

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): **April 12, 2019**

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.)

**4350 La Jolla Village Drive, Suite 800
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))

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 April 12, 2019, the Company issued a press release announcing the Independent Data Monitoring Committee's (IDMC) recommendation following the interim analysis from the TAPPAS randomized Phase 3 clinical trial of TRC105 in advanced angiosarcoma.

The TAPPAS trial is evaluating the combination of TRC105 with Votrient® (pazopanib) compared to single agent Votrient in advanced angiosarcoma patients, following the progression on or following systemic chemotherapy. The IDMC recommended the trial be terminated for futility following its review of the unblinded safety and efficacy data. As a result, the Company announced that it was terminating the TAPPAS trial as well as enrollment in all other Company-sponsored clinical trials of TRC105 in oncology.

The press release issued on April 12, 2019 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 April 12, 2019.
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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: April 12, 2019

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



TRACON Pharmaceuticals Announces Termination of Phase 3 TAPPAS Trial Based on the Recommendation of the Independent Data Monitoring Committee

Company to Host Investor Conference Call Today at 8:30 a.m. EDT / 5:30 a.m. PDT

San Diego, CA – April 12, 2019– TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer and, through our license to Santen Pharmaceutical Co. Ltd., wet age-related macular degeneration, today announced that its Phase 3 TAPPAS trial evaluating TRC105 in combination with Votrient (pazopanib) in patients with advanced or metastatic angiosarcoma was terminated for futility based on the recommendation of the Independent Data Monitoring Committee (IDMC) following its review of interim unblinded safety and efficacy data from more than 120 patients enrolled in the trial at the time of the analysis.

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 Votrient did not demonstrate clinically meaningful efficacy in patients with advanced or metastatic angiosarcoma,” said Charles Theuer, M.D. Ph.D., President and CEO of TRACON. “Given these data, we will terminate further enrollment in company sponsored trials of TRC105 in oncology. We will continue to support our partner, Santen, in their development of DE-122 in wet AMD, where the anti-angiogenic and anti-fibrotic properties of endoglin inhibition may be more relevant than in oncology. We will also continue to develop our other drug candidates, including TRC253 in partnership with Janssen and TJ004309 (also known as TJ-D5) in partnership with I-Mab, and, intend to advance candidates within I-Mab’s broad bispecific pipeline into the clinic in the US as early as the beginning of next year. We will also continue our business development efforts to source additional innovative products to fortify our pipeline through risk share and cost share arrangements. On a financial note, as a result of the expected savings to be generated from terminating TRACON sponsored trials of TRC105, we anticipate our current cash runway will now extend into the third quarter of 2020.”

Investor Conference Call

The Company will hold a conference call today at 8:30 a.m. EDT / 5:30 a.m. PDT to provide further details on the TAPPAS trial and TRACON’s clinical stage pipeline. The dial-in numbers are (877) 407-9039 for domestic callers and (201) 689-8470 for international callers. Please use passcode 13689814. A live webcast of the conference call will be available at <http://public.viaavid.com/index.php?id=134074>.

After the live webcast, a replay will remain available on TRACON’s website for 60 days.

About the TAPPAS trial in Advanced or Metastatic Angiosarcoma

4350 La Jolla Village Drive • Suite 800 • San Diego, California 92122 • P: 858.550.0780 • F: 858.550.0786
URL: www.traconpharma.com

The TAPPAS trial was designed to compare treatment with TRC105 and Votrient to treatment with single agent Votrient in up to 340 patients with advanced or metastatic angiosarcoma. 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, overall survival, safety and tolerability.

About TRC105 (carotuximab)

TRC105, the oncology formulation of 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 has received orphan designation for the treatment of soft tissue sarcoma in both the US and EU. The ophthalmic formulation of TRC105, DE-122, is currently being studied in the randomized Phase 2 AVANTE trial in patients with wet AMD. For more information about the clinical trials, please visit TRACON's website at www.traconpharma.com/clinical_trials.php.

About DE-122 (carotuximab)

DE-122, a novel ophthalmic formulation of carotuximab, is active in preclinical choroidal neovascularization (CNV) models and expected to enhance the effect of approved VEGF inhibitors used to treat wet AMD. DE-122 is being investigated in the Phase 2 randomized AVANTE trial assessing the efficacy and safety of intravitreal injections in combination with Lucentis® (ranibizumab) compared to Lucentis monotherapy in patients with wet AMD.

About TRACON

TRACON develops targeted therapies for cancer and, through our corporate partner Santen, ophthalmic diseases. The Company's clinical-stage pipeline includes: DE-122, the ophthalmic formulation of carotuximab 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, expected development milestones, TRACON's business development strategy, and TRACON's estimated cash runway following the discontinuation of TRC105 development. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical

development; 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 enter into additional collaboration or in-license agreements on acceptable terms or at all; 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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