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): December 14, 2022

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 8.01 Other Events.

On December 14, 2022, TRACON Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the independent data monitoring committee (the "IDMC") for the Company's ongoing ENVASARC Phase 2 pivotal trial recommended continued accrual as planned in both cohorts of the clinical trial: single agent envafolimab and envafolimab in combination with Yervoy (ipilimumab). The IDMC's recommendation followed its review of interim safety and efficacy data from 18 patients enrolled into each cohort who completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans), which identified a double-digit objective response rate assessed by blinded independent central review in each cohort, more than satisfying the prespecified futility rule. Envafolimab monotherapy and in combination with Yervoy was well tolerated, with only a single serious adverse event reported in the 36 patients that was considered of grade 1 (minor) severity. Responses were noted in patients regardless of weight at the 600 mg dose of envafolimab that was instituted following the previous IDMC review of interim safety and efficacy data from patients in the ENVASARC trial treated at the 300 mg dose of envafolimab. The Company now expects the IDMC's next review of interim safety and efficacy data in mid-2023, which will be conducted after the 46th patient in each cohort has completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans), and now expects to complete enrollment before the end of 2023.

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.

Date: December 14, 2022

TRACON Pharmaceuticals, Inc.

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