
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 8, 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.)

**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 August 8, 2017, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2017. 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 8, 2017 announcing its financial results for the quarter ended June 30, 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: August 8, 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
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99.1	Press release issued by TRACON Pharmaceuticals, Inc. on August 8, 2017 announcing its financial results for the quarter ended June 30, 2017.
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TRACON Pharmaceuticals Reports Second Quarter Financial Results and Provides Corporate Update

San Diego, CA – August 8, 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 second quarter ended June 30, 2017.

Second Quarter 2017 and Recent Corporate Highlights

- In July, TRACON and its partner, Santen Pharmaceutical Co. Ltd. (Santen), announced the initiation of a Phase 2a 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 DE-122 in combination with Lucentis® (ranibizumab) compared to Lucentis monotherapy in patients with wet AMD. The initiation of the Phase 2a study triggered a \$7.0 million milestone payment obligation to TRACON.
- In June, the Company presented positive clinical data from studies of TRC105 at the annual meeting of the American Society of Clinical Oncology (ASCO). In separate Phase 1b clinical trials combining TRC105 with Votrient® (pazopanib) in patients with soft tissue sarcoma and TRC105 with Inlyta® (axitinib) in patients with renal cell carcinoma (RCC), overall response to treatment showed a statistically significant association with baseline levels of certain soluble biomarkers. These biomarkers will be further assessed in the ongoing Phase 3 randomized TAPPAS trial that combines TRC105 with Votrient in angiosarcoma and the randomized Phase 2 TRAXAR trial that combines TRC105 with Inlyta in patients with RCC.
- In June, at the ASCO annual meeting, the National Cancer Institute (NCI) reported data from its trial of TRC102 in combination with Temodar® (temozolomide) in patients with refractory solid tumors. Based on partial responses in patients with ovarian cancer, non-small cell lung cancer and KRAS-positive colorectal cancer, the NCI elected to enroll expansion cohorts in each of these tumor types at the recommended Phase 2 oral dose of TRC102. The authors concluded that the combination of Temodar and TRC102 is active, and markers of DNA damage response (Rad51, γ -H2AX and/or pNbs1) were induced in 4 of 5 paired colon biopsies, indicating DNA damage following treatment.
- In May, positive results from the NCI-sponsored Phase 1/2 trial of TRC105 and Nexavar® (sorafenib) in patients with hepatocellular cancer (HCC) were e-published in the journal, *Clinical Cancer Research*. Overall response was assessed by the Response Evaluation Criteria in Solid Tumors (RECIST) across four dose groups. All observed responses occurred in the two highest dose groups, in which 5 of 15 (33%) patients demonstrated a response. Median progression free survival (PFS) was 3.8 months and median overall survival (OS) was 15.5 months. Nexavar was approved for the treatment of patients with advanced HCC based on data showing a median OS of 10.7 months versus 7.9 months with placebo in the multicenter SHARP trial. The ORR for Nexavar treatment by RECIST in the SHARP trial was 2%. TRACON is currently conducting a multicenter Phase 1/2 trial of TRC105 in combination with Nexavar in patients with HCC and expects to report initial data in the first half of 2018.

- In May, the Company announced the initiation of dosing in a Phase 1/2 clinical trial of TRC253 in patients with metastatic castration-resistant prostate cancer. The primary objectives of the Phase 1/2 study are to assess the safety of TRC253, determine its recommended Phase 2 dose and evaluate response by prostate-specific antigen (PSA) levels. In the Phase 2 portion of the trial, TRACON intends to incorporate circulating tumor DNA testing to allow for biomarker-directed therapy of patients who have progressed following treatment with an androgen receptor (AR) inhibitor.
- In May, the Company announced that preclinical data indicating the potential clinical utility of targeting endoglin in acute myeloid leukemia (AML) and B-cell acute lymphoblastic leukemia (B-cell ALL), was published in the May 4, 2017, issue of *Blood*, the official journal of the American Society of Hematology. TRACON has engaged key opinion leaders to discuss potential clinical trial designs for TRC105 in AML.

“We are encouraged by the continued clinical progress across our entire pipeline, including in hepatocellular cancer. The Phase 3 TAPPAS study of TRC105 in angiosarcoma continues to enroll well, and is on track to deliver key interim data in mid-2018. During the quarter, we also initiated dosing in the Phase 1/2 study of TRC253 in patients with prostate cancer and expect to complete the dose escalation portion of the study by the end of this year,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “Our non-oncology pipeline also achieved an important milestone with Santen’s recent initiation of the Phase 2 study of DE-122 in patients with wet AMD, and we look forward to the presentation of data from the Phase 1/2 study later this year.”

Expected Upcoming Milestones for 2017

- Presentation of data from the Phase 1/2 PAVE study of DE-122 in patients with wet AMD by Santen in the second half of 2017.
- 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 RCC in the second half of 2017.
- Completion of the dose escalation portion in the Phase 1/2 clinical trial of TRC253 in patients with prostate cancer in the second half of 2017.

Second Quarter 2017 Financial Results

- Cash, cash equivalents and short-term investments were \$32.0 million at June 30, 2017, compared to \$44.4 million at December 31, 2016. The reported cash balance does not include the \$7.0 million milestone payment from Santen, which the Company expects to receive in the third quarter.
 - Collaboration revenue for the second quarter of 2017 was \$0.6 million compared to \$0.8 million for the second quarter of 2016.
 - Research and development expenses for the second quarter of 2017 were \$4.9 million compared to \$6.8 million for the second quarter of 2016. The decrease was primarily a result of decreased TRC105 drug manufacturing expenses in 2017.
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- General and administrative expenses for the second quarter of 2017 were \$2.1 million compared to \$2.0 million for the second quarter of 2016.
- The net loss for the second quarter of 2017 was \$6.6 million compared to a net loss of \$8.3 million for the second 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 second quarter of 2017. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 63640830. 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) 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 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 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 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 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 mCRPC. 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, 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 Santen or the NCI 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Collaboration revenue	\$631	\$807	\$1,257	\$2,017
Operating expenses:				
Research and development	4,893	6,773	10,475	12,268
General and administrative	2,068	2,044	4,032	4,053
Total operating expenses	6,961	8,817	14,507	16,321
Loss from operations	(6,330)	(8,010)	(13,250)	(14,304)
Total other income (expense)	(236)	(287)	(463)	(519)
Net loss	\$(6,566)	\$(8,297)	\$(13,713)	\$(14,823)
Net loss per share, basic and diluted	\$(0.40)	\$(0.68)	\$(0.84)	\$(1.22)
Weighted-average common shares outstanding, basic and diluted	16,610,124	12,195,070	16,409,389	12,187,256

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

	June 30, 2017	December 31, 2016
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$26,001	\$35,710
Short-term investments	5,997	8,703
Prepaid and other assets	814	1,235
Total current assets	32,812	45,648
Property and equipment, net	78	82
Total assets	<u>\$32,890</u>	<u>\$45,730</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$6,536	\$6,213
Accrued compensation and related expenses	1,096	1,588
Current portion of deferred revenue	386	1,259
Long-term debt, current portion	1,162	333
Final payment due bank	-	850
Total current liabilities	9,180	10,243
Other long-term liabilities	372	21
Long-term debt, less current portion	6,043	7,130
Commitments and contingencies		
Stockholders' equity:		
Common stock	17	16
Additional paid-in capital	116,589	113,918
Accumulated deficit.....	(99,311)	(85,598)
Total stockholders' equity	17,295	28,336
Total liabilities and stockholders' equity	<u>\$32,890</u>	<u>\$45,730</u>

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