

VERTEX PHARMACEUTICALS INC / MA

Form 8-K

February 12, 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): February 12, 2018

VERTEX PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

MASSACHUSETTS

000-19319

04-3039129

(State or other jurisdiction of incorporation) (Commission File Number) (IRS Employer Identification No.)

50 Northern Avenue

Boston, Massachusetts 02210

(Address of principal executive offices) (Zip Code)

(617) 341-6100

(Registrant's telephone number, including area code)

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 February 12, 2018, the U.S. Food and Drug Administration approved SYMDEKO™ (tezacaftor/ivacaftor and ivacaftor) in patients with cystic fibrosis twelve years of age and older who have two copies of the F508del mutation in their cystic fibrosis transmembrane conductance regulator, or CFTR, gene, or who have at least one mutation that is responsive to tezacaftor/ivacaftor.

We have established a wholesale acquisition cost for SYMDEKO in the United States of \$292,000 on an annual basis (\$22,400 per 28-day pack).

We anticipate full-year 2018 total CF net product revenues of \$2.65 to \$2.80 billion from our three approved medicines - KALYDECO, ORKAMBI and SYMDEKO. The growth in 2018 is expected to be driven by an increased number of patients treated with Vertex's CF medicines, specifically from the launch of SYMDEKO in the U.S. and an increased number of patients treated with ORKAMBI outside of the U.S. We are reiterating that our combined GAAP research and development and sales, general, and administrative expenses in 2018 will be in the range of \$1.80 to \$1.95 billion and combined non-GAAP research and development and sales, general, and administrative expenses will be in the range of \$1.50 to \$1.55 billion.

Non-GAAP Financial Measures

In this Current Report on Form 8-K, our financial guidance is provided in accordance with accounting principles generally accepted in the United States (GAAP) and using certain non-GAAP financial measures. In particular, non-GAAP financial guidance excludes (i) stock-based compensation expense, (ii) expenses related to business development transactions including collaboration agreements and asset acquisitions, (iii) expenses related to consolidated variable interest entities and (iv) other adjustments. These results are provided as a complement to results provided in accordance with GAAP because management believes these non-GAAP financial measures help indicate underlying trends in our business, are important in comparing current results with prior period results and provide additional information regarding our financial position. Management also uses these non-GAAP financial measures to establish budgets and operational goals that are communicated internally and externally and to manage our business and to evaluate our performance. We adjust, where appropriate, for both revenues and expenses in order to reflect our operations. We provide guidance regarding product revenues in accordance with GAAP and provide guidance regarding combined research and development and sales, general, and administrative expenses on both a GAAP and a non-GAAP basis. The guidance regarding GAAP research and development expenses and sales, general and administrative expenses does not include estimates regarding expenses associated with any potential future business development activities.

Special Note Regarding Forward-Looking Statements

This report contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, including the guidance we are providing regarding 2018 expenses and total CF net product revenues. While we believe the forward-looking statements contained in this report are accurate, these forward-looking statements represent our beliefs only as of the date of this report and there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements. Those risks and uncertainties include, among other things, that expectations regarding our 2018 expenses and CF net product revenues may be incorrect (including because one or more of the assumptions underlying our expectations may not be realized) and other risks listed under Risk Factors in our annual report and quarterly reports filed with the Securities and Exchange Commission and available through our website at [www.vrtx.com](http://www.vrtx.com). We disclaim any obligation to update the information contained in this report as new information becomes available.

SEC Information

The information set forth in this Item 7.01 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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.

VERTEX PHARMACEUTICALS INCORPORATED  
(Registrant)

Date: February 12, 2018 /s/ Michael J. LaCascia  
Michael J. LaCascia  
Senior Vice President and General Counsel