TRACON Pharmaceuticals Reports Second Quarter 2018 Financial Results and Provides Corporate Update

August 8, 2018

SAN DIEGO, Aug. 08, 2018 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer and wet age-related macular degeneration, today announced financial results for the second quarter ended June 30, 2018.

Second Quarter 2018 and Recent Corporate Highlights

- In August, we submitted an amendment to the FDA for the Phase 3 TAPPAS trial of TRC105 for the treatment of angiosarcoma that is accruing at 26 sites in the United States and multiple sites in the United Kingdom and France. The amendment proposes an increase in the trial sample size to account for the fewer than expected number of events that define the endpoint of progression free survival, reflecting a higher than expected rate of withdrawal for progressive disease unconfirmed by central review. The amendment increases the number of patients analyzed at the interim analysis from 70 to 120. Although the trial is enrolling at a higher rate than expected, with more than 80 patients enrolled, the amendment is expected to delay the interim analysis until Q1 2019.

- In July, we completed enrollment in the Phase 1 portion of a Phase 1/2 trial of TRC253 and determined the recommended Phase 2 dose for patients with metastatic prostate cancer. Dosing in the Phase 2 portion of the trial commenced in August. The Phase 1/2 trial is designed to assess safety, determine the recommended Phase 2 dose and assess response by prostate-specific antigen (PSA) levels. If Janssen opts to reacquire TRC253 prior to or following completion of the Phase 1/2 trial, TRACON is entitled to receive a $45.0 million opt-in payment, up to $137.5 million in potential milestone payments and a low-single digit royalty.

- In June, preclinical data from two murine models assessing the activity of TRC105 in combination with a PD-1 antibody were presented at the 2018 International Cancer Microenvironment Society meeting. The combination of treatment with TRC105 and the PD-1 antibody significantly reduced tumor volume compared to treatment with either individual therapy in both tumor models. Survival was significantly improved with combination treatment versus the individual therapies, with long-term survival demonstrated in 30% to 60% of animals. Combination treatment also increased tumor specific T cells, indicating stimulation of an immune response. TRC105 is being developed with the PD-1 checkpoint inhibitor Opdivo in patients with lung cancer in a Phase 1 trial.

- In April, TRACON closed a private placement of its common stock and warrants providing aggregate gross proceeds of approximately $38.7 million. In conjunction with the financing, the Company appointed Ted Wang, Ph.D., Chief Investment Officer of Puissance Capital Management, to its Board of Directors.

“We anticipate significant news flow over the next few quarters with three major data events from TRC105 trials, including two randomized data points: top-line Phase 2 data in renal cell carcinoma and interim Phase 3 results in angiosarcoma” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “We continue to be encouraged by the rapid rate of accrual into the Phase 3 TAPPAS angiosarcoma trial.”

Expected Upcoming Milestones

- Announcement of top-line data from the randomized Phase 2 TRAXAR trial of TRC105 in combination with Inlyta for patients with advanced or metastatic renal cell carcinoma is expected prior to the end of 2018.

- Announcement of data from the Phase 1b trial of TRC105 in combination with Opdivo in patients with non-small cell lung cancer is expected prior to the end of 2018.

- Announcement of the results of the interim analysis from the Phase 3 pivotal TAPPAS trial of TRC105 in angiosarcoma is expected in Q1 2019.

Second Quarter 2018 Financial Results

- Cash, cash equivalents and short-term investments were $53.4 million at June 30, 2018, compared to $34.5 million at December 31, 2017. We expect our current cash, cash equivalents and short-term investments to fund operations into Q4 2019.

- Research and development expenses for the second quarter of 2018 were $8.1 million compared to $4.9 million for the second quarter of 2017. The increase was primarily attributable to increased TRC105 drug manufacturing activities in the second quarter of 2018 as compared to the 2017 period.

- General and administrative expenses for the second quarter of 2018 were $1.6 million compared to $2.1 million for the second quarter of 2017.

- Net loss for the second quarter of 2018 was $9.8 million compared to $6.6 million for the second quarter of 2017.

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 2018. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 3189378. 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)

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 a pivotal Phase 3 trial in angiosarcoma and multiple Phase 2 clinical trials, in combination with VEGF inhibitors, as well as in a Phase 1 trial with Opdivo. 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 randomized Phase 2 trial for patients with wet AMD. 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 androgen receptor (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 metastatic castration-resistant prostate cancer. 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 and ophthalmic 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 being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule 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 clinical trials and availability of clinical data, expected development milestones, 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 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 third party collaborators complete on-going trials or initiate additional trials of TRACON's product candidates; the fact that TRACON's collaboration agreements are subject to early termination; 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	Six Months Ended

	June 30, 2018	2017	June 30, 2018	2017
Collaboration revenue	$ -	$ 631	$ 3,000	$ 1,257
Operating expenses:				
Research and development	8,115	4,893	17,553	10,475
General and administrative	1,622	2,068	3,373	4,032
Total operating expenses	9,737	6,961	20,926	14,507
Loss from operations	(9,737)	(6,330)	(17,926)	(13,250)
Total other income (expense)	(17)	(236)	(192)	(463)
Net loss	$ (9,754)	$ (6,566)	$ (18,118)	$ (13,713)
Net loss per share, basic and diluted	$ (0.33)	$ (0.40)	$ (0.76)	$ (0.84)
Weighted-average common shares outstanding, basic and diluted	29,706,717	16,610,124	23,992,497	16,409,389

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

	June 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 34,434	$ 29,467
Short-term investments	18,933	4,999
Prepaid and other assets	1,494	1,591
Total current assets	54,861	36,057
Property and equipment, net	59	73
Total assets	$ 54,920	$ 36,130
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,511	$ 6,800
Accrued compensation and related expenses	821	1,494
Current portion of deferred revenue	-	667
Long-term debt, current portion	-	2,837
Total current liabilities	11,332	11,798
Other long-term liabilities	372	409
Deferred revenue	-	2,333
Long-term debt, less current portion	6,258	4,603
Commitments and contingencies		
Stockholders' equity:		
Common stock	30	18
Additional paid-in capital	159,747	121,670
Accumulated deficit	(122,819)	(104,701)
Total stockholders' equity	36,958	16,987
Total liabilities and stockholders' equity	$ 54,920	$ 36,130

Company Contact:
Charles Theuer
Chief Executive Officer
(858) 550-0780 ext.
ctheuer@traconpharma.com

Investor Contact:
Andrew McDonald
LifeSci Advisors LLC
646-597-6987
Andrew@lifesciadvisors.com

Primary Logo

Source: TRACON Pharmaceuticals, Inc.