Revance Therapeutics, Inc.
Form 8-K
December 05, 2017

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 5, 2017

REVANCE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**001-36297**	**75-0551645**
(State of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

Revance Therapeutics, Inc.

7555 Gateway Boulevard

Newark, California 94560

(Address of principal executive offices and zip code)

Registrant s telephone number, including area code: (510) 742-3400

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 (see General Instruction A.2. below):

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

RT002 Glabellar Lines

On December 5, 2017, Revance Therapeutics, Inc. (the Company) announced positive top-line results for DaxibotulinumtoxinA for Injection (RT002) in alleviating moderate-to-severe glabellar lines in two randomized, double-blind, placebo-controlled pivotal Phase 3 trials to evaluate the safety and efficacy of a single administration of RT002 for the treatment of moderate-to-severe glabellar lines in adults. The SAKURA 1 and SAKURA 2 trials enrolled a total of 609 patients at 30 sites in the U.S. and Canada. The key top-line results at Week 36 are as follows:

Primary Endpoint

Both SAKURA 1 and SAKURA 2 met the primary composite endpoint by delivering highly statistically significant improvement against placebo in reducing the severity of glabellar lines, i.e., the frown lines or wrinkles between the brows. The primary efficacy measurement was a composite of the proportion of patients who achieved a score of 0 or 1 (none or mild) and at least a two-point improvement from baseline at maximum contraction (frown) in glabellar line severity on both the Investigator Global Assessment-Facial Wrinkle Severity (IGA-FWS) and Patient Facial Wrinkle Severity (PFWS) scales at Week 4.

Percent of patients who achieved the primary composite endpoint:

SAKURA 1: 73.6 percent of patients vs. 0 percent for placebo ($p<0.0001$)
SAKURA 2: 74.0 percent vs. 1.0 percent for placebo ($p<0.0001$)

Percent of patients who said they were very satisfied or satisfied with their treatment experience:

SAKURA 1: 88 percent of patients
SAKURA 2: 91 percent of patients

Secondary Duration Endpoints

All secondary endpoints measuring reduction in severity of glabellar lines with RT002 compared to placebo were highly statistically significant at every time point evaluated to 24 weeks. There were several secondary endpoints used to evaluate duration of effect, including the proportion of patients achieving none or mild response on IGA-FWS compared to placebo, median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median time to return to baseline on both IGA-FWS and PFWS.

The percent of patients treated with RT002 who achieved a none or mild response on IGA-FWS at Week 24:

SAKURA 1: 35.3 percent vs. 2.0 percent for placebo ($p<0.0001$)
SAKURA 2: 29.4 percent vs. 2.0 percent for placebo ($p<0.0001$)

Median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS for patients treated with RT002:

SAKURA 1: 24.0 weeks
SAKURA 2: 23.9 weeks

Median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS for patients treated with RT002:

SAKURA 1: 27.7 weeks
SAKURA 2: 26.0 weeks

For comparison, an additional exploratory duration endpoint was evaluated, which mirrors the duration measure used in the BELMONT Phase 2 study.

Median duration of ³ 1 point improvement from baseline on IGA-FWS for patients treated with RT002:

SAKURA 1: 24.1 weeks
SAKURA 2: 24.1 weeks
BELMONT: 23.6 weeks

Safety

RT002 appeared to be generally safe and well-tolerated through the end of study at Week 36. Adverse events were mild, localized and transient. There were no treatment-related serious adverse events. The most common adverse events for RT002 in both studies combined were headache (6.4 percent) and injection site pain (3.7 percent). The incidence of eyelid ptosis and brow ptosis were 2.2 percent and 0.7 percent, respectively.

SAKURA 3

In addition to SAKURA 1 and SAKURA 2, a long-term safety trial, SAKURA 3, is fully enrolled with more than 2,500 patients at 66 sites in the U.S. and Canada and is expected to be completed in the second half of 2018. Once Sakura 3 is completed in the second half of 2018, the Company plans to submit a Biologics License Application in the first half of 2019 and, pending approval by the FDA, launch RT002 in the U.S. in 2020.

RT002 Cervical Dystonia

The Company is developing RT002 for the treatment of cervical dystonia. In November 2017, the Company announced that the Food and Drug Administration (FDA) granted orphan drug designation of RT001 for the treatment of cervical dystonia and that the Company plans to proceed to a Phase 3 program in cervical dystonia. The Company expects to commence its Phase 3 program in the second quarter of 2018 at multiple sites in the U.S., Canada and Europe.

RT002 Plantar Fasciitis

The Company is also developing RT002 for the treatment of plantar fasciitis. In October 2017, the Company completed patient enrollment in its Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of RT002 injectable in the therapeutic indication of plantar fasciitis. Topline week eight results from this study are expected in 2017. The Company initiated this Phase 2 trial in 2016 and entered into a clinical trial services agreement with a contract research organization, or CRO, to manage certain aspects of the trial. Under this agreement, the Company agreed to negotiate in good faith for a specified period of time the terms of a business relationship to exploit RT002 and the related study data. The CRO has proposed a material payment or other terms for its involvement in the development of the Company s plantar fasciitis program that are unacceptable to the Company. While the Company may continue to negotiate in good faith, the Company believes it has satisfied its obligations under the agreement even if it does not reach a mutually acceptable arrangement.

Forward-Looking Statements

This report contains forward-looking statements, including, without limitation, statements related to the Company s business strategy, timeline and other goals and market for its anticipated products, plans and prospects; statements about its ability to obtain regulatory approval; and statements about potential benefits of its drug product candidates and its technologies.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from the Company s expectations. These risks and uncertainties include, but are not limited to: the outcome, cost, and timing of the Company s product development activities and clinical trials; the uncertain clinical development process; the Company s ability to obtain and maintain regulatory approval of its drug product candidates; the Company s ability to obtain funding for its operations; the Company s plans to research, develop, and commercialize its drug product candidates; the Company s ability to achieve market acceptance of its drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; the size and growth potential of the markets for the Company s drug product candidates; the Company s ability to successfully commercialize its drug product candidates and the timing of commercialization activities; the rate and degree of market acceptance of the Company s drug product candidates; the Company s ability to develop sales and marketing capabilities; the accuracy of the Company s estimates regarding expenses, future revenues, capital requirements and needs for financing; the Company s ability to continue obtaining and maintaining intellectual property protection for its drug product candidates; and other risks. Detailed information regarding factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release may be found in the Company s periodic filings with the Securities and Exchange Commission (the SEC), including factors

described in the section entitled Risk Factors of the Company s quarterly report on Form 10-Q filed November 3, 2017. These forward-looking statements speak only as of the date hereof. The Company disclaims any obligation to update these forward-looking statements.

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.

Date: December 5, 2017

Revance Therapeutics, Inc.

By: /s/ Lauren P. Silvernail
Lauren P. Silvernail
Chief Financial Officer and Chief Business Officer