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 20, 2020**

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))

Securities registered pursuant to Section 12(b) of the Securities Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TCON	The Nasdaq Stock Market LLC

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 20, 2020, Janssen Pharmaceutica N.V. (Janssen) notified the Company that it would not opt-in to reacquire rights to TRC253 following its review of results from a Phase 2 clinical trial in metastatic castration-resistant prostate cancer. As a result, the Company retains global rights to TRC253 under the existing license and option agreement with Janssen. The Company is obligated to pay to Janssen development and regulatory based milestones totaling up to $45.0 million upon achievement of specific events and royalties in the low single digits based on annual net sales of TRC253, subject to certain specified reductions.

A press release related to the TRC253 update and issued on April 24, 2020 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 24, 2020.

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 24, 2020

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 Retains Global Rights to TRC253 Following Completion of a Phase 1/2 Trial

TRACON seeks licensing partner to
develop and commercialize TRC253 in China

San Diego, CA – April 24, 2020 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, today announced that it has retained global rights to and has sole responsibility for development and commercialization of TRC253 based on Janssen Pharmaceutica N.V.'s (Janssen's) decision not to exercise its option to reacquire global rights to TRC253 following a review of the Phase 2 data in prostate cancer patients with acquired resistance to Xtandi® or Erleada®. Under the original agreement, TRACON is obligated to make certain payments to Janssen if future development and regulatory milestones are achieved and to pay a royalty on net sales of TRC253.

TRACON has initiated an out-licensing process to identify a corporate partner to develop and commercialize TRC253 in China, where androgen receptor (AR) inhibitors are not widely accessible to patients with prostate cancer. TRACON does not expect to devote further resources to developing TRC253 absent establishing a partnership in China.

"While TRC253 is as active as Xtandi in prostate cancer cell lines and in patient-derived xenograft models, we determined during clinical development that the F877L androgen receptor mutation TRC253 was designed to treat was far less common than predicted, and the product candidate was not highly active in prostate cancer patients with acquired resistance to Xtandi or Erleada. Given the preclinical data that suggest TRC253 may be as active as Xtandi in an earlier line setting, we believe TRC253 can be developed and commercialized successfully in China where many prostate cancer patients do not have widely available access to Xtandi or Erleada," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "As we have established three corporate partnerships in China over the past three years, we have developed significant relationships with Chinese pharmaceutical and biotechnology companies that we intend to leverage to identify a potential partner for TRC253 in this large oncology indication."

In a Phase 1/2 trial, TRC253 was dosed to 72 patients with metastatic castrate resistant prostate cancer who had progressed on prior treatment that included the wild type AR inhibitor Xtandi or Erleada, including patients with F877L androgen receptor mutation. The recommended Phase 2 dose of 280 mg orally per day was well tolerated with grade 1 QTc prolongation being the most common adverse event. The PSA response rate in 63 patients evaluable for efficacy, including patients with the AR F877L mutation, patients with other point mutations of the AR or patients with another basis for resistance to Xtandi or Erleada, was 8%. Seventeen of 63 patients (27%) had stable disease for more than five months (and for as long as 12 months). TRC253 is as active as Xtandi in preclinical models of prostate cancer (Bush TL et al, Cancer Res July 1 2019 79 (13 Supplement) 2179-2179; DOI:10.1158/1538-7445.AM2019-2179) and has not been studied yet in patients without acquired resistance to Xtandi or Erleada.

About TRC253 (formerly JNJ-63576253)

TRC253 is a novel, orally bioavailable small molecule discovered and developed by Janssen that is a potent, high affinity competitive inhibitor of the androgen receptor (AR). TRC253 is also a pan-inhibitor of multiple AR

mutations, including the F877L mutation. The AR F877L mutation results in an alteration in the ligand binding domain that confers resistance to current AR inhibitors.

Activation of the AR is crucial for the growth of prostate cancer at all stages of the disease. Therapies targeting the AR have demonstrated clinical efficacy by extending time to disease progression, and in some cases, the survival of patients with metastatic castration-resistant prostate cancer. However, resistance to these agents is often observed and several molecular mechanisms of resistance have been identified, including amplification, overexpression or mutation of the AR.

TRC253 is intended to address resistance mechanisms to current AR inhibitors by specifically targeting mutations in the AR ligand binding domain. TRC253 also potently inhibits signalling through the wild type AR. These susceptible AR mutations have been identified using circulating tumor DNA assays, potentially allowing for selected patient biomarker-directed therapy. TRACON completed initial Phase 1 and Phase 2 clinical trials for the treatment of men with prostate cancer, following the completion of IND-enabling studies by Janssen.

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient product development platform. The Company’s clinical-stage pipeline includes: Envafolimab, a subcutaneous PD-L1 single-domain antibody being developed for the treatment of sarcoma; TRC253, a small molecule drug being developed of the treatment of prostate cancer; TRC102, a small molecule drug being developed for the treatment of lung cancer; and TJ004309, a CD73 antibody being developed for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads U.S. regulatory and clinical development and shares in the cost and risk of clinical development and leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the U.S. 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, including TRC253, plans to seek a partner for the development and commercialization of TRC253 in China, the potential benefits of TRACON’s product candidates, including TRC253, and future obligations and developments. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with drug development; whether TRACON will be able to complete a license for TRC253; 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 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.

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