FORM 8-K
(Unscheduled Material Events)

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Telephone 617-577-6000
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Industry Biotechnology & Drugs
Sector Healthcare
Fiscal Year 12/31
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 2.02. Results of Operations and Financial Condition.

On January 10, 2005, Vertex Pharmaceuticals Incorporated (the “Company”) issued a press release announcing its intention to review its 2004 achievements and to describe its 2005 product development goals and anticipated 2005 financial performance at JPMorgan’s 23rd Annual Healthcare Conference in San Francisco. Joshua Boger, Ph.D., Chairman and CEO of the Company will present this update. A live webcast of the presentation will be available on the Company’s website, www.vrtx.com, at 4:30 p.m. EST on January 10, 2005. An archived webcast of the presentation will be available on the Company’s website through January 24, 2005.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

See Item 2.02.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

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<th>Exhibit</th>
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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.
For Immediate Release

Vertex Pharmaceuticals Updates Business Progress and Announces 2005 Product Development Goals at 23rd Annual JPMorgan Healthcare Conference

Cambridge, MA, January 10, 2005 — Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today will review its 2004 achievements and will describe its 2005 product development goals and anticipated 2005 financial performance at JPMorgan’s 23rd Annual Healthcare Conference in San Francisco. The update will be presented by Joshua Boger, Ph.D., Chairman and CEO of Vertex Pharmaceuticals. A live webcast of the presentation will be available on Vertex’s website, www.vrtx.com, at 4:30 p.m. EST, January 10, 2005. An archived webcast of the presentation will be available on Vertex’s website through January 24, 2005.

“Our progress in 2004 was highlighted by significant clinical advances with our proprietary drug candidates, including the development of VX-950, one of the most promising in a new class of direct acting antivirals for the treatment of hepatitis C virus (HCV) infection,” stated Dr. Boger. “Additionally, we strengthened our financial profile based on performance in our existing collaborations, signing of three new partnerships, and an improvement in our convertible debt structure. The increased revenue from collaborations provides a financial platform to support investment in our product pipeline and deliver value from our clinical programs in 2005.”

2004 Corporate Achievements

Vertex reviewed its progress against 2004 milestones that enabled the Company to advance its business.

Financial Platform:

- Increased revenues, reduced loss as compared to 2003
- Entered new collaborations with Merck, Cystic Fibrosis Foundation Therapeutics and Mitsubishi Pharma, and amended a collaboration with Novartis
• Increased HIV product royalties
• Improved capital structure

Products:

• Advanced proprietary HCV candidates, including the initiation of a Phase IIb triple combination study (METRO) of the oral therapy MMPD (merimepodib) and the initiation of a Phase Ib study of VX-950 in HCV patients

• Advanced oral anti-cytokine product candidates, including completion of a Phase IIa study of VX-702 in acute coronary syndromes (ACS) that demonstrated a dose-dependent reduction in CRP and initiation of a Phase IIa study of VX-765 in psoriasis

• Named five new preclinical candidates from research, including a novel kinase inhibitor, VX-322, for treatment of cancer; a dual gyrase B/topoisomerase IV inhibitor, VX-692, for treatment of bacterial infection; and a novel ion channel modulator, VX-409, for treatment of pain

“The year ahead will be marked by a number of product development milestones in our core product pipeline that represent potential catalysts for value creation,” continued Dr. Boger. “In 2005, we will seek to build on our leadership position in the development of novel oral HCV therapies that could enhance or change the current standard of care in HCV. In the near-term, we look forward to obtaining clinical data in patients with hepatitis C that support VX-950’s profile as a breakthrough compound that could fundamentally shift the treatment paradigm in HCV. We also look forward to completing enrollment in the Phase IIb METRO study of MMPD and defining the registration path for the product.”

“Vertex also is a leader in the development of novel, oral anti-cytokine therapies. VX-702, our p38 MAP kinase inhibitor targeting the treatment of rheumatoid arthritis, and VX-765, our ICE inhibitor candidate for the treatment of psoriasis, both represent exciting new potential treatment options. In 2005, we expect to initiate clinical studies that we anticipate will further establish the clinical and commercial potential for these unique product opportunities,” continued Dr. Boger.

“Additionally, we expect to realize important progress with our collaborative development programs, including the Aurora kinase inhibitor, VX-680, which has just entered a Phase I study with Merck in cancer patients. VX-322 is advancing in preclinical development with Novartis,
also for cancer,” said Dr. Boger. “Progress in our ongoing drug discovery programs, as reflected by the recent advancement of new drug candidates into preclinical development, is expected to form the basis for new collaborations in the year ahead.”

**2005 Corporate Objectives**

Vertex today will outline its key 2005 financial and corporate objectives, which are designed to contribute to the Company’s goal of becoming a major drug company.

**Maintain and Enhance Financial Strength**

- Increase revenues (2005: $150-160 million), reduce loss (2005: $125-135 million) and maintain strong capital structure to support clinical investment
- Sign new collaborations, primarily focused on early-stage assets
- Increase HIV product royalties

**Advance Vertex-Driven Products Toward the Market, and Realize Value in Collaborations**

**HCV**

- Report data from a Phase Ib clinical study of VX-950 in 1H05 and file an Investigational New Drug application (IND) in 2H05 to initiate Phase II development in the U.S.
- Fully enroll the METRO study of merimepodib (MMPD) in 1H05 and define the registration path for MMPD in 2H05
- Complete in 2H05 a 28-day clinical virology study to evaluate the combination of oral compounds MMPD and ribavirin in HCV patients
- Initiate a Phase II triple combination study of MMPD in treatment-naïve patients in 2H05

**Oral Anti-Cytokines**

- Initiate and enroll a three-month, 200+ patient Phase II study of the oral p38 MAP kinase inhibitor VX-702 in rheumatoid arthritis
- Complete a four-week, Phase IIa safety and pharmacokinetic study of VX-765 in psoriasis
- Complete ongoing nonclinical toxicology evaluation of ICE inhibitor pralnacasan with partner Sanofi-Aventis
Cancer

- Complete initial Phase I clinical study with Merck of novel Aurora kinase inhibitor VX-680 in solid tumors with Merck, and initiate additional clinical studies
- Conduct preclinical program for the novel Flt-3/c-kit inhibitor VX-322 with Novartis

Drug Discovery

- Advance two or more new drug candidates from drug discovery into preclinical development

Financial Outlook

In today’s presentation, Vertex will provide estimates of certain financial performance targets for 2005. The Company expects its loss, excluding certain charge and gains, to be in the range of $125 to $135 million, with total revenues of $150 to $160 million. Vertex plans to provide complete 2005 financial guidance when it releases its year-end 2004 financial results on Wednesday, February 9, 2005. In conjunction with its year-end 2004 financial results announcement, the Company will host a conference call at 5:00 pm EST, February 9, 2005. The conference call also will be webcast to all interested parties on Vertex’s website, www.vrtx.com.

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 partners. Vertex’s product pipeline is principally focused on viral diseases, inflammation, autoimmune diseases and cancer. In collaboration with GlaxoSmithKline, Vertex co-promotes the HIV protease inhibitor, Lexiva® with GlaxoSmithKline.

Non-GAAP Financial Measures

In this press release, Vertex provides guidance for a 2005 loss range, excluding certain charges and gains, of $125 to $135 million, which is a non-GAAP financial measure. This guidance is provided as a complement to results which will be provided in accordance with GAAP because
management believes these non-GAAP financial measures help indicate underlying trends in the Company’s business, and uses these non-GAAP financial measures to establish budgets and operational goals that are communicated internally and externally, to manage the Company’s business and to evaluate its performance.

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

This press release may contain forward-looking statements, including statements that Vertex expects that (i) an increased revenue base from collaborations provides a platform to invest in its pipeline and deliver value from its clinical programs in 2005; (ii) Vertex will build on its leadership position in the development of novel oral HCV therapies that could enhance or change the current standard of care in HCV; (iii) Vertex will report data from a Phase Ib study of VX-950 in 1H05 and file an IND in 2H05; (iv) Vertex will complete enrollment in its METRO study of MMPD in 1H05 and define the registration path in 2H05; (v) Vertex will complete a 28-day clinical virology study of MMPD in combination with ribavirin in 2H05, and will initiate a Phase II triple combination study of MMPD in treatment-naïve patients in 2H05; (vi) Vertex expects to initiate clinical studies with VX-702 and VX-765 that will further establish the clinical and commercial potential for these compounds; (vii) Vertex will initiate and complete enrollment in a three-month Phase II study of VX-702 in 200+ patients with rheumatoid arthritis, and will report data from a four-week, Phase Ia study of VX-765 in patients with psoriasis; (viii) Vertex will realize important progress in its collaborative programs with Novartis, Merck and the Cystic Fibrosis Foundation and these collaborations will further strengthen Vertex’s revenue base; (ix) Vertex and partner Sanofi-Aventis will complete the ongoing nonclinical toxicology evaluation of pralnacasan in 2005; (x) with Merck, Vertex will complete a Phase I study of VX-680 and initiate additional clinical studies in 2005; (xi) with Novartis, Vertex will conduct the preclinical evaluation of VX-322 in 2005; (xii) Vertex will advance two or more new drug candidates from drug discovery into preclinical development in 2005; (xiii) Vertex will sign new collaborations in 2005 that are expected to strengthen further its revenue base and and provide a base for further value creation; and (xiv) its 2005 loss and revenues are expected to be in the range set forth above.

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 (i) Vertex’s expected revenue may not materialize, or unexpected events could result in the expected revenue levels being insufficient to support Vertex’s planned activities; (ii) clinical trials for one or more of Vertex’s drug candidates may not proceed as planned due to technical, scientific, or patient enrollment issues, final results from clinical trials will not reflect positive interim results, or clinical trial results may not be available when expected, or expected regulatory filings may not occur or may be delayed due to adverse clinical or non-clinical trial developments, any or all of which may adversely affect initiation or continuation of other planned clinical trials, and may adversely impact the Company’s position as a leader in certain of the fields in which it is operating; (iii) one or more of the Company’s existing collaborations may prove unsuccessful for scientific or other reasons, and collaborations for the future development of some or all of Vertex’s drug candidates may not be available on terms satisfactory to Vertex, if
at all; (iv) Vertex will be unable to realize its financial objectives due to a variety of commercial, financial, technical or collaboration considerations; and other risks listed under Risk Factors in Vertex’s form 10-K filed with the Securities and Exchange Commission on March 15, 2004 and amended on September 8, 2004.

Webcast:

Vertex Pharmaceuticals will webcast its corporate presentation at the 23rd Annual JPMorgan Healthcare Conference on January 10, 2005 at 4:30 p.m. EST. A link to the webcast will be available via the Internet at Vertex’s website, www.vrtx.com, in the Investor Center.


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