
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, 2017**

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.)

8910 University Center Lane, Suite 700
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))
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Item 2.02 Results of Operations and Financial Condition.

On February 28, 2017, TRACON Pharmaceuticals, Inc. (“TRACON”) issued a press release announcing its financial results for the quarter and year ended December 31, 2016. A copy of this press release is furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by TRACON Pharmaceuticals, Inc. on February 28, 2017 announcing its financial results for the quarter and year ended December 31, 2016.

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, 2017

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

Charles P. Theuer, M.D., Ph.D.

President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by TRACON Pharmaceuticals, Inc. on February 28, 2017 announcing its financial results for the quarter and year ended December 31, 2016



TRACON Pharmaceuticals Reports Fourth Quarter and Year-End 2016 Financial Results and Provides Corporate Update

San Diego, CA – February 28, 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 fourth quarter and year ended December 31, 2016.

“During the fourth quarter of 2016 and beginning of this year, we made significant progress toward several important corporate objectives, and anticipate a number of additional potentially value-creating milestones over the remainder of 2017,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “We have recently initiated dosing in the first pivotal study of TRC105 in patients with angiosarcoma in both the U.S. and Europe following beneficial discussions with regulators in both regions. In addition, we intend to initiate the first-in-human clinical trial of TRC253, one of the two compounds in-licensed from Janssen last year, in patients with prostate cancer in the first half of 2017. Finally, we expect our partner, Santen, to initiate Phase 2 development of DE-122, the ophthalmic formulation of TRC105, in wet AMD later this year. Importantly, we are leveraging our unique and differentiated product development platform to complete all of our development activities, and look forward to continued progress throughout the course of the year.”

Fourth Quarter 2016 and Recent Corporate Highlights

- In February 2017, the Company initiated dosing in the Phase 3 TAPPAS (a randomized Phase 3 trial of TRC105 And Pazopanib versus Pazopanib alone in patients with advanced AngioSarcoma) trial of TRC105. In January 2017, the Company announced that agreement was reached with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the protocol design, clinical endpoints and statistical analysis approach for the TAPPAS trial. This one-to-one randomized trial of TRC105 in combination with Votrient® (pazopanib) versus single agent Votrient features an adaptive enrichment design which allows for greater flexibility and efficiency to identify potential signs of clinical benefit.
- In February 2017, the Company announced that the combination of TRC105 and Avastin did not improve median PFS versus single agent Avastin in recurrent GBM patients, although the combination was associated with a non-significant increase in overall survival. Detailed survival data and the correlative analyses are expected to be presented at an oncology conference later this year.
- In January 2017, the FDA cleared the IND for TRC253, a small molecule competitive inhibitor of the wild type androgen receptor and androgen receptor mutations that confer resistance to Xtandi® (enzalutamide) and other drugs approved to treat prostate cancer. TRC253 was in-licensed as part of the Company’s strategic licensing collaboration with Janssen Pharmaceutica N.V. in September 2016. TRACON expects to initiate dosing in a Phase 1/2 trial of TRC253 in the first half of 2017.
- In November 2016, the Company closed an underwritten public offering of a total of 3,018,750 shares of its common stock resulting in total gross proceeds, before deducting underwriting discounts and commissions and other offering expenses, of \$17.4 million.

- In November 2016, updated data from the ongoing Phase 1b/2 study of TRC105 and Votrient in patients with angiosarcoma were presented at the Connective Tissue Oncology Society (CTOS) annual meeting. The presentation indicated the combination of TRC105 and Votrient continued to demonstrate encouraging signs of activity, including ongoing durable complete responses, and was well-tolerated.
- In November 2016, preclinical data from two separate liver fibrosis models were presented in a poster at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting entitled, “Endoglin Antibody Reduces the NAFLD Activity Score in the STAM Model of NASH and Reduces Liver Fibrosis Following Carbon Tetrachloride Treatment.” The poster also highlighted a marked reduction in cutaneous neurofibromatosis in a sarcoma patient following dosing with TRC105 and Votrient in a Phase 2 clinical trial, suggesting the potential clinical utility of an endoglin antibody for the treatment of patients with fibrosis.

Additional Expected 2017 Milestones

- Initiation of dosing in the Phase 1/2 trial of TRC253 in patients with prostate cancer.
- Presentation of data from expanded cohorts in the Phase 1 trial of TRC102 and Temodar® (temozolomide) by the National Cancer Institute.
- Completion of the Phase 1/2 PAVE study of DE-122 in patients with wet AMD by TRACON’s partner, Santen Pharmaceutical Co., Ltd. (Santen).
- Initiation of dosing in Santen’s Phase 2 AVANTE study, a randomized controlled Phase 2 trial of DE-122 and Lucentis® (ranibizumab) versus single agent Lucentis in patients with wet AMD.
- Announcement of top-line data from the randomized Phase 2 TRAXAR trial of TRC105 in combination with Inlyta® (axitinib) in patients with advanced or metastatic renal cell carcinoma.
- Completion of dose escalation in the Phase 1/2 clinical trial of TRC253.

Fourth Quarter 2016 Financial Results

- Cash, cash equivalents and short-term investments were \$44.4 million at December 31, 2016, compared to \$35.1 million and \$52.2 million at September 30, 2016 and December 31, 2015, respectively.
 - Collaboration revenue for the fourth quarter of 2016 was \$0.6 million, compared to \$1.4 million for the fourth quarter of 2015.
 - Research and development expenses for the fourth quarter of 2016 were \$4.8 million, compared to \$10.6 million for the fourth quarter of 2015. The decrease in 2016 as compared to 2015 primarily resulted from decreased TRC105 drug manufacturing expenses.
 - General and administrative expenses for the fourth quarter of 2016 were \$1.9 million, compared to \$1.7 million for the fourth quarter of 2015.
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- The net loss for the fourth quarter of 2016 was \$6.3 million, compared to a loss of \$11.0 million for the fourth quarter of 2015.

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 2016. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 73756754. 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 TRC105 and other Endoglin Antibodies

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 one Phase 3 and multiple Phase 2 clinical trials sponsored by TRACON or the National Cancer Institute for the treatment of solid tumors 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 Phase 1/2 trial for patients with wet AMD. TRC205, a second generation antibody to endoglin, is undergoing preclinical testing in models of fibrosis. For more information about the clinical trials, please visit TRACON's website at http://www.traconpharma.com/clinical_trials.php.

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.; and TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma. 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 initiation and 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, the NCI 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 the NCI completes on-going trials or sponsors 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.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Collaboration revenue	\$ 617	\$ 1,395	\$ 3,449	\$ 7,904
Operating expenses:				
Research and development	4,767	10,559	21,566	25,680
General and administrative	1,925	1,672	7,859	5,691
Total operating expenses	6,692	12,231	29,425	31,371
Loss from operations	(6,075)	(10,836)	(25,976)	(23,467)
Total other income (expense)	(239)	(211)	(1,032)	(943)
Net loss	(6,314)	(11,047)	(27,008)	(24,410)
Accretion to redemption value of redeemable convertible preferred stock	-	-	-	(31)
Net loss attributable to common stockholders	<u>\$ (6,314)</u>	<u>\$ (11,047)</u>	<u>\$ (27,008)</u>	<u>\$ (24,441)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.45)</u>	<u>\$ (0.91)</u>	<u>\$ (2.13)</u>	<u>\$ (2.20)</u>
Weighted-average common shares outstanding, basic and diluted	<u>14,099,380</u>	<u>12,166,905</u>	<u>12,677,910</u>	<u>11,115,651</u>

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

	December 31, 2016	December 31, 2015
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 35,710	\$ 41,373
Short-term investments	8,703	10,783
Prepaid and other assets	1,235	1,150
Total current assets	45,648	53,306
Property and equipment, net	82	173
Other assets	-	43
Total assets	<u>\$ 45,730</u>	<u>\$ 53,522</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,213	\$ 8,281
Accrued compensation and related expenses	1,588	1,163
Current portion of deferred revenue	1,259	3,353
Long-term debt, current portion	333	1,378
Final payment due bank	850	-
Total current liabilities	10,243	14,175
Other long-term liabilities	21	905
Long-term debt, less current portion	7,130	7,464
Commitments and contingencies		
Stockholders' equity:		
Common stock	16	12
Additional paid-in capital	113,918	89,556
Accumulated deficit	(85,598)	(58,590)
Total stockholders' equity	28,336	30,978
Total liabilities and stockholders' equity	<u>\$ 45,730</u>	<u>\$ 53,522</u>

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