

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): **February 28, 2018**

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 2.02 Results of Operations and Financial Condition.

On February 28, 2018, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 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

[Press release issued by TRACON Pharmaceuticals, Inc. on February 28, 2018 announcing its financial results for the quarter and year ended December 31, 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: February 28, 2018

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



TRACON Pharmaceuticals Reports Fourth Quarter and Year-End 2017 Financial Results and Provides Corporate Update

San Diego, CA – February 28, 2018– TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer and wet age-related macular degeneration, today announced financial results for the fourth quarter and year ended December 31, 2017.

Fourth Quarter 2017 and Recent Corporate Highlights

- In February, TRACON's partner, Santen Pharmaceutical Co. Ltd. (Santen), reported Phase I/II data for DE-122 (carotuximab) in patients with refractory wet age-related macular degeneration (AMD) at the 15th Annual Angiogenesis, Exudation, and Degeneration meeting organized by Bascom Palmer Eye Institute. The study assessed the safety, tolerability and bioactivity of a single intravitreal injection of DE-122 at four dose levels in 12 subjects with wet AMD refractory to vascular endothelial growth factor (VEGF) inhibitors. Improvement was observed in mean change in central retinal subfield thickness (CST) based on the spectral domain optical coherence tomography (SD-OCT) suggesting bioactivity of DE-122 in these refractory wet AMD patients. No serious adverse events were reported. Based on these results, Santen previously advanced DE-122 into a Phase 2a randomized controlled trial assessing the efficacy and safety of intravitreal injections in combination with Lucentis® (ranibizumab) compared to Lucentis monotherapy in patients with wet AMD that continues to enroll subjects, and which resulted in TRACON receiving a \$7.0 million milestone payment.
- In January, initial data from the ongoing open-label, non-randomized Phase 1b/2 study of TRC105 and Nexavar® (sorafenib) in patients with advanced hepatocellular carcinoma (HCC) were presented by Dr. Kanwal Raghav from the University of Texas MD Anderson Cancer Center at the 2018 ASCO Gastrointestinal Cancers Symposium. Partial responses by RECIST 1.1 occurred in 25% (2 of 8) of evaluable patients and a reduction of 50% or greater in alpha fetoprotein (AFP) concentration occurred in 38% (3 of 8) of evaluable patients, including both partial responses. Reduction in AFP, a tumor marker expressed in patients with HCC, in early treatment may help identify a favorable response to treatment. Adverse events typical of each drug were observed but did not increase in frequency or severity when the drugs were administered concurrently. The 25% response rate seen in this trial is consistent with the 25% (5 of 20) response rate reported in a Phase 1/2 trial of TRC105 and Nexavar conducted by the National Cancer Institute and published in *Clinical Cancer Research* in 2017. The response rates observed in both trials compare favorably with the 2% and 3% response rates in HCC patients reported for single agent Nexavar in its pivotal studies. The trial is currently ongoing, and we expect to complete the enrollment of approximately 33 patients by the end of 2018.
- In December, TRACON licensed development and commercialization rights outside of ophthalmology indications to TRC105 in China, Hong Kong, Macau, and Taiwan to Ambrx. Deal terms included a \$3.0 million upfront payment to TRACON, up to \$140.5 million in development and commercial milestones and potential high single digit to low teen royalties from net sales of TRC105 in the Ambrx territories. Ambrx is expected to file an IND later this year and to subsequently begin clinical development of TRC105 in China.
- In December, Brian Daniels, M.D., was appointed to TRACON's Scientific Advisory Board. Dr. Daniels was Senior Vice President at Bristol-Myers Squibb until 2014, where he chaired the development investment

committee and oversaw the development of Sprycel® (dasatinib), Ixempra® (ixabepilone), Yervoy® (ipilimumab), Empliciti® (elotuzumab), and Opdivo® (nivolumab). He is currently a venture partner at 5AM Ventures, and previously held senior level development-related positions at Merck and Genentech. In addition, Dr. Daniels previously served in multiple academic roles in the Department of Medicine at the University of California, San Francisco.

- In November, the first patient was dosed in a Phase 1b clinical trial of TRC105 in combination with Opdivo in patients with non-small cell lung cancer. The Phase 1b clinical trial is an open-label, dose-escalation and expansion cohort study of TRC105 and Opdivo in patients with non-small cell lung cancer that have received prior chemotherapy. The primary objectives of the Phase 1b study are to assess the safety of TRC105 when dosed with Opdivo, determine its recommended Phase 2 dose and evaluate the response rate. The trial incorporates tumor biopsy testing to determine if there is a correlation of tumor myeloid cell infiltration with response, in order to allow for potential biomarker-directed therapy in lung cancer patients.
- In November, TRACON presented updated data from the Phase 1b/2 study of TRC105 and Votrient® (pazopanib) in patients with soft tissue sarcoma, including angiosarcoma, at the Connective Tissue Oncology Society (CTOS) annual meeting. Median progression-free survival (PFS) was 7.8 months in 13 VEGF inhibitor naïve angiosarcoma patients treated with the combination of TRC105 and Votrient using either 10 mg/kg weekly dosing or the hybrid dosing schedule of TRC105. The reported median PFS compares favorably to the median PFS of 3 months reported in a retrospective study of single agent Votrient in patients with angiosarcoma. In the 17 patients who received prior treatment for metastatic disease, treatment duration on TRC105 and Votrient exceeded the duration of the most recent prior therapy in 7 of 12 VEGF naïve angiosarcoma patients and 2 of 5 patients who received a VEGF inhibitor as part of their most recent prior therapy. Treatment with the combination of TRC105 and Votrient continued to be well-tolerated and allowed for dosing of the combination for more than two years in the two patients who experienced complete responses to treatment.
- Enrollment continues in the Phase 1/2 trial of TRC253, TRACON's product candidate for treating prostate cancer that was in-licensed from Janssen. The Phase 1/2 trial is designed to assess the safety, determine a recommended Phase 2 dose and assess response by prostate-specific antigen (PSA) levels. If Janssen opts to reacquire TRC253 prior to or following completion of the Phase 1/2 trial, TRACON is entitled to receive a \$45.0 million opt-in payment, up to \$137.5 million in potential milestone payments and a low single digit royalty.

"We achieved important progress across our pipeline and continued to position the Company well for long-term success during the fourth quarter and throughout 2017," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Most importantly, our pivotal Phase 3 TAPPAS trial of TRC105 in angiosarcoma continues to enroll well across sites in the U.S. and now Europe, with the key interim analysis projected for later this year. Moreover, our recent partnership with Ambrx expands the development and potential commercial opportunity of TRC105 into China."

Expected Additional 2018 Milestones

- Completion of the dose escalation portion of the Phase 1/2 trial of TRC253 in patients with prostate cancer is expected in mid-2018.
- Announcement of top-line data from the randomized Phase 2 TRAXAR trial of TRC105 in combination with Inlyta for patients with advanced or metastatic renal cell carcinoma is expected in mid-2018.
- Announcement of the results of the interim analysis from the Phase 3 pivotal TAPPAS trial of TRC105 in angiosarcoma is expected in the second half of 2018.
- Presentation of data from the Phase 1b trial of TRC105 in combination with Opdivo in patients with non-small cell lung cancer is expected in the second half of 2018.

Fourth Quarter 2017 Financial Results

- Cash, cash equivalents and short-term investments were \$34.5 million at December 31, 2017, compared to \$44.4 million at December 31, 2016.
- There was no collaboration revenue for the fourth quarter of 2017 compared to \$0.6 million for the fourth quarter of 2016.
- Research and development expenses for the fourth quarter of 2017 were \$4.6 million compared to \$4.8 million for the fourth quarter of 2016.
- General and administrative expenses for the fourth quarter of 2017 were \$1.7 million compared to \$1.9 million for the fourth quarter of 2016.
- Net loss for the fourth quarter of 2017 was \$6.6 million compared to a net loss of \$6.3 million for the fourth 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 fourth quarter of 2017. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 1894785. 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 and ophthalmic 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 being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule 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 clinical trials and regulatory filings by TRACON or third parties, potential benefits of TRACON's collaborations, 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 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 third party collaborators complete on-going trials or initiates additional trials of TRACON's product candidates; 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 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 December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Collaboration revenue	\$ -	\$617	\$8,755	\$3,449
Operating expenses:				
Research and development	4,623	4,767	19,355	21,566
General and administrative	1,731	1,925	7,610	7,859
Total operating expenses	6,354	6,692	26,965	29,425
Loss from operations	(6,354)	(6,075)	(18,210)	(25,976)
Total other income (expense)	(206)	(239)	(893)	(1,032)
Net loss	\$(6,560)	\$(6,314)	\$(19,103)	\$(27,008)
Net loss per share, basic and diluted	\$(0.37)	\$(0.45)	\$(1.14)	\$(2.13)
Weighted-average common shares outstanding, basic and diluted	17,563,861	14,099,380	16,806,094	12,677,910

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

	December 31,	
	2017	2016
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$29,467	\$35,710
Short-term investments	4,999	8,703
Prepaid and other assets	1,591	1,235
Total current assets	36,057	45,648
Property and equipment, net	73	82
Total assets	\$36,130	\$45,730
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$6,800	\$6,213
Accrued compensation and related expenses	1,494	1,588
Current portion of deferred revenue	667	1,259
Long-term debt, current portion	2,837	333
Final payment due bank	-	850
Total current liabilities	11,798	10,243
Other long-term liabilities	409	21
Deferred Revenue	2,333	-
Long-term debt, less current portion	4,603	7,130
Commitments and contingencies		
Stockholders' equity:		
Common stock	18	16
Additional paid-in capital	121,670	113,918
Accumulated deficit	(104,701)	(85,598)
Total stockholders' equity	16,987	28,336
Total liabilities and stockholders' equity	\$36,130	\$45,730

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