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 10, 2020**

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 10, 2020, TRACON Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2020. 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 10, 2020 announcing its financial results for the quarter ended September 30, 2020.

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 10, 2020

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 2020 Financial Results and Provides Corporate Update

San Diego, CA – November 10, 2020 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted cancer therapeutics and utilizing a cost efficient, CRO-independent 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, 2020. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

"We made great progress during the quarter by securing capital from dedicated healthcare funds that extends our runway past expected ENVASARC registration trial interim data and into 2022. We expect to enroll patients at multiple sites in the ENVASARC trial this year and also expect our partners to submit envafolimab for approval in China before the end of the year," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We are focused on enrolling the ENVASARC trial expeditiously so we may deliver interim data in 2021, final data in 2022, and assuming positive clinical data and regulatory approval, potentially commercialize envafolimab in 2023 and thereby address a high unmet need within sarcoma."

Recent Corporate Highlights

Envafolimab

- In September, TRACON highlighted data from the registration trial of envafolimab in MSI-H/dMMR cancer that showed a 32% confirmed objective response rate (ORR) in patients (n=41) with MSI-H/dMMR colorectal cancer (CRC) who failed a fluoropyrimidine, oxaliplatin and irinotecan, and had at least two on-study tumor assessments. Twelve-month duration of response (DOR) was 75% and 12-month overall survival (OS) was 65%. The ORR in the overall population (n=103) was 43%, 12-month DOR was 92% and 12-month OS was 75%. Envafolimab demonstrated good tolerability and safety and there continued to be no infusion-related reactions. The 32% ORR is nearly identical to the 28% ORR reported for Opdivo and 33% ORR reported for Keytruda in separate trials of MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan.

TRC102

- In October, TRACON announced orphan drug designation from the U.S. FDA for TRC102 in malignant glioma, including glioblastoma. TRC102 is a small molecule inhibitor of DNA base inhibitor repair being studied in Phase 1 and Phase 2 trials sponsored by the National Cancer Institute.

Corporate

- In August, TRACON announced financings of approximately $10.0 million in the aggregate with multiple healthcare focused institutional investors through private placements of its common stock and pre-funded warrants. The financings were completed at market price, and TRACON expects that the net proceeds will extend its cash runway into 2022.

Expected Key Upcoming Milestones

- Enroll patients at multiple sites into the ENVASARC registration trial during the fourth quarter of 2020.
- Submission of envafolimab for approval in MSI-H/dMMR CRC to the National Medicinal Products Administration (NMPA) in China by our corporate partners 3D Medicines and Alphamab Oncology.
- Independent Data Monitoring Committee review of ENVASARC safety data in 1H 2021.
- FDA decision on orphan drug designation for envafolimab in sarcoma in 1H 2021.
- Interim ENVASARC efficacy and safety data in mid-2021.

Third Quarter 2020 Financial Results

- Cash and cash equivalents were $26.5 million at September 30, 2020, compared to $16.4 million at December 31, 2019. We expect our current cash and cash equivalents to fund operations into the first quarter of 2022.
- Research and development expenses for the third quarter of 2020 were $1.8 million, compared to $3.1 million for the third quarter of 2019.
- General and administrative expenses for the third quarter of 2020 were $2.1 million, compared to $2.0 million for the third quarter of 2019.
- Net loss for the third quarter of 2020 was $4.0 million, compared to $5.2 million for the third quarter of 2019.

Conference Call Details

Tuesday, November 10, at 4:30 PM Eastern Time / 1:30 PM Pacific Time

Domestic:	**855-779-9066**
International:	**631-485-4859**
Conference ID:	**7399456**

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 Envafolimab

Envafolimab (KN035), a novel, single-domain antibody against PD-L1, is the first subcutaneously injected PD-(L)1 inhibitor to be studied in registration trials. Envafolimab is currently dosing in a Phase 2 registration trial as a single agent in MSI-H/dMMR advanced solid tumor patients and a Phase 3 registration trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China sponsored by TRACON's corporate partners, 3D Medicines and Alphamab Oncology. In the Phase 2 registration trial, the confirmed ORR in MSI-H/dMMR CRC patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan was 32%, which was similar to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan and the 33% confirmed ORR reported for Keytruda in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan in cohort A of KEYNOTE-164.

About TRC102

TRC102 (methoxyamine) is a novel, 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 through a Cooperative Research and Development Agreement (CRADA) and has orphan drug designation from the US FDA in malignant glioma, including glioblastoma.

About TRC253

TRC253 is a Phase 3 ready 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 recently completed a Phase 1/2 clinical trial in prostate cancer conducted by TRACON. TRACON believes TRC253 can be developed and commercialized successfully in China and is actively seeking a strategic collaboration.

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 utilizing a capital efficient, CRO independent, product development platform. The Company's clinical-stage pipeline includes: Envafolimab, a PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; TRC253, a Phase 3 ready small molecule drug candidate for the treatment of prostate cancer; TRC102, a Phase 2 small molecule drug candidate for the treatment of lung cancer; and TJ004309, a CD73 antibody in Phase 1 development for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads U.S. 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 pipeline, 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 and its collaboration partners' plans to further develop product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development, regulatory and commercial milestones and timing thereof, estimated cash runway, 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 and regulatory approval of novel pharmaceutical products; whether TRACON or others will be able to complete or initiate clinical trials on TRACON's expected timelines, if at all, including due to risks associated with the COVID-19 pandemic; 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; 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,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$1,785	$3,056	$6,001	$12,617
General and administrative	2,063	2,025	6,045	5,867
Total operating expenses	3,848	5,081	12,046	18,484
Loss from operations	(3,848)	(5,081)	(12,046)	(18,484)
Total other expense	(144)	(118)	(418)	(254)
Net loss	$(3,992)	$(5,199)	$(12,464)	$(18,738)
Net loss per share, basic and diluted	$(0.38)	$(1.74)	$(1.69)	$(6.26)
Weighted-average common shares outstanding, basic and diluted	10,509,220	2,993,746	7,366,888	2,991,978

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

	September 30, 2020	December 31, 2019
Assets	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$26,451	$16,412
Prepaid and other assets	1,002	848
Total current assets	27,453	17,260
Property and equipment, net	13	23
Other assets	595	838
Total assets	$28,061	$18,121
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$6,409	$7,875
Accrued compensation and related expenses	1,080	1,355
Long-term debt, current portion	2,464	2,604
Total current liabilities	9,953	11,834
Other long-term liabilities	543	850
Long-term debt, less current portion	2,079	2,739
Commitments and contingencies		
Stockholders' equity:		
Common stock	14	4
Additional paid-in capital	190,270	165,028
Accumulated deficit	(174,798)	(162,334)
Total stockholders' equity	15,486	2,698
Total liabilities and stockholders' equity	$28,061	$18,121

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