# 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 25, 2004

# 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
(Address of principal executive offices)

02139

(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 2.02. Disclosure of Results of Operations and Financial Condition.

On October 25, 2004, Vertex Pharmaceuticals Incorporated issued a press release that reports its consolidated financial results for the quarter ended September 30, 2004 and provides an update on selected clinical developments during the same period.

A copy of the 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

Exhibit	Description of Document						
99.1	Press Release of Vertex Pharmaceuticals Incorporated, dated October 25, 2004, entitled "Vertex Pharmaceuticals Reports Third Quarter 2004 Financial Results and Provides Clinical Update".						

#### **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 25, 2004

/s/ Ian F. Smith Ian F. Smith

Senior Vice President and Chief Financial Officer

#### FOR IMMEDIATE RELEASE

#### Vertex Pharmaceuticals Reports Third Quarter 2004 Financial Results and Provides Clinical Update

- Company continues to achieve its financial and pipeline goals -

Cambridge, MA, October 25, 2004 — Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today reported consolidated financial results for the three months ended September 30, 2004.

For the quarter ending September 30, 2004, the Company's GAAP net loss was \$38.8 million, or \$0.49 per basic and diluted share, compared to a GAAP net loss of \$86.4 million, or \$1.12 per basic and diluted share, for the quarter ending September 30, 2003. The net loss for the quarter ending September 30, 2003 included a restructuring and other expense charge of \$42.4 million.

Excluding restructuring and other charges, the loss for the quarter ending September 30, 2004 was

\$36.2 million, or \$0.46 per basic and diluted share, compared to a loss of \$45.2 million, or \$0.59 per basic and diluted share, for the quarter ending September 30, 2003. The reduced loss was primarily the result of increased revenues.

Total revenues for the quarter ending September 30, 2004 increased \$11 million to \$26.8 million from \$15.8 million in 2003, primarily due to increased collaborative revenues from increased HIV product royalties from the sales of Lexiva® and from new collaborations.

Research and development expenses for the quarter ending September 30, 2004 were \$48.8 million compared to \$49.6 million for the third quarter of 2003. Sales, general and administrative expenses for the quarter ending September 30, 2004 were \$10.6 million, as compared to \$9.4 million for the third quarter of 2003.

Other interest expense, net, for the quarter ending September 30, 2004 was \$2.2 million compared to \$1.2 million for the third quarter of 2003.

At September 30, 2004, Vertex had approximately \$418 million in cash, cash equivalents and available for sale securities, \$232.4 million in convertible debt due February 2011 and \$82.6 million in convertible debt due September 2007.

#### **Selected Third Quarter Financial Highlights**

"Vertex continues on track to achieve its key financial goals for 2004," stated Ian Smith, Senior Vice President and Chief Financial Officer at Vertex. "We have strengthened our operating profile by driving revenue growth, primarily from new collaborations and HIV royalties, and balanced our R&D investment towards Vertex core compounds. Additionally, we improved our capital structure by deferring convertible debt obligations to 2011 and creating equity sensitivity in the newly exchanged convertible debt. In summary, these financial accomplishments provide a platform to support investment into important clinical trials for our proprietary compounds as we move into 2005."

- In the third quarter, Vertex earned \$4.4 million in HIV product royalties compared to \$2.0 million in the third quarter of 2003, which reflects sales growth of Lexiva<sup>®</sup> (fosamprenavir calcium) in the U.S. Also in the third quarter, Vertex's collaborator GlaxoSmithKline (GSK) launched Telzir<sup>®</sup> in the European Union, and recorded the first product sales in the United Kingdom, France and Germany.
- Primarily as a result of new collaborations entered into in the second quarter of 2004, collaborative R&D revenue increased by \$8.6 million from \$13.8 million in the third quarter of 2003 to \$22.4 million in the third quarter of 2004.
- In September 2004, Vertex exchanged approximately \$79.3 million in aggregate principal amount of its 5% Convertible Subordinated Notes due 2007 for approximately \$79.3 million in aggregate principal amount of newly issued 5.75% Convertible Senior Subordinated Notes due 2011. The Company now has \$82.6 million in convertible debt due in 2007 with a conversion price of \$92.26 per share and \$232.4 million in convertible debt due in 2011 with a conversion price of \$14.94 per share.

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#### Full-Year 2004 Financial Guidance

The following represents forward-looking guidance about the financial outlook for Vertex Pharmaceuticals. Vertex today reiterated its 2004 financial guidance that was originally provided on February 3, 2004. The Company expects that full-year 2004 loss, before charges and gains, will be in the range of \$140 to \$150 million. Additionally, the Company today revised upward, from

\$350 million to approximately \$375 million, its anticipated 2004 year-end cash, cash equivalents and marketable securities position. This increase is mainly driven by the successful completion and performance within collaborative arrangements.

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#### **Selected Third Quarter Clinical Highlights**

"In the third quarter, we continued to make progress against our 2004 product development goals," stated Joshua Boger, Ph.D., Chairman and CEO of Vertex Pharmaceuticals. "In the HCV area, we initiated the METRO (MErimepodib Triple cOmbination) study, a Phase IIb clinical study for merimepodib, our lead oral therapy for HCV. In addition, we successfully completed the Phase Ia trial for our lead oral HCV protease inhibitor VX-950, which has paved the way for us to initiate a proof-of-concept Phase Ib clinical trial in HCV patients to commence by the end of 2004."

Dr. Boger added, "We continue to make progress with our oral anti-cytokine programs targeting inflammation. Last week, we reported positive data from our Phase IIa pilot study of VX-702, our oral p38 MAP kinase inhibitor, demonstrating the ability of VX-702 to lower key biomarkers of inflammation in acute coronary syndromes (ACS). In addition, today we announced plans to start by the year-end a 28-day Phase IIa clinical trial of VX-765 in psoriasis patients.

VX-765 is an oral anti-cytokine drug that acts as a potent ICE (Interleukin-1 Converting Enzyme) inhibitor. The trial will focus primarily on safety, tolerability and pharmacokinetics in psoriasis patients and will get underway by the end of this year."

"Additionally, as part of a collaboration with GlaxoSmithKline, we announced today the start of a pilot Phase II trial of VX-385, a novel and highly potent HIV protease inhibitor which is active *in vitro* against HIV strains that are resistant to multiple anti-HIV drugs," commented Dr. Boger.

Dr. Boger concluded, "As we move through the remainder of 2004 and into 2005, we anticipate further progress in our research and clinical programs as we seek to advance products through important proof-of-concept studies and towards the market to enable sustained value creation."

#### HIV:

• Vertex today announced that GlaxoSmithKline has initiated a pilot Phase II study of the HIV protease inhibitor VX-385 (640385). The open-label Phase II trial will enroll approximately 30 patients with HIV who will receive VX-385 for up to 48 weeks. The trial will assess the safety, efficacy, and clinical activity of VX-385, and will use planned interim analyses as a basis for designing larger, randomized clinical trials to support product registration. In connection with the start of the trial for VX-385, Vertex expects to recognize as revenue a milestone payment in the fourth quarter of 2004.

#### HCV:

- In the third quarter, Vertex began patient enrollment in the METRO study, a Phase IIb clinical trial evaluating the oral HCV therapy merimepodib (MMPD) in patients with HCV who are non-responders to prior treatment with pegylated interferon and ribavirin. Vertex expects that the METRO study will enroll approximately 315 patients.
- In the third quarter of 2004, the Company announced the completion of the Phase Ia clinical study for VX-950, an investigational oral protease inhibitor for the treatment of HCV infection. Phase Ia results will be presented at an upcoming medical conference.

#### Autoimmune Diseases and Inflammation:

• In October, Vertex presented positive preliminary results from its Phase IIa study of VX-702 in acute coronary syndromes (ACS) at the Acute Cardiac Care 2004 conference in Rome. Results from this study demonstrated that VX-702 was well tolerated and reduced, in a dose-dependent manner, levels of C-reactive protein (CRP), a marker of inflammation.

#### Remaining 2004 Corporate Goals: Outlook

Vertex has accomplished a number of its business and clinical objectives this year, and the Company is on track to achieve its targeted milestones for 2004. Vertex outlined key objectives for the remainder of 2004:

- Establish new pharmaceutical collaborations
  - New collaborations would augment development and commercialization of proprietary compounds as well as support Vertex's discovery organization.
- Initiate multiple clinical trials by year-end
  - Begin a 28-day clinical virology study of MMPD in combination with ribavirin in patients with chronic hepatitis C.

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- Initiate a 14-day, multi-dose Phase Ib study of VX-950 in patients with chronic hepatitis C.
- Begin a 28-day, Phase IIa clinical trial to assess safety and pharmacokinetics of VX-765 in psoriasis patients.
- Vertex anticipates that Merck will initiate a Phase I study of VX-680, a novel Aurora kinase inhibitor, in cancer patients.
- Select new drug candidates for preclinical development
  - Vertex has advanced discovery efforts underway targeting kinases, ion channels, and bacterial gyrase, and anticipates advancing preclinical drug candidates from one or more of these programs in 2004.

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#### **Non-GAAP Financial Measures**

In this press release, Vertex's financial results are provided both in accordance with generally accepted accounting principles (GAAP) in the United States and using certain non-GAAP financial measures. In particular, Vertex provides its third quarter 2004 loss and guidance for full-year 2004 loss, excluding and before any charges or gains, both of which are non-GAAP financial measures. These results are provided as a complement to results 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.

#### **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. Vertex co-promotes the new HIV protease inhibitor Lexiva<sup>®</sup> (fosamprenavir calcium) with GlaxoSmithKline.

 $Lexiva^{\circledR} \ and \ Telzir^{\circledR} \ are \ registered \ trademarks \ of the \ GlaxoSmithKline \ group \ of \ companies.$ 

This press release may contain forward-looking statements, including statements that Vertex expects that (i) financial accomplishments provide a platform for Vertex to support investment to drive its proprietary clinical candidates; (ii) Vertex is positioned for clinical advancements in the areas of autoimmune disease and inflammation in the remainder of 2004, and that Vertex anticipates making further progress in research and clinical programs through the remainder of 2004 and into 2005; (iii) it will enter into new collaborations, begin a pilot clinical study of merimepodib in combination with ribavirin, initiate a proof-of-concept study of VX-950 in patients with chronic hepatitis C, and begin a 28-day study of VX-765 in psoriasis patients, by the end of this year, and advance additional new preclinical drug candidates from its research programs; (iv) Merck to initiate Phase I clinical development of VX-680 by the end of 2004; (v) the METRO

study will enroll approximately 315 patients; and (vi) its 2004 net loss and cash position to be within the ranges set forth above. 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 nonclinical or clinical studies or from

other sources, that Vertex will be unable to realize one or more of its financial objectives for 2004 as set forth above, due to any number of financial, technical or collaboration considerations, 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; and that it will be unable to enter into new collaborative relationships to support its research and development programs on acceptable terms, or at all, and other risks listed under Risk Factors in Vertex's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2004 and amended on September 8, 2004.

#### Vertex Pharmaceuticals Incorporated 2004 Third Quarter and Nine Month Results Consolidated Statement of Operations Data

(In thousands, except per share amounts)
(Unaudited)

		Three Mon Septeml		led		Nine Months Ended September 30,		
		2004		2003		2004		2003
Pharmaceutical revenues:								
Royalties	\$	4,403	\$	2.003	\$	10,996	\$	5,944
Collaborative R&D and other revenues	Ψ	22,425	Ψ	13,820	Ψ	51,886	Ψ	41,820
Total revenues	\$	26,828	\$	15,823	\$	62,882	\$	47,764
Costs and expenses:								
Royalty payments		1,466		797		3,640		2,117
Research and development		48,790		49,627		137,915		151,336
Sales, general & administrative		10,600		9,436		30,482		28,608
		60,856		59,860		172,037		182,061
Other interest expense, net		2,189		1,170		5,661		686
Loss excluding charge for retirement of 2007 convertible notes, restructuring and other expense and income from		·		·		·		
discontinued operations	\$	(36,217)	\$	(45,207)	\$	(114,816)	\$	(134,983)
Basic and diluted loss per common share excluding charge for retirement of 2007 convertible notes, restructuring and other expense and income from discontinued								
operations	\$	(0.46)	\$	(0.59)	\$	(1.46)	\$	(1.76)
SI 0 1 2005		(0.00)				(2.115)		
Charge for retirement of 2007 convertible notes (Note 1)		(993)		- (42.20.4)		(3,446)		(00.404)
Restructuring and other expense (Note 2) Income from discontinued operations (Note 3):		(1,561)		(42,394)		(5,216)		(90,424)
Gain on sale of assets		_		451		_		69,683
Income (loss) from discontinued operations		_		729		_		(14)
Total income from discontinued operations		_		1,180		_		69,669
Net loss	\$	(38,771)	\$	(86,421)	\$	(123,478)	\$	(155,738)
Basic and diluted net loss per common share	\$	(0.49)	\$	(1.12)	\$	(1.57)	\$	(2.03)
Basic and diluted weighted average number of common								
shares outstanding		78,742		77,067		78,403		76,750
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Note 1: In September 2004, the Company exchanged approximately \$79.3 million in aggregate principal amount of 5% Convertible Subordinated Notes due 2007 for approximately \$79.3 million in aggregate principal amount of newly issued 5.75% Convertible Senior Subordinated Notes due 2011. Together with the February 2004 issuance of approximately \$153.1 million notes, the Company has \$232.4 million in aggregate principal amount of 5.75% Convertible Senior Subordinated Notes due in 2011 and \$82.6 million in aggregate principal amount of its existing 5% Convertible Notes due in 2007.

The September 2004 transaction resulted in a charge of approximately \$1.0 million relating to the write-off of the remaining unamortized issuance charges for the \$79.3 million of the 2007 5% convertibles notes, which were retired. For the nine months ended September 30, 2004, the total charges related to the write-off of the remaining unamortized issuance charges for the February and September exchanges were approximately \$3.5 million.

Note 2: For the three and nine months ended September 30, 2004 and 2003, the Company incurred restructuring and other expense charges. The charge for the three and nine months ending September 30, 2004 is \$1.6 million and \$5.2 million, respectively, and relates primarily to an implied interest cost relating to the restructuring and other expense accrual. For the three and nine months ended September 30, 2003 the Company recorded \$42.4 million and \$90.4 million, respectively. Restructuring and other expense recorded for the three months ended September 30, 2003 relates to the incremental anticipated costs to exit a

lease, while the charge for the nine months ended September 30, 2003 includes anticipated costs to exit a facilities lease, operational restructuring charges and \$6.0 million of lease operating expense incurred prior to taking the lease restructuring charge. This expense has been estimated in accordance with FASB 146 "Accounting for Costs Associated with Exit or Disposal Activities" and is reviewed quarterly for changes in circumstances.

Note 3: The Company sold certain assets and liabilities of the Discovery Tools and Services business in March and December 2003, respectively. In October 2001, the FASB issued FASB 144 "Accounting for the Impairment of Long-Lived Assets" ("SFAS 144"). SFAS 144 provides a single accounting model for long-lived assets to be disposed of. The combination of the assets sold in March 2003 and in December 2003 represents a component of the Company's business that, beginning in 2002, had separately identifiable cash flows. As such, pursuant to SFAS No. 144, the tables presented in this release give effect to the disposition of the assets sold in March and December 2003, accounting for such assets as discontinued operations. For the three and nine months ended September 30, 2003 the Company recorded total income from discontinued operations of \$1.2 million and \$69.7 million, respectively, including a gain on the sale of assets.

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#### Vertex Pharmaceuticals Incorporated 2004 Third Quarter Results Condensed Consolidated Balance Sheet Data

(In thousands) (Unaudited)

	September 2004		December 31, 2003	
Assets	•			
Cash, cash equivalents and available for sale securities	\$	418,427	\$	583,164
Other current assets		14,405		10,642
Property, plant and equipment, net		68,179		80,083
Restricted cash		48,416		26,061
Other noncurrent assets		24,935		24,461
Total assets	\$	574,362	\$	724,411
Liabilities and Equity				
Deferred revenue, collaborator development loan and other current liabilities	\$	84,323	\$	69,541
Accrued restructuring and other expense		50,123		69,526
Deferred revenue — noncurrent		27,674		51,771
Collaborator development loan — noncurrent		19,997		18,460
Other long term obligations		2,925		7,268
Convertible notes (due 2007)		82,552		315,000
Convertible notes (due 2011)		232,448		· —
Stockholders' equity		74,320		192,845
Total liabilities and equity	\$	574,362	\$	724,411

## Conference Call and Webcast: Third Quarter 2004 Financial Results:

Vertex Pharmaceuticals will host a conference call today, October 25, 2004 at 5:00 p.m. Eastern Time to review financial results and recent developments. This call will be broadcast via the Internet at <a href="https://www.vrtx.com">www.vrtx.com</a> in the investor center until end of day on November 8, 2004. Alternatively, to listen to the call on the telephone, dial (800) 374-0296 (U.S. and Canada) or (706) 634-2394 (International).

The call will be available for replay via telephone commencing October 25, 2004 at 8:00 p.m. EDT running through 5:00 p.m. ET on November 1, 2004. The replay phone number for the U.S. and Canada is (800) 642-1687. The international replay number is (706) 645-9291 and the conference ID number is 1431841.

Vertex's press releases are available at www.vrtx.com.

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**Vertex Contacts:** 

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