

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): **March 10, 2015**

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))
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On March 10, 2015, TRACON Pharmaceuticals, Inc. (“TRACON”) issued a press release announcing its financial results for the year ended December 31, 2014. 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 March 10, 2015 announcing its financial results for the year ended December 31, 2014.

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: March 10, 2015

By: /s/ Charles P. Theuer
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 March 10, 2015 announcing its financial results for the year ended December 31, 2014.



TRACON Pharmaceuticals Reports 2014 Year-End Financial Results and Recent Corporate Highlights

*Phase 2 Clinical Trials of TRC105 continue to enroll patients
Strong cash position further strengthened by successful IPO in February 2015*

San Diego, CA – March 10, 2015 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, age-related macular degeneration and fibrotic diseases, today announced its financial results for the year ended December 31, 2014.

2014 and Recent Corporate Highlights

- In February 2015, at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium, TRACON reported positive results from a clinical trial of TRC105 in combination with Inlyta® (axitinib) in patients with advanced or metastatic renal cell carcinoma (RCC). In the Phase 1b study, the objective response rate was 29% (5 of 17 evaluable patients) and an additional 10 patients achieved stable disease using RECIST 1.1 criteria. Median progression-free survival (PFS) for all patients in the study was 8.4 months, while median PFS for the subset of clear cell RCC patients was 11.3 months. For comparison, the objective response rate seen in the large subgroup of VEGF receptor tyrosine kinase inhibitor (VEGFR TKI)-refractory patients treated with axitinib (n=194) in the axitinib AXIS Phase 3 study in second line clear cell RCC patients (a separate trial) was 11.3% and median PFS was 4.8 months. The combination of TRC105 and axitinib was well tolerated.
- In February 2015, Tracon successfully completed an initial public offering and concurrent private placement, which raised \$41 million in gross proceeds.
- In January 2015, at the ASCO Gastrointestinal Cancers Symposium, the National Cancer Institute (NCI) reported positive results from a clinical trial of TRC105 in combination with Nexavar® (sorafenib) in patients with hepatocellular carcinoma (HCC). Of the 13 patients treated at recommended Phase 2 doses of TRC105 (10 mg/kg or 15 mg/kg dosed every two weeks), 23% of patients (3 of 13) achieved a partial response using RECIST 1.1 criteria, in a setting where the expected partial response rate of sorafenib alone is 2%. The combination of TRC105 and sorafenib was well tolerated.
- In December 2014, at the American Society of Hematology annual meeting, Case Cancer Center reported positive results from a clinical trial of TRC102 in combination with Fludara® (fludarabine) in a Phase 1 clinical trial. Treatment with the combination of TRC102 and fludarabine was well tolerated and resulted in stable disease and partial response in patients previously treated with fludarabine.
- In December 2014, dosing was initiated in a randomized Phase 2b clinical study combining TRC105 with Inlyta® (axitinib) in patients with advanced or metastatic RCC.
- In September 2014, TRACON completed a \$27 million Series B financing led by New Enterprise Associates (NEA), BioMed Ventures and an additional institutional investor.
- In September 2014, dosing was initiated in a Phase 2 clinical study combining TRC105 with Votrient® (pazopanib) in patients with advanced soft tissue sarcoma.
- In March 2014, TRACON executed a global license agreement for the development of TRC105 in ophthalmology with Santen Pharmaceutical Co., Ltd. (Santen).

“TRACON had an extremely productive year in 2014, underscored by the continued advancement of TRC105 across multiple solid tumor indications,” said Charles P. Theuer, MD., Ph.D., President and CEO of TRACON. “The successful completion of our initial public offering last month significantly strengthened our balance sheet and left us well-positioned to develop TRC105 in combination with a variety of approved VEGF inhibitors in renal cell carcinoma, soft tissue sarcoma, liver cancer and glioblastoma in four separate Phase 2 clinical trials. We also expect to initiate additional clinical trials of TRC105-based combinations in lung cancer, breast cancer and colorectal cancer by the end of 2015.”

Ongoing and Future Development Activities

- TRACON is currently enrolling patients in three separate Phase 2 clinical trials: a randomized Phase 2b study combining TRC105 and axitinib in RCC, a Phase 2 study combining TRC105 and pazopanib in soft tissue sarcoma, and a single patient Phase 2 study combining TRC105 and Avastin® (bevacizumab) in a patient with choriocarcinoma.
- The NCI is currently enrolling patients in two separate Phase 2 clinical trials: a Phase 2 study combining TRC105 with sorafenib in HCC and a randomized Phase 2b study combining TRC105 with bevacizumab in patients with glioblastoma.
- TRACON expects that its partner, Santen will file an Investigational New Drug (IND) application for development of TRC105 (DE-122) in ophthalmology in 2015.
- The NCI is currently enrolling patients in a Phase 1 trial of oral TRC102 with Temodar® (temozolomide).

2014 Year-End Financial Results

At December 31, 2014, TRACON had cash and cash equivalents totaling \$35.0 million. In February 2015, the successful completion of the Company's initial public offering raised gross proceeds of \$41.0 million.

For the year ended December 31, 2014, TRACON reported a net loss of \$6.8 million compared to a net loss of \$7.7 million for 2013. The decrease in net loss in 2014 when compared to 2013 was primarily attributable to revenue totaling \$3.6 million

recorded in 2014 associated with the Santen license agreement with no corresponding revenue in 2013, offset by increased operating expenses in 2014 compared to 2013.

Research and development expenses for the years ended December 31, 2014 and 2013 were \$7.7 million and \$6.1 million, respectively. The increase in research and development expenses in 2014 as compared to 2013 was primarily due to increased clinical study expenses related to TRC105 and increased compensation related expenses due to increased headcount, partially offset by decreased manufacturing expenses in 2014.

General and administrative expenses for the years ended December 31, 2014 and 2013 were \$2.1 million and \$1.5 million, respectively. The increase in general and administrative expenses in 2014 as compared to 2013 was primarily a result of increased professional services, including accounting and legal expenses related to the Company's licensing activities, and compensation related expenses due to increased headcount in 2014.

About TRC105

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 clinical trials sponsored by both TRACON and the National Cancer Institute for the treatment of multiple solid tumor types in combination with VEGF inhibitors. TRC105 is also being developed in combination with VEGF inhibitor treatments in age-related macular degeneration. For more information about the clinical trials, please visit TRACON's website at http://www.traconpharma.com/clinical_trials.php.

About TRC102

TRC102 is a novel, clinical stage small molecule inhibitor of the DNA base excision repair pathway that causes resistance to alkylating and antimetabolite chemotherapeutics. TRC102 is currently being studied in clinical trials sponsored by both the National Cancer Institute and Case 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, age-related macular degeneration and fibrotic diseases. TRACON's current pipeline includes two clinical stage product candidates: TRC105, an anti-endoglin antibody that is being developed for the treatment of multiple solid tumor types, and TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma. Both TRC105 and TRC102 are being developed for treatment in combination with currently available therapies. 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 ability further develop TRC105, expectations regarding the initiation of future clinical trials, the timing of Santen's filing of an IND application, and TRACON's ability to successfully complete its ongoing clinical trials and development programs. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON will be able to complete or initiate clinical trials on its expected timelines, if at all; the fact that future preclinical studies and clinical trials may not be successful; the fact that TRACON has limited control over whether Santen advances TRC105 (DE-122) in ophthalmological indications; 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 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 Statements of Operations (in thousands, except share and per share data)

	Years Ended December 31,		
	2014	2013	2012
Collaboration revenue	\$ 3,598	\$ —	\$ —
Operating expenses:			
Research and development	7,652	6,076	3,777
General and administrative	2,125	1,484	1,449
Total operating expenses	9,777	7,560	5,226
Loss from operations	(6,179)	(7,560)	(5,226)
Total other income (expense)	(630)	(148)	298

Net loss	(6,809)	(7,708)	(4,928)
Accretion to redemption value of redeemable convertible preferred stock	(297)	(248)	(216)
Net loss attributable to common stockholders	<u>\$ (7,106)</u>	<u>\$ (7,956)</u>	<u>\$ (5,144)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (4.40)</u>	<u>\$ (4.93)</u>	<u>\$ (3.19)</u>
Weighted-average shares outstanding, basic and diluted	<u>1,615,044</u>	<u>1,614,851</u>	<u>1,614,851</u>

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

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	\$35,000	\$2,276
Prepaid and other assets	728	99
Total current assets	<u>35,728</u>	<u>2,375</u>
Property and equipment, net	97	20
Other assets	2,346	24
Total assets	<u>\$38,171</u>	<u>\$2,419</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$3,974	\$1,273
Current portion of deferred revenue	4,357	—
Preferred stock warrant liabilities	246	97
Long-term debt, current portion	<u>4,676</u>	<u>677</u>
Total current liabilities	<u>13,253</u>	<u>2,047</u>
Deferred rent	50	12
Deferred revenue	2,546	—
Accrued expenses	358	11
Long-term debt, less current portion	4,258	1,764
Commitments and contingencies		
Redeemable convertible preferred stock	49,880	23,929
Stockholders' deficit:		
Common stock	2	2
Additional paid-in capital	2,004	2,025
Accumulated deficit	<u>(34,180)</u>	<u>(27,371)</u>
Total stockholders' deficit	<u>(32,174)</u>	<u>(25,344)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$38,171</u>	<u>\$2,419</u>

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