
**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 8, 2016

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 November 8, 2016, TRACON Pharmaceuticals, Inc. (“TRACON”) issued a press release announcing its financial results for the quarter ended September 30, 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 November 8, 2016 announcing its financial results for the quarter ended September 30, 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: November 8, 2016

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 November 8, 2016 announcing its financial results for the quarter ended September 30, 2016.



TRACON Pharmaceuticals Reports Third Quarter 2016 Financial Results and Provides Corporate Update

Strategic Licensing Collaboration with Janssen Expanded TRACON's Oncology Portfolio and Validated Company's Unique Clinical Development Capabilities

Key Elements of Initial Phase 3 Trial of TRC105 Confirmed Through Discussions with U.S. FDA and European Regulatory Agencies

San Diego, CA – November 8, 2016 – 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, 2016, and provided an update on recent corporate events.

Third Quarter 2016 and Recent Corporate Highlights

- Entered into a strategic licensing collaboration with Janssen Pharmaceutica N.V. (Janssen) for two novel oncology assets from Janssen's early development portfolio. TRC253, intended for the treatment of men with prostate cancer, is a Phase 1/2 ready novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR) and multiple AR mutant receptors that may display drug resistance to Xtandi® (enzalutamide). TRC694, intended for the treatment of patients with hematologic malignancies, including myeloma, is a pre-clinical asset that is a potent, oral inhibitor of NF-kB inducing kinase (NIK).
- Concurrent with the strategic licensing collaboration, Johnson & Johnson Innovation – JJDC, Inc. (JJDC) completed a \$5.0 million equity investment in TRACON through the purchase of 840,022 shares of common stock at \$5.95 per share determined by the average of the daily volume weighted average closing prices of the common stock as reported on NASDAQ for the five days prior to the date of the purchase.
- Announced the successful completion of an End-of-Phase 2 meeting with the United States Food and Drug Administration (FDA) and a Protocol Assistance Meeting with the European Medicines Agency (EMA). TRACON reached agreement with both regulatory agencies regarding key elements of the Phase 3 program for TRC105 in angiosarcoma and expects to initiate the Phase 3 study by year-end, following an expected special protocol assessment (SPA) agreement with the FDA.
- Reported updated results from a Phase 1b clinical trial combining TRC105 with Inlyta® (axitinib) in patients with advanced or metastatic renal cell carcinoma (RCC) at the European Society for Medical Oncology (ESMO) 2016 Congress. Median progression free survival (PFS) of 11.3 months was observed in all RCC patients in the study, including those patients with clear cell RCC, the most prevalent form of RCC. An objective response rate (ORR) of 29% was also seen in the trial. For comparative purposes, median PFS observed in the large subgroup of VEGFR TKI-refractory patients treated with Inlyta (n=194) in the Inlyta AXIS Phase 3 study in second line clear cell RCC patients (a separate trial) was 4.8 months and the ORR was 11.3%.

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URL: www.traconpharma.com

- Initiated dosing in a global Phase 2 trial of TRC105 in patients with gestational trophoblastic neoplasia, or GTN (including choriocarcinoma). The primary endpoint of the trial is response rate and TRACON expects to enroll a total of 30 patients.

“During the third quarter, we accomplished a number of key value-creating milestones that have significantly strengthened our product development efforts,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “The Janssen licensing deal expands our portfolio of potential first-in-class oncology therapies and provides validation of our unique product development platform. Additionally, our positive interactions with both U.S. and European regulators enabled us to establish the key elements of our initial Phase 3 pivotal study for TRC105, which we look forward to initiating in December 2016 or early 2017.”

Expected Milestones over Remainder of 2016 or Early 2017

- Updated data on angiosarcoma patients treated with TRC105 in combination with Votrient from the Phase 1b/2 trial will be presented at the Connective Tissue Oncology Society (CTOS) meeting in Lisbon, Portugal on November 11.
- Pre-clinical data for TRACON’s endoglin antibodies in models of liver fibrosis and non-alcoholic steatohepatitis (NASH) will be presented at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting (The Liver Meeting®) in Boston on November 13.
- Completion of an SPA agreement with the FDA for a global Phase 3 pivotal trial of TRC105 in angiosarcoma.
- Announcement of top-line data from the randomized Phase 2 trial of TRC105 in combination with Avastin® (bevacizumab) in glioblastoma patients being conducted through the National Cancer Institute Clinical Therapy Evaluation Program (NCI CTEP).

Third Quarter 2016 Financial Results

- Cash and cash equivalents were \$35.1 million at September 30, 2016, compared to \$36.2 million and \$52.2 million at June 30, 2016 and December 31, 2015, respectively. The September 30, 2016 balance includes the \$5.0 million equity investment from JJDC.
 - Collaboration revenue for the third quarter of 2016 was \$0.8 million, compared to \$1.2 million for the third quarter of 2015.
 - Research and development expenses for the third quarter of 2016 were \$4.5 million, compared to \$5.9 million for the third quarter of 2015. The decrease in 2016 as compared to 2015 primarily resulted from decreased TRC105 drug manufacturing expenses, offset by increased clinical study related expenses and expenses associated with acquiring TRC253 and TRC694.
 - General and administrative expenses for the third quarter of 2016 were \$1.9 million, compared to \$1.5 million for the third quarter of 2015. The increase in 2016 as compared to 2015 was primarily a result of increased compensation related expenses from increased headcount in 2016.
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- The net loss for the third quarter of 2016 was \$5.9 million, compared to a loss of \$6.4 million for the third 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 third quarter 2016. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 10003680. 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 (carotuximab)

TRC105 (carotuximab) 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 multiple Phase 2 clinical trials sponsored by TRACON or the National Cancer Institute for the treatment of solid tumor types in combination with VEGF inhibitors. 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. The Company is also developing two programs in-licensed from Janssen Pharmaceutica N.V. – TRC253, a small molecule inhibitor of wild type androgen receptor (AR) and multiple AR mutations that confer drug resistance, which is intended for the treatment of men with prostate cancer, and TRC694, a small molecule inhibitor of NF-kB inducing kinase (NIK), which is intended for the treatment of patients with hematologic malignancies, including myeloma. 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, and expected development milestones, availability of additional clinical data, plans to complete an SPA agreement with the FDA. 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.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Collaboration revenue	\$815	\$1,180	\$2,832	\$6,509
Operating expenses:				
Research and development	4,531	5,885	16,799	15,121
General and administrative	1,881	1,530	5,934	4,019
Total operating expenses	6,412	7,415	22,733	19,140
Loss from operations	(5,597)	(6,235)	(19,901)	(12,631)
Total other income (expense)	(274)	(212)	(793)	(732)
Net loss	(5,871)	(6,447)	(20,694)	(13,363)
Accretion to redemption value of redeemable convertible preferred stock	-	-	-	(31)
Net loss attributable to common stockholders	<u><u>\$(5,871)</u></u>	<u><u>\$(6,447)</u></u>	<u><u>\$(20,694)</u></u>	<u><u>\$(13,394)</u></u>
Net loss per share attributable to common stockholders, basic and diluted	<u><u>\$(0.48)</u></u>	<u><u>\$(0.53)</u></u>	<u><u>\$(1.70)</u></u>	<u><u>\$(1.24)</u></u>
Weighted-average common shares outstanding, basic and diluted	<u><u>12,227,081</u></u>	<u><u>12,117,988</u></u>	<u><u>12,200,628</u></u>	<u><u>10,761,383</u></u>

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

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$29,648	\$41,373
Short-term investments	5,465	10,783
Prepaid and other assets	1,395	1,150
Total current assets	36,508	53,306
Property and equipment, net	106	173
Other assets	-	43
Total assets	\$36,614	\$53,522
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$6,697	\$8,281
Accrued compensation and related expenses	1,188	1,163
Current portion of deferred revenue	1,749	3,353
Long-term debt, current portion	3,536	1,378
Total current liabilities	13,170	14,175
Other long-term liabilities	874	905
Long-term debt, less current portion	4,786	7,464
Commitments and contingencies		
Stockholders' equity:		
Common stock	13	12
Additional paid-in capital	97,055	89,556
Accumulated deficit	(79,284)	(58,590)
Total stockholders' equity	17,784	30,978
Total liabilities and stockholders' equity	\$36,614	\$53,522

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