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 3, 2017**

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.)

8910 University Center Lane, Suite 700 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))

Item 8.01 Other Events.

On January 3, 2017, TRACON Pharmaceuticals, Inc. (TRACON) issued a press release announcing that it had reached an agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the protocol design, clinical endpoints and statistical analysis approach for the Company's Phase 3 study evaluating TRC105 for the treatment of patients with advanced angiosarcoma.

TRACON intends to conduct the Phase 3 TAPPAS trial (a randomized Phase 3 trial of **T**RC105 **A**n d **P**azopanib versus **P**azopanib alone in patients with advanced **A**ngio**S**arcoma) at sites in both the United States and Europe. This one-to-one randomized trial of TRC105 in combination with Votrient® (pazopanib) versus Votrient alone will initially enroll 124 patients. The trial features an adaptive design that, based on an interim analysis, can allow for sample size re-estimation up to a maximum of 200 patients, as well as possible enrichment of more responsive patients with cutaneous angiosarcoma. The primary endpoint of the trial is progression-free survival (PFS), with overall survival (OS) as a secondary endpoint.

The press release issued on January 3, 2017 is attached hereto as Exhibit 99.1.

Forward-Looking Statements

This report and the exhibit hereto contain forward-looking statements, including statements regarding the potential benefits that may be derived from the SPA, 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 will realize expected benefits from the SPA; the fact that the SPA does not guarantee regulatory approval, even if the planned Phase 3 trial meets the agreed-upon endpoints; 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; and whether TRACON will be able to obtain additional financing. 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
99.1	Press release issued by TRACON Pharmaceuticals, Inc. dated January 3, 2017.

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 3, 2017

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by TRACON Pharmaceuticals, Inc. dated January 3, 2017.

Exhibit 99.1

TRACON Pharmaceuticals Receives Special Protocol Assessment (SPA) Agreement from FDA for Phase 3 Clinical Trial of TRC105 in Angiosarcoma

SPA Agreement Reached with FDA on Trial Design, Endpoints and Statistical Approach for TAPPAS Trial

San Diego, CA – January 3, 2017– 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 (AMD) and fibrotic diseases, announced today that it has reached an agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the protocol design, clinical endpoints and statistical analysis approach for the Company's Phase 3 study evaluating TRC105 for the treatment of patients with advanced angiosarcoma.

"The SPA agreement represents a significant milestone for TRACON, as it provides us with a clearly defined development and regulatory pathway for TRC105, our lead clinical program, for the treatment of angiosarcoma," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We appreciate the FDA's engagement and guidance during the SPA process and look forward to dosing the first patients in the trial during early 2017."

TRACON intends to conduct the Phase 3 TAPPAS trial (a randomized Phase 3 trial of **T**RC105 **A**n d **P**azopanib versus **P**azopanib alone in patients with advanced **A**ngio**S**arcoma) at sites in both the United States and Europe. This one-to-one randomized trial of TRC105 in combination with Votrient® (pazopanib) versus Votrient alone will initially enroll 124 patients. The trial features an adaptive design that, based on an interim analysis, can allow for sample size re-estimation up to a maximum of 200 patients, as well as possible enrichment of more responsive patients with cutaneous angiosarcoma. The primary endpoint of the trial is progression-free survival (PFS), with overall survival (OS) as a secondary endpoint.

Further details of the Phase 3 clinical trial are available on www.clinicaltrials.gov under NCT02979899.

About Special Protocol Assessment (SPA)

The SPA process is one in which a sponsor asks the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a drug product's efficacy. An SPA agreement indicates concurrence with the adequacy and acceptability of specific critical elements of protocol design, endpoints and analysis. Additionally, it provides a binding agreement with FDA's review division with respect to the elements agreed to in the SPA process that are considered critical to ensuring the trial has the potential to support a future marketing application. However, final marketing approval depends upon the results of efficacy, the safety profile, and an evaluation of the risk/benefit of treatment demonstrated in the Phase 3 clinical trial, among other requirements, and the FDA may revoke or alter its agreement under certain circumstances. For further information regarding the SPA process, please visit the FDA website at www.fda.gov.

About TRC105 (carotuximab)

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 (NCI) 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 Angiosarcoma

Angiosarcoma is an aggressive form of soft tissue sarcoma (STS) of endothelial cell origin that is associated with poor prognosis. Angiosarcoma has a 5-year survival rate of less than 12%, which highlights the aggressive nature of this tumor when compared to a 5-year survival rate of approximately 56% for all STS. Angiosarcoma can arise in any soft tissue structure. About half of patients present with a primary cutaneous lesion. Risk factors include prior radiation exposure as well as inflammatory damage in chronically sun exposed skin. Angiosarcoma has also been associated with chronic lymphedema. Although resection with curative intent followed by adjuvant radiotherapy is the treatment of choice for localized disease amenable to surgery, approximately 50% of these patients will develop metastases and die from the disease. Furthermore, metastases are frequently present at diagnosis, and resection of metastases is rarely feasible.

Angiosarcoma is an extremely rare disease and meets the definition for an orphan disease in the US and European Union (EU), the two regions for which the Phase 3 TAPPAS study is planned. TRC105 has received orphan designation for the treatment of soft tissue sarcoma in both the US and EU. The annual incidence of angiosarcoma in the US was reported by the NCI in 2015 to be 475 cases. In the EU the incidence of angiosarcoma is 0.01 per 10,000, accounting for an estimated 508 cases annually.

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.

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 the potential benefits that may be derived from the SPA, 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 will realize expected benefits from the SPA; the fact that the SPA does not guarantee regulatory approval, even if the planned Phase 3 trial meets the agreed-upon endpoints; 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 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.

Company Contact:	Investor Contact:
Casey Logan	Andrew McDonald
Chief Business Officer	LifeSci Advisors LLC
(858) 550-0780 ext. 236	646-597-6987
clogan@traconpharma.com	Andrew@lifesciadvisors.com