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 24, 2019

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)*	*(I.R.S. 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 Par Value Per Share	VRTX	The Nasdaq Global Select Market

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 8.01 Other Events.

We are updating a prior disclosure of certain preclinical data relating to our APOL1-mediated kidney disease program as of October 24, 2019. The lead development candidate in this program, VX-147, is in a Phase 1 clinical trial and the clinical development program is continuing unchanged.

In June 2019, we initiated Phase 1 clinical development of VX-147 in healthy volunteers. In July, we disclosed that VX-147 had entered clinical development and provided one set of efficacy data from a preclinical mouse model within a corporate slide presentation. This preclinical study was one of six studies, including cell-based and *in vitro* studies, (i) that supported the potential efficacy of VX-147 for the treatment of APOL1-mediated kidney diseases, and (ii) that were included in our investigational new drug application, or IND, for VX-147.

In a subsequent review of the specific set of mouse data that was provided in the corporate slide presentation, we identified discrepancies that render this set of data unreliable. We have therefore disqualified these data from further consideration. We have subsequently re-verified the data from the other five preclinical efficacy studies that support clinical development of VX-147 and are included in the VX-147 IND. The preclinical safety package contained in the IND is unaffected by the disqualification of this one set of mouse efficacy data. We promptly notified the U.S. Food and Drug Administration (FDA) of these findings, and the FDA supports our plan to continue the VX-147 clinical development program without change.

The Phase 1 clinical trial evaluating VX-147 is ongoing and is on track to be completed in the fourth quarter of 2019. If these Phase 1 results are positive, we plan to initiate a Phase 2 proof-of-concept clinical trial in 2020 to evaluate whether VX-147 can reduce protein levels in urine in patients with APOL-1-mediated focal segmental glomerular sclerosis, or FSGS. We also continue to advance multiple other APOL1 inhibitors through preclinical development.

Special Note Regarding Forward-Looking Statements.

This report contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, our plans and expectations regarding (i) the Phase 1 clinical trial evaluating VX-147, (ii) a Phase 2 proof-of concept clinical trial evaluating VX-147, and (iii) the advancement of APOL1 inhibitors through preclinical development. While Vertex believes the forward-looking statements contained in this report are accurate, these forward-looking statements represent Vertex's beliefs only as of the date of this report, and there are a number of risks and uncertainties that could cause actual events or results to differ materially from those expressed or implied by such forward-looking statements. Those risks and uncertainties include, among other things, that the data from the company's development programs may not support registration or further development of its compounds due to safety, efficacy or other reasons, and other risks listed under Risk Factors in Vertex's annual report and subsequent quarterly reports filed with the Securities and Exchange Commission and available through Vertex's website at www.vrtx.com. Vertex disclaims any obligation to update the information contained in this report as new information becomes available.

Vertex is voluntarily providing the above update due to our belief in the importance of data integrity and transparency.

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: October 24, 2019

/s/ Michael Parini

Michael Parini
Executive Vice President, Chief Legal and Administrative Officer