
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): **July 25, 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 July 25, 2017, TRACON Pharmaceuticals, Inc. (“TRACON”) issued a press release announcing that Santen Pharmaceutical Co. Ltd. (“Santen”) has initiated a Phase 2a clinical study of DE-122 in patients with wet age-related macular degeneration (AMD). DE-122 is the ophthalmic formulation of TRACON’s proprietary anti-endoglin antibody, TRC105. The initiation of the Phase 2a study triggers Santen’s obligation to make a US\$7.0 million milestone payment to TRACON under the terms of the companies’ license agreement related to DE-122.

A copy of this press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by TRACON Pharmaceuticals, Inc. dated July 25, 2017.

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: July 26, 2017

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

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press release issued by TRACON Pharmaceuticals, Inc. dated July 25, 2017.



Exhibit 99.1

Santen and TRACON Announce Initiation of a Phase 2a Study of DE-122 for the Treatment of Wet Age-Related Macular Degeneration

Osaka, Japan (July 26, 2017) and San Diego, CA (July 25, 2017) – Santen Pharmaceutical Co. Ltd. (Santen) and TRACON Pharmaceuticals, Inc. (NASDAQ:TCON, TRACON) today announced that Santen has initiated a Phase 2a clinical study of DE-122 in patients with wet age-related macular degeneration (AMD).

The Phase 2a study is a randomized controlled trial assessing the efficacy and safety of intravitreal injections of DE-122 in combination with Lucentis® (ranibizumab) compared to Lucentis monotherapy in patients with wet AMD. DE-122 is the ophthalmic formulation of TRACON's proprietary anti-endoglin antibody, TRC105. The initiation of the Phase 2a study triggers a US\$7 million milestone payment from Santen to TRACON.

"Santen is a global pharmaceutical company specialized in the field of ophthalmology, and we are committed to delivering novel medicines for the treatment of high unmet need ophthalmic conditions on a global basis. With limited treatment options available for retinal disease, including wet AMD, Santen is pleased at the development progress of DE-122, which we hope will allow Santen to contribute in new ways to improving the quality of life of patients suffering from retinal disease such as wet AMD," said Akira Kurokawa, President and CEO of Santen.

"The initiation of the trial represents an important opportunity to expand the scope of our endoglin antibodies to areas of significant unmet medical need beyond oncology," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Data generated to date suggest the novel mechanism of action of DE-122 has the potential to combine effectively with approved VEGF inhibitors, the current standard of care, in patients with wet AMD."

In March 2014, Santen licensed the global development rights to DE-122 in ophthalmology from TRACON. In June 2015, Santen filed an Investigational New Drug (IND) application for DE-122 with the U.S. Food and Drug Administration (FDA).

About DE-122

DE-122 is the ophthalmic formulation of TRACON's proprietary anti-endoglin antibody, TRC105, and is being studied in Santen's Phase 1/2 study in the U.S. to investigate the safety of single DE-122 intravitreal injection for the treatment of refractory wet AMD.

About TRC105

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 one Phase 3 clinical trial and multiple Phase 2 clinical trials sponsored by both TRACON and the National Cancer Institute for the treatment of solid tumors in combination with VEGF inhibitors. TRC105 has received orphan designation for the treatment of soft tissue sarcoma in both the U.S. and EU. For more information about the clinical trials, please visit TRACON's website at www.traconpharma.com/clinical_trials.php.



About Wet AMD

Wet AMD is the leading cause of blindness in the elderly in the world and is caused by excessive growth and leakage of blood vessels at the back of the eye that leads to a chronic and often rapid loss of vision. Existing therapies for the disease are limited including treatment targeting the VEGF pathway.

About Santen

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, marketing and sales of pharmaceuticals. Santen is the market leader in Japan for prescription ophthalmic pharmaceuticals and sells products in approximately 60 countries. As a leading company in the field of ophthalmology, Santen aims to contribute to society by supplying valuable products and services to satisfy unmet medical needs. For more details, please see Santen's website (www.santen.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; 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.

Santen Forward-looking Statements

Information provided in this press release contains so-called "Forward-looking Statements." The realizations of these forecasts are subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial condition are subject to the effects of change in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

TRACON Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding TRACON's receipt of the milestone payment associated with Santen's initiation of the Phase 2a clinical study and the potential of DE-122 as a treatment for wet AMD. Forward-looking statements speak only as of the date of this press release and TRACON does not undertake any obligation to update or revise these statements, except as may be required by law. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include, but are not limited to, whether TRACON's collaboration with Santen will continue and both parties will continue to perform their obligations under the license agreement, whether Santen will continue clinical trials of DE-122 and risks associated with the development of investigational drug products. For a further description of these and other risks facing TRACON, please see the risk factors described in TRACON's filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements



speaks only as of the date of this press release and TRACON undertakes no obligation to update or revise these statements, except as may be required by law.

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