Revance Therapeutics, Inc.
Form 8-K
October 29, 2015

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): October 29, 2015

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 October 29, 2015 announcing positive results from its multi-center BELMONT Phase 2 active comparator study of RT002, a botulinum toxin type A investigational drug product candidate for injection, for the treatment of glabellar lines. During a conference call and webcast scheduled to be held at 8:00 a.m. Eastern Time on October 29, 2015, 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 October 29, 2015, the Company announced positive 24-week results from its multi-center BELMONT Phase 2 active comparator study of RT002 injectable for the treatment of glabellar lines. The ongoing study for the treatment of glabellar lines in 268 subjects compared the safety, efficacy and duration of effect of three doses of RT002 against placebo, and current market leader, BOTOX Cosmetic/ VISTABEL®. The topline interim data showed that RT002 achieved its primary efficacy measurement for all three doses at 4 weeks. The study demonstrated 6-month RT002 median duration of effect based upon at least 1-point improvement in glabellar lines at maximum frown on the Investigator Global Assessment-Facial Wrinkle Severity (IGA-FWS) scale.

Key interim results of the BELMONT trial are as follows:

The 4-week primary efficacy measurement of at least 1-point improvement in frown lines based on the IGA-FWS scale for all three doses (20 Units, 40 Units and 60 Units) of RT002 was highly statistically significant ($p < 0.001$) as compared to placebo for all three doses.

All doses of RT002 achieved a 100 percent response rate of at least 1-point improvement in frown lines, based on the IGA-FWS scale at 4 weeks versus a 95 percent response rate for BOTOX Cosmetic.

RT002 efficacy showed a dose response. RT002 40U was statistically significant to BOTOX Cosmetic on all three responder definitions for the IGA-FWS median duration of effect. On the IGA-FWS duration of response, RT002 demonstrated a 23.6 week median duration verses BOTOX Cosmetic with an 18.8 week median duration ($p=0.020$).

More than twice as many subjects receiving 40 Units and 60 Units of RT002 in the study maintained none or mild wrinkles on the IGA-FWS scale, as compared to BOTOX Cosmetic at Week 16 (p£0.002).

Outcomes reported by subjects were consistent with investigator findings of duration and efficacy of RT002.

Across all cohorts, RT002 appeared to be generally safe and well-tolerated. Adverse events were generally mild, localized and transient. No subjects receiving 20 Units and 40 Units of RT002 experienced ptosis (eyelid droop). There were no serious adverse events or evidence of any systemic exposure at any of the three doses evaluated.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits.

Number	Description
99.1	Company slide presentation dated October 29, 2015.
99.2	Press Release dated October 29, 2015.

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: October 29, 2015

Revance Therapeutics, Inc.

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

EXHIBIT INDEX

Number	Description
99.1	Company slide presentation dated October 29, 2015.
99.2	Press Release dated October 29, 2015.