

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 28, 2018**

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 November 28, 2018, TRACON Pharmaceuticals, Inc. (the “Company”) and I-Mab entered into separate strategic collaboration and clinical trial agreements (the “Collaboration Agreements”) for the development of multiple immuno-oncology programs, including I-Mab’s proprietary CD73 antibody TJD5 (the “TJD5 Agreement”) as well as up to five proprietary bispecific antibodies currently under development by I-Mab (the “Bispecific Agreement”).

TJD5 Agreement

Pursuant to the TJD5 Agreement, the Company and I-Mab will collaborate on developing the TJD5 antibody, with the Company bearing the costs of filing an IND and for Phase 1 clinical trials, with the parties sharing costs equally for Phase 2 clinical trials and with the Company and I-Mab bearing 40% and 60%, respectively, of the costs for Phase 3 clinical trials. I-Mab will also be responsible for the cost of certain non-clinical activities and the supply of TJD5 and any reference drugs used in the development activities. Each of the parties also agreed for a specified period of time to not develop or license to or from a third party any monoclonal antibody targeting CD73 or any other biologic for certain indications that a joint steering committee selects for TJD5 development.

In the event that I-Mab licenses rights to TJD5 to a third party, the Company would be entitled to receive varying portions of royalty and non-royalty consideration received by I-Mab with respect to territories outside the China territory. In the event that I-Mab commercializes TJD5, the Company would be entitled to receive a royalty on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the European Union and Japan in the mid-single digits. The portions of certain third party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which the Company would be entitled escalate based on the phase of development the Company completes under the TJD5 Agreement, ranging from a high-single digit percentage of non-royalty consideration to a mid-teen percentage of non-royalty consideration and double digit percentage of royalty consideration.

The TJD5 Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to TJD5. I-Mab may also terminate the TJD5 Agreement if the Company causes certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJD5 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical study (in which case the Company would be entitled to a pre-specified termination fee) or following the completion of the first Phase 2 clinical study (in which case the Company would be entitled to a pre-specified termination fee and either a percentage of non-royalty consideration I-Mab may receive as part of a license to a third party or an additional payment if TJD5 is approved for marketing outside Greater China before a third party license is executed (and the Company would continue to be entitled to the payments described in the paragraph above).

Bispecific Agreement

Pursuant to the Bispecific Agreement the Company and I-Mab may mutually select through a joint steering committee (“JSC”) up to five of I-Mab’s bispecific antibody product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, the Company will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical studies, and the Company will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical studies, in each case within North America. Subject to I-Mab’s right to co-promote an approved product candidate, the Company will be responsible for commercializing any approved product candidates in North America, and the parties will share profits and losses equally in North America. The Company would also be entitled to tiered low single digit royalties on net sales of product candidates in the European Union and Japan.

At any time prior to completing the first pivotal clinical study for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical study costs for a product candidate or the JSC decides to cease development over the Company’s objections after initiating Phase 3 clinical studies, the Company will have an option to obtain an exclusive license to such product candidate in all territories except China and Korea

and any other territories in which I-Mab previously licensed rights to a third party. If the Company exercises the option, it would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, the Company would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time the Company obtained the exclusive license, which include a double digit million dollar upfront payment, as well as development milestone payments that begin upon completion of a pivotal study, sales milestone payments, and a single to double digit royalty on net sales.

Each party agreed that for a specified period of time, it would not develop or license to or from any third party any bispecific monoclonal antibody targeting the same two biological targets as those of any selected product candidates under the Bispecific Agreement.

If development of any selected product candidates is terminated by a decision of the JSC, all rights to the product candidate will revert to I-Mab, subject to the Company's rights to obtain an exclusive license in certain circumstances. If development is terminated after submission of an IND and prior to initiating Phase 3 clinical studies or after initiating Phase 3 clinical studies and with the Company's concurrence, then the Company would be entitled to tiered low single digit royalties on net sales of the product candidate in North America, the European Union and Japan.

The Bispecific Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or with respect to any selected product candidate, for safety reasons related to that product candidate.

Press Release

On November 28, 2018, the Company issued a press release with respect to entering into the agreements described under Item 8.01 of this current report. 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 November 28, 2018.</u>
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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 4, 2018

By: /s/ Charles P. Theuer, M.D., Ph.D.

Charles P. Theuer, M.D., Ph.D.

President and Chief Executive Officer



TRACON Pharmaceuticals and I-Mab Biopharma Announce Strategic Partnerships for Multiple Immuno-Oncology Programs

*I-Mab's Broad and Innovative Pipeline to Leverage
TRACON's U.S. Product Development Solution Platform*

San Diego, CA – November 28, 2018 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, and I-Mab Biopharma (“I-Mab”), a China-based clinical stage biopharmaceutical company exclusively focused on the development of innovative biologics in immuno-oncology and autoimmune diseases, today jointly announced the establishment of a series of strategic collaborative partnerships for developing multiple immuno-oncology programs, including I-Mab’s proprietary CD73 antibody TJD5, a novel immuno-oncology asset with best-in-class potential from I-Mab’s broad immuno-oncology portfolio, as well as several proprietary bispecific antibodies (“BsAbs”) under development by I-Mab.

TRACON and I-Mab entered into a cost-sharing product development collaboration whereby TRACON will be responsible for the regulatory and clinical development of TJD5 and up to five of the BsAbs in North America, with the majority of the development effort expected to occur in the U.S. TRACON will bear the costs of early phases of clinical trials and I-Mab will share the costs for more advanced development stages and commercialization. TRACON will also share the North America rights of any selected BsAbs with I-Mab for each collaborative program, with opt-in rights to in-license the BsAbs from I-Mab in certain territories.

“There is a great strategic fit between the two companies. We have complementary development capabilities and share a passion for science. We are pleased to work with TRACON to facilitate clinical development of TJD5 and any selected BsAbs in North America through a capital efficient partnership,” said Jingwu Zang, M.D., Ph.D., CEO of I-Mab. “This partnership recognizes and values the potential of our innovative assets and strong drug discovery and development capabilities.” “Partnering with TRACON is an important part of our global development strategy to bring innovative biologics to patients worldwide. It further strengthens our presence in North America following the establishment of our US office and is the latest addition to our growing global partnerships spanning from drug candidates to clinical assets,” Zang added.

“We are excited to enter into this broad strategic transaction with I-Mab, an innovative biologics company with a broad pipeline of immuno-oncology assets with great potential to impact the treatment of cancer patients. We are particularly impressed with the similarities in corporate cultures between I-Mab and TRACON,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “This agreement expands TRACON’s portfolio of potential first-in-class and best-in-class immuno-oncology therapies and further validates TRACON’s product development solution for companies looking to develop innovative products in the U.S. In particular, we believe our existing in-house drug development expertise can reduce both the cost and time of clinical development for our partners and, when combined with our willingness to cost share, this can be an attractive development option. Given TRACON’s ability to expand our development capacity for additional products, we expect to continue leveraging our platform.”

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About TJD5

TJD5 is a novel, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to adenosine, which is highly immunosuppressive. TJD5 is currently completing IND-enabling studies and is expected to begin clinical testing in the U.S. in the first half of 2019 in a trial to assess safety and preliminary efficacy as a single agent and when combined with PD-1/PD-L1 checkpoint inhibitors in patients with advanced solid tumors.

About TRACON

TRACON develops targeted therapies for cancer and ophthalmic 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 by corporate partner Santen Pharmaceutical Company Ltd.; TRC102, a small molecule being developed for the treatment of lung cancer and solid tumors; and TRC253, a small molecule 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 I-Mab

I-Mab is a dynamic and fast-growing global company exclusively focused on developing first-in-class and best-in-class biologics in the areas of immuno-oncology and autoimmune diseases through internal R&D capabilities and global partnerships. I-Mab's pipeline is driven by the company's development strategy to address unmet needs in China and to bring innovative assets to the world. The company is prepared to submit additional INDs in order to initiate clinical trials in China and the U.S., including multiple Phase II and Phase III studies. I-Mab is on a fast track towards becoming an end-to-end fully integrated biopharma company. The company has been well-recognized by capital markets with the recent \$220 million Series C financing representing one of the largest amounts ever raised by an innovative biotech company in China. www.i-mabbiopharma.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 I-Mab's plans to further develop product candidates, potential benefits of the collaborations between TRACON and I-Mab, expectations regarding the timing of regulatory submissions and clinical trials, potential payments and activities under the collaboration with I-Mab, expected development milestones, TRACON's plans to leverage its product development platform and potential benefits derived from the platform, and potential utility of TRACON's product candidates. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON or others will be able to complete or initiate clinical trials on TRACON's expected timelines, if at all; 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's collaboration agreements are subject to early termination; whether any BsAbs are selected to be developed under TRACON's and I-Mab's collaboration, 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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