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): April 03, 2024

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** **(Address of Principal Executive Offices)**	**92122** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 550-0780

(Former Name or Former Address, if Changed Since Last Report)

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 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 April 3, 2024, TRACON Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the ENVASARC Phase 2 pivotal trial will continue as planned following a review of ongoing safety and efficacy data by the independent data monitoring committee (the "IDMC") on April 2, 2024. The ENVASARC Phase 2 pivotal trial completed enrollment in March 2024 with a total of 82 patients in cohort C of treatment with single agent envafolimab at 600 mg SQ every three weeks and final data are expected in the third quarter of 2024.

The IDMC reviewed interim safety and efficacy data from 73 patients enrolled into cohort C who had the opportunity to complete two on-treatment scans (a minimum of 12 weeks of treatment). The objective response rate (the "ORR") was 11% by investigator review and the confirmed ORR by blinded independent central review (the "BICR") was 5.5% (four patients). Median duration of response by BICR was greater than six months. Envafolimab has been well tolerated without the development of a single drug-related serious adverse event of grade 3 or higher. The primary endpoint of the study is achievement of an objective response in nine of 82 patients (11%) treated with envafolimab by BICR and median duration of response of greater than six months is a key secondary endpoint.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Forward-Looking Statements

Statements contained in this current report 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 the Company's expectations for the timing and scope of its clinical trials as well as timely achievement of expected endpoints and goals, the timing and expected results of clinical data, whether the ENVASARC trial will achieve its primary endpoint, and the potential for envafolimab to become a treatment option for patients with the refractory sarcoma subtypes of UPS and MFS. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: the Company's ability to remain listed on a national securities exchange, risks associated with clinical development and regulatory approval of pharmaceutical product candidates; risks relating to the Company's ability to continue as a going concern; risks relating to cost variability of clinical trials; whether other therapies are developed and compete with the Company's product candidates; whether the Company or others will be able to complete or initiate clinical trials on the Company's expected timelines, if at all, including due to risks associated with macroeconomic and geopolitical events; the fact that future clinical results may not be consistent with preliminary results or results from prior studies; potential changes in regulatory requirements in the United States and foreign countries; the Company'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 the Company will be able to obtain additional financing on favorable terms or at all; and other risks described in the Company'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. the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by the Company on April 3, 2024.
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

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.

Date: April 3, 2024

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

TRACON Pharmaceuticals Provides Update on Ongoing ENVASARC Phase 2 Pivotal Trial Following Independent Data Monitoring Committee Recommendation to Continue the Trial as Planned

ENVASARC Trial is Fully Enrolled and Final Data are Expected in Third Quarter 2024

San Diego, CA – April 3, 2024 – TRACON Pharmaceuticals (NASDAQ: TCON), a clinical stage biopharmaceutical company utilizing a cost-efficient, CRO-independent Product Development Platform (PDP) to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies, today announced the independent data monitoring committee (IDMC), following a review of ongoing safety and efficacy data on April 2, recommended the ENVASARC Phase 2 pivotal trial continue as planned. The ENVASARC Phase 2 pivotal trial completed enrollment in March 2024 with a total of 82 evaluable patients in cohort C of treatment with single agent envafolimab at 600 mg SQ every three weeks and final data are expected in the third quarter of 2024.

The IDMC reviewed interim safety and efficacy data from 73 patients enrolled into cohort C who had the opportunity to complete two on-treatment scans (a minimum of 12 weeks of treatment). The objective response rate (ORR) is currently 11% by investigator review and the confirmed ORR by blinded independent central review (BICR) is currently 5.5% (four patients). Median duration of response by BICR is greater than six months. Envafolimab has been well tolerated without the development of a single drug-related serious adverse event of grade 3 or higher. The primary endpoint of the study is achievement of an objective response in nine of 82 patients (11%) treated with envafolimab by BICR and median duration of response of greater than six months is a key secondary endpoint.

“Subcutaneous envafolimab has been generally well tolerated and continues to demonstrate durable single agent activity in a subset of these sarcoma patients,” said James Freddo, M.D., TRACON’s Chief Medical Officer. “An additional five objective responses confirmed by central review are needed to achieve our goal in the 82 patient cohort of single agent envafolimab treatment.”

“We believe that achievement of the primary endpoint in the ENVASARC trial would position envafolimab to become a potentially compelling treatment option for patients with the refractory sarcoma subtypes of UPS and MFS,” said Charles Theuer, M.D., Ph.D., TRACON’s Chief Executive Officer

About ENVASARC (NCT04480502)

The ENVASARC pivotal trial is a multicenter, open label, randomized, non-comparative, parallel cohort study at 30 top cancer centers in the United States and the United Kingdom that began dosing in December 2020. The primary endpoint is ORR by blinded central review of nine responses in cohort C of 82 evaluable patients with duration of response a key secondary endpoint. The trial is fully enrolled and the primary endpoint will continue to be evaluated.

About TRACON

TRACON utilizes a cost-efficient, CRO-independent, product development platform to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies. TRACON believes it can serve as a solution for companies without clinical capabilities who wish to become CRO-independent. To learn more about TRACON, 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 expectations for the timing and scope of its clinical trials as well as timely achievement of expected endpoints and goals, the timing and expected results of clinical data, whether the ENVASARC trial will achieve its primary endpoint, and the potential for envafolimab to become a treatment option for patients with the refractory sarcoma subtypes of UPS and MFS. 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 pharmaceutical product candidates; risks relating to TRACON's ability to continue as a going concern; risks relating to cost variability of clinical trials; whether other therapies are developed and compete with TRACON's product candidates; 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 macroeconomic and geopolitical events; the fact that future clinical results may not be consistent with preliminary results or results from prior studies; 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 on favorable terms or at all; 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 except as required by law.

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