TRACON Pharmaceuticals Reports Fourth Quarter and Year-End 2023 Financial Results and Provides Corporate Update

March 5, 2024 9:02 PM EST

SAN DIEGO, March 05, 2024 (GLOBE NEWSWIRE) -- 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, 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 later this quarter. We expect to report updated response rate data shortly thereafter and before the end of this quarter, with final data anticipated in the second half of 2024," said Charles Theuer, M.D., Ph.D., TRACON's Chief Executive Officer. "We also expect to leverage our Product Development Platform to generate non-dilutive capital through either an additional license or by replacing a CRO and executing clinical trials for partners at a lower cost compared to a CRO but still at a premium to our costs using a pay for performance model."

Recent Corporate Highlights

- In December, we announced updated interim data from the ENVASARC Phase 2 pivotal trial in the initial 46 patients treated with single agent envafolimab. The objective response rate (ORR) was 15% 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 by BICR in nine of 80 patients (11.25%) treated with envafolimab and median duration of response of greater than six months is a key secondary endpoint.

- In November, we licensed our Product Development Platform (PDP) to a clinical stage biotech company for an upfront payment of $3.0 million.

Expected Upcoming Milestones

- Complete accrual of the ENVASARC pivotal trial this quarter and report updated response rate data shortly thereafter and before the end of the quarter.

- Report final data from ENVASARC pivotal trial in the second half of 2024.

- Continue to leverage TRACON's cost-efficient, CRO-independent PDP to generate non-dilutive capital.

Fourth Quarter 2023 Financial Results

- Cash, cash equivalents and restricted cash were $8.6 million at December 31, 2023, compared to $17.5 million at December 31, 2022.

- License revenue for the fourth quarter of 2023 was $3.0 million and was due to the license of our PDP to a clinical stage biotech company.

- Research and development expenses for the fourth quarter of 2023 were $1.5 million, compared to $3.9 million for the fourth 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 fourth quarter of 2023 were $1.1 million,

compared to $2.0 million for the fourth quarter of 2022. The decrease was primarily attributable to lower legal expenses.

- Net income for the fourth quarter of 2023 was $0.4 million, compared to a net loss of $7.0 million for the fourth 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 Phase 2 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, TRACON's plans to further develop product candidates; TRACON's plans to further license out its platform; 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; 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 needs substantial additional capital to continue as a going concern and to enroll or complete its ongoing clinical trials as currently planned, if at all; 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, including ENVARSAC, 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 December 31,	Year Ended December 31,

	2023	2022	2023	2022
Revenue	$3,045	$ —	$12,045	$ —
Operating expenses:				
Research and development	1,494	3,875	12,277	13,888
General and administrative	1,144	1,957	6,666	14,006
Arbitration success fees	—	—	2,375	—
Total operating expenses	2,638	5,832	21,318	27,894
Income (loss) from operations	407	(5,832)	(9,273)	(27,894)
Total other income (expense)	32	(1,165)	5,685	(1,241)
Net income (loss)	$439	$(6,997)	$(3,588)	$(29,135)
Earnings (loss) per share, basic and diluted	$0.01	$(0.31)	$(0.11)	$(1.39)
Weighted-average common shares outstanding, basic	40,195,856	22,293,735	32,745,708	20,919,118
Weighted-average common shares outstanding, diluted	40,206,186	22,293,735	32,745,708	20,919,118

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$8,564	$17,433
Prepaid and other assets	526	795
Total current assets	9,090	18,228
Property and equipment, net	37	51
Restricted Cash	73	67
Other assets	905	1,123
Total assets	$10,105	$19,469
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$9,755	$11,107
Accrued compensation and related expenses	427	1,457
Long-term debt, current portion	—	9,807
Total current liabilities	10,182	22,371
Other long-term liabilities	732	969
Arbitration financing payable	—	3,280
Commitments and contingencies		
Stockholders' deficit:		
Common stock	44	23
Additional paid-in capital	239,646	229,737
Accumulated deficit	(240,499)	(236,911)
Total stockholders' deficit	(809)	(7,151)
Total liabilities and stockholders' deficit	$10,105	$19,469

Company Contact:
Charles Theuer
Chief Executive Officer
(858) 550-0780
ctheuer@traconpharma.com

Investor Contact:
Brian Ritchie
LifeSci Advisors LLC
(212) 915-2578
britchie@lifesciadvisors.com