal.

In poster presentation 2569989 entitled, "TRC105 in Combination with Pazopanib in Patients with Advanced Angiosarcoma," data from 18 angiosarcoma patients treated with either the combination of TRC105 (carotuximab) and Votrient, or with single agent TRC105 followed by the combination of TRC105 and Votrient, were presented:

- For the initial five angiosarcoma patients enrolled in the original Phase 1b/2 clinical trial, the median progression-free survival (mPFS) is greater than 16.6 months. For the nine chemotherapy-refractory angiosarcoma patients treated with the combination of TRC105 and Votrient, three of whom had also previously progressed on Votrient treatment (and includes the initial five patients), mPFS is 5.6 months. Three of the nine patients remain on treatment, including two patients with durable complete responses (CRs), now on treatment for 19 and 26 months, respectively. For comparison, mPFS with single agent Votrient was 3.0 months with no CRs in a previously completed retrospective analysis of 30 chemotherapy-refractory and Votrient-naïve angiosarcoma patients.
- An additional group of nine angiosarcoma patients was enrolled and treated initially with single agent TRC105 followed by the combination of TRC105 and Votrient at progression. The mPFS in these nine patients treated initially with single agent TRC105 was similar to the mPFS reported in late-stage trials of single agent VEGF inhibitors, including Votrient and Nexavar® (sorafenib). Four of the nine patients remain on study with either single agent TRC105 or the combination of TRC105 and Votrient, including one patient with a partial response.
- TRC105 administered at its recommended Phase 2 dose of 10 mg/kg weekly was well-tolerated in combination with Votrient at its approved dose, which allowed for prolonged dosing without an increase in the frequency or severity of adverse events typical of each individual drug.

"The combination of TRC105 and Votrient has now been used to treat a total of 18 angiosarcoma patients and we continue to see encouraging signs of activity in this group of patients with limited therapeutic options," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Looking forward, we remain on track to initiate a randomized Phase 3 study of TRC105 with Votrient in patients with angiosarcoma at sites in the U.S. and Europe later this year or early 2017. Using the valuable input previously received from both U.S. and EU regulators, the trial will utilize an adaptive design that allows sample size re-estimation and patient enrichment. Importantly, we have submitted the trial design to the FDA for a Special Protocol Assessment (SPA)."

The poster is available on TRACON's website at [www.traconpharma.com](http://www.traconpharma.com).

### **About TRC105 (carotuximab)**

TRC105 (carotuximab) 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 multiple Phase 2 clinical trials sponsored by TRACON or the National Cancer Institute for the treatment of solid tumor types in combination with VEGF inhibitors. The ophthalmic formulation of TRC105, DE-122, is currently in a Phase 1/2 trial for patients with wet AMD. TRC205, a second generation antibody to endoglin, is undergoing preclinical testing in models of fibrosis.

### **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.; and TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma. The Company is also developing two programs in-licensed from Janssen Pharmaceutica N.V. – TRC253, a small molecule inhibitor of wild type androgen receptor (AR) and multiple AR mutant receptors that may display drug resistance, which is intended for the treatment of men with prostate cancer, and TRC694, a small molecule inhibitor of NF-kB inducing kinase (NIK), which is intended for the treatment of patients with hematologic malignancies, including myeloma. To learn more about TRACON and its product candidates, visit TRACON's website at [www.traconpharma.com](http://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 and expectations regarding the initiation, design and timing of future clinical trials by TRACON or third parties. 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; whether TRACON is able to obtain a special protocol assessment agreement with the FDA for the planned Phase 3 trial of TRC105; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; 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

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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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## **TRACON Pharmaceuticals Presents Clinical and Preclinical Data from Models of NASH and Liver Fibrosis at the 2016 AASLD Annual Meeting**

**San Diego, CA – November 13, 2016** – 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 presented data at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting, taking place November 11-15 in Boston, MA.

Preclinical data were presented from two separate liver fibrosis models in a poster presentation entitled, “Endoglin Antibody Reduces the NAFLD Activity Score in the STAM Model of NASH and Reduces Liver Fibrosis Following Carbon Tetrachloride Treatment.” Highlights include:

- Treatment with an endoglin antibody significantly decreased the percentage of the liver fibrosis area induced by carbon tetrachloride. A group of mice treated with endoglin antibody demonstrated lower collagen deposition with less frequent formation of bridging fibrosis than the isotype-matched and disease control groups.
- Treatment with endoglin antibodies significantly reduced the non-alcoholic fatty liver disease (NAFLD) activity score (NAS) in a model of non-alcoholic steatohepatitis (NASH), known as the STAM™ model. Endoglin antibodies demonstrated hepatoprotective, anti-inflammatory and anti-fibrotic effects. In addition, an endoglin antibody that competitively inhibited bone morphogenic protein (BMP) binding to endoglin more effectively reduced the NAS, suggesting that inhibition of BMP function is an important mechanism of action of endoglin antibodies in models of fibrosis.

The poster also highlighted a marked reduction in cutaneous neurofibromatosis in a sarcoma patient following dosing with TRACON's TRC105 and Votrient® (pazopanib) in a Phase 2 clinical trial, suggesting the potential of an endoglin antibody as an effective treatment for patients with fibrosis.

The poster is available on TRACON's website at [www.traconpharma.com](http://www.traconpharma.com).

### **About TRACON's Endoglin Antibody Portfolio**

TRC105 (carotuximab) 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 multiple Phase 2 clinical trials sponsored by TRACON or the National Cancer Institute for the treatment of solid tumor types in combination with VEGF inhibitors. The ophthalmic formulation of TRC105, DE-122, is currently in a Phase 1/2 trial for patients with wet AMD. TRC205, a second generation antibody to endoglin, is undergoing preclinical testing in models of fibrosis.

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## About TRACON

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