

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): **March 8, 2023**

**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 2.02 Results of Operations and Financial Condition.**

On March 8, 2023, TRACON Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2022. A copy of this press release is furnished as Exhibit 99.1 hereto.

The information provided in this Item 2.02 of this Current Report on Form 8-K, including the exhibits, 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, nor shall it be deemed incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release issued by TRACON Pharmaceuticals, Inc. on March 8, 2023 announcing its financial results for the quarter and year ended December 31, 2022.</a>
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 8, 2023

**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 Reports Fourth Quarter and Year-End 2022 Financial Results and Provides Corporate Update

**San Diego, CA – March 8, 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 financial results for the fourth quarter and year ended December 31, 2022. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

“The significant progress we achieved in the fourth quarter sets up 2023 to be a potentially transformational year for TRACON,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “In December we announced interim efficacy results from the ongoing ENVASARC pivotal trial demonstrating that envafolimab achieved a double-digit objective response rate, both as a single agent and in combination with Yervoy, in 36 patients with refractory sarcoma. We also secured a non-dilutive non-recourse financing of up to \$30 million related to the I-Mab arbitration award decision which we expect this month, of which \$3.5 million was funded in December. Importantly, accrual in ENVASARC remains ahead of projections and we expect the second and final interim efficacy analysis of 92 patients in the third quarter, after each patient has had two on-study scans, and to complete accrual before year end, leading to final data in 2024.”

### Recent Corporate Highlights

- In November 2022, we announced dosing of the first patient in a Phase 1/2 trial that studies envafolimab with our proprietary CTLA-4 antibody YH001 in combination with doxorubicin in front line sarcoma.
- In November 2022, we completed the Phase 1 study of the CD73 antibody TJ4309, triggering I-Mab’s right to reacquire the asset for a payment to TRACON of \$9M.
- In December 2022, we announced positive interim results in the ENVASARC Phase 2 pivotal trial based on a double-digit objective response rate (ORR) by central radiographic review in the cohort of single agent envafolimab (N=18) and the cohort of envafolimab given in combination with Yervoy (N=18). The primary endpoint of the pivotal ENVASARC trial is achievement of an 11.25% ORR by central radiographic review in either 80 patient cohort.
- In December 2022, we announced a non-recourse non-dilutive financing of up to \$30M related to the arbitration with I-Mab. We received \$3.5M up front and the remainder will be available subject to the award exceeding a threshold and satisfaction of other conditions.

## Expected Upcoming Milestones

- Report the binding decision of the International Chamber of Commerce Arbitration Panel on the ongoing arbitration involving the TJ4309 and bispecific antibody agreements with I-Mab Biopharma where we are seeking to recover over \$200 million in damages, which we expect in the first quarter of 2023.
- Report the second and final interim efficacy analysis from the ENVASARC pivotal trial following the review of more than 12 weeks of efficacy data (including two on-study CT scans) by the independent data monitoring committee from 46 patients who receive envafolimab as a single agent and 46 patients who receive envafolimab in combination with Yervoy®, which we expect in the third quarter of 2023.
- Complete full accrual of the ENVASARC pivotal trial before the end of 2023.
- Report Phase 1 data from the Phase 1/2 clinical trial of YH001 in combination with envafolimab and doxorubicin in patients with soft tissue sarcoma, which we expect in the second half of 2023.

## Fourth Quarter 2022 Financial Results

- Cash and cash equivalents were \$17.4 million at December 31, 2022, compared to \$24.1 million at December 31, 2021, and is expected to fund the company into mid-2023.
- Research and development expenses for the fourth quarter of 2022 were \$3.9 million, compared to \$3.1 million for the fourth quarter of 2021.
- General and administrative expenses for the fourth quarter of 2022 were \$2.0 million, compared to \$4.6 million for the fourth quarter of 2021. The decrease was primarily attributable to legal expenses incurred in the fourth quarter of 2021 in connection with the arbitration with I-Mab.
- Net loss for the fourth quarter of 2022 was \$7.0 million, compared to \$7.7 million for the fourth quarter of 2021.

## Conference Call Details

To access the call by phone, please register using this [link](#) and you will be provided with dial-in details.

A live webcast of the conference call will be available online from the Investor/Events and Presentation page of the Company's website at [www.traconpharma.com](http://www.traconpharma.com).

After the live webcast, a replay will remain available on TRACON's website for 60 days.

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## **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 YH001**

YH001 is an IgG1 antibody against CTLA-4 that has shown enhanced antibody dependent cellular cytotoxicity and complement dependent cytotoxicity in vitro. In preclinical studies YH001 demonstrated superior T cell activation and superior tumor growth inhibition activity compared to ipilimumab. YH001 also demonstrated superior activity compared to ipilimumab in human transgenic mouse tumor models when combined with a PD-(L)1 antibody. In these models, single agent YH001 depleted regulatory T cells and increased CD8+ T cells in tumor tissue. YH001 is being studied with envafolimab and doxorubicin in a Phase 1/2 clinical trial sponsored by TRACON (NCT05448820), and has been studied in multiple Phase 1 trials in China and Australia sponsored by TRACON's corporate partner Eucure, a division of Biocytogen.

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## **About TRC102**

TRC102 (methoxyamine) is a novel small molecule inhibitor of the DNA base excision repair pathway, which is a pathway that causes resistance to alkylating and antimetabolite chemotherapeutics. TRC102 is currently being studied in multiple Phase 1 and Phase 2 clinical trials sponsored by the National Cancer Institute through a Cooperative Research and Development Agreement (CRADA) and has orphan drug designation from the FDA in malignant glioma, including glioblastoma.

## **About TJ004309**

TJ004309 is a novel, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular adenosine monophosphate to adenosine, which is highly immunosuppressive. TJ004309 was studied in a Phase 1 trial sponsored by TRACON (NCT03835949) to assess safety and preliminary efficacy as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® in patients with advanced solid tumors.

## **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](http://www.traconpharma.com).

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## 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 of the final binding decision from the ICC Tribunal regarding the legal disputes involving the TJ004309 and bispecific antibody agreements with I-Mab Biopharma; whether the size of the award in the I-Mab arbitration will result in additional funding through our non-recourse financing relating to the arbitration; whether TRACON will recover any of the \$200 million in damages it is seeking in its arbitration with I-Mab; the timing for TRACON’s completion of the TJ4309 Phase 1 trial and whether I-Mab will terminate the TJ4309 license and pay \$9 million to TRACON; the initiation of dosing in TRACON’s Phase 1/2 clinical trial of envafolimab with YH001 and doxorubicin; TRACON’s expectations regarding the funding of its operations through its current cash and cash equivalents into mid-2023; TRACON’s and its collaboration partners’ plans to further develop product candidates; expectations regarding the timing and scope of clinical trials 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; potential utility of product candidates; 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 arbitrations and the risk that the ICC Tribunal delays the date by which it will render its decision or decides that TRACON is not entitled to recover any or only a portion of the damages that it is seeking; 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, and whether I-Mab will pay TRACON \$9 million to terminate the TJ4309 license in connection with completion of the TJ4309 Phase 1 trial; 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; 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; 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.

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**TRACON Pharmaceuticals, Inc.**  
**Unaudited Condensed Consolidated Statements of Operations**  
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
License revenue	\$—	\$—	\$—	\$346
Operating expenses:				
Research and development	3,875	3,064	13,888	11,146
General and administrative	1,957	4,599	14,006	17,547
Total operating expenses	5,832	7,663	27,894	28,693
Loss from operations	(5,832)	(7,663)	(27,894)	(28,347)
Total other expense	(1,165)	(49)	(1,241)	(320)
Net loss	<u>\$ (6,997)</u>	<u>\$ (7,712)</u>	<u>\$ (29,135)</u>	<u>\$ (28,667)</u>
Net loss per share, basic and diluted	<u>\$ (0.31)</u>	<u>\$ (0.40)</u>	<u>\$ (1.39)</u>	<u>\$ (1.66)</u>
Weighted-average common shares outstanding, basic and diluted	<u>22,293,735</u>	<u>19,442,526</u>	<u>20,919,118</u>	<u>17,252,637</u>

**TRACON Pharmaceuticals, Inc.**  
**Unaudited Condensed Consolidated Balance Sheets**  
(in thousands)

	December 31, 2022	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$17,433	\$24,072
Prepaid and other assets	795	864
Total current assets	18,228	24,936
Property and equipment, net	51	50
Restricted Cash	67	—
Other assets	1,123	1,571
Total assets	\$19,469	\$26,557
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$11,107	\$10,753
Accrued compensation and related expenses	1,457	1,532
Long-term debt, current portion	9,807	1,391
Total current liabilities	22,371	13,676
Other long-term liabilities	969	1,167
Arbitration financing payable	3,280	—
Commitments and contingencies		
Stockholders' equity:		
Common stock	23	19
Additional paid-in capital	229,737	219,471
Accumulated deficit	(236,911)	(207,776)
Total stockholders' equity	(7,151)	11,714
Total liabilities and stockholders' equity	\$19,469	\$26,557

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