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): September 15, 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** **(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 7.01 Regulation FD Disclosure.

As previously disclosed, in July 2023, TRACON Pharmaceuticals, Inc. (the "Company") agreed to and collected a settlement of $22.0 million in full satisfaction of the previously announced April 2023 arbitration award from I-Mab Biopharma ("I-Mab"). Net of the repayment of the arbitration financing payable and $4.4 million of Success Fees (as defined below) held in a client trust account by the Company's legal counsel, the Company collected $7.1 million.

In connection with the I-Mab arbitration, the Company entered into a contingency fee arrangement with its legal counsels whereby counsels agreed to defer a portion of their legal fees (the "Success Fees") and would receive payment of the Success Fees in full or at a low single digit multiple depending on the amount awarded and contingent upon actual recovery of proceeds from an arbitration award. On September 15, 2023, the Company received payment of $2.0 million from the client trust account as well as the write-off of approximately $322,000 in invoices, and the Company's legal counsel received $2.4 million from client the trust account following negotiations among the Company and its legal counsels regarding the amount of the Success Fees owed to the legal counsels.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events.

On September 18, 2023, the Company announced that the ENVASARC Phase 2 pivotal trial satisfied the futility threshold of 3 responses out of 46 and based on the results of the second and final mandated independent data monitoring committee ("IDMC") efficacy review, the trial will continue as planned.

The IDMC reviewed interim safety and efficacy data from 46 patients enrolled into cohort C of treatment with single agent envafolimab who completed two on-treatment scans (a minimum of 12 weeks of efficacy evaluations). The objective response rate ("ORR") in the initial 46 patients treated with single agent envafolimab was 13% by investigator review and 8.7% by blinded independent central review ("BICR"). The ORR assessed by BICR, all of which were confirmed responses, satisfied the prespecified futility rule of 3 responses out of 46 and envafolimab monotherapy was generally well tolerated. Median duration of response by BICR was greater than six months. The primary endpoint of the study is achievement of an ORR in nine of 80 patients (11.25%) treated with envafolimab by BICR and median duration of response of greater than six months is a key secondary endpoint.

The trial has enrolled more than 60 of the planned 80 patients and full accrual of the ENVASARC pivotal trial is expected in the fourth quarter of this year with final data anticipated in mid-2024.

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 in this current report regarding TRACON's expectations for the timing and scope of its ENVASARC Phase 2 pivotal trial as well as TRACON's expectation for 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 IDMC and BICR, and continued timely accrual in the ENVASARC Phase 2 pivotal trial. 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, including that the ENVASARC Phase 2 pivotal trial may not achieve its primary and secondary endpoints; 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 (including the ENVASARC Phase 2 pivotal trial) or initiate clinical trials on TRACON's expected timelines, if at all, including due to risks associated with clinical, 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; 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". 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 September 18, 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: September 18, 2023

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

Exhibit 99.1

TRACON Pharmaceuticals Announces ENVASARC Phase 2 Pivotal Trial Exceeded Futility Threshold at Final Interim Analysis and Will Continue as Planned

Full ENVASARC accrual expected in Q4 and final data expected in mid-2024

San Diego, CA – September 18, 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 that the ENVASARC Phase 2 pivotal trial more than satisfied the futility threshold of 3 responses out of 46 based on the results of the second and final mandated independent data monitoring committee (IDMC) efficacy review, and the trial will continue as planned.

The IDMC reviewed interim safety and efficacy data from 46 patients enrolled into cohort C of treatment with single agent envafolimab who completed two on-treatment scans (a minimum of 12 weeks of efficacy evaluations). The objective response rate (ORR) in the initial 46 patients treated with single agent envafolimab was 13% by investigator review and 8.7% by blinded independent central review (BICR). The ORR assessed by BICR, all of which were confirmed responses, more than satisfied the prespecified futility rule and envafolimab monotherapy was generally well tolerated. Median duration of response by BICR was greater than six months. The primary endpoint of the study is achievement of an ORR in nine of 80 patients (11.25%) treated with envafolimab by BICR and median duration of response of greater than six months is a key secondary endpoint.

“Envafolimab continues to demonstrate durable single agent activity and has been generally well tolerated,” said James Freddo, M.D., TRACON’s Chief Medical Officer. “Our goal is the demonstration of nine objective responses by BICR in the 80 patient cohort of single agent envafolimab treatment.”

“We continue to believe that these data position envafolimab to become a potentially compelling treatment option for patients with the refractory sarcoma subtypes of UPS and MFS based on the ORR and tolerability data to date,” said Charles Theuer, M.D., Ph.D., TRACON’s Chief Executive Officer.

The trial has enrolled more than 60 of the planned 80 patients and full accrual of the ENVASARC pivotal trial is expected in the fourth quarter of this year with final data anticipated in mid-2024.

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 ENVASARC Phase 2 pivotal trial as well as TRACON's expectation for 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 IDMC and BICR, continued timely accrual in the ENVASARC Phase 2 pivotal trial, and the potential for envafolimab to become a treatment option. 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, including that the ENVASARC Phase 2 pivotal trial may not achieve its primary and secondary endpoints; 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 (including the ENVASARC Phase 2 pivotal trial) or initiate clinical trials on TRACON's expected timelines, if at all, including due to risks associated with clinical, 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; 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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