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): November 09, 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 2.02 Results of Operations and Financial Condition.

On November 9, 2023, TRACON Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2023. 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.

Exhibit No.	Description
99.1	Press release issued by TRACON Pharmaceuticals, Inc. on November 9, 2023 announcing its financial results for the quarter ended September 30, 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: November 9, 2023

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

TRACON Pharmaceuticals Reports Third Quarter 2023 Financial Results and Provides Corporate Update

San Diego, CA – November 9, 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 third quarter ended September 30, 2023. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

"We are on track to complete enrollment of 80 patients treated with single agent envafolimab in the ongoing pivotal ENVASARC trial this year. The data monitoring committee recommended the study continue as planned in September based on a review of 46 patients and since then more than 20 additional patients have enrolled. We expect to report updated response rate data before the end of the year, with final data anticipated mid-2024," said Charles Theuer, M.D., Ph.D., TRACON's Chief Executive Officer. "We also expect to license our Product Development Platform to one or more companies this year to allow them to transform their clinical operations."

Recent Corporate Highlights

- In September, we announced the ENVASARC Phase 2 pivotal trial more than exceeded the futility threshold at the second and final interim analysis and will proceed as planned. 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), all of which were confirmed responses. Envafolimab monotherapy was generally well tolerated and 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. Since the announcement, more than 20 additional patients have enrolled.

- In July, we announced collection of the arbitration award of $22M from I-Mab Biopharma.

Expected Upcoming Milestones

- Complete accrual of the ENVASARC pivotal trial in the fourth quarter of 2023 and release updated response rate data before the end of the year.

- Continue to leverage TRACON's cost-efficient, CRO-independent product development platform to generate non-dilutive capital by the end of the year.

- Final data from ENVASARC pivotal trial in mid-2024.

Third Quarter 2023 Financial Results

- Cash, cash equivalents and restricted cash were $7.8 million at September 30, 2023, compared to $17.5 million at December 31, 2022.
- Research and development expenses for the third quarter of 2023 were $2.3 million, compared to $4.1 million for the third quarter of 2022. The decrease was primarily related to enrollment into only cohort C in the ongoing ENVASARC pivotal trial.
- General and administrative expenses for the third quarter of 2023 were $1.3 million, compared to $2.3 million for the third quarter of 2022. The decrease was primarily attributable to lower legal expenses.
- We received a refund of $2.0 million in arbitration success fees from our law firm in addition to the write off of approximately $0.3 million in legal fees in the third quarter of 2023.
- We recorded other income of approximately $13.0 million in the third quarter of 2023 in conjunction with the collection of the arbitration award.
- Net income for the third quarter of 2023 was $10.8 million, compared to a net loss of $6.4 million for the third quarter of 2022.

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.

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

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. TRACON is enrolling patients in ENVARSAC 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, expectations regarding TRACON’s cash runway; TRACON’s and its collaboration partners’ plans to further develop product candidates; TRACON’s plans to further license out its platform, including the potential costs saving and other benefits related thereto; 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; expectations regarding the envafolimab treatment continuing to generate a double-digit objective response rates; expected results of the ad hoc safety review analysis from the ENVASARC pivotal trial and the timing of those results; expected development, regulatory and commercial milestones and timing thereof; potential utility of product candidates; and TRACON’s business development strategy and goals, including the ability to enter into additional collaborations. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: 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, ; 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 except as required by law.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Collaboration revenue	$0	$-	$9,000	$-
Operating expenses:				
Research and development	2,326	4,097	10,783	10,013
General and administrative	1,262	2,280	5,522	12,049
Arbitration success fees	(2,000)	-	2,375	-
Total operating expenses	1,588	6,377	18,680	22,062
Loss from operations	(1,588)	(6,377)	(9,680)	(22,062)
Total other income (expense)	12,351	(58)	5,653	(76)
Net income (loss)	$10,763	$(6,435)	$(4,027)	$(22,138)
Earnings (loss) per share, basic and diluted	$0.29	$(0.30)	$(0.13)	$(1.08)
Weighted-average common shares outstanding, basic	36,770,038	21,469,977	30,462,400	20,455,877
Weighted-average common shares outstanding, diluted	36,856,064	21,469,977	30,462,400	20,455,877

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$7,763	$17,433
Prepaid and other assets	577	795
Total current assets	8,340	18,228
Property and equipment, net	40	51
Restricted Cash	72	67
Other assets	961	1,123
Total assets	$9,413	$19,469
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$10,622	$11,107
Accrued compensation and related expenses	1,080	1,457
Long-term debt, current portion	-	9,807
Total current liabilities	11,702	22,371
Other long-term liabilities	795	969
Arbitration financing payable	-	3,280
Commitments and contingencies		
Stockholders' deficit:		
Common stock	31	23
Additional paid-in capital	237,823	229,737
Accumulated deficit	(240,938)	(236,911)
Total stockholders' deficit	(3,084)	(7,151)
Total liabilities and stockholders' deficit	$9,413	$19,469

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