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): June 13, 2023

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

(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 June 20, 2023, TRACON Pharmaceuticals, Inc. (the "Company") announced the positive results of an ad hoc six-month independent data monitoring committee ("IDMC") review for its ongoing ENVASARC Phase 2 pivotal trial.

The IDMC reviewed interim safety and efficacy data from more than 80 patients equally randomized into cohort C of single agent envafolimab or cohort D of envafolimab given in combination with Yervoy. Patients in cohort C who had at least two on study CT scans continued to demonstrate a double-digit ORR assessed by investigator and blinded independent central review. Envafolimab was well tolerated without a single greater than grade 2 drug related adverse event. A mandated interim analysis in the third quarter of 2023 is planned to be conducted after the 46th patient treated with envafolimab has completed a minimum of 12 weeks of efficacy evaluations and includes a futility rule that is being exceeded to date based on the current data.

The combination of envafolimab with Yervoy did not demonstrate the Company's desired synergy compared to single agent envafolimab and the Company will terminate enrollment in cohort D, which is expected to result in a reduction in trial costs and potential acceleration of the timeline to final ENVASARC data. Enrollment of the separate trial of the Company's CTLA-4 antibody YH001 with envafolimab and doxorubicin will continue, based on multiple responses seen in the Phase 1 portion of the trial to date that is designed to determine the optimal dose of YH001 in combination with envafolimab and doxorubicin. The Company expects to report YH001 trial data at the Connective Tissue Oncology Society annual meeting in November 2023.

Forward Looking Statement

Statements contained in this current report regarding matters that may occur in the future are "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements in this current report regarding the timing and results of future data from, and analyses regarding, the Company's clinical trials, the expected cost and timing benefits to the ENVASARC Phase 2 pivotal trial due to the Company's termination of cohort D, and the timing and scope of enrollment in clinical trials. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied by such forward-looking statements. In particular, risks related to clinical development and regulatory approval of pharmaceutical products, including the variability of cost and timing of results, among other factors, could cause results to differ materially from those expressed or implied by such forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. The Company undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by TRACON Pharmaceuticals, Inc. on June 20, 2023.
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.

Date: June 20, 2023

By: /s/ Charles P. Theuer, M.D., Ph.D.

Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer

TRACON Pharmaceuticals Announces Positive Results Based on Ongoing Double-Digit Objective Response Rate for Single Agent Envafolimab in the ENVASARC Phase 2 Pivotal Trial

Single Agent Envafolimab ORR Exceeded Futility Rule that will be Applied at the Interim Efficacy Analysis Expected in Q3

Continuing Double-Digit Objective Response Rate (ORR) by Blinded Independent Central Review Achieved to Date in Single Agent Envafolimab Cohort without any > Grade 2 Drug Related Toxicity

Full ENVASARC Accrual Expected in Q4

San Diego, CA – June 20, 2023 – TRACON Pharmaceuticals (NASDAQ: TCON), a clinical stage biopharmaceutical company utilizing 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, today announced the positive results of a six-month independent data monitoring committee (IDMC) review for the ongoing ENVASARC Phase 2 pivotal trial.

The IDMC reviewed interim safety and efficacy data from more than 80 patients equally randomized into cohort C of single agent envafolimab or cohort D of envafolimab given in combination with Yervoy. Patients in cohort C who had at least two on study CT scans continued to demonstrate a double-digit ORR assessed by investigator and blinded independent central review. Envafolimab was well tolerated without a single > grade 2 drug related adverse event. A planned interim analysis in the third quarter will be conducted after the 46th patient treated with envafolimab has completed a minimum of 12 weeks of efficacy evaluations and includes a futility rule that is currently being exceeded based on available data.

“We are pleased with the single agent activity of envafolimab that continues to generate a double-digit ORR, as well as the safety data showing envafolimab is well tolerated,” said James Freddo, M.D., TRACON’s Chief Medical Officer. “We believe the current response rate indicates that we remain on track to achieve the primary endpoint of the study of a minimum 11.25% objective response rate. We remain excited by the emerging data and for envafolimab’s potential to become a differentiated treatment for sarcoma patients.”

The combination of envafolimab with Yervoy did not demonstrate synergy when compared to single agent envafolimab and the Company will terminate enrollment in cohort D. This is expected to result in a reduction in trial costs and acceleration of the timeline to final ENVASARC data.

Enrollment of the separate trial of TRACON's CTLA-4 antibody YH001 with envafolimab and doxorubicin will continue, based on multiple responses seen in the Phase 1 portion of the trial to date using a higher dose of the CTLA-4 antibody. Phase 1 is designed to determine the optimal dose of YH001 in combination with envafolimab and doxorubicin, and the Company expects to report trial data at the Connective Tissue Oncology Society (CTOS) annual meeting in November.

"Achieving a double-digit ORR with a well-tolerated safety profile positions 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. "The sole approved treatment for these patients is Votrient, which achieved a 4% ORR and carries a black box warning for fatal liver toxicity."

About Envafolimab

Envafolimab (KN035), a single-domain antibody against PD-L1 invented by Alphamab Oncology and licensed by TRACON, is the first approved subcutaneously injected PD-(L)1 inhibitor. Envafolimab was approved by the Chinese NMPA in November 2021 in adult patients with MSI-H/dMMR advanced solid tumors who failed systemic treatment and have no satisfactory alternative treatment options. In December 2019, Alphamab Oncology, 3D Medicines and TRACON entered into a collaboration whereby TRACON has the right to develop and commercialize envafolimab in soft tissue sarcoma in North America. Envafolimab is currently being studied in the ENVASARC Phase 2 pivotal trial in the United States sponsored by TRACON and a Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China sponsored by TRACON's corporate partners, Alphamab Oncology and 3D Medicines. TRACON has received orphan drug designation from the U.S. Food and Drug Administration for envafolimab for patients with soft tissue sarcoma and fast track designation from the U.S. Food and Drug Administration for envafolimab (KN035) for patients with locally advanced, unresectable or metastatic undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS) who have progressed on one or two prior lines of chemotherapy.

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. ENVASARC is enrolling patients with UPS or MFS who have progressed following one or two lines of prior treatment and have not received an immune checkpoint inhibitor. A total of 80 patients will receive treatment with single agent envafolimab at 600 mg every three weeks. The primary endpoint is objective response rate by central review with duration of response a key secondary endpoint.

About TRACON

TRACON is a clinical-stage biopharmaceutical company utilizing 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. 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; YH001, a potential best-in-class CTLA-4 antibody in Phase 1 development; and TRC102, a Phase 2 small molecule drug candidate for the treatment of lung cancer. TRACON is actively seeking additional corporate partnerships through a profit-share or revenue-share partnership, or through franchising TRACON's product development platform. TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States or who wish to become CRO-independent. 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 expectations for the timing and scope of its clinical trials as well as timely achievement of expected endpoints and goals, the availability and expected results of clinical data and the timing of future reviews of data by the Independent Data Monitoring Committee, continued timely accrual in the ENVASARC Phase 2 pivotal trial, the potential for envafolimab to become a treatment option and the expected cost and timing benefits to the ENVASARC Phase 2 pivotal trial due to TRACON's termination of cohort D. 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 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; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials, initiate additional trials or seek regulatory approval 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; expectations on the timing of TRACON's recovery of the award from the arbitration with I-Mab and the effects of any recovery on TRACON's cash runway; 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.

Company Contact:
Charles Theuer
Chief Executive Officer
(858) 550-0780
ctheuer@traconpharma.com

Investor Contact:
Brian Ritchie
LifeSci Advisors LLC
(212) 915-2578
britchie@lifesciadvisors.com