

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): **November 7, 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.)

**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))

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.

On November 7, 2017, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2017. A copy of this press release is furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.

Description

99.1	<u>Press release issued by TRACON Pharmaceuticals, Inc. on November 7, 2017 announcing its financial results for the quarter ended September 30, 2017.</u>
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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: November 7, 2017

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

TRACON Pharmaceuticals Reports Third Quarter Financial Results and Provides Corporate Update

San Diego, CA – November 7, 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 and fibrotic diseases, today announced financial results for the third quarter ended September 30, 2017.

Third Quarter 2017 and Recent Corporate Highlights

- We continue to enroll patients in the randomized Phase 3 TAPPAS trial of TRC105 combined with Votrient® (pazopanib) for the treatment of advanced angiosarcoma. Currently, more than 20 sites are open for accrual in the U.S., and sites in EU countries are expected to be open by year-end. As a reminder, the initial TAPPAS sample size of 124 patients is designed to detect an improvement in progression-free survival (PFS) from four to seven months. The trial uses an adaptive design that allows for expansion of patient numbers and selective enrollment of a responsive subtype of angiosarcoma while preserving type-1 error. TRACON expects that the interim analysis will be conducted in the second half of 2018.
- In October, two posters highlighting TRC105 were presented at the 18th World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (IASLC) in Yokohama, Japan. Initial data from patients in the ongoing Phase 1b study of TRC105 in combination with Avastin® (bevacizumab) and chemotherapy for the treatment of non-squamous cell lung cancer were presented. Three of eight (37%) evaluable patients had partial responses by RECIST 1.1, including one patient who achieved an 81% reduction in tumor volume. The complete enrollment of approximately 18 patients is expected by the end of 2018. In addition, investigators at the University of Alabama-Birmingham presented a “trials in progress” poster which detailed the study design of the Phase 1b dose-escalation trial of TRC105 and Opdivo® (nivolumab) in patients with metastatic non-small cell lung cancer that is open for accrual.
- In September, TRACON announced that enrollment was completed in the randomized Phase 2b TRAXAR study of TRC105 and Inlyta® (axitinib) in patients with advanced or metastatic renal cell carcinoma (RCC). The Company expects to report top-line PFS data from this study in early 2018 based on the observed rate of events of disease progression or death that define the PFS endpoint. We expect the study to have at least 80 events confirmed by the independent central review committee at the time of data readout, which should provide at least 70% power to detect an improvement in PFS from 4.8 months with Inlyta to 7.2 months with the combination of TRC105 and Inlyta. PFS will also be assessed in patients with predefined levels of two soluble biomarkers, osteopontin and TGF- β receptor III, which correlated with response in the Phase 1 portion of the trial.
- In July, following completion of the Phase 1/2 PAVE trial, TRACON and its partner, Santen Pharmaceutical Co. Ltd. (Santen), announced initiation of the randomized Phase 2a AVANTE study of DE-122, the ophthalmic formulation of TRC105, for the treatment of patients with wet age-related macular degeneration (AMD). The Phase 2a study is a randomized controlled trial designed to assess the safety and efficacy of repeated intravitreal injections of two different doses of DE-122 in combination with Lucentis® (ranibizumab) compared to single agent Lucentis in patients with wet AMD. The Phase 2a study initiation resulted in a \$7.0 million milestone payment to TRACON.

“The recently achieved progress across our pipeline positions us well for several important potentially value-creating milestones in the first half of 2018,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “In addition, we are highly encouraged by our partner Santen’s decision to advance DE-122 into the randomized Phase 2 AVANTE study in wet AMD.”

Expected Upcoming Milestones Through 1H ‘18

- Presentation of updated safety, pharmacokinetics and efficacy data from the completed Phase 1b/2 trial of TRC105 and Votrient in patients with angiosarcoma at the annual meeting of the Connective Tissue Oncology Society (CTOS) in Maui on November 9, 2017.
- Presentation of early response data from the multicenter Phase 1/2 trial of TRC105 and Nexavar® (sorafenib) in patients with hepatocellular carcinoma.
- Completion of dose escalation in the Phase 1/2 clinical trial of TRC253 in patients with prostate cancer.
- Announcement of top-line data from the randomized Phase 2 TRAXAR trial of TRC105 in combination with Inlyta.
- Presentation of data from Santen’s completed Phase 1/2 PAVE trial of DE-122.

Third Quarter 2017 Financial Results

- Cash, cash equivalents and short-term investments were \$35.9 million at September 30, 2017, compared to \$44.4 million at December 31, 2016.
- Collaboration revenue for the third quarter of 2017 was \$7.5 million compared to \$0.8 million for the third quarter of 2016.
- Research and development expenses for the third quarter of 2017 were \$4.3 million compared to \$4.5 million for the third quarter of 2016.
- General and administrative expenses for the third quarter of 2017 were \$1.8 million compared to \$1.9 million for the third quarter of 2016.
- Net income for the third quarter of 2017 was \$1.2 million compared to a net loss of \$5.9 million for the third quarter of 2016.

Investor Conference Call

The Company will hold a conference call today at 4:30 p.m. EST / 1:30 p.m. PST to provide an update on corporate activities and to discuss the financial results of its third quarter of 2017. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 7458759. A live webcast of the conference call will be available online from the Investor/Events and Presentation page of the Company’s website at www.traconpharma.com.

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

About Carotuximab (TRC105)

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 a pivotal Phase 3 trial in angiosarcoma and multiple Phase 2 clinical trials, in combination with VEGF inhibitors. TRC105 has received orphan designation for the treatment of soft tissue sarcoma in both the U.S. and EU. The ophthalmic formulation of TRC105, DE-122, is currently in a randomized Phase 2 trial for patients with wet AMD. For more information about the clinical trials, please visit TRACON's website at www.traconpharma.com/clinical_trials.php.

About TRC253

TRC253 is a novel, orally bioavailable small molecule that is a potent, high affinity competitive inhibitor of the androgen receptor (AR) and AR mutations, including the F876L (also known as F877L) mutation. The AR F876L mutation results in an alteration in the AR ligand binding domain that confers resistance to therapies for prostate cancer. 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 gene amplification, overexpression, alternative splicing, and point mutation of the AR.

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.; TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule that is being developed for the treatment of prostate cancer. 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, expectations regarding the timing of future clinical trials by TRACON or third parties, expected development milestones, availability of additional clinical data and potential utility of TRACON's product candidates. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON, Santen or others will be able to complete or initiate clinical trials on TRACON's expected timelines, if

at all; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that TRACON has limited control over whether or when Santen or other any other third party completes on-going trials or initiates additional trials of TRACON's product candidates; 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.

TRACON Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Collaboration revenue	\$7,498	\$815	\$8,755	\$2,832
Operating expenses:				
Research and development	4,257	4,531	14,732	16,799
General and administrative	1,847	1,881	5,879	5,934
Total operating expenses	6,104	6,412	20,611	22,733
Income (loss) from operations	1,394	(5,597)	(11,856)	(19,901)
Total other income (expense)	(224)	(274)	(687)	(793)
Net income (loss)	\$1,170	\$(5,871)	\$(12,543)	\$(20,694)
Net income (loss) per share, basic and diluted	\$0.07	\$(0.48)	\$(0.76)	\$(1.70)
Weighted-average common shares outstanding, basic	16,828,801	12,227,081	16,550,730	12,200,628
Weighted-average common shares outstanding, diluted	17,137,311	12,227,081	16,550,730	12,200,628

TRACON Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	September 30,	December 31,
	2017	2016
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$32,864	\$35,710
Short-term investments	3,000	8,703
Prepaid and other assets	1,441	1,235
Total current assets	37,305	45,648
Property and equipment, net	71	82
Total assets	<u>\$37,376</u>	<u>\$45,730</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$6,505	\$6,213
Accrued compensation and related expenses	1,325	1,588
Current portion of deferred revenue	-	1,259
Long-term debt, current portion	1,994	333
Final payment due bank	-	850
Total current liabilities	9,824	10,243
Other long-term liabilities	407	21
Long-term debt, less current portion	5,329	7,130
Commitments and contingencies		
Stockholders' equity:		
Common stock	17	16
Additional paid-in capital	119,940	113,918
Accumulated deficit	(98,141)	(85,598)
Total stockholders' equity	<u>21,816</u>	<u>28,336</u>
Total liabilities and stockholders' equity	<u>\$37,376</u>	<u>\$45,730</u>

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