

**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): **August 10, 2010**

VERTEX PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

MASSACHUSETTS
(State or other jurisdiction of
incorporation)

000-19319
(Commission File Number)

04-3039129
(IRS Employer Identification No.)

130 Waverly Street
Cambridge, Massachusetts 02139
(Address of principal executive offices) (Zip Code)

(617) 444-6100
(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))

Item 8.01. Other Events.

On August 10, 2010, we issued a press release in which we reported results from the ILLUMINATE Phase 3 clinical trial of our lead drug candidate telaprevir. A copy of that press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit</u>	<u>Description of Document</u>
99.1	Press Release, dated August 10, 2010

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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: August 10, 2010

/s/ Kenneth S. Boger
Kenneth S. Boger
Senior Vice President and General Counsel

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News Release

Phase 3 ILLUMINATE Study Supports 24-Week Telaprevir-Based Therapy Within a Response-Guided Regimen for People with Hepatitis C Who Had Not Received Prior Treatment

-Viral cure rates of 92% and 88% with 24- and 48-week regimens, respectively, in people who met certain response criteria-

-Safety and tolerability results were similar to those seen in the Phase 3 ADVANCE study-

Cambridge, MA, August 10, 2010 — Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced results from the Phase 3 ILLUMINATE study, which was designed to evaluate whether there was any benefit to extending therapy from 24 to 48 weeks in people whose hepatitis C virus (HCV) was undetectable at weeks 4 and 12 of treatment (extended rapid viral response or eRVR). People in the trial who met these eRVR criteria and who remained on treatment were then randomized at week 20 to receive 24 or 48 weeks of total treatment. People who did not meet these criteria were assigned to 48 weeks of pegylated-interferon and ribavirin therapy.

Sustained viral response (SVR or viral cure) rates of 92% and 88% were observed in the randomized 24- and 48-week telaprevir-based treatment groups, respectively. 72% of all 540 people treated with telaprevir in the study achieved a viral cure. The safety and tolerability profile of the telaprevir-based regimen was consistent with results reported previously from the pivotal Phase 3 ADVANCE study.

“The viral cure rates seen in ILLUMINATE showed that there was no benefit to extending telaprevir-based therapy to 48 weeks for the majority of people,” said Kenneth Sherman, M.D., Ph.D., Professor of Medicine at the University of Cincinnati College of Medicine, Director of the Division of Digestive Diseases for UC Health and Principal Investigator of the trial. “Patients who had a rapid response to telaprevir-based regimens at weeks 4 and 12 had a high likelihood of achieving a cure with 24 weeks of total treatment, which may provide important information to motivate people to continue therapy.”

“Data from ILLUMINATE and ADVANCE support our belief that the use of 24-week telaprevir-based therapy within a response-guided regimen may provide an important future treatment option for people with hepatitis C,” said Robert Kauffman, M.D., Ph.D., Senior Vice President and Chief Medical Officer for Vertex.

Telaprevir is an investigational, oral inhibitor of HCV protease, an enzyme essential for viral replication, and is being developed by Vertex Pharmaceuticals in collaboration with Tibotec Pharmaceuticals and Mitsubishi Tanabe Pharma. Results from the ILLUMINATE study are expected to supplement data obtained from ADVANCE and REALIZE - the two pivotal Phase 3 studies of telaprevir - as part of a New Drug Application submission to the U.S. Food and Drug Administration planned for the fourth quarter of 2010.

Efficacy Results from ILLUMINATE

Primary analysis for people who met certain response criteria*:

24-week telaprevir-based treatment regimen:

- SVR Rate: 92% (149/162)
- Relapse Rate: 5.7% (9/159)

48-week telaprevir-based treatment regimen:

- SVR Rate: 88% (140/160)
- Relapse Rate: 1.9% (3/154)

**Reflects people whose hepatitis C virus was undetectable (<25 IU/mL and undetectable by Roche COBAS Taqman HCV test) at weeks 4 and 12 (eRVR) and who remained on treatment through week 20.*

Overall efficacy analysis for all patients treated with telaprevir in ILLUMINATE (ITT or intent-to-treat analysis):

- SVR Rate: 72% (388/540)
- Relapse Rate: 7.7% (36/469)
- Rapid Viral Response (RVR) Rate: 72% (389/540)
- Extended RVR (eRVR): 65% (352/540)

Safety & Tolerability Results from ILLUMINATE

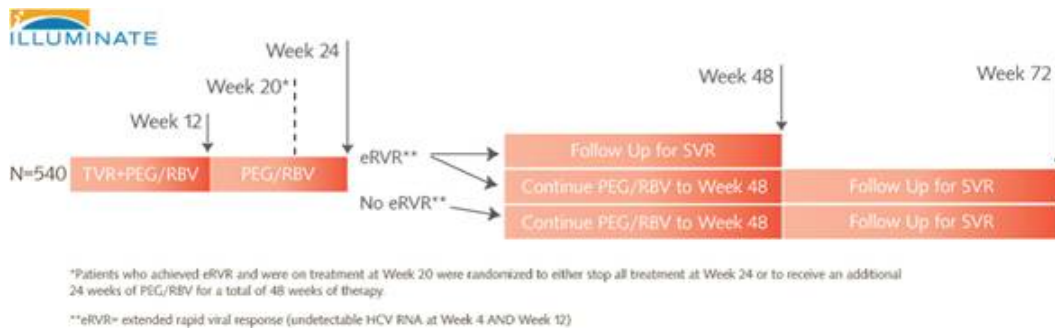
The safety and tolerability profile of the telaprevir-based regimen in the ILLUMINATE study was similar to results reported from the Phase 3 ADVANCE study. The most

common adverse events reported in the ILLUMINATE study, in order of frequency, were fatigue, pruritus, nausea, anemia, rash and headache. The majority of these adverse events were mild or moderate. Adverse events leading to discontinuation of all study drugs during the 12-week telaprevir dosing period occurred in 6.9% of people in the study. Treatment discontinuation of all drugs due to anemia and rash occurred in 1.1% and 0.6% of people in the study, respectively, during the telaprevir dosing period. Like in ADVANCE, the use of erythropoiesis-stimulating agents (ESAs) was not allowed in this study.

Data from ILLUMINATE have been submitted for presentation at the 2010 Annual Meeting of the American Association for the Study of Liver Diseases.

About the ILLUMINATE Trial

ILLUMINATE was a Phase 3, supplemental, open-label, randomized study in people infected with genotype 1 chronic hepatitis C, the most common form of the virus in the U.S. and Europe, who had not been previously treated (treatment-naïve). In this study, people who met protocol-defined response criteria of achieving eRVR were randomized at week 20 to receive 24 or 48 weeks of total treatment. The primary endpoint of the study was the proportion of patients who achieved SVR in the randomized treatment groups, and evaluated by a non-inferiority analysis. Based on this analysis, the study achieved its primary endpoint of non-inferiority with respect to SVR rates in the randomized 24 and 48-week telaprevir-based arms. The trial enrolled people at 76 clinical trial sites in the U.S. and Europe. A greater proportion of people in the ILLUMINATE study (approximately 90%) were enrolled at U.S. sites compared to the proportion in ADVANCE. As in all studies evaluating telaprevir-based regimens, patients received no more than 12 weeks of triple therapy (telaprevir, pegylated-interferon and ribavirin) followed by pegylated-interferon and ribavirin only, as part of either 24 or 48 weeks of total treatment, as noted in the trial design below.



About the Telaprevir Development Program

To date, more than 2,500 people with hepatitis C have received telaprevir-based therapy as part of Phase 2 studies and the Phase 3 ADVANCE, ILLUMINATE and REALIZE trials. Together, these studies enrolled people with genotype 1 hepatitis C who had not been treated for their disease previously as well as people who had been treated before but did not achieve a viral cure. The telaprevir clinical development program is the largest conducted to date for any investigational direct-acting antiviral hepatitis C therapy.

Phase 3 ADVANCE Trial

The pivotal Phase 3 ADVANCE study evaluated telaprevir-based response-guided regimens in 1,095 treatment-naïve patients. Data from this trial has been accepted for presentation at the 2010 Annual Meeting of the American Association for the Study of Liver Diseases.

Phase 3 REALIZE Trial

The second pivotal Phase 3 study, REALIZE, which is being conducted by Vertex's collaborator Tibotec, is evaluating telaprevir-based regimens in approximately 650 people who did not achieve a viral cure with a prior pegylated-interferon based treatment. REALIZE is the only current Phase 3 study of an investigational hepatitis C therapy to enroll a difficult-to-treat population that includes patients who had a null response and failed to achieve a viral cure with a prior course of hepatitis C therapy. Topline data from REALIZE are expected in September 2010.

Vertex retains commercial rights to telaprevir in North America. Tibotec has rights to commercialize telaprevir in Europe, South America, Australia, the Middle East and certain

other countries. Mitsubishi Tanabe Pharma has rights to commercialize telaprevir in Japan and certain Far East countries.

About Hepatitis C

Hepatitis C is a liver disease caused by the hepatitis C virus, which is found in the blood of people with the disease.(2) According to a 2010 report from the Institute of Medicine, up to 3.9 million people in the United States have chronic hepatitis C and 75% of those infected are unaware of it.(3) Approximately 60 percent of genotype 1 patients who undergo an initial 48-week regimen with pegylated-interferon and ribavirin, the currently approved treatment regimen, do not achieve a SVR (4),(5),(6) or viral cure.(1)

Hepatitis C is spread through direct contact with the blood of infected people.(2) Though many people with hepatitis C may not experience symptoms, others may have symptoms such as fatigue, fever, jaundice and abdominal pain.(2) Chronic hepatitis C can lead to serious and life-threatening liver problems, including liver damage, cirrhosis, liver failure, or liver cancer.(2) If treatment is not successful and a person does not achieve a viral cure, they remain at risk for progressive liver disease.(7),(8),(9),(10),(11) In the United States, hepatitis C is the leading cause of liver transplantations and is reported to contribute to 4,600 to 12,000 deaths annually.(8) The majority of people with hepatitis C were born between 1946 and 1964, accounting for two of every three people with chronic hepatitis C.(11) Over the next 20 years, total annual medical costs for people with hepatitis C are expected to more than double, from \$30 billion today to approximately \$85 billion.(11)

About Vertex

Vertex Pharmaceuticals Incorporated is a global biotechnology company committed to the discovery and development of breakthrough small molecule drugs for serious diseases. The Company's strategy is to commercialize its products both independently and in collaboration with major pharmaceutical companies. Vertex's product pipeline is focused on viral diseases, cystic fibrosis, inflammation, autoimmune diseases, epilepsy, cancer, and pain.

Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

Lexiva is a registered trademark of the GlaxoSmithKline group of companies.

Additional resources for media, including a hepatitis C backgrounder and glossary of common terms, are available at: <http://investors.vrtx.com/press.cfm>

References:

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- (6) McHutchison JG, Lawitz EJ, Shiffman ML, et al; IDEAL Study Team. Peginterferon alfa-2b or alfa-2a with ribavirin for treatment of hepatitis C infection. *N Engl J Med*. 2009;361:580-593.
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- (8) Davis, G.L., Alter, M. J. , El-Serag, H. Clinical—Liver, Pancreas, and Biliary Tract. *Journal of Gastroenterology*. 2010;138: 513-521.
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- (10) Veldt, B.J., Heathcote, J., Wedmeyer, H. Sustained virologic response and clinical outcomes in patients with chronic hepatitis C and advanced fibrosis. *Annals of Internal Medicine*. 2007; 147: 677-684.
- (11) Pyenson, B., Fitch, K., Iwasaki, K. Consequences of Hepatitis C Virus (HCV): Costs of a Baby Boomer Epidemic of Liver Disease. Milliman, Inc. This report was commissioned by Vertex Pharmaceuticals, Inc. May, 2009.

Special Note Regarding Forward-looking Statements

This press release contains forward-looking statements, including statements regarding (i) the potential importance of the ILLUMINATE results as described above by Drs. Sherman and Kauffman, (ii) data from ILLUMINATE supporting 24-week telaprevir-based therapy within a response-guided regimen, (iii) the expectation that results from ILLUMINATE will supplement data obtained from ADVANCE and REALIZE, (iv) the planned submission of a New Drug Application for telaprevir in the fourth quarter of 2010 and (v) the expectation that topline data from REALIZE will be available in September 2010. While the Company believes the forward-looking statements contained in this press release are accurate, 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 future outcomes from clinical trials of telaprevir (including the REALIZE clinical trial) may not be favorable or may be less favorable than the outcomes reported from ILLUMINATE, ADVANCE and earlier clinical trials of telaprevir; that the Company could experience unforeseen delays in submitting the NDA for telaprevir and/or obtaining approval to market telaprevir; that there may be varying interpretations of the data from the telaprevir clinical trials; and that future scientific, clinical, competitive or other market factors may adversely affect the potential for telaprevir-based combination therapy and the other risks listed under Risk Factors in Vertex's annual report and quarterly reports filed with the Securities and Exchange Commission and available through the Company's website at www.vrtx.com. The Company disclaims any obligation to update the information contained in this press release as new information becomes available

Vertex Pharmaceuticals will host a conference call on Tuesday, August 10, 2010 at 8:30 a.m. ET to review recent developments. To listen to the call on the telephone, dial 888-466-4587 (U.S. and Canada) or 719-325-2180 (International) and the conference ID number is 6448142. Vertex is also providing a podcast MP3 file available for download on the Vertex website at www.vrtx.com.

The call will be available for replay via telephone commencing August 10, 2010 at 12:00 p.m. ET running through 5:00 p.m. on August 24, 2010. The replay phone number for the U.S. and Canada is 888-203-1112. The international replay number is 719-457-0820 and the conference ID number is 6448142. Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. on August 17, 2010.

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