

**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): **June 6, 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))

Item 8.01 Other Events.

On June 6, 2016, TRACON Pharmaceuticals, Inc. (TRACON) issued a press release announcing interim results from the on-going Phase 1b/2 clinical trial of TRC105 in combination with Votrient® (pazopanib) in soft tissue sarcoma, data from a Phase 2 clinical trial of TRC105 in combination with Avastin® (bevacizumab) in patients with glioblastoma (GBM) who had progressed on prior Avastin monotherapy, and data reported by the National Cancer Institute (NCI) from a clinical trial of TRC102 in combination with Temodar® (temozolomide) in patients with refractory solid tumors.

Phase 1b/2 Trial of TRC105 with Votrient in Advanced Soft Tissue Sarcoma

In the on-going Phase 1b/2 clinical trial of TRC105 in combination with Votrient, 81 patients with advanced soft tissue sarcoma, including five patients with angiosarcoma, were originally enrolled and received treatment with the combination of TRC105 and Votrient. The trial protocol was amended to enroll an additional cohort of up to 13 patients with angiosarcoma, and nine of these patients are evaluable for efficacy. Four of the patients began treatment with the combination of TRC105 and Votrient and the other five patients initiated treatment with TRC105 monotherapy with transition to treatment with the combination at RECIST 1.1 defined progression on the monotherapy. Data as of May 27, 2016, are summarized below:

- The combination of TRC105 and Votrient has demonstrated encouraging signs of activity in the five angiosarcoma patients enrolled in the original cohort of the Phase 1b/2 trial; all patients had radiographic tumor reductions, including two durable complete responses (CRs) by RECIST 1.1, and median progression-free survival (PFS) was greater than 12.9 months. For comparison, PFS with single agent Votrient was 3.0 months with no CRs in a previously completed retrospective study of 30 angiosarcoma patients. Signs of clinical or radiologic activity were also observed in three of four patients enrolled in the angiosarcoma expansion cohort treated initially with TRC105 and Votrient. Notable findings include:
 - A patient with cutaneous angiosarcoma had an ongoing CR by RECIST 1.1 and continues on study in month 21. The patient had previously progressed within 15 weeks following treatment with docetaxel combined with Votrient.
 - A patient with cutaneous angiosarcoma had an ongoing CR by RECIST 1.1 and continues on study in month 14. The patient had previously progressed within 4 weeks following treatment with doxorubicin.
 - An additional patient with visceral angiosarcoma enrolled in the angiosarcoma expansion cohort demonstrated the eradication of a non-target lesion and a significant reduction in a target lesion, and continues on study in month 5. The patient had previously progressed within 4 weeks following treatment with gemcitabine, doxorubicin and docetaxel.

- Five angiosarcoma patients were initially treated with TRC105 monotherapy in the angiosarcoma expansion cohort, of whom four remain on study with either TRC105 monotherapy or TRC105 and Votrient combination treatment.
- Endoglin expression on archival tumor tissue across all sarcoma subtypes was not associated with improved PFS. Median PFS in patients with tumor endoglin expression, 3.9 months, was not statistically different from median PFS in patients without tumor endoglin expression, possibly reflecting the effect of subsequent therapies and tumor heterogeneity on tumor endoglin expression.
- 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.

Phase 2 Trial of TRC105 with Avastin in Patients with Avastin-Refractory Glioblastoma

Data from a Phase 2 trial of TRC105 in combination with Avastin in patients with GBM who had progressed on prior Avastin monotherapy is summarized as follows:

- The combination of TRC105 and Avastin was well-tolerated with no apparent increase in the frequency or severity of adverse events typically associated with each individual drug.
- Overall survival (OS) of 5.8 months was observed in Avastin-refractory patients (n=15), which exceeded the historic OS of 4.0 months seen in a similar patient population treated in separate studies with single agent Avastin.
- A separate randomized Phase 2 trial comparing treatment with the combination of TRC105 and Avastin to single agent Avastin in Avastin-naïve GBM patients is fully enrolled with data expected by the end of 2016.

Phase 1 Trial of TRC102 with Temodar in Patients with Solid Tumors

NCI reported the following data from a trial of TRC102 in combination with Temodar in patients with refractory solid tumors to determine the safety, tolerability and maximum tolerated dose (MTD) of the combination.

- A total of 34 patients were enrolled in the trial, four of whom had a partial response (PR) (non-small cell lung cancer, ovarian cancer (2) and colon cancer); one further PR occurred in a patient with colon cancer, but was unconfirmed as a result of a concurrent illness; 9 patients had stable disease, 16 patients had progressive disease, and 5 were not evaluable.
- Three of the PRs were durable and lasted longer than 6 months.
- The MTD was reached at a dose level of TRC102 at 150 mg given orally on days 1-5 with Temodar at 150 mg/m² given orally on days 1-5, and further dose escalation resulted in hematologic toxicity.
- The observation of four PRs demonstrates that the combination of TRC102 and Temodar is active, and hematologic toxicity was manageable.
- The combination of TRC102 and Temodar is currently being evaluated in a Phase 2 trial of patients with glioblastoma.

The press release issued on June 6, 2016 is attached hereto as Exhibit 99.1.

Forward-Looking Statements

This report and the exhibit hereto contain forward-looking statements, including statements regarding TRACON's plans and timing with respect to a Phase 3 trial of TRC105 in angiosarcoma, the timing with respect to an on-going Phase 2 clinical trial of TRC105 in Avastin-naïve GBM patients, and other development plans and potential benefits of TRACON's product candidates. Forward-looking statements speak only as of the date of this report and TRACON does not undertake any obligation to update or revise these statements, except as may be required by law. 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 results of subsequent studies may not be consistent with results of prior studies, TRACON's and NCI's ability to identify and enroll patients in on-going and planned clinical trials, potential delays in completing on-going clinical trials and initiating new clinical trials, whether TRACON's product candidates will be shown to be safe and effective in subsequent studies, and TRACON's and NCI's 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.

Exhibit No.	Description
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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: June 7, 2016

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by TRACON Pharmaceuticals, Inc. dated June 6, 2016.



TRACON Pharmaceuticals Announces Positive Results from TRC105 and TRC102 Clinical Trials at American Society of Clinical Oncology (ASCO) 2016 Annual Meeting

Median PFS greater than 12 months with continued durable complete responses observed in angiosarcoma patients treated with TRC105 and Votrient® in Phase 1b/2 trial

Partial responses seen in solid tumor patients treated with TRC102 and Temodar®

San Diego, CA — June 6, 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 reported positive results from three separate clinical trials evaluating its two clinical stage product candidates, TRC105 and TRC102. Data were presented at the American Society of Clinical Oncology (ASCO) 2016 Annual Meeting in Chicago.

Phase 1b/2 Trial of TRC105 with Votrient (pazopanib) in Advanced Soft Tissue Sarcoma

In this Phase 1b/2 trial, 81 patients with advanced soft tissue sarcoma, including five patients with angiosarcoma, were originally enrolled and received treatment with the combination of TRC105 and Votrient. The trial protocol was amended to enroll an additional cohort of up to 13 patients with angiosarcoma, and nine of these patients are evaluable for efficacy. Four of the patients began treatment with the combination of TRC105 and Votrient and the other five patients initiated treatment with TRC105 monotherapy with transition to treatment with the combination at RECIST 1.1 defined progression on the monotherapy. Data as of May 27, 2016, are summarized below:

- The combination of TRC105 and Votrient has demonstrated encouraging signs of activity in the five angiosarcoma patients enrolled in the original cohort of the Phase 1b/2 trial; all patients had radiographic tumor reductions, including two durable complete responses (CRs) by RECIST 1.1, and median progression-free survival (PFS) was greater than 12.9 months. For comparison, PFS with single agent Votrient was 3.0 months with no CRs in a previously completed retrospective study of 30 angiosarcoma patients. Signs of clinical or radiologic activity were also observed in three of four patients enrolled in the angiosarcoma expansion cohort treated initially with TRC105 and Votrient. Notable findings include:
 - A patient with cutaneous angiosarcoma had an ongoing CR by RECIST 1.1 and continues on study in month 21. The patient had previously progressed within 15 weeks following treatment with docetaxel combined with Votrient.
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 - Endoglin expression on archival tumor tissue across all sarcoma subtypes was not associated with improved PFS. Median PFS in patients with tumor endoglin expression, 3.9 months, was not statistically different from median PFS in patients without tumor endoglin expression, possibly reflecting the effect of subsequent therapies and tumor heterogeneity on tumor endoglin expression.
 - 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 continues to demonstrate encouraging signs of activity and has been well-tolerated in angiosarcoma patients treated in this Phase 1b/2 study. Given the limited therapeutic options available for the treatment of this aggressive tumor type, we look forward to the further investigation of this novel therapy in a Phase 3 trial,” said Robert Maki, M.D., Ph.D., Professor of Medicine, Tisch Cancer Institute, Mount Sinai School of Medicine.

“The strong data that continues to emerge from the study of TRC105 with Votrient in patients with angiosarcoma support the further clinical advancement of this novel combination,” 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 later this year at sites in the U.S. and Europe.”

Phase 2 Trial of TRC105 with Avastin® (bevacizumab) in Patients with Avastin-Refractory Glioblastoma

TRACON also reported data from a Phase 2 trial of TRC105 in combination with Avastin in patients with glioblastoma (GBM) who had progressed on prior Avastin monotherapy:

- The combination of TRC105 and Avastin was well-tolerated with no apparent increase in the frequency or severity of adverse events typically associated with each individual drug.
- Overall survival (OS) of 5.8 months was observed in Avastin-refractory patients (n=15), which exceeded the historic OS of 4.0 months seen in a similar patient population treated in separate studies with single agent Avastin.
- A separate randomized Phase 2 trial comparing treatment with the combination of TRC105 and Avastin to single agent Avastin in Avastin-naïve GBM patients is fully enrolled with data expected by the end of 2016.

Phase 1 Trial of TRC102 with Temodar (temozolomide) in Patients with Solid Tumors

The National Cancer Institute (NCI) reported data from a trial of TRC102 in combination with Temodar in patients with refractory solid tumors to determine the safety, tolerability and maximum tolerated dose (MTD) of the combination.

- A total of 34 patients were enrolled in the trial, four of whom had a partial response (PR) (non-small cell lung cancer, ovarian cancer (2) and colon cancer); one further PR occurred in a patient with colon cancer, but was unconfirmed as a result of a concurrent illness; 9 patients had stable disease, 16 patients had progressive disease, and 5 were not evaluable.
- Three of the PRs were durable and lasted longer than 6 months.
- The MTD was reached at a dose level of TRC102 at 150 mg given orally on days 1-5 with Temodar at 150 mg/m² given orally on days 1-5, and further dose escalation resulted in hematologic toxicity.
- The observation of four PRs demonstrates that the combination of TRC102 and Temodar is active, and hematologic toxicity was manageable.
- The combination of TRC102 and Temodar is currently being evaluated in a Phase 2 trial of patients with glioblastoma.

All posters are available on TRACON's website at: <http://www.traconpharma.com/publications.php>

About TRC105 and other Endoglin Antibodies

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 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. For more information about the clinical trials, please visit TRACON's website at http://www.traconpharma.com/clinical_trials.php.

About TRC102

TRC102 (methoxyamine) is a novel, clinical-stage 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 or Case Comprehensive Cancer Center. For more information about the clinical trials, please visit TRACON's website at http://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.; and TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma. 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 a Phase 3 trial of TRC105 in angiosarcoma, the timing with respect to an on-going Phase 2 clinical trial of TRC105 in Avastin-naïve GBM patients, and other development plans and potential benefits of TRACON's product candidates. Forward-looking statements speak only as of the date of this press release and TRACON does not undertake any obligation to update or revise these statements, except as may be required by law. 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 results of subsequent studies may not be consistent with results of prior studies, TRACON's and NCI's ability to identify and enroll patients in on-going and planned clinical trials, potential delays in completing on-going clinical trials and initiating new clinical trials, whether TRACON's product candidates will be shown to be safe and effective in subsequent studies, and TRACON's and NCI's 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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