

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): **March 9, 2020**

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.)

**4350 La Jolla Village Drive, Suite 800
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))

Securities registered pursuant to Section 12(b) of the Securities Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	TCON	The Nasdaq Stock Market LLC

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 March 9, 2020, TRACON Pharmaceuticals, Inc. and Santen Pharmaceutical Co. issued a joint press release announcing the discontinuation of development of DE-122 for Wet AMD based on top-line data from the recently completed Phase2a AVANTE clinical study. Top-line data indicated DE-122 did not improve visual acuity when combined with Lucentis as compared to single-agent Lucentis.

The press release issued on March 9, 2020 is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.****Exhibit No.****Description**

99.1

[Press release issued by TRACON Pharmaceuticals, Inc. on March 9, 2020.](#)

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: March 9, 2020

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

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

President and Chief Executive Officer



Santen and TRACON Discontinue Development of DE-122 for Wet Age-Related Macular Degeneration

March 9, 2020, Osaka, Japan and San Diego, CA - Santen Pharmaceutical Co., Ltd. (Head Office: Osaka; hereinafter, "Santen") and TRACON Pharmaceuticals, Inc. (Head Office: San Diego, CA; hereinafter, "TRACON") today announced the discontinuation of the development of DE-122 for the treatment of wet age-related macular degeneration (wAMD) following the review of recently obtained top-line data from the Phase 2a AVANTE clinical study.

The Phase 2a AVANTE clinical study is a randomized controlled trial that assessed visual acuity in wAMD patients following six monthly treatments with a combination of DE-122 and Lucentis or single agent Lucentis. Topline data indicated that DE-122 did not improve visual acuity when combined with Lucentis as compared to single agent Lucentis treatment, the primary endpoint of the trial. Following review of the data, the two companies have decided to discontinue the development of DE-122. Santen licensed the development rights to DE-122 in the ophthalmic field from TRACON in 2014.

The discontinuance is not expected to have a material impact on Santen financial results in the fiscal year ending March 31, 2020.

About Santen

As a specialized company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan and its products now reach patients in over 60 countries. With scientific knowledge and organizational capabilities nurtured over a nearly 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen's website (www.santen.com).

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient product development platform. The Company's clinical-stage pipeline includes: Envafohimab, a subcutaneous PD-L1 single-domain antibody to be developed for the treatment of sarcoma; TRC102, a small molecule drug being developed for the treatment of lung cancer; TRC253, a small molecule drug being developed for the treatment of prostate cancer; and TJ004309, a CD73 antibody being developed for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads regulatory and clinical development and shares in the cost and risk of clinical development and leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies

without clinical and commercial capabilities in the U.S. 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 forward-looking statements. The achievement of these forecasts is 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 conditions are subject to the effects of changes 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.

Contact

Santen Pharmaceutical Co., Ltd.
Corporate Communications Group
+81-6-4802-9360, ir@santen.com

TRACON Pharmaceuticals, Inc.
Mark Wiggins
Chief Business Officer
(858) 251-3492
mwiggins@traconpharma.com