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): **August 7, 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 August 7, 2019, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended June 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 August 7, 2019 announcing its financial results for the quarter ended June 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: August 7, 2019

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

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

San Diego, CA – August 7, 2019 – 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 through our 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 second quarter ended June 30, 2019.

Recent Corporate Highlights

- In August, our partner Santen announced the completion of enrollment in the randomized Phase 2 AVANTE study of DE-122 in combination with Lucentis® (ranibizumab) in patients with wet age-related macular degeneration (AMD).

- In July, we initiated dosing of the first patient in a Phase 1 study of TJ004309 (CD73 antibody) as a single agent and in combination with Tecentriq® (atezolizumab), a PD-L1 checkpoint inhibitor marketed by Roche, in patients with advanced solid tumors.

- In June, data from the ongoing Phase 1/2 clinical trial of TRC253 in metastatic castrate resistant prostate cancer patients were published in the 2019 ASCO Proceedings. 22 patients who had progressed on prior Xtandi® (enzalutamide) or Erleada™ (apalutamide) treatment were enrolled into one of six cohorts of escalating doses of TRC253. The single patient with a F877L androgen receptor (AR) point mutation at baseline remained on treatment for 49 weeks with a partial response by RECIST. The remaining 21 patients did not have a F877L AR point mutation at baseline, and 48% (10) remained on study for at least 6 months and one patient had a greater than 50% decrease in prostate specific antigen. TRC253 was well-tolerated and no drug-related serious adverse events were reported.

“We are excited to have initiated clinical development of TJ004309 and next look forward to collaborating on up to five bispecific antibodies with I-Mab Biopharma beginning with the first IND in 2020,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “We also continue to evaluate opportunities to establish new corporate partnerships. We are focused on ex-U.S. companies with first-in-class, best-in-class or fast follower clinical stage assets that could benefit from accessing our product development platform, which we believe offers a rapid and capital-efficient U.S. drug development and commercialization solution.”

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.

- Presentation of Phase 2 data from Phase 1/2 clinical trial of TRC253 in metastatic castrate resistant prostate cancer to Janssen is expected in the second half of 2020, whereupon Janssen will 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 and a low single-digit royalty on net sales.

Second Quarter 2019 Financial Results

- Cash, cash equivalents and short-term investments were $26.3 million at June 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 second quarter of 2019 were $4.3 million compared to $8.1 million for the second quarter of 2018. The decrease was primarily attributable to lower manufacturing expenses due to the discontinuation of the TRC105 program.

- General and administrative expenses for the second quarter of 2019 were $1.9 million compared to $1.6 million for the second quarter of 2018.

- Net loss for the second quarter of 2019 was $6.3 million compared to $9.8 million for the second 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 second quarter 2019. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 7498077. 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 utility of product candidates, potential events under collaboration and license agreements, and TRACON's business development strategy. 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 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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Collaboration revenue	$-	$-	$-	$3,000
Operating expenses:				
Research and development	4,347	8,115	9,561	17,553
General and administrative	1,893	1,622	3,842	3,373
Total operating expenses	6,240	9,737	13,403	20,926
Loss from operations	(6,240)	(9,737)	(13,403)	(17,926)
Total other income (expense)	(86)	(17)	(136)	(192)
Net loss	$(6,326)	$(9,754)	$(13,539)	$(18,118)
Net loss per share, basic and diluted	$(0.21)	$(0.33)	$(0.45)	$(0.76)
Weighted-average common shares outstanding, basic and diluted	29,929,364	29,706,717	29,910,789	23,992,497

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

	June 30, 2019	December 31, 2018
Assets	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$26,336	$25,136
Short-term investments	-	13,968
Prepaid and other assets	594	1,499
Total current assets	26,930	40,603
Property and equipment, net	32	45
Other assets	989	-
Total assets	$27,951	$40,648
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$10,466	$10,947
Accrued compensation and related expenses	937	1,464
Long-term debt, current portion	2,536	1,084
Total current liabilities	13,939	13,495
Other long-term liabilities	1,036	368
Long-term debt, less current portion	4,057	5,343
Commitments and contingencies		
Stockholders' equity:		
Common stock	30	30
Additional paid-in capital	162,088	161,072
Accumulated deficit	(153,199)	(139,660)
Total stockholders' equity	8,919	21,442
Total liabilities and stockholders' equity	$27,951	$40,648

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