Revance Therapeutics, Inc.
Form 8-K
April 19, 2018

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): April 19, 2018

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 7.01 REGULATION FD DISCLOSURE.

On April 19, 2018, Revance Therapeutics, Inc. (the Company) issued a press release announcing its first Investor Day in New York City. During the Investor Day, Company management will discuss key company updates, announcements and market trends. A copy of the press release is filed as Exhibit 99.1 hereto and is incorporated by reference herein. The slide presentation for Investor Day 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 filed as Exhibit 99.1 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 April 19, 2018, the Company issued a press release announcing its first Investor Day in New York City and provided the following key company updates and announcements:

Key Company Updates and Announcements

Research & Development:

The company intends to provide an overview on its highly purified daxibotulinumtoxinA and the mechanism of action for drug product candidate DaxibotulinumtoxinA for Injection (RT002):

RT002 s proprietary peptide excipient serves as a unique stabilizing agent. No human serum albumin (HSA) or animal-sourced ingredients, which can potentially be a source of disease transmission, are used in the production of RT002.

Based on stability studies to date, RT002 may not require refrigeration during storage or shipping.

Demonstrated dosing and duration of response is not linear because 20 units of the leading neuromodulator, onabotulinumtoxinA (BOTOX®), and 40 units of RT002 contain nearly the same amount of active 150 kDa neurotoxin (0.17 ng 150 kDa vs 0.18 ng 150 kDa, respectively).

In vitro data supports the hypothesis that RT002 has strong membrane binding at the site of injection, which the company believes contributes to long duration of effect and high response rates.

Clinical, Regulatory and Launch Milestones:

Revance expects to complete and report the SAKURA Phase 3 open-label safety study consisting of approximately 2,500 enrolled patients in the second half of 2018 and is on track to file its Biologics Licensing Application (BLA) for RT002 to treat glabellar (frown) lines in first half of 2019. Product launch is expected in 2020, assuming FDA approval.

The following clinical programs for DaxibotulinumtoxinA for Injection (RT002) remain on track:

Cervical dystonia: The ASPEN Phase 3 program with RT002 for the treatment of moderate to severe isolated cervical dystonia is planned for initiation in the second quarter of 2018. Program is expected to include a single pivotal trial of approximately 300 patients and an open-label safety study to include approximately 300 patients from the U.S., Canada and Europe.

Plantar fasciitis: The 16-week results from the now completed Phase 2a trial in plantar fasciitis showed a 58% reduction in pain from baseline along with a strong placebo response, based on the visual analog scale (VAS) for pain. A follow-on Phase 2 trial for plantar fasciitis is planned for the second half of 2018. Study is expected to be double-blinded, placebo-controlled utilizing two doses of RT002.

The company is announcing two new clinical programs for RT002 in neuroscience indications with plans to initiate:

Upper limb spasticity: A Phase 2 dosing study in adult upper limb spasticity in the fourth quarter of 2018 with a goal to reduce the number of annual treatments.

Chronic migraine: A Phase 2 study in 2019 using a novel approach to treat chronic migraine to optimize the number of injections and designed to achieve long duration of effect.

Market and Commercialization:

The neurotoxin market was estimated to be $4 billion in 2017 and is currently expected to grow to $7 billion by 2024.*

Recent published surveys on neuromodulators indicates that duration is the #1 unmet need for physicians and long-lasting effect is the #1 patient request.

The company has established the Revance Product Launch Velocity Plan covering sales, marketing, digital outreach and commercial operations and is preparing for an anticipated launch of RT002 for the treatment of glabellar lines in 2020.

* Source: Global Industry Analysts, Inc. Botulinum Toxin A Global Strategic Business Report, Jan 2018

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits.

Number	**Description**
99.1	Press Release dated April 19, 2018
99.2	Company slide presentation dated April 19, 2018

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: April 19, 2018

Revance Therapeutics, Inc.

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