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): **November 7, 2018**

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.)

4350 La Jolla Village Drive, Suite 800 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))

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 November 7, 2018, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2018. A copy of this press release is furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by TRACON Pharmaceuticals, Inc. on November 7, 2018 announcing its financial results for the quarter ended September 30, 2018.

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: November 7, 2018

By: /s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer

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

San Diego, CA – November 7, 2018– 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 third quarter ended September 30, 2018.

Third Quarter 2018 and Recent Corporate Highlights

- In September, we announced the publication of results from a Phase 1b clinical trial combining TRC105 with Inlyta® (axitinib) in patients with advanced or metastatic renal cell carcinoma (RCC) in *The Oncologist*. These data were previously presented at the European Society for Medical Oncology (ESMO) 2016 Congress in Copenhagen, Denmark. The open-label dose escalation and expansion Phase 1b study enrolled a total of 18 patients (17 of whom were evaluable for response) who had received at least one prior line of therapy with a VEGF receptor tyrosine kinase inhibitor. Patients in the trial received a combination of TRC105 and Inlyta and demonstrated an objective response rate (ORR) of 29%, an 88% overall disease control rate, and a median progression-free survival (PFS) of 11.3 months. For comparison, in a separate trial, the ORR seen in the large subgroup of VEGFR TKI-refractory patients treated with Inlyta (n=194) in the Inlyta AXIS Phase 3 study in second-line clear cell RCC patients was 11.3%, and median PFS was 4.8 months. The publication also noted that plasma levels of TGF-β receptor 3 (betaglycan) at baseline were significantly higher in patients who experienced a confirmed partial response, while levels of osteopontin were significantly lower at baseline for patients that achieved a confirmed partial response. Both markers correlated with time on study and their potential prognostic value will be investigated in the ongoing Phase 2b TRAXAR study. TRACON's Phase 2b TRAXAR clinical trial of TRC105 in combination with Inlyta completed enrollment of 150 patients with advanced or metastatic RCC in Q3 2017 and top-line data are expected in December 2018.

- In September, we announced that the sample size of the Phase 3 TAPPAS clinical trial of TRC105 in combination with Votrient was amended to increase the sample size to account for a higher than expected rate of withdrawal for progressive disease not confirmed by central review. The amended protocol was reviewed and accepted by the FDA, with retention of the special protocol assessment (SPA) agreement. We expect the interim analysis to determine the final sample size and eligible patient population of the trial in Q1 2019. The trial design was published in *Annals of Oncology* in October 2018 and was recognized as the Most Innovative Trial of 2017 by the Clinical and Research Excellence Awards.

- In September we submitted updated data from the Phase 1/2 trial of TRC105 and Nexavar in patients with hepatocellular carcinoma (HCC) to the Gastrointestinal Cancers Symposia of ASCO, which meets in January 2019 in San Francisco. The trial completed Phase 1 enrollment and is currently enrolling up to 21 patients in the Phase 2 portion with overall response rate as the primary endpoint. Two of nine evaluable patients in the Phase 1 portion of the trial had durable confirmed partial responses (22%). For comparison, in separate Phase 3 trials, the durable confirmed partial responses seen with Nexavar in patients with HCC was 2% and 3%.

- In October we completed dose escalation of the Phase 1 trial of TRC105 in combination with Opdivo in lung cancer patients. We are currently enrolling two expansion cohorts of 12 patients each, one with patients naïve to PD-1/PD/L1 inhibitor therapy and one with patients who have relapsed following prior PD-1/PD-L1 therapy. We expect to provide top line safety and efficacy data from patients in the Phase 1 portion of the trial in December 2018.

- In July we completed the Phase 1 portion of a Phase 1/2 trial of TRC253 in patients with metastatic prostate cancer and are now enrolling patients in the Phase 2 portion of the trial at approximately 20 sites in the US. In the Phase 2 portion of the trial, we are incorporating circulating tumor DNA testing in order to allow for biomarker-directed therapy of prostate cancer patients who have progressed following treatment with an androgen receptor inhibitor. We now expect top line Phase 2 data in 2020, rather than 2019, due to slower than expected enrollment resulting from a lower than anticipated frequency of a specific tumor mutation targeted by TRC253 among metastatic prostate cancer patients. As a reminder, we licensed TRC253 from Janssen and if they exercise their right to reacquire the asset following Phase 2 proof of concept data, TRACON will be entitled to receive a $45M payment, up to $137.5M in additional potential milestones, and a low single digit royalty on sales.

“We anticipate significant potential catalysts over the next two quarters, including two randomized data points: top-line Phase 2 data from TRAXAR in renal cell carcinoma and interim Phase 3 results from TAPPAS in angiosarcoma” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “Of note, we continue to be encouraged by the rapid rate of accrual into the Phase 3 TAPPAS angiosarcoma trial.”

Expected Upcoming Milestones

- Announcement of safety and efficacy data from the Phase 2 trial of TRC102 in combination with Temodar in patients with glioblastoma at the Society for Neuro-Oncology annual meeting in November 2018.

- Announcement of top-line data, including biomarker correlations, from the randomized Phase 2 TRAXAR trial of TRC105 in combination with Inlyta for patients with advanced or metastatic RCC is expected in December 2018.

- Announcement of safety and efficacy data from the Phase 1b trial of TRC105 in combination with Opdivo in patients with non-small cell lung cancer is expected in December 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.

Third Quarter 2018 Financial Results

- Cash, cash equivalents and short-term investments were $47.2 million at September 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 third quarter of 2018 were $7.0 million compared to $4.3 million for the third quarter of 2017. The increase was primarily attributable to increased TRC105 drug manufacturing activities and direct clinical trial expenses in the third quarter of 2018 as compared to the 2017 period.

- General and administrative expenses for the third quarter of 2018 were $2.1 million compared to $1.8 million for the third quarter of 2017.

- Net loss for the third quarter of 2018 was $9.1 million compared to net income of $1.2 million for the third quarter of 2017. The net income in the third quarter of 2017 was a result of receiving and recognizing as revenue a $7.0 million milestone payment from Santen.

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 third 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 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 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. 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 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. TRACON is actively seeking additional corporate partnerships whereby it shares in the cost and risk of clinical development and commercialization of new product candidates. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States. 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 and scope of clinical trials and availability of clinical data, expected development milestones, estimated cash runway, 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; the possibility of unexpected expenses or other uses of TRACON's cash resources; 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 September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Collaboration revenue	$-	$7,498	$3,000	$8,755
Operating expenses:				
Research and development	6,976	4,257	24,529	14,732
General and administrative	2,107	1,847	5,480	5,879
Total operating expenses	9,083	6,104	30,009	20,611
(Loss) income from operations	(9,083)	1,394	(27,009)	(11,856)
Total other expense	(2)	(224)	(194)	(687)
Net (loss) income	$(9,085)	$1,170	$(27,203)	$(12,543)
Net (loss) income per share, basic and diluted	$(0.30)	$0.07	$(1.05)	$(0.76)
Weighted-average common shares outstanding, basic	29,837,486	16,828,801	25,962,237	16,550,730
Weighted-average common shares outstanding, diluted	29,837,486	17,137,311	25,962,237	16,550,730

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

	September 30, 2018	December 31, 2017
Assets	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$28,193	$29,467
Short-term investments	18,978	4,999
Prepaid and other assets	1,268	1,591
Total current assets	48,439	36,057
Property and equipment, net	52	73
Total assets	$48,491	$36,130
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$12,062	$6,800
Accrued compensation and related expenses	1,156	1,494
Current portion of deferred revenue	-	667
Long-term debt, current portion	370	2,837
Total current liabilities	13,588	11,798
Other long-term liabilities	371	409
Deferred revenue	-	2,333
Long-term debt, less current portion	5,973	4,603
Commitments and contingencies		
Stockholders' equity:		
Common stock	30	18
Additional paid-in capital	160,433	121,670
Accumulated deficit	(131,904)	(104,701)
Total stockholders' equity	28,559	16,987
Total liabilities and stockholders' equity	$48,491	$36,130

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