

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 14, 2022**

TRACON Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36818

(Commission File Number)

34-2037594

(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

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 September 14, 2022, TRACON Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration has granted it Fast Track designation 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. A copy of that press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated September 14, 2022
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 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



TRACON Pharmaceuticals Announces Fast Track Designation by the FDA for Envafolelimab for the Treatment of the Soft Tissue Sarcoma Subtypes of UPS and MFS

San Diego, CA – September 14, 2022 – TRACON Pharmaceuticals, Inc. (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, announced today that the U.S. Food and Drug Administration (FDA) has granted fast track designation for the development of 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.

“We applied for fast track designation based on activity observed in the ENVASARC Phase 2 pivotal trial and are pleased to receive this notification from the FDA,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “Soft tissue sarcoma is a disease in need of new treatments and we expect to provide data through the ENVASARC pivotal trial showing superior efficacy and safety of envafolimab compared to currently approved therapy for refractory soft tissue sarcoma. Accrual in the pivotal ENVASARC trial remains robust and we expect to report an independent data monitoring committee interim safety review and interim efficacy review in the fourth quarter.”

The FDA designed the fast track process to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Fast track designation can confer important benefits, including the potential eligibility for priority review of a Biologics License Application, if relevant criteria are met, as discussed in our Annual Report on Form 10-K for the year ended December 31, 2021.

About Envafolelimab

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 pivotal ENVASARC Phase 2 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.

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. TRACON expects the trial to enroll more than 160 patients with UPS or MFS who have progressed following one or two lines of prior treatment and have not received an immune checkpoint inhibitor, with 80 patients enrolled into a cohort of treatment with single agent envafolimab at 600 mg every three weeks and 80 patients enrolled into a cohort of treatment with envafolimab at 600 mg every three weeks with Yervoy®. The primary endpoint is objective response rate by central review with duration of response a key secondary endpoint.

4350 La Jolla Village Drive • Suite 800 • San Diego, California 92122 • P: 858.550.0780 • F: 858.550.0786
URL: www.traconpharma.com

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; 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 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 the timing and results of data from TRACON's ENVASARC Phase 2 pivotal trial, including reports of the independent data monitoring committee, TRACON's plans to further develop its product candidates, expectations regarding the timing and scope of clinical trials, continued accrual of the ENVASARC pivotal trial, expected development and regulatory milestones and timing thereof, the expected benefits of the FDA's fast track designation and the potential benefits of product candidates. 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; 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 the COVID-19 pandemic or other 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.

Company Contact:

Mark Wiggins

Chief Business Officer

(858) 251-3492

mwiggins@traconpharma.com

Investor Contact:

Brian Ritchie

LifeSci Advisors LLC

(212) 915-2578

britchie@lifesciadvisors.com