

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): May 23, 2006

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 7.01. Regulation FD Disclosure.

On May 23, 2006, Vertex Pharmaceuticals Incorporated issued a press release that announced the initiation of the first of two major Phase II studies of VX-950 in treatment-naïve patients. A copy of that press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B-2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

<u>Exhibit</u>	<u>Description of Document</u>
99.1	Press Release of Vertex Pharmaceuticals Incorporated, dated May 23, 2006, titled "Vertex Pharmaceuticals Initiates the First of Two Major Phase II Studies of VX-950 in Treatment-Naïve HCV Patients."

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: May 23, 2006

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



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News Release

FOR IMMEDIATE RELEASE

Vertex Pharmaceuticals Initiates the First of Two Major Phase II Studies of VX-950 in Treatment-Naïve HCV Patients

- *PROVE 1 & PROVE 2 Studies Expected to Enroll 580 Patients* -

Cambridge, MA, May 23, 2006 - Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today reported that it has initiated PROVE 1, a major Phase II study of VX-950, an investigational oral hepatitis C virus (HCV) protease inhibitor. In addition, the Company today announced it expects to initiate PROVE 2, a second major Phase II study in June. The studies will be conducted in the United States and Europe as part of a global Phase II development program for VX-950. Together, the two studies are expected to evaluate sustained viral response (SVR) rates in 580 treatment-naïve patients infected with genotype 1 HCV.

Vertex's global Phase II development program in treatment-naïve patients has three objectives: to evaluate the optimal SVR rate that can be achieved with VX-950 therapy in combination with the current standard of care, to evaluate the optimal treatment duration for VX-950, and to evaluate the role of ribavirin in VX-950-based therapy. In addition to these two major studies, Vertex expects to begin additional clinical studies of VX-950 in the second half of the year, including a Phase IIb study in patients who failed prior standard of care treatment. Vertex anticipates this Phase IIb study to enroll approximately 400 patients. By the end of the first quarter of 2007, Vertex expects to have enrolled approximately 1,000 patients in clinical trials of VX-950.

"PROVE 1 is the largest clinical study to date of an HCV protease inhibitor in triple combination therapy in a treatment-naïve patient population, and provides us with the first opportunity to assess the potential to enhance sustained virologic response rates with a shortened treatment duration with VX-950, along with peginterferon and ribavirin," said John McHutchison, M.D., Duke University and Lead Investigator for the PROVE 1 study.

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"Throughout this Phase II study, we will further develop a clinical and safety database and increase our experience with VX-950 among clinicians and patients."

VX-950 Program Update

PROVE Studies

The two studies announced today are the initial studies in a program of the "Investigation of HCV Protease Inhibition for Viral Eradication" (PROVE). The PROVE 1 and PROVE 2 studies have been designed as major, complementary studies to be conducted in the United States and Europe that will evaluate the ability of VX-950 to achieve SVR with short duration combination therapy. Following consultations with regulatory authorities in the U.S. and Europe, trial designs have been completed. Vertex expects the PROVE 1 and PROVE 2 studies to enroll 580 patients at more than 55 centers worldwide. Vertex expects that these studies, taken together, will provide a substantial evaluation of the potential of VX-950-based therapy to achieve SVR.

Phase II Studies for VX-950

Treatment Regimen	Patients in PROVE 1	Patients in PROVE 2	TOTAL
12-week regimens of VX-950 in combination with pegylated interferon (peg-IFN) and ribavirin (RBV)	20	80	100
12-week regimens of VX-950 in combination with only peg-IFN	0	80	80
12-week regimens of VX-950 in combination with peg-IFN and RBV, followed by 12 weeks of therapy with peg-IFN and RBV	80	80	160
12-week regimens of VX-950 in combination with peg-IFN and RBV, followed by 36 weeks of therapy with peg-IFN and RBV	80	0	80
Standard of Care HCV Treatment	80	80	160
Total	260	320	580

PROVE 1 Study in the U.S.

Vertex has initiated in the U.S., a four-arm, 260-patient Phase II study of VX-950 known as PROVE 1. The first dosing of patients will occur in June. The primary objective of this study is to assess the proportion of patients in each study arm who achieve SVR, defined as undetectable (less than 10 IU/mL, as measured by the Roche TaqMan® assay) HCV RNA 24 weeks after the completion of dosing. In the study, there will be an initial

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randomization of 80 patients equally across all four treatment arms. There will be a second randomization of an additional 180 patients across three treatment arms focused on 24 and 48 weeks of therapy. The study will be conducted in approximately 35 centers in the U.S. The study arms include:

- 12 weeks of therapy, with VX-950 dosed at 750 mg every eight hours (q8h) in combination with standard doses of pegylated-interferon (peg-IFN) and ribavirin (RBV); or
- 24 weeks of therapy, with VX-950 dosed at 750 mg every eight hours (q8h) in combination with standard doses of peg-IFN and RBV for 12 weeks, then continuing for another 12 weeks with peg-IFN and RBV alone; or
- 48 weeks of therapy, with VX-950 dosed at 750 mg every eight hours (q8h) in combination with standard doses of peg-IFN and RBV for 12 weeks, then continuing for another 36 weeks with peg-IFN and RBV alone; or
- A control arm with peg-IFN and RBV dosed for 48 weeks

Patients in the 12 and 24-week treatment arms who achieve a rapid viral response (RVR) defined as undetectable (less than 10 IU/mL) viral levels by the end of week 4, and who maintain this status through to either week 10 or 20 respectively, will stop all treatment at the 12 or 24-week time point and will be followed post-treatment to evaluate whether they achieve SVR. Patients in these treatment arms who do not meet the RVR criterion will continue on peg-IFN and RBV for a total duration of 48 weeks. The 48-week treatment arm that contains VX-950 will evaluate whether 36 weeks of additional treatment with peg-IFN and RBV adds substantially to the SVR rate compared to 12 weeks of additional treatment with peg-IFN and RBV.

PROVE 2 Study in Europe

In June, Vertex will initiate in Europe, a four-arm, 320-patient Phase II study of VX-950, known as PROVE 2. The primary objective of this study is to assess the proportion of patients in each study arm who achieve SVR, defined as undetectable (less than 10 IU/mL) HCV RNA 24 weeks after the completion of dosing. In the study, 320 patients will be

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randomized equally across all four treatment arms, providing a total of 80 patients per arm. The study will be conducted in more than 20 centers in Europe. The study arms include:

- 12 weeks of therapy, with VX-950 dosed at 750 mg every eight hours (q8h) plus a standard dose of pegylated-interferon (peg-IFN); or
- 12 weeks of therapy, with VX-950 dosed at 750 mg every eight hours (q8h) plus standard doses of peg-IFN and ribavirin (RBV); or

- 24 weeks of therapy, with VX-950 dosed at 750 mg every eight hours (q8h) plus standard doses of peg-IFN and RBV for 12 weeks, then continuing for another 12 weeks with peg-IFN and RBV alone; or
- A control arm with peg-IFN and RBV dosed for 48 weeks

As in the PROVE 1 study, patients in the 12 and 24-week treatment arms who achieve a rapid viral response (RVR) defined as undetectable (less than 10 IU/mL) viral levels by the end of week 4, and who maintain this status through to either week 10 or 20 respectively, will stop all treatment at the 12 or 24-week time point and will be followed post-treatment to evaluate whether they achieve SVR. Patients in these treatment arms who do not meet the RVR criterion will continue on peg-IFN and RBV for a total duration of 48 weeks. The 24-week treatment arm will evaluate whether 12 weeks of additional treatment with peg-IFN and RBV adds substantially to the SVR rate compared to 12 weeks of VX-950 in combination with peg-IFN and RBV.

Additional Studies

In addition, Vertex expects to further broaden the VX-950 development program to evaluate VX-950 in other treatment regimens and patient populations. In the second half of the year, Vertex plans to initiate a Phase IIb study in patients who failed prior standard of care treatment. Vertex anticipates this Phase IIb study to enroll approximately 400 patients. The Company also expects to begin a multi-dose, drug-drug interaction study of VX-950 and low-dose ritonavir in the second half of this year. By the end of the first quarter of 2007, Vertex expects to have enrolled approximately 1,000 patients in clinical trials of VX-950.

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“In clinical trials to date, VX-950 has consistently demonstrated rapid and dramatic reductions in HCV RNA levels,” said John Alam, M.D., Executive Vice President of Medicines Development and Chief Medical Officer for Vertex. “We believe the 2006 global Phase II program will establish VX-950’s clinical profile by answering key questions about SVR rates, treatment duration and the role of ribavirin. We will receive the first clinical data from this global Phase II program starting in Fall 2006.”

Data Presentations for VX-950

On May 21, 2006, Vertex announced results for a 28-day, Phase II study of VX-950 in combination with peg-IFN and RBV at the Digestive Disease Week® (DDW®) Conference in Los Angeles, California, which showed that plasma HCV RNA levels were below the limit of detection (10 IU/mL) in 12 of 12 patients at the end of 28 days of treatment with VX-950 in combination with peg-IFN and RBV. Researchers also reported that 11 of these patients continued to have no detectable virus in their blood at the end of 12 additional weeks of follow-on peg-IFN and RBV dosing. On April 29, 2006, at the 41st Annual Meeting of the European Association for the Study of the Liver (EASL), Vertex presented initial results for a 14-day, Phase Ib study of VX-950 and peg-IFN, which showed that at day 14, the majority of patients (6 of 8) receiving the combination had HCV RNA levels below the limit of quantitation (30 IU/mL), and 4 of 8 patients had HCV RNA levels below the limit of detection (10 IU/mL). Researchers reported for the first time at EASL that 8 of 8 patients who received VX-950 and peg-IFN in combination for 14 days had no detectable virus in their blood at the end of 12 additional weeks of peg-IFN and RBV dosing.

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. HCV, a serious public health concern affecting 3.4 million individuals in the United States, is spread through direct contact with the blood of infected people. Though many people with hepatitis C may not experience symptoms, others may have symptoms such as jaundice, abdominal pain, fatigue and fever. Hepatitis C

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significantly increases a person's risk for developing long-term infection, chronic liver disease, cirrhosis or death. The burden of liver disease associated with HCV infection is increasing, and current therapies provide sustained benefit in only about 50% of patients with genotype 1 HCV, the most common strain of the virus.

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 principally focused on viral diseases, inflammation, autoimmune diseases and cancer. Vertex co-promotes the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

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

TaqMan[®] is a registered trademark of Hoffman-La Roche Inc.

Safe Harbor Statement

This press release may contain forward-looking statements, including statements that (i) Vertex expects to have the first clinical data from this Phase II program beginning in the fall of 2006; (ii) planned studies will build extensive clinical activity and safety experience with VX-950 among clinicians and patients; (iii) the PROVE 1 study will begin dosing patients in June; (iv) the PROVE 2 study will be initiated in June; (v) Vertex will initiate later in 2006 a Phase II study of VX-950 in approximately 400 patients who have failed prior HCV therapy; and (vi) by the end of the first quarter of 2007, Vertex expects to have enrolled approximately 1,000 patients in clinical trials of VX-950. While management makes its best efforts to be accurate in making forward-looking statements, such statements are subject to risks and uncertainties that could cause Vertex's actual results to vary materially. These risks and uncertainties include, among other things, the risks that clinical trials for VX-950 may not proceed as planned due to technical, scientific, or patient enrollment issues, or disagreements with regulatory authorities over trial design or other matters, that the scale and scope of future clinical and nonclinical studies may change and will be determined in significant part by data collected in ongoing and future trials, that further clinical studies of VX-950 may not reflect the results obtained in early clinical and

nonclinical studies, that ongoing nonclinical studies, including toxicology studies, will yield currently unanticipated negative outcomes that could adversely affect planned clinical trials, that results from the Company's clinical trials commenced during 2006 will be

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insufficient to support a Phase III program without additional trials and consequent delay in the timetable for potential approval, and other risks listed under Risk Factors in Vertex's form 10-K filed with the Securities and Exchange Commission on March 16, 2006.

Conference Call and Webcast: PROVE Study Update

Vertex Pharmaceuticals will host a conference call today, May 23, 2006 at 9:00 a.m. EDT to review the VX-950 global Phase II program. This call will be broadcast via the Internet at www.vrtx.com in the investor center. Alternatively, to listen to the call on the telephone, dial (800) 374-0296 (U.S. and Canada) or (706) 634-2224 (International). Alternatively, Vertex is providing a podcast MP3 file available for download on the Vertex website, www.vrtx.com.

The call will be available for replay via telephone commencing May 23, 2006 at 12:00 p.m. EDT running through 5:00 p.m. EDT on May 30, 2006. The replay phone number for the US and Canada is (800) 642-1687. The international replay number is (706) 645-9291 and the conference ID number is 9742527. Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. EDT on June 6, 2006.

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