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 5, 2019**

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))

Securities registered pursuant to Section 12(b) of the Securities Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TCON	The Nasdaq Stock Market LLC

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 5, 2019, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. 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 5, 2019 announcing its financial results for the quarter ended September 30, 2019.

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 5, 2019

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

Exhibit 99.1

TRACON Pharmaceuticals Reports Third Quarter 2019 Financial Results and Provides Corporate Update

San Diego, CA – November 5, 2019 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer as well as wet age-related macular degeneration through a license to Santen Pharmaceutical Co. Ltd., and utilizing our product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the U.S., today announced financial results for the third quarter ended September 30, 2019.

Recent Corporate Highlights

- In October, we entered into a Common Stock Purchase Agreement (the "2019 Purchase Agreement") of up to $15.0 million with Aspire Capital Fund, LLC ("Aspire Capital") which has committed to purchase up to $15.0 million of shares of the Company's common stock at TRACON's request from time to time during the 30-month period of the purchase agreement and at prices based on the market price at the time of each sale. Upon entering into the 2019 Purchase Agreement, the prior Common Stock Purchase Agreement executed in March 2017 was terminated.

- In November, we agreed with Janssen that the more than 70 currently enrolled patients in the Phase 1/2 trial of TRC253 are sufficient to determine the risk-benefit profile of the drug in three cohorts of metastatic castrate resistant prostate cancer patients: those with a F877L mutation, those with another undisclosed androgen receptor point mutation, and those with another basis for resistance to Xtandi or Erleada. While not mature, the available Phase 2 data indicate a lower than expected initial response rate and prevalence of the F877L mutation.

"We are pleased to have entered into another transaction with Aspire Capital as this $15 million purchase agreement can serve as an option to secure capital to continue our current clinical development efforts and aim to further leverage our product development platform of CRO-independent development that includes U.S. commercialization expertise," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Our goal remains to establish new corporate partnerships to develop and commercialize first-in-class, best-in-class or fast follower clinical stage assets."

Expected Upcoming Milestones

- Top-line data, including the primary endpoint of mean change in best corrected visual acuity at six months, from the randomized Phase 2 AVANTE trial of DE-122 in patients with wet AMD are expected in the first half of 2020. In this trial DE-122 is being combined with Lucentis and being compared with Lucentis single agent treatment.

- The Phase 2 POC data from the Phase 1/2 clinical trial of TRC253 in metastatic castrate resistant prostate cancer is now expected in the first half of 2020, whereupon Janssen have an exclusive option to reacquire full rights to TRC253 for an opt-in payment of $45 million to TRACON, and obligations to pay regulatory and commercialization milestones totaling up to $137.5 million upon achievement of specified events, in addition to a low single-digit royalty on net sales. If Janssen does not opt in TRACON can advance TRC253 independently, in which case TRACON would owe Janssen up to $45 million upon achievement of specified events, in addition to a low single-digit royalty on net sales.

- Top line data for the Phase 1 dose escalation study of TJ004309, a CD73 antibody, as a single agent and in combination with Tecentriq, a marketed PD-L1 antibody being supplied by Roche, is expected in the second half of 2020. We are developing TJ004309 in collaboration with I-Mab Biopharma.

- Nomination and IND filing of the initial bispecific antibody (BsAb) from the I-Mab pipeline is expected in the second half of 2020. The I-Mab pipeline includes PD-L1 x IL-7, PD-L1 x CD47, PD-L1 x CD73, PD-L1 x B7-H3, and PD-L1 x 4-1BB antibodies. TRACON and I-Mab previously entered into a cost-sharing product development collaboration whereby TRACON will be responsible for the regulatory and clinical development of up to five of the BsAbs in North America and Europe, with the majority of the development effort expected to occur in the U.S. TRACON will bear the costs of early phases of clinical trials and I-Mab will share the costs for more advanced development stages and commercialization. TRACON will share the North America rights of any selected BaAbs with I-Mab for each collaborative program and retains an opt-in right to in-license the BsAbs from I-Mab ex-greater China.

Third Quarter 2019 Financial Results

- Cash, cash equivalents and short-term investments were $19.1 million at September 30, 2019 compared to $39.1 million at December 31, 2018. We expect our current cash, cash equivalents and short-term investments to fund operations into the third quarter of 2020.

- Research and development expenses for the third quarter of 2019 were $3.1 million compared to $7.0 million for the third quarter of 2018. The decrease was primarily attributable to lower manufacturing expenses and clinical trial expenses due to the discontinuation of the TRC105 program.

- General and administrative expenses for the third quarter of 2019 were $2.0 million compared to $2.1 million for the third quarter of 2018.

- Net loss for the third quarter of 2019 was $5.2 million compared to $9.1 million for the third quarter of 2018.

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 third quarter 2019. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 3896667. 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 DE-122 (carotuximab)

DE-122, an ophthalmic formulation of carotuximab, is active in preclinical choroidal neovascularization (CNV) models and designed to enhance the effect of approved VEGF inhibitors used to treat wet AMD. DE-122 is being investigated in the Phase 2 randomized AVANTE trial assessing the efficacy and safety of intravitreal injections in combination with Lucentis® (ranibizumab) compared to Lucentis monotherapy in patients with wet AMD.

About TRC253

TRC253 is a novel, orally bioavailable small molecule drug that is a potent, high affinity competitive inhibitor of the androgen receptor (AR) and AR mutations, including the F877L mutation. The AR F877L mutation results in an alteration in the AR ligand binding domain that confers resistance to therapies for prostate cancer. 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. TRC253 is currently being studied in a Phase 1/2 clinical trial in prostate cancer. For more information about the clinical trial, please visit TRACON's website at www.traconpharma.com/clinical_trials.php

About TJ004309

TJ004309 is a novel, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to adenosine, which is highly immunosuppressive. TJ004309 is currently being studied in a Phase 1 trial to assess safety and preliminary efficacy as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq in patients with advanced solid tumors.

About TRACON

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company's clinical-stage pipeline includes: DE-122, the ophthalmic formulation of carotuximab, an endoglin antibody that is being developed for patients with wet AMD through a license to Santen Pharmaceutical Company Ltd.; TRC102, a small molecule drug being developed for the treatment of lung cancer; TRC253, a small molecule drug being developed for the treatment of prostate cancer; and TJ004309, a CD73 antibody being developed for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads regulatory and clinical development and shares in the cost and risk of clinical development and leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the U.S. 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 product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development milestones, estimated cash runway, potential access to future capital, potential utility of product candidates, potential events under collaboration and license agreements, and TRACON’s business development strategy and goals to enter into additional collaborations. 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; whether TRACON will be able to enter into additional collaboration agreements on favorable terms or at all; whether and when any bispecific antibodies are developed under TRACON’s collaboration with I-Mab; 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,	
	2019	**2018**	**2019**	**2018**
Collaboration revenue	$-	$-	$-	$3,000
Operating expenses:				
Research and development	3,056	6,976	12,617	24,529
General and administrative	2,025	2,107	5,867	5,480
Total operating expenses	5,081	9,083	18,484	30,009
Loss from operations	(5,081)	(9,083)	(18,484)	(27,009)
Total other income (expense)	(118)	(2)	(254)	(194)
Net loss	$(5,199)	$(9,085)	$(18,738)	$(27,203)
Net loss per share, basic and diluted	$(0.17)	$(0.30)	$(0.63)	$(1.05)
Weighted-average common shares outstanding, basic and diluted	29,937,457	29,837,486	29,919,776	25,962,237

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

	September 30, 2019	December 31, 2018
Assets	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$19,053	$25,136
Short-term investments	-	13,968
Prepaid and other assets	1,217	1,499
Total current assets	20,270	40,603
Property and equipment, net	27	45
Other assets	915	-
Total assets	$21,212	$40,648
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$9,204	$10,947
Accrued compensation and related expenses	1,056	1,464
Long-term debt, current portion	2,570	1,084
Total current liabilities	12,830	13,495
Other long-term liabilities	945	368
Long-term debt, less current portion	3,402	5,343
Commitments and contingencies		
Stockholders' equity:		
Common stock	30	30
Additional paid-in capital	162,403	161,072
Accumulated deficit	(158,398)	(139,660)
Total stockholders' equity	4,035	21,442
Total liabilities and stockholders' equity	$21,212	$40,648

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