

## TRACON Pharmaceuticals Reports Second Quarter 2015 Financial Results and Provides Corporate Update

Phase 2 clinical trials of TRC105 suggest activity in angiosarcoma and hepatocellular carcinoma

IND filed for the initiation of clinical trials in wet AMD

Cash balance of \$61.2 million at June 30, 2015

**San Diego, CA – August 5, 2015** – 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 its financial results for the second quarter ended June 30, 2015.

### **Second Quarter 2015 and Recent Corporate Highlights**

- In June 2015, TRACON's partner, Santen Pharmaceutical Co. Ltd., Inc., filed an Investigational New Drug (IND) Application with the U.S. Food and Drug Administration (FDA) for the initiation of clinical studies for DE-122 in patients with wet AMD. DE-122 is the ophthalmic formulation of TRACON's proprietary antiendoglin antibody, TRC105. Under the terms of our licensing agreement with Santen, the IND filing for DE-122 triggered a \$3 million milestone payment to TRACON.
- In June 2015, at the American Society of Clinical Oncology (ASCO) Annual Meeting, TRACON reported positive results from the dose escalation Phase 1b portion of a Phase 1b/2 study of TRC105 in combination with Votrient® (pazopanib) in 18 patients with advanced soft tissue sarcoma. All patients were treated with the combination of TRC105 given once weekly (8 mg/kg or 10 mg/kg) and Votrient at its approved dose of 800 mg per day. The combination was well-tolerated with no dose limiting toxicity observed. One patient with angiosarcoma, a tumor type known to express high levels of endoglin, has an ongoing complete response by RECIST and remains on treatment as of week 45. In addition, in the ongoing Phase 2 portion of the study, a second patient with angiosarcoma also has an ongoing complete response by RECIST and remains on treatment as of week 15.
- In June 2015, TRACON conducted a successful End-of-Phase 1 meeting with the FDA on the development of TRC105 in sarcoma in order to obtain concurrence on non-clinical and manufacturing activities that will be needed to begin Phase 3 development and complete the subsequent submission of a marketing application.
- In June 2015, at the ASCO Annual Meeting, the National Cancer Institute (NCI) reported updated results from a clinical trial of TRC105 in combination with Nexavar® (sorafenib) in patients with hepatocellular carcinoma (HCC). Of the 10 patients with measurable disease treated at recommended Phase 2 doses of TRC105 (10 mg/kg or 15 mg/kg dosed every two weeks), 40% of patients (4 of 10) achieved partial responses by RECIST, in a setting where the expected partial response rate of Nexavar alone is 2%.



- In June 2015, at the ASCO Annual Meeting, Case Cancer Center (Cleveland, OH) reported updated results from a Phase 1b clinical trial of TRC102 in combination with Temodar® (temozolomide) in patients with refractory solid tumors. The combination of TRC102 and Temodar was well tolerated, there were no pharmacologic interactions between the two drugs and TRC102 target concentrations were achieved. Antitumor activity was noted in patients with ovarian cancer and neuroendocrine tumors.
- In May 2015, the FDA granted Fast Track designation for the development of TRC105 in patients with advanced renal cell carcinoma (RCC).

"We made substantial progress on both the clinical and regulatory fronts during the second quarter, our first full quarter as a public company. We presented positive data on multiple pipeline products, continued to advance our lead program, TRC105, across multiple solid tumor indications, and saw a significant step in the expansion of our clinical pipeline beyond oncology with the IND filing by our partner, Santen, in wet AMD," said Charles P. Theuer, M.D., Ph.D., President and CEO of TRACON. "We are particularly excited by the ongoing complete responses seen in angiosarcoma, a tumor type known to express high levels of endoglin, and expect to initiate a Phase 3 trial in this indication in 2016."

## **Upcoming Development Milestones**

- TRACON expects to initiate four additional clinical studies of TRC105 before the end of 2015:
  - A multicenter Phase 1b/2 trial of TRC105 and Nexavar in patients with HCC.
  - A Phase 1b trial of TRC105 with Avastin and carboplatin and paclitaxel in patients with non-small cell lung cancer.
  - A Phase 1b/2 trial of TRC105 with Afinitor and Femara in the neo-adjuvant setting in patients with advanced breast cancer.
  - A Phase 1b trial of TRC105 with Stivarga in patients with colorectal cancer.
- TRACON expects the NCI to initiate four additional clinical studies of TRC102 in the next nine months:
  - A Phase 2 trial of TRC102 and Temodar in glioblastoma.
  - A Phase 1b trial of TRC102 and Alimta<sup>®</sup> (pemetrexed) and cisplatin in patients with refractory solid tumors.
  - A Phase 2 trial of TRC102 and Alimta in patients with mesothelioma.
  - A Phase 1b trial of TRC102 and chemoradiation therapy in patients with lung cancer.
- TRACON expects to present data at the World Congress on Gestational Trophoblastic Neoplasia in September 2015 from a single patient Phase 2 study combining TRC105 and Avastin in a patient with refractory and metastatic choriocarcinoma. Choriocarcinoma is a tumor type, like angiosarcoma, known to express high levels of endoglin.



### **Second Quarter 2015 Financial Results**

- Cash and cash equivalents were \$61.2 million at June 30, 2015, compared to \$65.3 million and \$35.0 million at March 31, 2015 and December 31, 2014, respectively. This balance does not include a \$3 million milestone payment that was earned, but not received, during the quarter.
- Collaboration revenue for the second quarter of 2015 was \$4.2 million, compared to \$1.1 million for the second quarter of 2014. The increase in collaboration revenue for the 2015 period as compared to the 2014 period was a result of the \$3 million milestone payment triggered by Santen's filing of the IND in wet AMD in June 2015.
- Research and development expenses for the second quarter of 2015 were \$5.4 million, compared to \$1.6 million for the second quarter of 2014. The increase in 2015 as compared to 2014 was primarily due to increased manufacturing activities and clinical study related expenses related to TRC105, and increased compensation related expenses due to increased headcount in 2015.
- General and administrative expenses for the second quarter of 2015 were \$1.5 million, compared to \$0.4 million for the second quarter of 2014. The increase in the 2015 period as compared to the 2014 period was primarily due to increased expenses as a result of being a public company and increased compensation related expenses due to increased headcount in 2015.
- The net loss for the second quarter of 2015 was \$2.9 million, compared to a loss of \$1.0 million for the second quarter of 2014.

#### **Investor Conference Call**

The Company will hold a conference call today at 4:30 p.m. EDT / 1:30 p.m. PDT to provide an update on corporate activities and to discuss the financial results of its second quarter 2015. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 93406510. A live webcast of the conference call will be available online from the Investor/Events and Presentation page of the Company's website at <a href="https://www.traconpharma.com">www.traconpharma.com</a>.

After the live webcast, a replay will remain available on TRACON's website for 60 days.

#### **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 multiple Phase 2 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 wet AMD. For more information about the clinical trials, please visit TRACON's website at <a href="http://www.traconpharma.com/clinical trials.php">http://www.traconpharma.com/clinical trials.php</a>.



#### **About Wet AMD**

Wet AMD is the leading cause of blindness worldwide in the elderly and is caused by excessive growth and leakage of blood vessels at the back of the eye that leads to a chronic and often rapid loss of vision. Existing therapies for the disease are limited, including treatment targeting the VEGF pathway.

#### **About TRC102**

TRC102 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 clinical trials sponsored by both the National Cancer Institute and Case Comprehensive Cancer Center. For more information about the clinical trials, please visit TRACON's website at <a href="http://www.traconpharma.com/clinical-trials.php">http://www.traconpharma.com/clinical-trials.php</a>.

#### **About TRACON**

TRACON develops targeted therapies for cancer, wet AMD 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 renal cell carcinoma, soft tissue sarcoma, hepatocellular carcinoma, glioblastoma and choriocarcinoma, 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 <a href="https://www.traconpharma.com">www.traconpharma.com</a>.

#### **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 regulatory submissions and determinations. 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 Santen advances TRC105 (DE-122) in ophthalmological indications or whether the NCI 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 Statements of Operations (in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Collaboration revenue	\$4,197	\$1,069	\$5,329	\$1,425
Operating expenses:				
Research and development	5,405	1,560	9,236	2,821
General and administrative	1,476	400	2,489	827
Total operating expenses	6,881	1,960	11,725	3,648
Loss from operations	(2,684)	(891)	(6,396)	(2,223)
Total other income (expense)	(237)	(89)	(520)	(118)
Net loss	(2,921)	(980)	(6,916)	(2,341)
Accretion to redemption value of redeemable				
convertible preferred stock	-	(66)	(31)	(132)
Net loss attributable to common stockholders	\$(2,921)	\$(1,046)	\$(6,947)	\$(2,473)
= -				
Net loss per share attributable to common				
stockholders, basic and diluted	\$(0.24)	\$(0.65)	\$(0.69)	\$(1.53)
Weighted-average common shares outstanding,				
basic and diluted	12,096,599	1,614,851	10,071,838	1,614,851



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

	June 30,	December 31,
	2015	2014
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$61,164	\$35,000
Prepaid and other assets	4,315	728
Total current assets	65,479	35,728
Property and equipment, net	143	97
Other assets	40	2,346
Total assets	\$65,662	\$38,171
Liabilities, Redeemable Convertible Preferred Stock and		
Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	\$6,097	\$3,974
Current portion of deferred revenue	4,789	4,357
Preferred stock warrant liabilities	-	246
Long-term debt, current portion		4,676
Total current liabilities	10,886	13,253
Deferred revenue	400	2,546
Other long-term liabilities	773	408
Long-term debt, less current portion	6,812	4,258
Commitments and contingencies		
Redeemable convertible preferred stock	-	49,880
Stockholders' equity (deficit):		
Common stock	12	2
Additional paid-in capital	87,875	2,004
Accumulated deficit	(41,096)	(34,180)
Total stockholders' equity (deficit)	46,791	(32,174)
Total liabilities, redeemable convertible preferred stock and	4	
stockholders' equity (deficit)	\$65,662	\$38,171

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