Revance Therapeutics, Inc.
Form 8-K
December 12, 2016

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 12, 2016

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))

ITEM 7.01 REGULATION FD DISCLOSURE.

As reported under Item 8.01 of this current report on Form 8-K, Revance Therapeutics, Inc. (the Company) issued a press release on December 12, 2016 announcing positive results from its Phase 2 open-label, dose-escalating clinical study to evaluate the safety and preliminary efficacy of its investigational drug product candidate, DaxibotulinumtoxinA for Injection (RT002) for the treatment of cervical dystonia, a muscle movement disorder. During a conference call and webcast scheduled to be held at 4:30 PM Eastern Time on December 12, 2016, Company management will discuss the results from the study. The slide presentation for the conference call and webcast is furnished as Exhibit 99.1 hereto and is incorporated by reference herein. A copy of the press release is furnished as Exhibit 99.2 hereto and is incorporated by reference herein.

The furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the slides is summary information that is intended to be considered in the context of more complete information included in the Company s filings with the Securities and Exchange Commission (the SEC) and other public announcements that the Company has made, including the press release furnished as Exhibit 99.2 hereto, and may make from time to time by press release or otherwise.

The information in this Item 7.01 of this current report on Form 8-K and Exhibits 99.1 and 99.2 attached hereto shall not be deemed filed for purposes of Section 18 of the Securities Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

ITEM 8.01 OTHER EVENTS

On December 12, 2016, the Company announced positive results from its Phase 2 open-label, dose-escalating clinical study to evaluate the safety and preliminary efficacy of RT002 injectable for the treatment of cervical dystonia. The topline interim data showed that RT002 injectable appeared to be generally safe and well-tolerated, demonstrated median duration of >24 weeks, and displayed clinically significant impact on cervical dystonia signs and symptoms. The trial enrolled 37 subjects and follows three sequential treatment cohorts for up to a total of 24 weeks after treatment for each cohort. The trial s first cohort of 12 subjects received a single dose of up to 200 units of RT002 injectable, the second cohort of 12 subjects received between 200 and 300 units, and the third cohort received from 300 to 450 units. Later-enrolled subjects in the second and third cohorts have yet to complete the trial s 24-week protocol. Today s results are therefore preliminary, with final results expected in the first half of 2017.

Key interim results of the cervical dystonia trial are as follows:

SAFETY: In all three cohorts, RT002 injectable appeared to be generally safe and well-tolerated. There were no serious adverse events and no dose-dependent increase in adverse events. The treatment-related adverse events were transient and mild to moderate in severity, except for one case of neck pain reported as severe, with a duration of 2 days. The most common adverse events were dysphagia, or difficulty in swallowing (10.8%), injection site redness (8.1%), injection site pain (5.4%), muscle tightness (5.4%) and muscle weakness (5.4%). For reference, trials for botulinum type A products approved to treat cervical dystonia have adverse events for dysphagia ranging from 13% to 39%.

EFFICACY: The trial s 4-week primary efficacy measurement was the improvement in dystonia symptoms as determined by reduction from baseline on the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)-Total score. RT002 injectable showed a

clinically significant mean reduction of 16.9 from baseline, or 38%, across all three cohorts. In cohort one, with a mean dose of 174 units, the majority of the 44% reduction observed in the TWSTRS-Total score at Week 4 was preserved at Week 24, with a 33% mean reduction from baseline observed. Clinically meaningful mean reductions in the TWSTRS Severity, Disability and Pain subscales were consistent and observed at all follow-up visits in the first cohort. Later-enrolled subjects in the second and third cohorts have not yet reached the 24-week point. For reference, placebo-controlled trials with botulinum type A products approved to treat cervical dystonia had a reduction in the TWSTRS-Total score from baseline of 14% to 26% at Week 4.

DURATION OF EFFECT: Duration of effect for this trial was defined as the number of weeks from treatment until the return of symptoms that warrant retreatment, based on the subject s target TWSTRS score. The median duration of effect was at least 24 weeks for subjects in cohort one (n=12), and at least 16 weeks for subjects in cohort two (n=11), using the complete 16 week follow up data. In cohort one, no subjects had returned to baseline at Week 24 and only one subject in cohort two, to date, has returned to baseline, which occurred at the Week 24 visit. In cohort one, RT002 achieved a median duration of at least 24 weeks based on three different assessments, including 1) the number of weeks from treatment until a subject reaches or exceeds their target TWSTRS-Total score, 2) improvement (score >0) on the Clinician Global Impression of Change (CGIC), and 3) TWSTRS-Total score return to baseline. For reference, current treatment of cervical dystonia calls for injection of botulinum toxin approximately every 3 months, or 4 times per year.

The Company also has recently enrolled patients in its Phase 3 SAKURA clinical trial of RT002 injectable for the treatment of moderate to severe glabellar lines in adults and initiated a Phase 2 placebo-controlled trial of RT002 injectable for the management of plantar fasciitis. Results for both studies are expected in 2017.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits.

Number	Description
99.1	Company slide presentation dated December 12, 2016.
99.2	Press Release dated December 12, 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.

Date: December 12, 2016

Revance Therapeutics, Inc.

By: /s/ Lauren P. Silvernail
Lauren P. Silvernail
Executive Vice President, Corporate Development and Chief Financial Officer

EXHIBIT INDEX

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