
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): **December 20, 2017**

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))

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 December 20, 2017, TRACON Pharmaceuticals, Inc. (the “Company”) entered into a license agreement with Ambrx, Inc. (Ambrx). Under the license agreement, the Company granted Ambrx exclusive rights to develop and commercialize TRC105 in all indications (excluding ophthalmology, which are held by Santen Pharmaceutical Co., Ltd.) in China (including Hong Kong and Macau) and Taiwan. The Company is entitled to receive an upfront payment of \$3.0 million, and is eligible to receive development and regulatory milestones of up to \$10.5 million, and commercial sales milestones of up to \$130.0 million. The Company is also eligible to receive tiered royalties from the high single digits to low teens on net sales of TRC105 in the Ambrx territories.

On December 21, 2017, the Company issued a press release announcing its entry into the license agreement. A copy of the press release is attached hereto at Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.

	Description
99.1	<u>Press release issued by TRACON Pharmaceuticals, Inc. on December 21, 2017.</u>

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.

Dated: December 21, 2017

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 and Ambrx Announce Development and Commercialization Agreement for TRC105 in China

Initial Focus in China on Angiosarcoma and Hepatocellular Carcinoma

Total Value of Deal up to \$143.5 Million for TRACON, Including a \$3 Million Upfront Payment and Potential Milestones, Plus Potential Tiered Royalties

San Diego, CA – December 21, 2017 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration and fibrotic diseases, and Ambrx, Inc., today announced that they have entered into a licensing agreement for the development and commercialization of TRACON's proprietary endoglin antibody, TRC105 (carotuximab), in China.

The transaction grants Ambrx the exclusive rights to develop and commercialize TRC105 in all indications (excluding ophthalmology, which are held by Santen Pharmaceutical Co., Ltd.) in China (including Hong Kong and Macau) and Taiwan. TRACON will receive an upfront payment of \$3 million, and is eligible to receive development and regulatory milestones of up to \$10.5 million, and commercial sales milestones of up to \$130 million. TRACON is also eligible to receive tiered royalties from the high single digits to low teens on net sales of TRC105 in the Ambrx territories.

"We are excited to expand the development and commercialization opportunities for TRC105 into the Chinese market with a strong partner. The Ambrx management team has a strong track record of drug development in China and are backed by a top-tier syndicate of investors," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We look forward to Ambrx filing a Clinical Trial Application (CTA) for TRC105 in China, which we expect to occur in 2018, contributing to the ongoing enrollment of the Phase 3 TAPPAS trial in angiosarcoma, and leading the development of TRC105 in hepatocellular carcinoma (HCC) in China."

"Ambrx is delighted to partner with TRACON to develop this potential first-in-class medicine that we believe can benefit patients with significant unmet medical needs, including HCC, in China. With Ambrx's proven expertise in pre-clinical, regulatory and clinical development, especially in the area of cancer therapeutics, we are uniquely positioned to bring this innovative molecule to China for patients with angiosarcoma and HCC," said Alex Qiao, Chief Executive Officer of Ambrx.

Ambrx intends to file an initial CTA with the Chinese Food and Drug Administration (CFDA) in 2018.

About TRC105 (carotuximab)

TRC105 is a novel, clinical stage antibody to endoglin, a protein overexpressed on proliferating endothelial cells that is essential for angiogenesis, the process of new blood vessel formation. TRC105 is currently being studied in the pivotal Phase 3 TAPPAS trial in angiosarcoma and multiple Phase 2 clinical trials, in combination with VEGF inhibitors. TRC105 has received orphan designation for the treatment of soft tissue sarcoma in both the U.S. and EU. The ophthalmic formulation of TRC105, DE-122, is currently in a randomized Phase 2 trial for patients with wet AMD. For more information about the clinical trials, please visit TRACON's website at www.traconpharma.com/clinical_trials.php.

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URL: www.traconpharma.com

About TRACON

TRACON develops targeted therapies for cancer, ophthalmic and fibrotic diseases. The Company's clinical-stage pipeline includes: TRC105, an endoglin antibody that is being developed for the treatment of multiple cancers; DE-122, the ophthalmic formulation of TRC105 that is being developed in wet AMD through a collaboration with Santen Pharmaceutical Company Ltd.; TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule that is being developed for the treatment of prostate cancer. To learn more about TRACON and its product candidates, visit TRACON's website at www.traconpharma.com.

About Ambrx

Ambrx is a biopharmaceutical company based in San Diego and Shanghai with a mission to deliver breakthrough protein therapeutics using its own proprietary site specific conjugation technology. The Company's lead clinical stage asset is ARX788, a site-specific ADC targeting Her2-positive breast cancer that is currently in Phase 1. In addition to organic drug development, Ambrx is seeking opportunities to in-license China rights to clinical stage drug candidates that resolve unmet medical needs and to further develop and commercialize these assets within the territory. Ambrx is majority owned by a consortium of Chinese investors, including Fosun Pharma, HOPU Investments, Everbright Limited Healthcare Fund and WuXi PharmaTech. More information about Ambrx, its technology platform and drug candidate pipeline can be found at www.ambrx.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 TRACON's and Ambrx's plans to further develop TRC105, the timing for an initial CTA filing with the CFDA, the potential for TRC105 as a treatment for cancer and TRACON's potential receipt of future payments under the agreement with Ambrx. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether Ambrx will be able to file an initial CTA with the CFDA on expected timelines, if at all; whether Ambrx will subsequently be able to start clinical development of TRC105 in China, the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; potential changes in regulatory requirements in the United States, China and other countries; whether future milestones under the license agreement will be achieved and whether TRC105 is commercialized in the Ambrx territories; the fact that the license agreement is subject to early termination; 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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