

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): **August 10, 2016**

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.)

**8910 University Center Lane, Suite 700
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))

Item 2.02 Results of Operations and Financial Condition.

On August 10, 2016, TRACON Pharmaceuticals, Inc. (“TRACON”) issued a press release announcing its financial results for the quarter ended June 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 August 10, 2016 announcing its financial results for the quarter ended June 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: August 10, 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 August 10, 2016 announcing its financial results for the quarter ended June 30, 2016.



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

San Diego, CA – August 10, 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 second quarter ended June 30, 2016.

Second Quarter 2016 and Recent Corporate Highlights

- Presented data from the Phase 1b/2 study of TRC105 in combination with Votrient® (pazopanib) at the American Society for Clinical Oncology (ASCO) Annual Meeting. The combination of TRC105 and Votrient demonstrated encouraging signs of activity in the five angiosarcoma patients enrolled in the first cohort of the Phase 1b/2 trial. All of these patients had radiographic tumor reductions, including two durable complete responses (CRs) by RECIST 1.1, and median progression-free survival (PFS) for the five angiosarcoma patients was greater than 12.9 months. For comparison, PFS was 3.0 months with no CRs in a previously completed study with single agent Votrient in 30 angiosarcoma patients. Signs of clinical or radiologic activity were also observed in three of four patients enrolled in the trial's angiosarcoma expansion cohort and treated initially with TRC105 and Votrient.
- Reported data from a Phase 2 trial of TRC105 in combination with Avastin® (bevacizumab) in patients with glioblastoma who had progressed on prior Avastin monotherapy at ASCO. Overall survival (OS) of 5.8 months was observed in Avastin-refractory patients (n=15) treated with the combination, which exceeds the historic OS of 4.0 months seen in a similar patient population treated in separate studies with single agent Avastin.
- The National Cancer Institute (NCI) reported encouraging data from a Phase 1 trial of TRC102 in combination with Temodar® (temozolomide) in patients with refractory solid tumors at ASCO. A total of 34 patients were enrolled in the trial, four of whom had confirmed partial responses (PR); one further PR occurred in a patient with colon cancer, but was unconfirmed as a result of a concurrent illness; nine patients had stable disease, 16 patients had progressive disease, and five were not evaluable for radiographic response. Three of the PRs were durable and lasted longer than six months. The combination of TRC102 and Temodar was safe and well-tolerated and is currently being evaluated in a Phase 2 trial of patients with glioblastoma.
- Opened initial sites and commenced dosing of patients in the EU in order to speed enrollment into the TRACON-sponsored Phase 2b randomized TRAXAR trial of TRC105 and Inlyta in renal cell cancer. The Company is adjusting its development timeline and now anticipates completing enrollment and announcing top-line PFS data in the first half of 2017. The exact timing for top-line PFS data will still depend on the number and timing of progression events that occur. TRACON continues to expect that an interim futility analysis will occur in 2016.
- The World Health Organization has recommended carotuximab as the International Nonpropriety Name (INN) for TRC105.

- The European Medicines Agency (EMA) granted TRC105 orphan drug designation for the treatment of patients with soft tissue sarcoma, indicating concurrence that TRC105 may offer significant benefit versus approved drugs for this rare disease.
- Initiated a Phase 1b/2 clinical trial evaluating TRC105 in combination with Nexavar® (sorafenib) in patients with hepatocellular cancer. TRACON expects approximately 39 patients to enroll in the study and top-line data are anticipated in 2017.
- Initiated dosing in a Phase 1/2 neoadjuvant study evaluating TRC105 in combination with the mTor inhibitor Afinitor® (everolimus) and the aromatase inhibitor Femara® (letrozole) in patients with breast cancer prior to surgery. Approximately 35 patients are expected to enroll in the study and top-line data are anticipated in 2017.

“We continue to make significant progress across our entire pipeline, and anticipate initiating two important clinical studies later this year in cancer types that have been highly responsive to TRC105 treatment to date,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “We remain on track to initiate our first pivotal Phase 3 study of TRC105 in patients with angiosarcoma by the end of the year and should begin enrolling our Phase 2 study in gestational trophoblastic neoplasia (GTN) patients within the next few months. In addition, we continue to advance TRC105 in multiple Phase 2 studies in other tumor types for which we expect data readouts to begin later this year and continue throughout 2017.”

Expected 2016 Milestones

- Presentation of data on additional angiosarcoma patients treated with TRC105 in combination with Votrient are expected at the Connective Tissue Oncology Society (CTOS) meeting in November.
- Initiation of a global Phase 3 pivotal trial of TRC105 in angiosarcoma is expected in the fourth quarter of 2016.
- Initiation of a global Phase 2 trial of TRC105 in GTN (including choriocarcinoma) is expected in the second half of 2016.
- Top-line data from the randomized Phase 2 trial of TRC105 in combination with Avastin in glioblastoma patients are expected by the end of 2016.
- Presentation of pre-clinical data related to TRACON's endoglin antibodies in models of liver fibrosis and non-alcoholic steatohepatitis (NASH), at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting (The Liver Meeting®) in November 2016.

Second Quarter 2016 Financial Results

- Cash and cash equivalents were \$36.2 million at June 30, 2016, compared to \$45.5 million and \$52.2 million at March 31, 2016 and December 31, 2015, respectively.

- Collaboration revenue for the second quarter of 2016 was \$0.8 million, compared to \$4.2 million for the second quarter of 2015. The decrease in collaboration revenue for the 2016 period as compared to the 2015 period was primarily the result of the \$3.0 million milestone payment triggered by Santen's filing of an IND in wet AMD in June 2015.
- Research and development expenses for the second quarter of 2016 were \$6.8 million, compared to \$5.4 million for the second quarter of 2015. The increase in 2016 as compared to 2015 primarily resulted from increased clinical study and manufacturing expenses related to TRC105, and increased compensation related expenses from increased headcount in 2016.
- General and administrative expenses for the second quarter of 2016 were \$2.0 million, compared to \$1.5 million for the second quarter of 2015. The increase in the 2016 period as compared to the 2015 period was primarily a result of increased compensation related expenses from increased headcount in 2016.
- The net loss for the second quarter of 2016 was \$8.3 million, compared to a loss of \$2.9 million for the second 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 second quarter 2016. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 59381366. 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 TRC102

TRC102 (methoxyamine) is a novel, clinical-stage small molecule inhibitor of the DNA base excision repair pathway, which is a pathway that causes resistance to alkylating and antimetabolite chemotherapeutics. TRC102 is currently being studied in multiple Phase 1 and Phase 2 clinical trials sponsored by the National Cancer Institute or Case Comprehensive Cancer Center. 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, and expected development milestones and availability of additional clinical data. 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Collaboration revenue	\$807	\$4,197	\$2,017	\$5,329
Operating expenses:				
Research and development	6,773	5,405	12,268	9,236
General and administrative	2,044	1,476	4,053	2,489
Total operating expenses	8,817	6,881	16,321	11,725
Loss from operations	(8,010)	(2,684)	(14,304)	(6,396)
Total other income (expense)	(287)	(237)	(519)	(520)
Net loss	(8,297)	(2,921)	(14,823)	(6,916)
Accretion to redemption value of redeemable convertible preferred stock	-	-	-	(31)
Net loss attributable to common stockholders	<u>\$ (8,297)</u>	<u>\$ (2,921)</u>	<u>\$ (14,823)</u>	<u>\$ (6,947)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.68)</u>	<u>\$ (0.24)</u>	<u>\$ (1.22)</u>	<u>\$ (0.69)</u>
Weighted-average common shares outstanding, basic and diluted	<u>12,195,070</u>	<u>12,096,599</u>	<u>12,187,256</u>	<u>10,071,838</u>

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

	June 30, 2016	December 31, 2015
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$34,020	\$41,373
Short-term investments	2,137	10,783
Prepaid and other assets	1,570	1,150
Total current assets	37,727	53,306
Property and equipment, net	128	173
Other assets	43	43
Total assets	\$37,898	\$53,522
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$6,600	\$8,281
Accrued compensation and related expenses	979	1,163
Current portion of deferred revenue	2,186	3,353
Long-term debt, current portion	3,471	1,378
Total current liabilities	13,236	14,175
Other long-term liabilities	877	905
Long-term debt, less current portion	5,694	7,464
Commitments and contingencies		
Stockholders' equity:		
Common stock	12	12
Additional paid-in capital	91,492	89,556
Accumulated deficit	(73,413)	(58,590)
Total stockholders' equity	18,091	30,978
Total liabilities and stockholders' equity	\$37,898	\$53,522

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