

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): **May 10, 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

**8910 University Center Lane, Suite 700
San Diego, California 92122**

(Former Address)

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 May 10, 2017, TRACON Pharmaceuticals, Inc. (“TRACON”) issued a press release announcing its financial results for the quarter ended March 31, 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 May 10, 2017 announcing its financial results for the quarter ended March 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: May 10, 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 May 10, 2017 announcing its financial results for the quarter ended March 31, 2017.



TRACON Pharmaceuticals Reports First Quarter Financial Results and Provides Corporate Update

San Diego, CA – May 10, 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 first quarter ended March 31, 2017.

First Quarter 2017 and Recent Corporate Highlights

- In April, preclinical data for TRC694, the Company's small molecule inhibitor of NF-kB inducing kinase (NIK), were presented at the annual meeting of the American Association for Cancer Research. The data demonstrated that TRC694 potently inhibits NIK in vitro and potently inhibits human myeloma and lymphoma cell lines in vivo. TRACON expects to file an IND for TRC694 in 2018.
- In March, TRACON initiated a Phase 1/2 clinical trial of TRC253 in patients with metastatic castration-resistant prostate cancer (mCRPC). TRC253 is a novel, orally bioavailable small molecule high affinity competitive inhibitor of the androgen receptor (AR) and AR mutations.
- In March, the Company entered into a Common Stock Purchase Agreement with Aspire Capital Fund, LLC ("Aspire Capital") providing for the sale of up to \$21.0 million of common stock. Under the terms of the Agreement, Aspire Capital made an initial purchase of \$1.0 million of TRACON common stock at \$4.50 per share. In addition, Aspire Capital has committed to purchase up to \$20.0 million of additional shares of the Company's common stock at TRACON's request from time to time during a 30-month period at prices based on the market price at the time of each sale.
- In February, the Company initiated dosing in its Phase 3 TAPPAS trial (a randomized Phase 3 trial of **TRC105 And Pazopanib** versus **Pazopanib** alone in patients with advanced **AngioSarcoma**). In January 2017, the Company announced that it received a Special Protocol Assessment (SPA) agreement from the U.S. Food and Drug Administration (FDA). The SPA covers the protocol design, clinical endpoints and statistical analysis approach used for the TAPPAS trial. The TAPPAS trial was recently awarded "Most Innovative Trial Design" at the 2017 Clinical and Research Excellence Awards.
- In February, the Company announced that the NCI-sponsored trial of the combination of TRC105 and Avastin® (bevacizumab) did not demonstrate improvement in median PFS versus single agent Avastin in recurrent GBM patients, although the combination was associated with a non-significant increase in overall survival. The Company expects the NCI to present detailed survival data and correlative analyses at the annual meeting of the American Society of Clinical Oncology (ASCO) in June.

"We made several important advancements in our pipeline and corporate operations since the beginning of 2017. Following the receipt of guidance from European regulators and an SPA agreement from the FDA, we initiated dosing in the TAPPAS trial, the first pivotal study of TRC105 in patients with angiosarcoma. In addition, we recently initiated the first-in-human clinical trial of TRC253, one of the two compounds TRACON in-licensed from Janssen last year, in patients with prostate cancer," said Charles Theuer, M.D., Ph.D., President and CEO of

TRACON. “Our agreement with Aspire Capital provides TRACON with additional flexibility to execute on our business plan and deliver important data points throughout the remainder of 2017.”

Expected Upcoming Milestones for 2017

- Initiation of dosing in the Phase 1/2 trial of TRC253 in patients with prostate cancer in the second quarter of 2017.
- Presentation of data from expanded cohorts in the Phase 1 trial of TRC102 and Temodar® (temozolomide) by the National Cancer Institute at ASCO in June.
- Presentation of data from the Phase 1/2 PAVE study of DE-122 in patients with wet AMD by TRACON’s partner, Santen Pharmaceutical Co., Ltd., in the second half of 2017.
- 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, in the second half of 2017.
- Availability 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 in the second half of 2017.
- Completion of dose escalation in the Phase 1/2 clinical trial of TRC253 in the second half of 2017.

First Quarter 2017 Financial Results

- Cash, cash equivalents and short-term investments were \$36.7 million at March 31, 2017, compared to \$44.4 million at December 31, 2016.
 - Collaboration revenue for the first quarter of 2017 was \$0.6 million, compared to \$1.2 million for the first quarter of 2016.
 - Research and development expenses for the first quarter of 2017 were \$5.6 million, compared to \$5.5 million for the first quarter of 2016.
 - General and administrative expenses for the first quarter of 2017 and 2016 were \$2.0 million.
 - The net loss for the first quarter of 2017 was \$7.1 million, compared to a net loss of \$6.5 million for the first quarter of 2016.
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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 first quarter 2017. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 15138572. 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 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 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.; 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 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, and potential benefits of TRACON's common stock purchase agreement with Aspire Capital. 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, including pursuant to the common stock purchase agreement with Aspire Capital; 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,	
	2017	2016
Collaboration revenue	\$626	\$1,210
Operating expenses:		
Research and development	5,582	5,495
General and administrative	1,964	2,009
Total operating expenses	7,546	7,504
Loss from operations	(6,920)	(6,294)
Total other income (expense)	(227)	(232)
Net loss	<u><u>\$(7,147)</u></u>	<u><u>\$(6,526)</u></u>
Net loss per share, basic and diluted	<u><u>\$(0.44)</u></u>	<u><u>\$(0.54)</u></u>
Weighted-average common shares outstanding, basic and diluted	<u><u>16,206,424</u></u>	<u><u>12,179,442</u></u>

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

	March 31, 2017	December 31, 2016
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$32,221	\$35,710
Short-term investments	4,498	8,703
Prepaid and other assets	1,126	1,235
Total current assets	37,845	45,648
Property and equipment, net	75	82
Total assets	<u>\$37,920</u>	<u>\$45,730</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$5,702	\$6,213
Accrued compensation and related expenses	932	1,588
Current portion of deferred revenue	871	1,259
Long-term debt, current portion	343	333
Final payment due bank	-	850
Total current liabilities	7,848	10,243
Other long-term liabilities	337	21
Long-term debt, less current portion	6,747	7,130
Commitments and contingencies		
Stockholders' equity:		
Common stock	17	16
Additional paid-in capital	115,716	113,918
Accumulated deficit.....	(92,745)	(85,598)
Total stockholders' equity	22,988	28,336
Total liabilities and stockholders' equity	<u>\$37,920</u>	<u>\$45,730</u>

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