VERTEX PHARMACEUTICALS INC / MA
Form 8-K
June 01, 2005

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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 31, 2005**

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.)

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 June 1, 2005, Vertex Pharmaceuticals Incorporated ("Vertex," the "Company," "we," "us" and "our") issued a press release entitled "Vertex Pharmaceuticals Announces Proposed Public Offering of Common Stock," announcing a proposed public offering of 9,500,000 shares of the Company's common stock (and up to an additional 1,425,000 shares issuable upon exercise of the underwriters' over-allotment option) pursuant to an already effective shelf registration statement. A copy of that press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

In connection with the proposed offering described above, the Company is providing the following updated disclosure.

Recent Developments

Vertex HCV Drug Candidates

We are developing two drug candidates targeting HCV infection through different mechanisms. Our most advanced compound is the IMPDH inhibitor merimepodib, which targets HCV indirectly and currently is in Phase IIb development. IMPDH inhibitors appear to work additively or synergistically with other treatments for HCV, including ribavirin. Vertex's second HCV drug candidate, VX-950, is one of the most advanced of a new class of antiviral treatments in development for HCV infection. We believe VX-950 has the potential to change the treatment paradigm for HCV infection.

VX-950 investigational oral viral protease inhibitor for Hepatitis C

Our investigational oral protease inhibitor, VX-950, targets HCV directly, by inhibiting hepatitis C NS3-4A protease, an enzyme necessary for HCV replication. On May 10, 2005, we announced interim results indicating that VX-950 was well-tolerated and demonstrated potent antiviral activity in a Phase Ib clinical trial. Anti-viral activity and preliminary safety data were further presented by one of the clinical investigators on May 17, 2005 at the Digestive Disease Week scientific conference ("DDW").

The data presented at DDW showed that significant reductions in HCV-RNA were observed in HCV-infected patients taking VX-950 over a period of 14 days across three dose groups 450 milligrams every 8 hours, 1,250 milligrams every 12 hours, or 750 milligrams every 8 hours. After three days of treatment, the median reduction in HCV-RNA was greater than 3 log10, a reduction of at least 1,000-fold, in all three dose groups. In the dose group receiving 750 milligrams of VX-950 every 8 hours, there was a further reduction in viral levels between days 3 and 14 of treatment, with a median HCV-RNA reduction of 4.4 log10, a 25,000-fold reduction, at day 14. At the end of 14 days of treatment, 4 of 8 patients in the 750 milligrams dose group tested HCV-RNA negative in the quantitative Roche COBAS TaqMan assay (<30 IU/mL), and 2 of these 4 patients tested undetectable in the qualitative Roche COBAS TaqMan assay (limit of detection 10 IU/mL). Initial pharmacokinetic analyses indicate that trough blood plasma concentrations of VX-950 in the 750 milligrams dose group were approximately 42% higher than in the 450 milligrams dose group and approximately 46% higher than the 1250 milligrams dose group. Patients in all three dose groups were HCV genotype I and predominantly non-responders to interferon-based therapy.

Across the three dose groups, a total of five of the 28 patients given VX-950 in the Phase Ib study tested HCV-RNA negative in the quantitative Roche COBAS TaqMan assay (<30 IU/mL), reaching this level between day 11 and day 14. Following completion of the 14-day dosing period, a slow increase in HCV-RNA levels was observed in these five patients during a 28-day post-dosing period. Twenty-eight days after receiving their last dose of VX-950, two patients still had viral levels that were more than 1 log10 below their pre-treatment levels.

Preliminary data indicate that across the three dose groups, VX-950 was well-tolerated, with no serious adverse events or treatment discontinuations reported. In addition, no elevations of the liver

enzymes ALT/AST or other adverse clinical chemistry findings were reported. Complete safety and pharmacokinetic analyses of the data from the Phase Ib study, along with viral sequencing and viral kinetic analyses, are ongoing.

Based on the results of the Phase Ib clinical study, we plan to explore the development of VX-950 both as a monotherapy and in combination with other therapies for HCV infection. We currently are planning to initiate a 14-day Phase Ib combination clinical study with a limited number of patients involving VX-950 and pegylated interferon (one of the two drugs currently used in the standard treatment for HCV infection) before the end of the year. We also plan to consult with the FDA and European regulatory authorities on additional specific development plans. Pending these discussions and those with clinical experts in the field, we currently are further planning to initiate a Phase II combination clinical study before the end of the year involving VX-950 and pegylated interferon in patients who have not previously been treated for HCV infection. In addition, we are currently planning to initiate a Phase II study of VX-950 administered as a monotherapy. Major objectives of the Phase II program will be to evaluate dose, dose regimen and treatment duration required to obtain sustained virologic responses in treated patients. We anticipate treatment durations of both one and three months in the initial Phase II VX-950 and pegylated interferon combination clinical study, and a three month treatment duration in the initial Phase II monotherapy clinical study.

We expect to file an investigational new drug ("IND") application in the second half of 2005 to support Phase II clinical development of VX-950 in the United States. In anticipation of that IND filing, we are continuing our ongoing formulation and toxicology activities. The VX-950 formulation used in the Phase Ib study allowed us to achieve good exposure following oral dosing, but we have been working to improve the formulation for purposes of pharmacokinetic performance and other characteristics. Our formulation development work to date has identified prototype formulations that achieve higher blood concentrations in animals and lower variability than the formulation used in the Phase Ib clinical study. We are in the process of further scale-up and expect to produce a solid dosage formulation in the second half of 2005 for use in the Phase II clinical program. In addition, prior to filing an IND, we expect to complete a number of non-clinical toxicology studies in support of the treatment durations in the Phase II clinical studies.

Hepatitis C Virus Infection

HCV infection causes chronic inflammation in the liver. In a majority of patients, HCV infection can persist for decades and eventually lead to cirrhosis, liver failure and liver cancer. HCV infection represents a significant medical problem worldwide. Sources at the Centers for Disease Control have estimated that approximately 2.7 million Americans are chronically infected with HCV, and the World Health Organization estimates that there are as many as 185 million chronic carriers of the virus worldwide.

The current standard treatment for HCV infection is a combination of pegylated interferon and ribavirin. Not only is this treatment regimen associated with significant side effects, including fatigue, flu-like symptoms, depression and anemia, but approximately 50% of patients infected with HCV genotype I, the most common HCV genotype in the United States, fail to show long-term sustained response to the therapy. As a result, new safe and effective treatment options for HCV infection are needed.

Rheumatoid Arthritis

VX-702- Investigational Oral p38 MAP Kinase Inhibitor for Rheumatoid Arthritis

On May 31, 2005, we began screening patients in our Phase II clinica study with VX-702, a p38 MAP kinase inhibitor. p38 MAP kinase is involved in a variety of cellular processes, including the onset and progression of inflammation. When activated, p38 MAP kinase triggers production of cytokines

TNF-alpha and IL-1beta, which are associated with a broad range of acute and chronic inflammatory diseases, including rheumatoid arthritis ("RA"). Based on their mechanism of action, p38 MAP kinase inhibitors could play an important role in the future treatment of a variety of inflammatory diseases.

The study will help define the safety, tolerability and clinical activity of VX-702 in approximately 300 patients with moderate to severe RA treated for three months. The double-blind, randomized, placebo controlled Phase II study will assess two doses of VX-702 compared to placebo. VX-702 will be dosed once-daily as monotherapy. We expect enrollment in this study to involve approximately 50 centers in Europe. The primary endpoint of the study is to measure the reduction in clinical signs and symptoms of RA in patients after 12 weeks of treatment using the American College of Rheumatology ("ACR 20") criteria for defining clinical improvement in RA patients. ACR 20 is a standardized measure of the number of patients who achieve at least a 20% improvement in ACR-specified measurement of RA activity. Measurements of ACR 50 and ACR 70 improvement will also be used to define clinical response to treatment with VX-702. We expect enrollment in the study to be completed by the end of 2005.

We will conduct this trial with financial support from Kissei Pharmaceutical Co., Ltd. Vertex and Kissei entered into a strategic alliance in 1997 to design, develop and commercialize orally active p38 MAP kinase inhibitors. Under the terms of this agreement, we hold development and commercial rights in the United States and Europe for our p38 MAP kinase inhibitors. Kissei holds development and commercial rights for VX-702 in Japan and certain Asian countries.

In the U.S. alone, more than two million people are afflicted with chronic RA, causing pain, swelling, stiffness and loss of function in affected joints. Although the cause of RA is unknown, women are three times more likely than men to be afflicted with the disease. Anti-TNF agents, all of which must be administered by injection, are the leading treatment for moderate to severe RA, and U.S. sales for this class of agents reached $3.2 billion in 2004.

2005 Financial Guidance

This section contains forward-looking guidance about the financial outlook for the Company. Today, we have reiterated our 2005 financial guidance that we provided in our Form 10-Q filed with the Securities and Exchange Commission on May 9, 2005. The key financial measures for which we have provided guidance in 2005 are as follows:

Loss: We expect that our full year loss in 2005 will be in the range of $125 million to $135 million, before certain charges and gains, including any additional credits or charges associated with our Kendall Square lease.

Revenues: We expect that total revenue will be in the range of $150 million to $160 million in 2005. This is expected to be comprised of approximately $100 million of collaborative R&D revenues from existing collaborations, including $90 million in contracted collaborative R&D funding and approximately $10 million of revenue from milestone payments under existing collaborations, $25 million to $29 million from HIV product royalties, and an anticipated additional $20 million to $30 million from new research and product development agreements.

Research and Development (R&D) Expense: We project that R&D expense will be in the range of $225 million to $240 million for 2005. The forecasted increase over the 2004 R&D expense level of $192 million is mainly driven by increased clinical development investment in our Vertex-controlled programs.

Sales, General and Administrative (SG&A) Expense: We expect SG&A expense to be in the range of $42 million to $46 million for 2005.

Cash, Cash Equivalents and Available for Sale Securities: Excluding the impact of the proposed offering, we expect cash, cash equivalents and marketable securities to be in excess of $250 million at the end of 2005.

Our guidance for our full year 2005 loss, excluding any charges or gains, is a non-GAAP financial measure. We are providing this non-GAAP financial measure because management believes it helps indicate underlying trends in our business, and uses the non-GAAP financial measure to establish budgets and operational goals that are communicated internally and externally, to manage our business and to evaluate its performance.

Special Note Regarding Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These statements relate to future events and our future financial performance. These statements include but are not limited to statements:

that VX-950 has the potential to change the treatment paradigm for HCV infection;

that the Company expects to explore development of VX-950 as a monotherapy and as part of a combination therapy;

that we plan to file an IND and initiate Phase Ib and Phase II combination clinical studies involving VX-950 before the end of the year;

that we plan to initiate a Phase II study of VX-950 as a monotherapy;

relating to the proposed objectives and treatment durations of our clinical studies;

that we expect to produce a solid dosage formulation of VX-950 in the second half of 2005;

that we expect to complete a number of non-clinical toxicology studies in support of the treatment durations in the Phase II clinical studies prior to filing the IND;

relating to our expected financial performance for 2005;

that based on their mechanism of action, p38 MAP kinase inhibitors could play an important role in the future treatment of a variety of inflammatory diseases; and

that we expect enrollment in the VX-702 Phase II clinical study to involve approximately 50 centers in Europe and to be completed by the end of 2005.

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "anticipates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of such terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results to differ materially from the results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. While management makes its best efforts to be accurate in making forward-looking statements, those statements are subject to risks and uncertainties that could cause Vertex's actual results to vary materially. Those risks and uncertainties include, among other things, the risk that any one or more of Vertex's internal and external drug development programs will not proceed as planned for technical, scientific or commercial reasons or due to patient enrollment issues or based on new information from non-clinical or clinical studies or from other sources, that Vertex will be unable to realize one or more of its financial objectives for 2005 as set forth above, due to any number of financial, technical or collaboration considerations, that unexpected costs associated with one of our programs will necessitate a reduction in our investment in other

programs, that future competitive or other market factors may adversely impact the commercial

potential for our product candidates in HCV and inflammation; that our drug discovery efforts will not ultimately result in commercial products due to scientific, medical or technical developments, that we will be unable to enter into new collaborative relationships to support our research and development programs on acceptable terms, or at all, that the key estimates and assumptions underlying our restructuring and other expense charge will turn out to be incorrect or not reflective of changing market conditions in the future, and other risks listed under Risk Factors in Vertex's prospectus supplement filed with the Securities and Exchange Commission on June 1, 2005. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by law.

Item 9.01. Financial Statements and Exhibits.

(c)

Exhibits

Exhibit	Description of Document
99.1	Press Release of Vertex Pharmaceuticals Incorporated, dated May 31, 2005, titled "Vertex Pharmaceuticals Announces Proposed Public Offering of Common Stock".

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 31, 2005

/s/ KENNETH S. BOGER

Kenneth S. Boger
Senior Vice President and General Counsel

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