Revance Therapeutics, Inc.
Form 8-K
December 04, 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): December 4, 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 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On December 4, 2018, Revance Therapeutics, Inc. (Revance or the Company) and Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd., a wholly-owned subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd (Fosun), entered into a license agreement (the Agreement) pursuant to which Revance has granted Fosun the exclusive rights to develop and commercialize the Company s proprietary DaxibotulinumtoxinA for Injection (RT002) (the Product) in mainland China, Hong Kong and Macau (the Territory) and certain sublicense rights.

Under the Agreement, Revance will receive a non-refundable upfront payment of $30 million within thirty (30) business days of the date of the Agreement and is eligible to receive (i) additional contingent payments of up to $230.5 million upon the achievement of specified milestones based on (a) the submission and approval of Biologics License Applications (BLAs) for certain aesthetic and therapeutic indications and (b) first time calendar year net sales, and (ii) tiered royalty payments in low double digit to high teen percentages on annual net sales. The royalty percentages are subject to reduction in the event that (i) the Company does not have any valid and unexpired patent claims that cover the Product in the Territory, (ii) biosimilars of the Product are sold in the Territory or (iii) Fosun needs to pay compensation to third parties for Fosun to either avoid patent infringement or market the Product in the Territory.

Under the Agreement, Fosun will have the right to import, develop, commercialize, market and sell the Product in the Territory or engage service providers for such activities, and Revance will be responsible for manufacturing the Product and supplying it to Fosun for its clinical and commercial activities in the Territory, subject to the terms of a supply agreement and a quality assurance agreement, each to be entered into between the parties in the six (6) months following the date of the Agreement. Except as provided in the Agreement, each party has retained all of its intellectual property rights.

During the term of the Agreement and an additional two (2) years from the termination date if Fosun terminates the Agreement, Fosun will not engage in any research, development, manufacture or commercialization of any product competitive with the Product; provided that such non-compete restrictions will expire if Revance fails to submit a BLA for the Product in the US by the end of 2020. Under the Agreement, Revance and Fosun will also establish a joint development committee, which will oversee the development and commercialization of the Product as well as all clinical and pre-clinical studies to be conducted by Fosun for the Product in the Territory.

The term of the Agreement will continue until Fosun s payment obligations have been performed or expired, unless sooner terminated by either party pursuant to the terms of the Agreement. Either party may terminate the Agreement for material breach by, or bankruptcy of, the other party. In addition, Revance may terminate the Agreement if Fosun challenges Revance s patents, and Fosun may terminate the Agreement upon one hundred twenty (120) days notice. In the event of a change of control of Revance, Revance or its successor will have the option to terminate the Agreement by paying Fosun a variable payment that depends on the stage of development of the Product.

The Agreement contains various representations and warranties, covenants and other provisions that are customary for a transaction of this nature. The representations, warranties and covenants contained in the Agreement were made only for purposes of the Agreement and as of specific dates, were solely for the benefit of the parties to the Agreement, and may be subject to limitations agreed upon by the parties. The representations and warranties may have been made for the purposes of allocating contractual risk between the parties to the Agreement instead of establishing these matters as facts.

The foregoing is a summary of the terms of the Agreement and is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to the Company s Annual Report on Form 10-K for the fiscal year ending December 31, 2018.

ITEM 7.01 REGULATION FD DISCLOSURE

The Company issued a press release on December 4, 2018, announcing clinical results from its SAKURA 3 Phase 3 trials of DaxibotulinumtoxinA for Injection (RT002) for the treatment of glabellar (frown) lines. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

During a conference call and webcast scheduled to be held at 5:30 a.m. Pacific Time on December 4, 2018, Company management will discuss the results from the study. The slide presentation for the conference call and webcast is furnished as Exhibit 99.2 hereto and is incorporated by reference herein.

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
RT002 Glabellar Lines

On December 4, 2018, the Company announced its long-acting neuromodulator DaxibotulinumtoxinA for Injection (RT002) with its proprietary stabilizing excipient peptide technology delivered positive top-line results in alleviating moderate-to-severe glabellar (frown) lines in the SAKURA 3 Phase 3 open-label, long-term safety study:

SAFETY

RT002 appeared to be generally well-tolerated, with no new tolerability or safety concerns reported. As was seen in the SAKURA 1 and SAKURA 2 pivotal trials, adverse events were mild, localized and transient. The rate of treatment-related adverse events decreased over successive treatments. The most common treatment-related adverse events per treatment of RT002 were headache (3.3 percent of treatments), injection site pain (2.7 percent) and injection site erythema (2.5 percent). There were no treatment-related serious adverse events. Eyelid ptosis was reported in 0.9 percent of treatments, decreased in frequency with successive treatments and was substantially lower than the rate observed in SAKURA 1 and SAKURA 2 (2.2 percent). The majority of ptosis events were characterized as mild in severity (85 percent) and transient.

EFFICACY

A high degree of efficacy was seen consistently across all three treatment cycles. Results were consistent with SAKURA 1 and SAKURA 2 based on the Investigator Global Assessment-Facial Wrinkle Severity (IGA-FWS) and Patient Facial Wrinkle Severity (PFWS) scales. As early as Week 1, over 90 percent of subjects across all three treatments had none or mild wrinkles.

At Week 4, the none or mild response rates as assessed by IGA-FWS were:

SAKURA 3: First treatment 95.8 percent; second treatment 96.6 percent; third treatment 97.7 percent

SAKURA 1: 97.5 percent

SAKURA 2: 97.5 percent

On the more stringent 2-point composite endpoint, which was the primary efficacy endpoint in SAKURA 1 and 2, efficacy improved with successive treatment cycles:

SAKURA 3: First treatment 73.2 percent; second treatment 77.7 percent; third treatment 79.6 percent

SAKURA 1: 73.6 percent

SAKURA 2: 74.0 percent

DURATION

As in the SAKURA 1 and SAKURA 2 pivotal trials, there were several secondary endpoints used to evaluate duration of effect, including median time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS. Duration was evaluated in the first two 36-week treatment cycles; the third treatment cycle was not evaluated for duration as the observation period ended at twelve weeks for the purpose of this study.

Median time to return to baseline wrinkle severity on both IGA-FWS and PFWS:

SAKURA 3: First treatment 28.0 weeks; second treatment 28.1 weeks

SAKURA 1: 27.7 weeks

SAKURA 2: 26.0 weeks

Median time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS:

SAKURA 3: First treatment 24.0 weeks; second treatment 24.1 weeks

SAKURA 1: 24.0 weeks

SAKURA 2: 23.9 weeks

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS
(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated December 4, 2018
99.2	Revance Therapeutics, Inc. Investor Presentation

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 4, 2018

Revance Therapeutics, Inc.

By: /s/ Caryn G. McDowell
Caryn G. McDowell
Senior Vice President, General Counsel &
Corporate Secretary