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): **September 27, 2016**

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.)

8910 University Center Lane, Suite 700 **San Diego, California**	**92122**
(Address of principal executive offices)	(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))

Item 1.01 Entry into a Material Definitive Agreement.

On September 27, 2016, TRACON Pharmaceuticals, Inc. (the "Company") entered into separate transactions with Janssen Pharmaceutica N.V. ("Janssen") and its affiliate, Johnson & Johnson Innovation-JJDC, Inc. ("JJDC") consisting of a license and option agreement with Janssen (the "License and Option Agreement") and a stock purchase agreement and investor agreement, each with JJDC (the "Stock Purchase Agreement" and the "Investor Agreement," respectively).

License and Option Agreement

Under the License and Option Agreement, Janssen granted the Company a license to technology and intellectual property to develop, manufacture and commercialize certain small molecule inhibitors of androgen receptor and androgen receptor mutations (the "AR Mutant Program"). Janssen maintains an option, which is exercisable until 90 days after the Company demonstrates clinical proof of concept with respect to the AR Mutant Program, to regain the rights to the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the AR Mutant Program. If Janssen exercises the option, Janssen will be obligated to pay the Company (i) a one-time option exercise fee of $45.0 million; (ii) regulatory and commercial based milestone payments totaling up to $137.5 million upon achievement of specified events; and (iii) royalties in the low single digits on annual net sales of AR Mutant Program products. If Janssen does not exercise the option, the Company would then have the right to retain worldwide development and commercialization rights to the AR Mutant Program, in which case, the Company would be obligated to pay to Janssen (x) development, and regulatory based milestone payments totaling up to $45.0 million upon achievement of specified events, and (y) royalties in the low single digits based on annual net sales of AR Mutant Program products, subject to certain specified reductions.

Under the License and Option Agreement, Janssen also granted the Company a license to technology and intellectual property to develop, manufacture and commercialize a bioavailable inhibitor of NF-kB inducing kinase (the "NIK Program" and, together with the AR Mutant Program, the "Programs"). With respect to the NIK Program, Janssen maintains a right, which is exercisable within 90 days following the date on which the Company demonstrates clinical proof of concept with respect to the NIK Program, to negotiate for a period of six months for a reversion of the related rights in the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the NIK Program. If Janssen does not exercise its right of first negotiation, or, if after exercise of such right, the Company and Janssen are unable to reach an agreement on the terms of a reversion and exclusive license, and, in either case, the Company continues the development of the NIK Program, then the Company would be obligated to pay Janssen (i) development and regulatory based milestone payments totaling up to $60.0 million upon achievement of specified events, and (ii) royalties in the low single digits based on annual net sales of NIK Program products, subject to certain specified reductions.

The Company is obligated to use diligent efforts to develop the Programs according to agreed upon development plans, timelines and budgets. For each Program that the Company retains, the Company is further obligated to use commercially reasonable efforts to develop, obtain marketing approval for, and commercialize licensed products. Until the expiration or earlier termination of the development term of the AR Mutant Program or the NIK Program, as applicable, under the License and Option Agreement, subject to specified exceptions, the Company has agreed not to research, develop or commercialize any compounds or products related to the AR Mutant Program or the NIK Program, as applicable, other than pursuant to the collaboration with Janssen.

The License and Option Agreement may be terminated for uncured breach, bankruptcy, or the failure or inability to demonstrate clinical proof of concept with respect to a particular Program during specified timeframes. In addition, the License and Option Agreement will automatically terminate (a) with respect to the AR Mutant Program, upon Janssen exercising its option in respect of the AR Mutant Program and making payment of the option exercise fee to the Company or, if Janssen does not exercise the option, upon the expiration of all payment obligations of the Company to Janssen with respect of the AR Mutant Program, and (b) with respect to the NIK Program, upon the Company and Janssen entering into an exclusive license agreement following Janssen's exercise of its right of first negotiation or, if Janssen's right of first negotiation with respect to the NIK Program expires and the Company and Janssen do not enter into an exclusive license agreement, upon the expiration of all payment obligations of the Company to Janssen with respect of the NIK Program. The Company may also terminate a Program or the Agreement in its entirety without cause, subject to specified conditions.

Stock Purchase Agreement

Under the terms of the Stock Purchase Agreement, the Company issued and sold to JJDC 840,022 shares of the Company's common stock at a purchase price of $5.95 per share, as determined by the average of the daily volume weighted average prices of the Common Stock as reported on NASDAQ for the five consecutive Trading Days prior to the date of this agreement, for an aggregate purchase price of approximately $5.0 million. There were no placement agents used, or any underwriting discounts or commissions paid with the sale and purchase of the shares.

The Shares were issued pursuant to the exemption from registration requirement of the Securities Act of 1933, as amended (the "Securities Act"), afforded by Section 4(a)(2) of the Securities Act, as a transaction to an accredited investor not involving a public offering. JJDC represented to the Company its intent to acquire the shares for investment only and not with a view to the resale or distribution of the shares.

Investor Agreement

Under the terms of the Investor Agreement, the Company granted JJDC certain rights to require the Company to register the shares for resale under the Securities Act. JJDC also agreed to certain transfer restrictions with respect to the shares and has further agreed to certain standstill provisions whereby, subject to certain exceptions, JJDC and its affiliates are obligated to refrain from taking certain actions with respect to the Company's common stock.

The License and Option Agreement, Stock Purchase Agreement and Investor Agreement also each contain other customary terms, conditions, representations, warranties and covenants of the parties.

The foregoing descriptions of the License and Option Agreement, Stock Purchase Agreement and Investor Agreement are not complete and are qualified in their entirety by reference to the full text of such agreements, each of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.

Item 3.02 Unregistered Sale of Equity Securities.

The information set forth in Item 1.01 of this current report under the heading "Stock Purchase Agreement" is incorporated herein by reference.

Item 8.01 Other Events.

On September 28, 2016, the Company issued a press release with respect to entering into the agreements described under Item 1.01 of this current report. A copy of the press release is attached hereto at Exhibit 99.1.

Additional Information about the AR Mutant Program

TRC253 (formerly JNJ-63576253) is a novel, orally bioavailable small molecule discovered and developed by Janssen Pharmaceuticals that is a potent, high affinity competitive inhibitor of the androgen receptor (AR). TRC253 is also a pan-inhibitor of multiple AR mutations, including the F876L mutation, and is under development for the treatment of men with prostate cancer. The AR F876L mutation results in an alteration in the ligand binding domain that confers resistance to current AR inhibitors. IND-enabling studies have been completed for TRC253 and the Company expects to initiate clinical development for the product candidate in the first half of 2017, following the completion of technology transfer from Janssen.

Activation of the AR is crucial for the growth of prostate cancer at all stages of the disease. Therapies targeting the AR have demonstrated clinical efficacy by extending time to disease progression, and in some cases, the survival of patients with metastatic castration-resistant prostate cancer. However, resistance to these agents is often observed and several molecular mechanisms of resistance have been identified, including amplification, overexpression or mutation of the AR.

TRC253 is intended to address resistance mechanisms to current AR inhibitors by specifically targeting mutations in the AR ligand binding domain. TRC253 also potently inhibits signalling through the wild type AR. These susceptible AR mutations have been identified using circulating tumor DNA, potentially allowing for selected patient biomarker-directed therapy.

Additional Information about the NIK Program

TRC694 (formerly JNJ-6420694) is a novel, potent, orally bioavailable inhibitor of NF-kB inducing kinase (NIK) with the potential to be first-in-class and was discovered by Janssen. In pre-clinical studies, TRC694 selectively repressed P52/RelB mediated non-canonical NF-kB gene expression and inhibited NIK and TRAF3 mutant cell line proliferation *in vitro* and tumor growth *in vivo*. The Company anticipates completing development of a companion diagnostic to enable patient-directed therapy and submitting an IND for TRC694 in 2018.

Genetic alterations leading to stabilization of NIK are found in a subset of B-cell malignancies: multiple myeloma, mantle-cell lymphoma (MCL, associated with ibrutinib), diffuse large B-cell lymphoma (DLBCL), cHL and CLL.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	Press release issued by TRACON Pharmaceuticals, Inc. on September 28, 2016.

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: September 28, 2016

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

EXHIBIT INDEX

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EXHIBIT 99.1

TRACON Pharmaceuticals Announces a Strategic Licensing Collaboration for Two Janssen Oncology Assets and a $5 Million Equity Investment from Johnson & Johnson Innovation – JJDC, Inc.

Strategic Transaction Validates TRACON's Unique Clinical Development Capabilities

$5 Million Equity Investment Strengthens TRACON's Balance Sheet

San Diego, CA – September 28, 2016 – 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, today announced a strategic licensing collaboration with Janssen Pharmaceutica N.V. (Janssen) for two novel oncology assets from Janssen's early development portfolio, with Janssen retaining certain rights to potentially reacquire the programs. Johnson & Johnson Innovation facilitated the collaboration. Johnson & Johnson Innovation – JJDC, Inc. (JJDC) also made a $5 million equity investment in TRACON through the purchase of common stock at a price of $5.95 per share.

Key Elements of the Transaction:

- The transaction grants TRACON the rights to develop two Janssen oncology programs: TRC253 (formerly JNJ-63576253), a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR) and multiple AR mutations that confer drug resistance, which is intended for the treatment of men with prostate cancer, and TRC694 (formerly JNJ-6420694), a novel, potent, orally bioavailable inhibitor of NF-kB inducing kinase (NIK), which is intended for the treatment of patients with hematologic malignancies, including myeloma.

- TRC253 has completed IND-enabling studies and TRACON expects to initiate a Phase 1/2 proof of concept (POC) clinical study in the first half of 2017. Following completion of the initial POC study, Janssen will have an exclusive option to reacquire full rights to TRC253 for an upfront payment of $45 million to TRACON, and obligations to pay regulatory and commercialization milestones totaling up to $137.5 million upon achievement of specified events and a low single-digit royalty. If Janssen does not exercise its exclusive option to reacquire the program, TRACON would then retain worldwide development and commercialization rights to the program and would be obligated to pay Janssen a total of up to $45 million in development and regulatory milestones upon achievement of specified events, in addition to a low single digit royalty.

- TRC694 is currently in preclinical development and TRACON expects to file an Investigational New Drug (IND) Application in 2018, following completion of additional preclinical studies. Upon completion of an initial clinical POC study, or at any time prior thereto, Janssen will have a right of first negotiation to reacquire the program on terms to be negotiated between the parties. If Janssen does not exercise the negotiation right or the parties cannot agree to terms following negotiations, and if TRACON continues development of TRC694, TRACON would be obligated to pay Janssen development and regulatory milestones totaling up to $60 million upon achievement of specified events and a low single-digit royalty.

“We are excited to enter into this innovative transaction with Janssen and Johnson & Johnson Innovation, and for the potential upside it provides our shareholders,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “This agreement expands our portfolio of potential first-in-class oncology therapies and leverages our existing drug development expertise. It also creates incremental opportunities for near-term non-dilutive funding and long-term value creation that complement our ongoing clinical development efforts with TRC105, our lead late-stage product candidate. Additionally, JJDC’s $5 million equity investment strengthens our balance sheet and is expected to offset the development expenses associated with these programs over the next 12 months.”

About TRC253 (formerly JNJ-63576253)

TRC253 is a novel, orally bioavailable small molecule discovered and developed by Janssen that is a potent, high affinity competitive inhibitor of the androgen receptor (AR). TRC253 is also a pan-inhibitor of multiple AR mutations, including the F876L mutation, and is under development for the treatment of men with prostate cancer. The AR F876L mutation results in an alteration in the ligand binding domain that confers resistance to current AR inhibitors. IND-enabling studies have been completed for TRC253 and TRACON expects to initiate clinical development for the product candidate in the first half of 2017, following the completion of technology transfer from Janssen.

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About TRC105 (carotuximab)

TRC105 (carotuximab) 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 multiple Phase 2 clinical trials sponsored by TRACON or the National Cancer Institute for the treatment of solid tumor types in combination with VEGF inhibitors. The ophthalmic formulation of

TRC105, DE-122, is currently in a Phase 1/2 trial for patients with wet AMD. TRC205, a second generation antibody to endoglin, is undergoing preclinical testing in models of fibrosis. For further information about the clinical trials, please visit TRACON's website at http://www.traconpharma.com/clinical_trials.php.

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.; and TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma. To learn more about TRACON and its product candidates, 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, statements regarding TRACON's plans to further develop its product candidates, including TRC253 and TRC694, expectations regarding the initiation and timing of future clinical trials, regulatory submissions and pre-clinical development activities, the potential benefits of TRACON's product candidates, including TRC253 and TRC694, estimated costs of developing TRC253 and TRC694, the potential for additional funding and shareholder value creation and future obligations and developments under TRACON's licensing arrangement with Janssen. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with drug development; whether TRACON will be able to complete or initiate pre-clinical development activities or clinical trials on TRACON's expected timelines or within expected budgets, if at all; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; whether Janssen exercises its rights to reacquire the rights to TRC253 or negotiate an in-license to TRC694 in the future; 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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