#### 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 4, 2019

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 Villa	ge 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))

Derecommencement 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 2.02 Results of Operations and Financial Condition.

Charles P. Theuer, M.D., Ph.D., President and Chief Executive Officer of TRACON Pharmaceuticals, Inc. ("TRACON"), and other executive officers will be presenting information that includes an estimate of TRACON's December 31, 2018 cash, cash equivalents and short-term investments and outstanding debt principal balances, at various upcoming meetings beginning January 6, 2019. The information is attached as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 7.01 Regulation FD Disclosure.

Charles P. Theuer, M.D., Ph.D., and other executive officers will be presenting the information attached as Exhibit 99.1 to this Current Report on Form 8-K at various upcoming meetings beginning January 6, 2019.

By furnishing this information, TRACON makes no admission as to the materiality of any information in this report. The information contained in this report and the exhibit hereto is intended to be considered in the context of TRACON's filings with the Securities and Exchange Commission and other public announcements that TRACON makes, by press release or otherwise, from time to time. TRACON undertakes no duty or obligation to publicly update or revise the information contained in this report or the exhibit hereto, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosure.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

#### Exhibit No.

99.1

Description Corporate Presentation, dated January 2019

#### 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 4, 2019

By: /s/ Charles P. Theuer, M.D., Ph.D. Charles P. Theuer, M.D., Ph.D.

President and Chief Executive Officer

TRACON PHARMACEUTICALS Investor Presentation

January 2019



NASDAQ: TCON

### **Forward-Looking Statements**

This presentation contains statements that are, or may be deemed to be, "forward-looking statements." In some cases these forwardlooking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," "potential," or, in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition, business strategy, current and prospective product candidates, planned clinical trials and preclinical activities, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success of development activities and business strategies, plans and objectives of management for future operations, and future results of anticipated product development efforts, including potential benefits derived therefrom. These statements involve substantial known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risks associated with conducting clinical trials, whether any of our product candidates will be shown to be safe and effective, our ability to finance continued operations, our reliance on third parties for various aspects of our business, competition in our target markets, our ability to protect our intellectual property, our ability to execute our business development strategy and in-license rights to additional pipeline assets, and other risks and uncertainties described in our filings with the Securities and Exchange Commission, including under the heading "Risk Factors". In light of the significant uncertainties in our forward-looking statements, you should not place undue reliance on these statements or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this presentation represent our estimates and assumptions only as of the date of this presentation and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this presentation.

This presentation also contains estimates, projections and other information concerning our industry, our business, and the markets for our drug candidates, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

## Investment Highlights: Late Stage Pipeline and Partnering Platform



### Broad Pipeline with Multiple Expected Near-term Readouts



<sup>4</sup> Part of a broad co-development and co-commercialization immune oncology partnership with I-Mab BioPharma (Shanghai) Co., Ltd. TRACON has certain royalty and non-royalty rights with respect to TJ4309; TRACON is responsible for development and commercialization of the bispecific programs in North America and shares profits and losses with I-Mab.



### **TRC105: Lead Program Expected Value Inflection Points**



 $\stackrel{\wedge}{\rightarrowtail}$  = interim inflection points



#### Targeting Endoglin Interrupts a VEGF Escape Mechanism and Potentiates PD-1 Checkpoint Inhibition



#### Enhancing VEGF Inhibition Represents a Substantial Potential Commercial Opportunity for TRC105

Indication	Approved VEGF Inhibitors	2017 VEGF Inhibitor Revenue <sup>1</sup>
1 <sup>st</sup> Line Liver	Nexavar (sorafenib)	\$940 M <sup>2</sup>
2 <sup>nd</sup> Line Soft Tissue Sarcoma	Votrient (pazopanib)	\$808 M <sup>3</sup>
Colorectal Cancer, Lung Cancer	Avastin (bevacizumab) Cyramza (ramucirumab) Zaltrap (ziv-aflibercept) Stivarga (regorafenib)	\$6.8 B \$758 M \$85 M \$355 M
WetAMD	Eylea (aflibercept) Lucentis (ranibizumab)	\$6.3 B \$3.3 B

#### Opportunity to build upon multiple VEGF inhibitor products by improving efficacy via inhibition of angiogenesis



1 GlobalData.

2 Nexavar is approved in HCC, RCC and thyroid cancer. The majority of Nexavar's sales are in HCC. 3 Votrient is approved in both RCC and advanced STS with the majority of sales in RCC.

### TRC105: Lead Asset Oncology Development Strategy



### Lead Indication: Angiosarcoma

- Ultra Orphan Indication: ~ 600 cases annually in the US and 1,200 in Europe; greater incidence in Asia<sup>1</sup>
- High Unmet Need: 5-year survival rate < 12% compared to 5-year survival rate of ~ 56% for all soft tissue sarcoma<sup>2</sup>
  - Treatment with chemotherapy (taxanes or doxorubicin) in the front line setting is associated with PFS of ~ 5 months and OS < 1 year<sup>3</sup>
  - Treatment with VEGF inhibitors in the second line setting is associated with PFS of 1.8 - 3.8 months and OS < 1 year</li>
- Two Subtypes: About 50% of patients present with a primary cutaneous lesion
- Market Potential: Estimated at \$100M+ in US/EU<sup>4</sup>

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<sup>1</sup>Suveillance, Epidemiology, and End Results Program, NCI, www.seer.cancer.gov; RARECARE database, <u>www.rarecare.eu</u> <sup>2</sup>www.cancerresearchuk.org <sup>3</sup>Penel et al, JCO 2008; Italiano et al, Cancer 2012 <sup>4</sup>TRACON estimate

#### High Unmet Need in Initial Pivotal Indication VEGF Inhibitors Have Limited Activity in Angiosarcoma

VEGF Inhibitor	Study	Patient Population	Activity
Votrient <sup>®₁</sup>	Retrospective analysis (CTOS 2016)	Angiosarcoma (n = 40)	<ul> <li>ORR = 20% (No CRs)</li> <li>PFS = 3.0 months</li> <li>OS = 9.9 months</li> </ul>
Votrient	Retrospective analysis (ASCO 2014)	Soft tissue sarcoma including 6 angiosarcoma patients	• No CR's
Nexavar®	Single agent study (Maki 2009)	Angiosarcoma (n = 37)	• ORR = 14% (1/37 CR) • PFS = 3.8 months
Nexavar	Single agent study (French sarcoma group)	Angiosarcoma (n = 41)	Cutaneous angiosarcoma • ORR = 15% (2/26 CR) • PFS = 1.8 months Visceral angiosarcoma • ORR = 13% (No CRs) • PFS = 3.8 months
Avastin®	Single agent study (Agulnik 2013)	Angiosarcoma (n = 23)	• ORR = 9% (No CRs) • PFS = 3.0 months



<sup>1</sup> Votrient is the only VEGF inhibitor approved for the treatment of soft tissue sarcoma based on the superior PFS versus placebo (4.6 versus 1.6 months) in the Phase 3 PALETTE study.

### TRC105 + Votrient is Active in Angiosarcoma

- · PFS in 13 VEGF inhibitor-naïve patients of 7.8 months vs. 3 month PFS expected with Votrient
- Majority of patients had superior time on treatment with TRC105 + Votrient compared to prior therapy.
- US and EU regulators allowed enrollment of treatment naive angiosarcoma patients into the Phase 3 TAPPAS trial

Study Duration of 9 Angiosarcoma Patients Treated with TRC105 + Pazopanib in the Original Phase 1b/2 Trial and 9 Patients in the Expansion Cohort



### TRC105 + Votrient Phase 1b/2 Observations

#### Patient #1 off study (due to AE) after 30+ months with ongoing CR



Data as of November 2017

#### Patient #2 maintained a CR for 28+ months



#### Patient #3 remained on treatment for 16 months



Day 0

Day 84

#### Phase 3 TAPPAS Randomized Trial in Angiosarcoma

TAPPAS: TRC105 And Pazopanib versus Pazopanib alone in patients with advanced Angiosarcoma



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# Phase 3 TAPPAS Trial in Angiosarcoma

Design recognized as Most Innovative Clinical Trial of 2017 Allows for sample size re-estimation or enrichment of cutaneous disease at the time of the interim analysis expected in 1Q 2019



## TRC105 + Nexavar in Liver Cancer

- NCI Phase 1/2 study published in Clinical Cancer Research partial response rate by RECIST of 25% across 4 dose levels; all responses occurred at two highest dose levels (10 or 15 mg/kg) of TRC105
  - Exceeded partial response rate of Nexavar in Phase 3 pivotal studies of 2 3%
  - Median OS of 15.5 months exceeded median OS of Nexavar in its pivotal Phase 3 of 10.7 months



- Multicenter Phase 1/2 trial in up to 33 patients is enrolling to confirm response rate

   Interim data presented at GI ASCO (January 2018): partial responses in 2 of first 8 evaluable patients
  - Additional data expected at GI ASCO January 2019
- Late stage development in HCC in greater China to be led by corporate partner Ambrx

## TRC105 Large Indication: TRC105 + Opdivo<sup>®</sup> in Lung Cancer

- Endoglin is a TGF-β co-receptor expressed on myeloid derived suppressor cells (MDSCs), cells not addressed by checkpoint inhibition
  - TGF-β signaling implicated as a primary means of tumor immune evasion that complements checkpoint inhibition and tumor mutational burden
- TRC105 potentiates PD-1 inhibition in syngeneic mouse tumor models



## TRC105 Large Indication: TRC105 + Opdivo<sup>®</sup> in Lung Cancer

- TRC105 + Opdivo Phase 1 trial in lung cancer
  - Dose escalation portion completed
    - · Combination was well tolerated without dose limiting toxicity
    - · One of six patients with ongoing partial response
    - · Two additional ongoing patients with stable disease
  - Expanded cohort portion
    - PD-1/PD-L1 checkpoint inhibitor naïve patients (N=12)
    - PD-1/PD-L1 checkpoint inhibitor relapsed patients (N=12)
- Data to be presented at International Association for the Study of Lung Cancer (IASLC) in February 2019 in Santa Monica by Dr. Francisco Robert of the University of Alabama, Birmingham



### Santen License for DE-122



- Global ophthalmology company with \$1.8 billion in annual revenue leads global development and commercialization for DE-122 (ophthalmic formulation of TRC105) in wet AMD and other eye diseases
- Deal terms
  - \$20M received
  - Santen pays all development costs and commercializes
  - Up to \$145M in additional milestones
  - Royalties in the high single digits to low teens
- Failed Phase 2 and 3 studies from Ophthotech and Regeneron place DE-122 in lead for VEGF inhibitor companion drug to build on \$9B market in wet AMD; high unmet need
- Regulatory path is well defined

#### Santen Development of DE-122 in wet AMD

- Phase 1/2 PAVE trial results presented February 10, 2018 at the Angiogenesis, Exudation and Degeneration meeting at Bascom Palmer Eye Institute
  - 8 out of 12 subjects demonstrated bioactivity: improved macular edema or visual acuity
  - Safe with no serious adverse events
- Phase 2 AVANTE randomized trial is enrolling data expected mid 2019



## **TRC102: Expected Value Inflection Points**

Companion Therapy	2019	2020
Alimta	Phase 2 Mesothelioma	
Alimta/cisplatin	Phase 1b Solid Tumors	
Temodar	Phase 1b Solid Tumors	
Chemoradiation	Phase 1b Lung	

- Small molecule designed to reverse resistance to chemotherapy and complement PARP inhibitors
- Inhibits base excision repair, a dominant pathway of DNA repair that allows for resistance to alkylating chemotherapy (e.g., Temodar<sup>®</sup>) and antimetabolite chemotherapy (e.g., Alimta<sup>®</sup>)
- · Current clinical development funded by National Cancer Institute

## **TRC102: Reversing Resistance to Chemotherapy**

Combination	Well Tolerated	Signs of Activity in Phase 1b/2	Ongoing Development
TRC102 + Alimta (Published in Investigational New Drugs, 2012)	$\checkmark$	Stable disease in patients with squamous cell lung cancer, a tumor type where Alimta is inactive	Phase 2 trial with Alimta in mesothelioma
TRC102 + Fludara (Published in Oncotarget, 2017)	$\checkmark$	Partial response and stable disease in patients previously treated with Fludara	
TRC102 + Temodar (Presented at ASCO 2017)	$\checkmark$	Partial responses in patients with lung, KRAS+ colorectal and ovarian cancer; induced biomarkers of DNA damage Rad51, pNbs1, and/or γ- H2AX	Phase 2 expansion cohorts added in lung, colorectal, and ovarian cancer; Phase 2 trial with Temodar in glioblastoma
TRC102 + Temodar in GBM (Presented at SNO 2018)	$\checkmark$	PFS of 11+ months in 2/19 patients with recurrent GBM that was associated with glycosylase expression	None

 Efforts are focused on identifying a biomarker (e.g., glycosylase expression) that will correlate with response to treatment with chemotherapy + TRC102

### Janssen In-Licenses: Expected Value Inflection Points

	2019	2020
TRC253	Phase 1/2 Prostate Cancer	
TRC694	Myeloma; Lymphoma IND	

 TRC253 is an antagonist of AR mutations that are resistance mechanisms for Xtandi
 and Erleada

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#### - Phase 1 trial completed July 2018; dosing in Phase 2

- TRC694 is a selective inhibitor of NF-kB-inducing kinase (NIK)
- TRACON was chosen because of our innovative product development platform

#### **TRC253 Deal Terms**

- Janssen has rights to re-acquire TRC253 for \$45M, additional potential milestones of \$137.5M and low single digit royalty
- If Janssen passes, TRACON retains all rights and will owe development and regulatory milestones of up to \$45M and a low single digit royalty to Janssen

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#### **TRC694 Deal Terms**

- Janssen has a right of first negotiation for TRC694 following Phase 1 POC
- TRACON owes development and regulatory milestones of up to \$60M and a low single digit royalty

# TRC253: Novel Androgen Receptor (AR) Mutant Inhibitor

- Designed to treat AR resistant prostate cancer
  - Occurs in ~10% of mCRPC cases
- Active against wild-type AR and many clinically relevant ligand binding domain mutations
- Clear path to POC data in targeted population using a companion diagnostic
- Phase 1 trial completed and Phase 2 trial now enrolling



#### **Multiple Mechanisms of Action**



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## TRC694: Novel NF-kB Inducing Kinase (NIK) Inhibitor

- NIK pathway is dysregulated in hematologic malignancies
  - Multiple myeloma (~12-20% of cases), mantle cell lymphoma (~17%), diffuse large B-cell lymphoma (~9-15%), CLL (~4% at diagnosis, higher later)
- Clear path to POC data in targeted population using a precision medicine approach→ IND expected in 2019



#### NIK is Critical for Non-Canonical NFκB Activation



Krappmann & Vincendeau, 2016

### I-Mab In-licenses: Expected Value Inflection Points



- CD73 Antibody
  - CD73 is receptor expressed on tumors that generates adenosine that suppresses the immune response to tumors.
  - TRACON and I-Mab share clinical development expenses starting with Phase 2
- Bispecific Antibodies
  - · Option to co-develop and co-commercialize up to 5 bispecific antibodies
  - TRACON and I-Mab share clinical development expenses starting with the pivotal trial
- No license payment by TRACON

#### **CD73 Antibody**

- TRACON is entitled to portions of royalty and non-royalty consideration received by I-Mab for territories outside China, ranging from a highsingle digit % of non-royalty consideration to a mid-teen % of non-royalty consideration and double digit % of royalty consideration.
- consideration and double digit % of royalty consideration.
  TRACON is entitled to receive a royalty on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the European Union and Japan in the mid-single digits.
- TRACON is entitled to pre-specified termination fee and either a % of non-royalty consideration I-Mab may receive as part of a license to a third party or an additional payment if TJ4309 is approved for marketing outside Greater China before a third party license is executed.

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#### **Bispecific Antibodies**

- TRACON will be responsible for commercializing in North America, and the parties will share profits and losses equally.
- TRACON is entitled to tiered low single digit royalties on net sales of product candidates in the European Union and Japan.
- Prior to P3 read-out, TRACON can opt-in to acquire global commercial rights outside of Korea and China for pre-specified upfront and milestone payments and royalties on net sales including a double digit million dollar upfront payment, as well as development milestone payments that begin upon completion of a pivotal study, sales milestones, and a single to double digit royalty on net sales.

#### Expected Milestones: Poised to Deliver on a Number of Clinical Programs in 2019 and 2020



Corporate Goal is to Collaborate on the Development of 2 Additional Assets

### **TRACON's Innovative Product Development Platform Could Benefit Innovative Pharmaceutical Companies**



#### TRACON Transitioned to CRO-Independent to Reduce Cost, Improve Quality, Decrease Timelines and Maintain Control



- Pharmacovigilance
- Study Management
- Data Management
- Bioinformatics & IT

- Statistics (Consultant)
- Clinical Supplies
- CMC & Regulatory with FDA and EMA
- Monitoring(Contract)

#### **Aligned Product Development Solution**

- · Cost, risk and profit share of partnered assets produces goal alignment
  - Platform can be applied to develop first-in-class, best-in-class or fast-follower oncology and other physician specialist prescribed products.
- U.S. NDA/BLA can be leveraged for regulatory filings in all major territories
- Industry recognition for clinical trial design (Clinical Research Excellence Awards 2017)
- Commercial presence in U.S. preserves value of product between corporate partners (and is possible in 2021-2022 through potential TRC105 approval)
- Collaborations with I-Mab and Janssen, including equity investment from JJDC, validates TRACON's product development platform

# Financial Overview (as of December 31, 2018)

Ticker	TCON (NASDAQ)
Cash, Cash Equivalents and Short-term Investments	\$39.1 million
Debt – Outstanding Principal	\$7.0 million
Common Shares O/S	29.9 million
Covering Analysts	Jim Birchenough (Wells Fargo) Bert Hazlett (BTIG) Chad Messer (Needham) Maury Raycroft (Jefferies)

## Investment Highlights: Late Stage Pipeline and Partnering Platform





### TRC105 Target: Endoglin is an Essential Non-VEGF Angiogenic Target

- Expressed on proliferating blood vessels in cancer and AMD
  - Essential for angiogenesis
  - Unfavorable prognostic marker
  - Up-regulated following VEGF inhibition
- Attenuated expression (Osler-Weber-Rendu syndrome) associated with improved cancer survival
- Genetic knockdown reverses resistance to VEGF inhibition
- Targeting VEGF and endoglin concurrently improves antitumor effects
- Targeting endoglin on myeloid derived suppressor cells (MDSCs) potentiates PD-1/PD-L1 inhibition in preclinical models







and the second

Normal Human Liver

Human Liver Cancer

Angiosarcoma

Human AMD Membrane

# Lead Endoglin Antibody TRC105 binds a precise endoglin epitope to inhibit BMP ENG BMPR2 ALK1 TRC105 binding and angiogenesis TRC105 also potently mediates antibody-dependent cell mediated cytotoxicity (ADCC) BMP9 SMAD 1/5/8 SMAD 1/5/8 Phosphorylated SMAD 1/5/8 Decreased phosphorylated SMAD 1/5/8 allows unopposed phospho-SMAD 2/3

Organized endothelial cell proliferation

signaling to restore a quiescent phenotype

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**TRC105:** 

## **TRC102: Reversing Resistance to Chemotherapy**



# **Team of Industry Experts**





#### TRACON

Aqouron.

Irius

Therapeutics

## SAB and Board Bring Deep Industry Experience

#### Scientific Advisory Board

- Charles Sawyers, MD Memorial Sloan Kettering Cancer Center
- William Kaelin, MD Harvard Medical School
- Jeff Hager, PhD Former CSO, Aragon
- Stanton Gerson, MD
   Case Cancer Center

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