

**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, 2010**

**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 October 25, 2010, we issued a press release in which we reported our consolidated financial results for the quarter ended September 30, 2010. 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>	<u>Description of Document</u>
99.1	Press Release, dated October 25, 2010.

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**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, 2010

/s/ Kenneth S. Boger  
Kenneth S. Boger





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## News Release

### Vertex Pharmaceuticals Reports Third Quarter 2010 Financial Results and Highlights Progress in Hepatitis C and Cystic Fibrosis Development Programs

*-Hepatitis C: New Drug Application submission for telaprevir on track for fourth quarter 2010-*

*-Cystic Fibrosis: Phase 3 registration program ongoing for VX-770-*

*-Pipeline: Ongoing proof-of-concept clinical trials in hepatitis C, cystic fibrosis, epilepsy and rheumatoid arthritis-*

*-Financial: Company ends third quarter with a cash position of \$1.2 billion-*

**Cambridge, MA, October 25, 2010** — Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today reviewed recent business and clinical progress and reported consolidated financial results for the quarter ended September 30, 2010.

“With the recent completion of our Phase 3 registration program for telaprevir, we remain on track to submit our New Drug Application in the coming weeks, marking what we believe will be an important milestone in our effort to bring telaprevir to people with hepatitis C,” said Matthew Emmens, Chairman, President and Chief Executive Officer of Vertex Pharmaceuticals.

Mr. Emmens continued, “Later this week, clinical investigators will present Phase 3 data for telaprevir at the annual AASLD meeting in Boston. We continue to have high confidence in the potential for telaprevir to help the majority of people with hepatitis C — regardless of their treatment history — and we look forward to sharing additional telaprevir data with the medical community.

“Importantly, with a cash position of \$1.2 billion at the end of the third quarter, we will enter 2011 with the financial strength needed to support the planned launch of telaprevir as well as the continued discovery and development of other new breakthrough medicines,” concluded Mr. Emmens.

## Hepatitis C

### ***Telaprevir Phase 3 Program Complete; Rolling NDA Submission On Track***

- In the third quarter, Vertex completed its Phase 3 registration program for telaprevir. The company remains on track to complete the submission of its rolling New Drug Application (NDA) for telaprevir in combination with pegylated-interferon and ribavirin in the fourth quarter of 2010 with clinical data from its three Phase 3 trials in people who had not been previously treated for hepatitis C and in people who received prior treatment but were not cured.

### ***Phase 3 ADVANCE and ILLUMINATE Trials to be Presented at AASLD This Week***

- Vertex expects that final sustained viral response (SVR or viral cure) and safety data from the Phase 3 ADVANCE and ILLUMINATE trials will be presented as part of oral presentation sessions at the upcoming annual meeting for the American Association for the Study of Liver Diseases (AASLD or The Liver Meeting), being held October 29 to November 2 in Boston. In total, eight Vertex abstracts were accepted for presentation at the AASLD meeting.

### ***Initiation of Phase 3b Clinical Trial to Evaluate Twice-Daily (BID) Dosing of Telaprevir***

- Vertex today announced the initiation of a Phase 3b clinical trial to evaluate twice-daily dosing of telaprevir (1,125 mg; BID) compared to three-times-daily dosing of telaprevir (750 mg; q8h) in combination with pegylated-interferon and ribavirin for people with genotype 1 hepatitis C. Patient screening for enrollment in the study is expected to start in November 2010. Additional details on this trial were provided today in a separate press release.

### ***Ongoing Phase 2 Trial Evaluating Combination Regimens of VX-222 and Telaprevir***

- Vertex announced today that it has modified its clinical trial evaluating telaprevir dosed in combination with Vertex’s lead HCV polymerase inhibitor, VX-222. The company will discontinue Arm A of this study as a result of patients meeting a pre-defined stopping rule related to viral breakthrough during the first four weeks of dosing. Arm A was designed to evaluate a two-drug regimen of VX-222 (low dose; 100 mg) and telaprevir (1,125 mg) both dosed twice daily without pegylated-interferon and ribavirin. The additional three arms of the study are continuing without modification, and no viral breakthrough has been reported in these arms.

- This Phase 2 proof-of-concept trial began dosing patients in August 2010 and is designed to evaluate safety and SVR rates using 12-week response-guided regimens of telaprevir/VX-222-based combination therapy in people with genotype 1 hepatitis C. The trial is continuing to evaluate treatment regimens that include four-drug regimens of telaprevir, VX-222, pegylated-interferon and ribavirin, as well as a two-drug regimen of only telaprevir (1,125 mg) and a higher dose of VX-222 (400 mg), both dosed twice daily.

- Trial sites have now completed patient recruitment, which Vertex expects will enable it to reach the initial target enrollment of 100 patients for the study. Vertex expects to obtain on-treatment clinical data from this trial in the first half of 2011 and SVR data in the second half of 2011.

### ***Enrollment Complete in Phase 2 Trial Evaluating Telaprevir in People Co-Infected with Hepatitis C Virus and Human Immunodeficiency Virus***

- Vertex today announced that it has completed enrollment of 60 patients in a Phase 2 clinical trial of telaprevir-based regimens in people who are infected with genotype 1 hepatitis C virus and the human immunodeficiency virus (HIV), also known as HCV-HIV co-infection. The primary endpoint of the trial is to evaluate the safety and tolerability of telaprevir-based therapy in people co-infected with HCV and HIV. A secondary endpoint is to evaluate SVR, or viral cure, rates.
- The trial enrolled 13 people who had not previously received treatment for hepatitis C and who were not currently being treated for HIV infection. The trial also enrolled 47 people who had not previously received treatment for hepatitis C and who were currently being treated for HIV infection with highly active antiretroviral therapy (HAART). Of the 47 patients on HAART, 23 were receiving a Reyataz-based regimen and 24 were receiving Atripla.

### **Cystic Fibrosis**

#### ***Phase 3 Registration Program for VX-770***

- Three trials of the novel cystic fibrosis transmembrane conductance regulator protein (CFTR) potentiator VX-770 are fully enrolled and ongoing as part of a global Phase 3 registration program focused on patients with the G551D mutation.

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- Data from the Phase 3 registration program of VX-770 are expected in the first half of 2011. Pending results from the Phase 3 registration program, Vertex expects to submit a New Drug Application for VX-770 in the second half of 2011.

#### ***Initiation of Combination Trial of VX-770 and VX-809***

- Vertex recently initiated a Phase 2a clinical trial that is evaluating combination regimens of VX-809 and VX-770 in people with cystic fibrosis who have two copies of the F508del mutation. Additional details on this trial can be found in a press release issued on October 18.

### **Pipeline**

#### ***Proof-of-Concept Trials of VX-765 in Epilepsy and VX-509 in Rheumatoid Arthritis***

- Vertex expects to complete a Phase 2 proof-of-concept trial of the novel caspase-1 inhibitor VX-765 in epilepsy in 2010. Top-line data, including safety and seizure frequency data, are expected later this year.
- Enrollment is ongoing in a Phase 2 proof-of-concept clinical trial of the novel Janus kinase 3 (JAK3) inhibitor VX-509 in rheumatoid arthritis (RA). Interim data from the trial are expected in 2011.

### **Third Quarter Results**

For the quarter ended September 30, 2010, the company's GAAP net loss was \$209.0 million, or \$1.04 per share, including certain charges totaling \$34.4 million, compared to a GAAP net loss for the quarter ended September 30, 2009 of \$149.6 million, or \$0.84 per share, including certain charges totaling \$22.6 million.

The non-GAAP loss, before certain charges, for the quarter ended September 30, 2010 was \$174.6 million, or \$0.87 per share, compared to \$126.9 million, or \$0.71 per share, for the quarter ended September 30, 2009. The increase in the company's 2010 non-GAAP loss was attributable to increased costs to support advancement of telaprevir toward potential launch.

Total revenues for the quarter ended September 30, 2010 were \$23.8 million, compared to \$25.0 million for the third quarter of 2009.

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Research and development (R&D) expenses for the quarter ended September 30, 2010 were \$170.4 million, compared to \$132.1 million for the third quarter of 2009. The increase reflects greater commercial supply investment for telaprevir and increases in other development activities.

Sales, general and administrative (SG&A) expenses for the quarter ended September 30, 2010 were \$48.9 million, compared to \$36.6 million for the third quarter of 2009. This increase reflects building of capabilities, including an increase in the number of employees and our commercial investments, to support advancement of telaprevir toward potential launch.

At September 30, 2010, Vertex had \$1.2 billion in cash, cash equivalents and marketable securities. In September 2010, Vertex issued \$400.0 million of 3.35% convertible senior subordinated notes due 2015, with a conversion price of approximately \$48.83 per share.

### **Full Year 2010 Financial Guidance**

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

The company is today reiterating its guidance for 2010 non-GAAP loss of approximately \$600 million, as provided on February 4, 2010, and for its 2010 GAAP net loss of approximately \$750 million, as provided on July 28, 2010.

## 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 third quarter 2010 and 2009 loss, and guidance for its projected 2010 loss, excluding stock-based compensation and executive transition expenses, restructuring expense, acquisition-related expenses, loss on exchange of convertible subordinated notes, and revenue and expenses related to certain September 2009 financial transactions. 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, are important in comparing current results with prior period results and provide additional information regarding its financial position. Management also uses these non-

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

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

Reyataz is a registered trademark of Bristol-Myers Squibb.

Atripla is a registered trademark of Bristol-Myers Squibb and Gilead Sciences, LLC.

### Special Note Regarding Forward-looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, including statements regarding (i) Vertex remaining on track to submit its New Drug Application for telaprevir in the fourth quarter of 2010; (ii) clinical investigators presenting Phase 3 data for telaprevir at AASLD; (iii) the potential for telaprevir to help the majority of people with hepatitis C regardless of their treatment history; (iv) the company entering 2011 with the financial strength needed to support the planned launch of telaprevir as well as the continued discovery and development of other new breakthrough medicines; (v) the expectation that patient screening for the Phase 3b clinical trial of telaprevir will start in November 2010; (vi) the telaprevir/VX-222 Phase 2 clinical trial being designed to evaluate safety and SVR rates using telaprevir/VX-222 based combination therapy and continuing to evaluate treatment regimens that include four-drug regimens and a two-drug regimen of only telaprevir and VX-222; (vii) Vertex expecting to reach its initial target enrollment of 100 patients, and to obtain on-treatment clinical data from the Phase 2 clinical trial of telaprevir and VX-222 in the first half of 2011 and SVR data in the second half of 2011; (viii) the expectation that data from the Phase 3 registration program for VX-770 will be available in the first half of 2011 and the possibility that the company will submit a New Drug Application for VX-770 in the second half of 2011; (ix) the expectation that the company will complete and receive top-line data from a clinical trial of VX-765 in 2010; (x) the expectation that interim data from a Phase 2 clinical trial of VX-509 will be received in 2011; and (xi) the company's expectations regarding its 2010 non-GAAP and GAAP net loss. 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

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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 may not be favorable, that regulatory authorities may require supplemental clinical trials in order to support registration of telaprevir and/or VX-770, that planned or potential clinical trials may be delayed or may not be conducted, that the company may not be able to successfully develop telaprevir, VX-770, VX-509, VX-765 or combination therapies involving telaprevir and VX-222 or VX-770 and VX-809, that the company's expectations regarding its 2010 GAAP and non-GAAP net loss may be incorrect, 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](http://www.vrtx.com). The company disclaims any obligation to update the information contained in this press release as new information becomes available.

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**Vertex Pharmaceuticals Incorporated**  
**2010 Third Quarter and Nine Month Results**  
**Consolidated Statements of Operations Data**  
(in thousands, except per share amounts)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
<b>Revenues:</b>				
Royalty revenues	\$ 8,173	\$ 7,834	\$ 21,842	\$ 19,891
Collaborative revenues	15,622	17,123	56,004	48,109

Total revenues	23,795	24,957	77,846	68,000
Costs and expenses:				
Royalty expenses	3,228	3,712	9,681	10,555
Research and development expenses (R&D)	170,434	132,132	468,528	415,044
Sales, general & administrative expenses (SG&A)	48,855	36,572	125,322	97,618
Restructuring expense	866	774	3,758	4,283
Acquisition-related expenses (Note 2)	—	—	—	7,793
Total costs and expenses	223,383	173,190	607,289	535,293
Loss from operations	(199,588)	(148,233)	(529,443)	(467,293)
Net interest expense (Note 1)	(3,458)	(1,332)	(10,157)	(3,947)
Change in fair value of derivative instruments (Note 1)	(5,911)	—	(34,634)	—
Loss on exchange of convertible subordinated notes (Note 3)	—	—	—	(12,294)
Net loss	<u>\$ (208,957)</u>	<u>\$ (149,565)</u>	<u>\$ (574,234)</u>	<u>\$ (483,534)</u>
Basic and diluted net loss per common share	\$ (1.04)	\$ (0.84)	\$ (2.87)	\$ (2.86)
Basic and diluted weighted-average number of common shares outstanding	200,887	178,735	200,080	169,137

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
<b>Non-GAAP Loss and Loss per Common Share Reconciliation</b>				
GAAP Net Loss	\$ (208,957)	\$ (149,565)	\$ (574,234)	\$ (483,534)
Pro Forma Adjustments:				
Stock-based compensation and executive transition expenses included in R&D	\$ 16,979	\$ 13,509	\$ 49,034	\$ 54,244
Stock-based compensation and executive transition expenses included in SG&A	6,789	8,365	18,516	19,985
Total stock-based compensation and executive transition expenses	\$ 23,768	\$ 21,874	\$ 67,550	\$ 74,229
Expenses related to September 2009 financial transactions (Note 1)	9,738	—	45,746	—
Loss on exchange of convertible subordinated notes (Note 3)	—	—	—	12,294
Restructuring expense	866	774	3,758	4,283
Acquisition-related expenses (Note 2)	—	—	—	7,793
Non-GAAP Loss	<u>\$ (174,585)</u>	<u>\$ (126,917)</u>	<u>\$ (457,180)</u>	<u>\$ (384,935)</u>
Basic and diluted non-GAAP loss per common share	\$ (0.87)	\$ (0.71)	\$ (2.28)	\$ (2.28)

**Note 1:** The change in fair value of derivative instruments and a portion of the net interest expense reflected in the Consolidated Statements of Operations Data, and the liabilities related to milestone transactions reflected in the Condensed Consolidated Balance Sheets Data, relate to two financial transactions that the Company entered into in September 2009 relating to future milestone payments under the Company's collaboration agreement with Janssen Pharmaceutica, N.V. During the three and nine months ended September 30, 2010, the Company recorded interest expense of \$3.8 million and \$11.1 million, respectively, related to its secured notes (due 2012) and an additional aggregate expense of \$5.9 million and \$34.6 million, respectively, related to the changes in estimated fair values of the rights to the \$95.0 million in potential future milestone payments and the derivative embedded in the secured notes (due 2012).

**Note 2:** The acquisition-related expenses reflected in the Consolidated Statements of Operations Data, and the intangible assets, the goodwill and the deferred tax liability reflected in the Condensed Consolidated Balance Sheets Data, relate to the Company's acquisition of ViroChem Pharma Inc. in 2009.

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**Note 3:** In the second quarter of 2009, the Company recorded a non-cash loss related to an exchange of \$143.5 million in aggregate principal amount of 4.75% convertible senior subordinated notes due February 2013 (the "2013 Notes"), plus interest, for 6.6 million shares of newly issued common stock.

In the first quarter of 2010, the holders of \$32.1 million in aggregate principal amount of the 2013 Notes converted their 2013 Notes into 1.4 million shares of the Company's common stock in full satisfaction of the 2013 Notes.

In September 2010, the Company completed an offering of \$400.0 million aggregate principal amount of 3.35% convertible senior subordinated notes due October 2015 (the "2015 Notes"). The 2015 Notes are convertible, at the option of the holder, into common stock at a price equal to approximately \$48.83 per share, subject to adjustment under certain circumstances. The 2015 Notes bear interest at the rate of 3.35% per year, and the Company is required to make

semi-annual interest payments on the outstanding principal balance of the notes on April 1 and October 1 of each year. This transaction resulted in net proceeds of \$391.6 million to the Company.

**Condensed Consolidated Balance Sheets Data**

(in thousands)  
(unaudited)

	September 30, 2010	December 31, 2009
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 1,203,011	\$ 1,284,913
Other current assets	23,428	22,113
Property and equipment, net	65,439	62,279
Restricted cash	34,090	30,313
Intangible assets (Note 2)	518,700	518,700
Goodwill (Note 2)	26,102	26,102
Other non-current assets	18,059	11,068
<b>Total assets</b>	<b>\$ 1,888,829</b>	<b>\$ 1,955,488</b>
<b>Liabilities and Stockholders' Equity</b>		
Other liabilities	\$ 163,650	\$ 172,273
Accrued restructuring expense	33,238	34,017
Deferred tax liability (Note 2)	160,278	160,278
Deferred revenues	276,939	300,531
Convertible notes (Note 3)	400,000	32,071
Liabilities related to milestone transactions (Note 1)	204,628	159,972
Stockholders' equity (Note 3)	650,096	1,096,346
<b>Total liabilities and stockholders' equity</b>	<b>\$ 1,888,829</b>	<b>\$ 1,955,488</b>
Common shares outstanding (Note 3)	203,101	199,955

**Conference Call and Webcast: Third Quarter Financial Results:**

Vertex Pharmaceuticals will host a conference call and webcast today, Monday, October 25, 2010 at 5:00 p.m. ET to review financial results and recent developments. This call and webcast will be broadcast via the Internet at [www.vrtx.com](http://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 (888) 221-9518 (U.S. and Canada) or (913) 312-1513 (International). Vertex is also providing a podcast MP3 file available for download on the Vertex website at [www.vrtx.com](http://www.vrtx.com).

The call will be available for replay via telephone commencing October 25, 2010 at 8:00 p.m. ET running through 5:00 p.m. ET on November 1, 2010. The replay phone number for the U.S. and

Canada is (888) 203-1112. The international replay number is (719) 457-0820 and the conference ID number is 7497635. Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. ET on November 8, 2010.

Vertex's press releases are available at [www.vrtx.com](http://www.vrtx.com).

(VRTX-GEN)

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