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 24, 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 8.01 Other Events.

On April 24, 2023, TRACON Pharmaceuticals, Inc. (the "Company") received notification from the arbitral tribunal (the "Tribunal") of the International Court of Arbitration of the International Chamber of Commerce in the Company's arbitration with I-Mab Biopharma ("I-Mab") of the final award to the Company. The Tribunal found in favor of the Company for certain claims. As a result, the Tribunal declared the Phase 1 clinical trial of TJ004309 Agreement "Complete," as that term is defined in the TJ004309 Agreement as of January 2022. The Tribunal also determined that the Company is entitled to approximately $23.0 million, which includes the $9.0 million prespecified termination fee payable by I-Mab under the TJ003409 Agreement, plus interest, and certain of the Company's legal fees, costs and disbursements incurred in connection with the arbitration. In November 2018, the Company entered into two separate strategic collaboration and clinical trial agreements with I-Mab for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 (the "TJ003409 Agreement") as well as up to five proprietary bispecific antibodies (the "BsAb Agreement") currently under development by I-Mab. Pursuant to the arbitration award, the TJ004309 Agreement and the BsAb Agreement have been terminated. The decision by the arbitrator is final and binding on the parties. The award to the Company did not exceed the prespecified threshold under the non-recourse financing agreement entered into by the Company and certain investors in December 2022, and therefore the Company will not receive any additional funds under such agreement.

The Company has determined that its cash runway, inclusive of the amounts it expects to recover pursuant to the award, extends its cash runway into 2024.

Forward-Looking Statements

Statements made in this 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 expected cash runway, inclusive of the amounts the Company expects to recover pursuant to the award. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: the risks associated with future costs related to the arbitration or collection of amounts awarded, 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 report 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by TRACON Pharmaceuticals, Inc. on April 25, 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.

TRACON Pharmaceuticals, Inc.

Date: April 25, 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 Arbitration Award in Dispute with I-Mab

San Diego, CA – April 25, 2023 – 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, today announced that the tribunal in the arbitration against I-Mab conducted under the Rules of Arbitration of the International Chamber of Commerce (ICC) rendered an award to TRACON in the aggregate amount of approximately $23.0 million.

In November 2018, TRACON entered into two separate strategic collaboration and clinical trial agreements with I-Mab for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 as well as up to five proprietary bispecific antibodies under development by I-Mab. I-Mab commenced arbitration in June 2020, after TRACON invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations. I-Mab initiated the arbitration seeking a declaration that they were not in breach of either agreement, and TRACON filed counterclaims soon thereafter. Among other findings, the ICC tribunal deemed the TJ004309 trial complete as of January 2022, which entitled TRACON to $9.0 million plus interest, and awarded legal fees and costs to TRACON. The award is made pursuant to a binding arbitration, and both agreements are now terminated.

"We are pleased to receive an award from the ICC tribunal, that we believe will extend our runway into 2024 past the expected interim efficacy results from ENVASARC," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We remain focused on the pivotal ENVASARC Phase 2 trial and expect to complete enrollment this year."

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 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 as well as multiple Phase 1 and Phase 2 clinical trials 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 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. 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.

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 1/2 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 recoverability and timing of recovery for the award determined by the ICC tribunal for TRACON; expectations regarding TRACON's cash runway; expectations regarding the timing and scope of clinical trials, enrollment and availability of clinical data, including the timing and results of accrual and data from TRACON's ENVASARC Phase 2 pivotal trial and a report of the IDMC on its second interim efficacy analysis; expected development, regulatory and commercial milestones and timing thereof; and TRACON's business development strategy and goals to enter into additional collaborations. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: the inherent uncertainty regarding recovery of arbitration awards and the timing of such recovery; the risk that TRACON's cash runway will be less than currently anticipated; risks associated with clinical development and regulatory approval of novel pharmaceutical 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 geopolitical and macroeconomic events, such as the COVID-19 pandemic, the ongoing military conflict between Ukraine and Russia and related sanctions; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials or initiate additional trials of TRACON's product candidates; 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; 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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