# 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): April 21, 2008

# VERTEX PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

MASSACHUSETTS

**000-19319** (Commission File Number)

04-3039129 (IRS Employer Identification No.)

(State or other jurisdiction of incorporation)

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 2.02. Results of Operations and Financial Condition.

On April 21, 2008, we issued a press release in which we reported our consolidated financial results for the quarter ended March 31, 2008. 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.

The information set forth in Exhibit 99.1 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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.

(d) Exhibits

<u>Exhibit</u> 99.1

Press Release, dated April 21, 2008.

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Description of Document

#### 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)

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

Date: April 21, 2008

#### Vertex Pharmaceuticals Reviews Clinical Advancements and Reports First Quarter 2008 Financial Results

# —Telaprevir data in HCV patients who failed current therapies to be presented at EASL— —Pharmacokinetic analyses in HCV patients show potential for twice-daily dosing of telaprevir— —VX-770 for cystic fibrosis to advance based on positive results reported in March 2008—

Cambridge, MA, April 21, 2008 — Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today reported consolidated financial results for the quarter ended March 31, 2008.

"In the first quarter of 2008, we made important progress to advance and differentiate the profile of our hepatitis C virus protease inhibitor telaprevir," said Joshua Boger, Ph.D., President and Chief Executive Officer of Vertex Pharmaceuticals. "The ADVANCE clinical trial, started in March, is the first Phase 3 study initiated for an HCV protease inhibitor and provides us with a potential first-to-market position in the treatment-naïve patient population. In addition, we will present early data in patients who failed prior treatment with pegylated interferon and ribavirin at EASL later this week that highlight telaprevir's potential in this important patient population that has a high level of unmet need and limited treatment options."

"Additionally, we continue to advance other proprietary drug candidates in our pipeline targeting important disease areas, and in March we announced promising early clinical results for the oral potentiator drug candidate VX-770 in patients with cystic fibrosis," continued Dr. Boger. "Our broad development investment is supported by a balance sheet that we strengthened in the quarter by raising \$400 million through debt and equity offerings, enabling us to end the quarter with \$750 million in cash and marketable securities."

#### **Telaprevir Development Program**

#### Phase 3 Development in Treatment-Naïve Population

• In March, Vertex initiated and began patient dosing in a Phase 3 clinical trial of the investigational hepatitis C virus (HCV) protease inhibitor telaprevir. The Phase 3

ADVANCE trial is a global 3-arm pivotal trial that is focused on 24-week telaprevir-based regimens that utilize rapid viral response (RVR) criteria.

- Vertex expects to complete enrollment of this trial during the fourth quarter of 2008 and expects to have sustained viral response (SVR) data from the study in the first half of 2010.
- Two abstracts with data from the PROVE 1 and PROVE 2 clinical trials in treatment-naïve patients have been accepted for presentation during the 43rd Annual Meeting of the European Association for the Study of the Liver (EASL) in Milan, April 23-27, 2008. Key data to be presented include SVR24 data from all arms of PROVE 1 and SVR12 data from the control arm of PROVE 2.

### Telaprevir Development in Patients Who Have Failed to Achieve SVR with Current Therapy

- Vertex is conducting PROVE 3, a Phase 2b clinical trial of telaprevir-based combination therapy in patients with genotype 1 HCV who did not achieve an SVR with a previous pegylated interferon-based treatment. Vertex expects to complete an interim analysis of PROVE 3 in May and submit data to regulatory authorities in the United States and Europe.
- Vertex is also conducting study 107, an open-label study that is enrolling patients with genotype 1 HCV who did not achieve an SVR with previous interferon-based treatment in the control arms of PROVE 1, PROVE 2 or PROVE 3. Preliminary data through week 12 from study 107 will be presented as a late-breaker poster at EASL.

#### Additional Telaprevir Clinical Trials

Vertex and Tibotec are evaluating the potential role of telaprevir in important HCV sub-populations as well as different dosing regimens for telaprevir.

Tibotec is conducting a Phase 2 clinical study in Europe to evaluate a twice-daily dosing schedule of telaprevir (1125mg every 12 hours) in combination with pegylated interferon and ribavirin, as compared to the current dosing schedule (750mg every 8 hours). The study is now fully enrolled. Preliminary evaluation of pharmacokinetics supports continuation of both the twice-daily and three times daily dosing arms in the study. Preliminary pharmacokinetic analyses of pre-dose samples taken on day 8 of

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dosing in approximately 50 patients in this study indicate that trough concentrations in those patients receiving a twice-daily dosing schedule are similar to trough concentrations of a three times daily dosing schedule, and are also similar to trough concentrations observed in PROVE 1 and PROVE 2. Additional safety and efficacy data from this ongoing Phase 2 study will be needed to further characterize telaprevir's ability to be dosed in this twice-daily regimen.

Tibotec is also conducting Phase 2 studies to evaluate telaprevir in patients infected with genotype 2, genotype 3 and genotype 4 HCV.

# • Next-generation HCV protease inhibitor in Phase 1 clinical development

Vertex is advancing a portfolio of HCV protease inhibitors with potentially differentiated profiles. VX-500 is now being dosed in a Phase 1a clinical trial, and VX-813 is expected to enter Phase 1 development in the second half of 2008.

Updates on the status of telaprevir clinical trials are available at www.clinicaltrials.gov.

#### **Pipeline of Novel Drug Candidates**

#### Novel oral programs targeting protein defects that cause cystic fibrosis (CF) are advancing

- In March, Vertex reported the first proof-of-concept data from Part 1 of a Phase 2a trial of VX-770, an investigational Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) potentiator compound for the treatment of CF. The interim analysis showed improved lung function and improved function of CFTR protein, as measured by changes in sweat chloride levels and changes in chloride ion transport in the upper airway as measured by changes in nasal potential difference, after dosing VX-770 as an oral agent for 14 days. Through 14 days of dosing, VX-770 appeared to be well-tolerated.
- · Vertex expects these data to be presented at the 31<sup>st</sup> European Cystic Fibrosis Society Annual Conference in Prague, June 11-14.

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- In the second quarter, Vertex plans to proceed to Part 2 of the trial, which will enroll approximately 18 patients with the G551D mutation in at least one allele for dosing of VX-770 up to 28 days.
- Vertex is also conducting a Phase 1a trial of VX-809, an investigational CFTR corrector compound for the treatment of CF. Depending on the results from the Phase 1a trial, Vertex plans to initiate a Phase 1b trial in patients with CF in mid-2008.

#### Additional Advancements in Pipeline

- Vertex expects to begin clinical development of a novel janus kinase 3 (JAK3) inhibitor, VX-509, with broad potential in the treatment of multiple immune-mediated inflammatory diseases, in mid-2008.
- In the second quarter, Vertex's collaborator, Merck & Co., Inc., is expected to initiate a Phase 1 clinical trial of the Aurora kinase inhibitor MK-5108 (VX-689) in patients with advanced and/or refractory tumors. Merck continues to evaluate efficacy and safety data for the Aurora kinase inhibitor MK-0457 (VX-680) for the treatment of cancer following the previously announced suspension of clinical trial enrollment for this compound.
- In the first quarter, Vertex and GlaxoSmithKline ended their agreement for the development and commercialization of certain novel, subtype selective sodium channel modulators for the treatment of pain.

#### **First Quarter Results**

For the quarter ended March 31, 2008, the Company's GAAP net loss was \$96.2 million, or \$0.72 per share, compared to a GAAP net loss for the quarter ended March 31, 2007 of \$80.7 million, or \$0.64 per share. The increase in the Company's 2008 GAAP net loss was principally driven by a decrease in collaborative revenues, partially offset by a decline in research and development (R&D) expenses,

The non-GAAP loss, before stock-based compensation and restructuring charges, for the quarter ended March 31, 2008 was \$82.5 million, or \$0.61 per share, compared to \$63.4 million, or \$0.50 per share, for the quarter ended March 31, 2007.

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Total revenues for the quarter ended March 31, 2008 were \$41.7 million, compared to \$68.8 million for the first quarter of 2007. The decrease is primarily due to a reduction in non-recurring milestone revenues and reimbursement revenues recognized from R&D collaborations in 2007. R&D collaborative revenues continue to be an important source of funding and in early April, the Company achieved a \$45.0 million milestone in connection with dosing of the first patients in the telaprevir Phase 3 ADVANCE clinical trial, which the Company expects to fully recognize in the second quarter.

Research and development (R&D) expenses for the quarter ended March 31, 2008 were \$114.6 million, compared to \$132.6 million in R&D expenses for the first quarter of 2007. The decrease reflects investment activity in 2007 to support advancement of the PROVE 1 and PROVE 2 trials and investment into our commercial supply chain, while 2008 investment reflects reduced activity during the period of preparation for advancement of telaprevir into the Phase 3 registration program. We anticipate that our R&D investment will increase commensurate with increased development activity as telaprevir progresses through later stage development.

Sales, general and administrative (SG&A) expenses for the quarter ended March 31, 2008 were \$21.6 million, compared to \$16.5 million for the first quarter of 2007. This increase reflects building of infrastructure, including an increase in the number of employees and our initial commercial investments, to support advancement of telaprevir.

Other income, net, for the quarter ended March 31, 2008 was \$2.6 million, compared to \$7.9 million for the first quarter of 2007. This decrease resulted from a lower level of invested funds and portfolio yields reflecting the broader economic environment.

At March 31, 2008, Vertex had \$749.6 million in cash, cash equivalents and marketable securities. Additionally, the Company has \$287.5 million of convertible senior subordinated debt due in 2013, with a conversion price of \$23.14.

## Full Year 2008 Financial Guidance

This section contains forward-looking guidance about the financial outlook for Vertex Pharmaceuticals.

Vertex today is reiterating its guidance for 2008 GAAP and non-GAAP loss, revenue, and expense, which originally was provided on February 11, 2008.

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

In this press release, Vertex's financial results are provided both in accordance with accounting principles generally accepted in the United States (GAAP) and using certain non-GAAP financial measures. In particular, Vertex provides its first quarter 2008 and 2007 loss and guidance for its projected 2008 loss, excluding restructuring charges and stock-based compensation expense, which in each case results in a non-GAAP financial measure. 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 are important in comparing current results with prior period results. Management also uses these non-GAAP financial measures to establish budgets and operational goals that are communicated internally and externally, and to manage the Company's business and to evaluate its performance. A reconciliation of non-GAAP financial results to GAAP financial results is included in the attached financial statements.

#### **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, inflammation, autoimmune diseases, cancer, pain and cystic fibrosis. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

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

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#### **Special Note Regarding Forward-looking Statements**

This press release contains forward-looking statements, including statements regarding our expectations that (i) telaprevir has a potential first-to-market position in the treatment-naïve patient population, (ii) the early data in patients who failed prior treatment that we will present at EASL will highlight telaprevir's potential in this important patient population, (iii) the clinical trial design for Vertex's Phase 3 clinical trial will be as described in this press release, (iv) with respect to the Phase 3 clinical trial, we will complete enrollment in the fourth quarter of 2008 and have SVR data in the first half of 2010, (v) we will present data at EASL regarding PROVE 1, PROVE 2 and the 107 study as described in this press release, (vi) we will complete an interim analysis of PROVE 3 in May 2008 and submit data to regulatory authorities, (vii) we will advance a portfolio of HCV protease inhibitors with potentially differentiated profiles and will advance VX-813 into clinical development in the second half of 2008, (viii) VX-770 interim data will be presented at the 31<sup>st</sup> European Cystic Fibrosis Society Annual Conference, (ix) we will proceed to Part 2 of the Phase 2a trial with VX-770 in the second quarter of 2008 and that the design of part 2 of this trial will be as described in this press release, (x) depending on results from an ongoing Phase 1a clinical trial, we plan to initiate a Phase 1b clinical trial of VX-809 in patients with CF in mid-2008, (xi) VX-509 will begin clinical development in mid-2008, and has a broad potential in the treatment of multiple immune-mediated inflammatory diseases, (xii) in the second quarter of 2008, Merck expects to initiate a Phase 1 clinical trial of MK-5108 (VX-689) in patients with advanced and/or refractory tumors and that Merck continues to evaluate efficacy and safety data for MK-0457 (VX-680), (xiii) R&D investment will increase, (xiv) we will recognize in full the \$45.0 million milestone in the second quarter of 2008, (xv) additionally data from the ongoing Phase 2 trial will allow us to further characterize telaprevir's ability to be dosed in a twice-daily regimen, and the Company's projected 2008 annual loss, revenues, R&D expense, and SG&A expense, will be within the ranges stated above in the Company's financial guidance. 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 the outcomes for each of its planned clinical trials and studies, and in particular its planned clinical trials of telaprevir, may not be favorable, that regulatory authorities may require supplemental clinical trials in order to support registration of telaprevir in any particular indication, that there may be varying interpretations of data produced by one or more of our clinical trials, that enrollment may be more difficult or slower than we currently anticipate or that planned clinical trials may not start when planned due to regulatory issues, site startup delays, availability of clinical trial material or other reasons, that regulatory authorities will require more extensive data for a telaprevir NDA filing than currently expected, that one or more of the Company's assumptions underlying its revenue expectations including clinical and scientific progress that could lead to milestone payments under existing collaboration agreements or other payments under new collaborations — or its expense expectations — including estimates of the variables that go into determining stock-based compensation expenses will not be realized, or that Vertex will be unable to realize one or more of its financial objectives for 2008 due to unexpected and costly program delays or any number of other financial, technical or collaboration considerations, that unexpected costs associated with one or more of the Company's programs will necessitate a reduction in its investment in other programs or a change in the Company's financial projections, that future competitive or other market factors may adversely affect the commercial potential for the Company's product candidates in HCV or other potential indications, that due to scientific, medical or technical developments, the

Company's drug discovery efforts will not ultimately result in commercial products or assets that can generate revenue, that we will be unable to enter into new collaborative relationships on acceptable terms, and 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. We disclaim any obligation to update the information contained in this press release as new information becomes available.

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Vertex Pharmaceuticals Incorporated 2008 First Quarter Results Consolidated Statements of Operations Data (In thousands, except per share amounts) (Unaudited)

	 2008	 2007
Revenues:		
Royalties	\$ 10,851	\$ 9,796
Collaborative and other R&D revenues	 30,824	 59,014
Total revenues	 41,675	 68,810
Costs and expenses:		
Royalty payments	3,576	3,269
Research and development (R&D)	114,582	132,578
Sales, general & administrative (SG&A)	21,623	16,537
Restructuring expense	 630	 5,055
Total costs and expenses	140,411	157,439
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Loss from operations	 (98,736)	 (88,629)
Other income, net	2,582	7,901
Net loss	\$ (96,154)	\$ (80,728)
Basic and diluted net loss per common share	\$ (0.72)	\$ (0.64)
Basic and diluted weighted average number of common shares outstanding	134,471	125,756
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		Three Months Ended March 31,		
Non-GAAP Loss and Loss per Common Share Reconciliation		2008	2007	
GAAP net loss	\$	(96,154)	\$ (80,728)	
Pro Forma Adjustments:				
Stock-based compensation expense included in R&D (Note 1):		10,830	10,302	
Stock-based compensation expense included in SG&A (Note 1):		2,242	2,018	
Total stock-based compensation expense		13,072	12,320	
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Restructuring expense (Note 2)		630	5,055	
			<u> </u>	
Non-GAAP loss	\$	(82,452)	\$ (63,353)	
Basic and diluted non-GAAP loss per common share	\$	(0.61)	\$ (0.50)	
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**Note 1:** For the three months ended March 31, 2008, the Company incurred \$13.1 million in stock-based compensation expense of which \$10.8 million is included in research and development expenses and \$2.2 million is included in sales, general and administrative expenses. For the three months ended March 31, 2007, the Company incurred \$12.3 million in stock-based compensation expense of which \$10.3 million is included in research and development expenses and \$2.0 million is stock-based compensation expenses.

**Note 2:** For the three months ended March 31, 2008, the Company incurred restructuring expense charges of \$0.6 million. The charge is primarily a result of the imputed interest charge related to the restructuring liability. For the three months ended March 31, 2007, the Company incurred restructuring expense charges of \$5.1 million. The charge is the result of incremental lease obligations related to the revision of certain key estimates and assumptions about building operating costs as well as the imputed interest charge related to the restructuring liability. The expense and the related liability have been estimated in accordance with SFAS 146 "Accounting for Costs Associated with Exit or Disposal Activities" and are reviewed quarterly for changes in circumstances.

**Note 3:** In February 2008, the Company completed a public offering of 6,900,000 shares of common stock, including the underwriters' over-allotment of 900,000 shares, at a price of \$17.14 per share. This transaction resulted in net proceeds of \$112.1 million to the Company. The net proceeds include an underwriting discount of \$5.3 million and other expenses of the offering estimated at approximately \$0.9 million that were recorded as an offset to additional paid-in-capital.

**Note 4:** In February 2008, the Company completed an offering of \$287.5 million aggregate principal amount of 4.75% convertible senior subordinated notes due February 2013 (the "2013 Notes"), including \$37.5 million aggregate principal amount of notes purchased by the underwriters pursuant to their overallotment option. The 2013 Notes are convertible, at the option of the holder, into common stock at a price equal to \$23.14 per share, subject to adjustment under certain circumstances. The 2013 Notes bear interest at the rate of 4.75% per year, and the Company is required to make semi-annual interest payments on the outstanding principal balance of the notes on February 15 and August 15 of each year, beginning on August 15, 2008. This transaction resulted in net proceeds of \$278.0 million to the Company. The net proceeds include an underwriting discount of \$8.6 million and other expenses of the offering estimated at approximately \$0.9 million that were recorded as deferred issuance costs.

## Vertex Pharmaceuticals Incorporated 2008 First Quarter Results Condensed Consolidated Balance Sheets Data (In thousands) (Unaudited)

	]	March 31, 2008	December 31, 2007	
Assets				
Cash, cash equivalents and marketable securities	\$	749,643	\$	467,796
Other current assets		34,295		35,980
Property and equipment, net		64,712		66,509
Restricted cash		30,258		30,258
Other non-current assets		10,597		934
Total assets	\$	889,505	\$	601,477
Liabilities and Stockholders' Equity				
Other current liabilities	\$	123,696	\$	148,148
Accrued restructuring expense		34,809		35,292
Deferred revenues		119,248		126,745
Collaborator development loan (due 2008)		19,997		19,997
Convertible notes (due 2013) (Note 4)		287,500		_
Stockholders' equity		304,255		271,295
Total liabilities and stockholders' equity	\$	889,505	\$	601,477
Common shares outstanding (Note 3)		140,383		132,876

#### **Conference Call and Webcast: First Quarter Financial Results:**

Vertex Pharmaceuticals will host a conference call and webcast today, Monday, April 21, 2008 at 5:00 p.m. EDT to review financial results and recent developments. This call and webcast will be broadcast via the Internet at www.vrtx.com. It is suggested that webcast participants go to the web site at least 10 minutes in advance of the call to ensure that they can access the slides. The link to the webcast is available on the Events and Presentations button on the home page.

To listen to the call on the telephone, dial (800) 374-0296 (U.S. and Canada) or (706) 634-2224 (International). 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 April 21, 2008 at 8:00 p.m. EDT running through 5:00 p.m. EDT on April 28, 2008. 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 41884143. Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. EDT on May 5, 2008.

Vertex's press releases are available at www.vrtx.com. (VRTX-GEN)

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## **Vertex Contacts:**

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