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Vertex Reports 2010 Financial Results and Highlights Recent Progress in Hepatitis C and Cystic Fibrosis Development Programs

-Hepatitis C: Regulatory agencies in U.S., Europe and Canada to provide accelerated reviews of telaprevir applications-

-Cystic Fibrosis: First Phase 3 registration data for VX-770 expected in first quarter 2011; potential regulatory submissions in the U.S. and E.U. in second half of 2011-

-Financial: Vertex enters 2011 with more than \$1 billion in cash, cash equivalents and marketable securities-

CAMBRIDGE, Mass., Feb 3, 2011 (BUSINESS WIRE)-- [Vertex Pharmaceuticals Incorporated](#) (Nasdaq: VRTX) today provided an update on recent progress in its late-stage development programs in hepatitis C virus (HCV) infection and cystic fibrosis (CF) and reported consolidated financial results for the year ended December 31, 2010.

"Vertex enters 2011 in a strong financial position as we prepare for the planned launch of telaprevir," said Matthew Emmens, Chairman, President and Chief Executive Officer of Vertex Pharmaceuticals. "Our primary focus remains on making telaprevir available to people with hepatitis C as quickly as possible, and we are encouraged that regulatory agencies in the U.S., Europe and Canada will each provide an accelerated review of telaprevir, with the first approval decision currently expected in the U.S. in May of this year.

"We will also soon receive the first Phase 3 registration data for VX-770 in cystic fibrosis, which if positive will form the basis for planned regulatory submissions for approval in the U.S. and E.U. in the second half of the year.

"Additionally, we believe that our financial position will support our key business objectives through 2012, at which time we expect to begin generating earnings as a cashflow positive company," concluded Mr. Emmens.

Recent Clinical Development Progress

In a press release issued on January 9, 2011, Vertex provided a comprehensive business update, including planned clinical development milestones for 2011. Vertex today provided the following additional updates, reflecting recent progress in its development programs:

- **Accelerated Reviews of Telaprevir Application from U.S., E.U. and Canadian Regulatory Authorities**
 - In January, the U.S. FDA accepted for filing Vertex's New Drug Application (NDA) for telaprevir and granted the company's request for six-month Priority Review. A target review date of May 23, 2011 was set under the Prescription Drug User Fee Act (PDUFA) for the FDA's approval decision. Also in January, Vertex completed a New Drug Submission (NDS) to the Therapeutic Product Directorate (TPD) of Health Canada seeking approval for telaprevir in Canada. Telaprevir was also granted Priority Review in Canada.
 - Vertex today announced that the European Medicines Agency (EMA) has notified our collaborator Janssen that its telaprevir Marketing Authorisation Application (MAA) was valid and acceptable for review. The EMA previously accepted the telaprevir MAA for accelerated assessment, which is granted to new medicines of major public health interest.
- **Continued Progress in Phase 2 Study of Telaprevir and VX-222**
 - Vertex is conducting a Phase 2 clinical trial evaluating multiple 12-week and 24-week, response-guided regimens of telaprevir, Vertex's lead medicine in development for hepatitis C, dosed in combination with its hepatitis C virus polymerase inhibitor VX-222. The study currently includes three treatment arms. Two of the treatment arms are fully enrolled and are evaluating four-drug combinations of telaprevir (1,125 mg; BID), VX-222 (400 mg or 100 mg; BID), Pegasys[®] (pegylated-interferon alfa-2a) and Copegus[®] (ribavirin). All of the people in the four-drug treatment arms will have reached the 12-week timepoint in the study by the end of February.
 - On-treatment data from the study are expected in the first quarter of 2011 from both of the four-drug treatment

arms.

- o In addition, enrollment is expected to begin in the first quarter of 2011 for a three-drug treatment arm of this study designed to evaluate the potential of an all-oral, interferon-free regimen of telaprevir (1,125 mg), VX-222 (400 mg) and ribavirin dosed twice daily.

Full Year 2010 Financial Results

For the year ended December 31, 2010, the company's GAAP net loss was \$754.6 million, or \$3.77 per share, including certain charges totaling \$148.9 million. The GAAP net loss for the year ended December 31, 2009 was \$642.2 million, or \$3.71 per share, including certain charges totaling \$134.7 million.

The non-GAAP loss, before certain charges, for the year ended December 31, 2010 was \$605.7 million, or \$3.02 per share, compared to \$507.5 million, or \$2.93 per share, for the year ended December 31, 2009. The increase in the company's 2010 non-GAAP loss was principally attributable to increased costs related to launch preparation activities for telaprevir, including the significant expansion of our commercial organization and increased commercial supply investment.

Total revenues for the year ended December 31, 2010 were \$143.4 million, compared to \$101.9 million for the year ended December 31, 2009. The increase is primarily due to an increase in revenues from Mitsubishi Tanabe for commercial supply of telaprevir.

Research and development (R&D) expenses for the year ended December 31, 2010 were \$637.4 million, including \$65.2 million in stock-based compensation expense, compared to \$550.3 million, which included \$67.4 million in stock-based compensation and executive transition expenses, for the year ended December 31, 2009. The increase in Vertex's R&D investment is principally due to continued investment in the development programs for telaprevir, VX-770 and earlier-stage programs, and increased commercial supply investment for telaprevir. Vertex and Tibotec share certain costs of development activities for telaprevir.

Sales, general and administrative (SG&A) expenses for the year ended December 31, 2010 were \$187.8 million, which included \$25.9 million in stock-based compensation expense, compared to \$130.2 million, which included \$24.8 million in stock-based compensation and executive transition expenses, for the year ended December 31, 2009. This increase primarily reflects expenses related to the significant expansion of our commercial organization for telaprevir and VX-770, including the hiring of the commercial management team and more than 100 field-based employees to support the potential future sale of telaprevir.

Other expense, net, for the year ended December 31, 2010 was \$58.5 million, compared to other expense, net, of \$28.2 million for the year ended December 31, 2009. This increase in other expense resulted primarily from non-cash expenses in 2010 related to the company's September 2009 financial transactions, which were partially offset by losses incurred in 2009 on the exchanges of convertible senior subordinated notes.

At December 31, 2010, Vertex had approximately \$1.03 billion in cash, cash equivalents and marketable securities.

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

Operating Expenses: Vertex expects operating expenses, consisting of Research and Development (R&D) expense and Sales, General and Administrative (SG&A) expense, to be in the range of \$890 to \$930 million in 2011, excluding costs of revenues and approximately \$105 million in stock-based compensation expense, as compared to \$734 million in 2010, excluding \$91 million in stock-based compensation expense. The components of this 2011 operating expense are:

- R&D Expense: The company expects that R&D expense levels for 2011 will be similar to R&D expense levels for 2010. The principal development investment will continue to be focused on hepatitis C and cystic fibrosis, with the investment in research activities generally comparable with prior years.
- SG&A Expense: The company expects that SG&A expense will increase in 2011 to fund the continued expansion of the company's commercial function for telaprevir and VX-770 and investment in activities and employees to support the potential launch and future sale of telaprevir.

Non-GAAP Financial Measures

In this press release, Vertex's financial results and financial guidance 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 fourth quarter and full-year 2010 and 2009 loss, excluding stock-based compensation and executive transition expenses, restructuring expense, acquisition-related expenses, loss on exchanges of convertible subordinated notes, intangible asset impairment charges, net of tax, 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-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.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2010	2009	2010	2009
Revenues:				
Royalty revenues	\$ 8,402	\$ 8,429	\$ 30,244	\$ 28,320
Collaborative revenues	57,122	25,460	113,126	73,569
	<u>65,524</u>	<u>33,889</u>	<u>143,370</u>	<u>101,889</u>
Costs and expenses:				
Royalty expenses	3,049	3,647	12,730	14,202
Research and development expenses (R&D)	168,888	135,230	637,416	550,274
Sales, general & administrative expenses (SG&A)	62,478	32,574	187,800	130,192
Restructuring expense (credit)	(2,257)	1,957	1,501	6,240
Intangible asset impairment charges (Note 2)	---	7,200	---	7,200
Acquisition-related expenses (Note 2)	---	---	---	7,793
	<u>232,158</u>	<u>180,608</u>	<u>839,447</u>	<u>715,901</u>
Loss from operations	<u>(166,634)</u>	<u>(146,719)</u>	<u>(696,077)</u>	<u>(614,012)</u>
Net interest expense (Note 1)	(7,163)	(4,235)	(17,320)	(8,182)
Change in fair value of derivative instruments (Note 1)	(6,595)	(1,847)	(41,229)	(1,847)
Loss on exchanges of convertible subordinated notes (Note 3)	---	(5,843)	---	(18,137)
Net loss	<u>\$(180,392)</u>	<u>\$(158,644)</u>	<u>\$(754,626)</u>	<u>\$(642,178)</u>
Basic and diluted net loss per common share	\$(0.90)	\$(0.86)	\$(3.77)	\$(3.71)
Basic and diluted weighted-average number of common shares outstanding	201,355	185,492	200,402	173,259
Non-GAAP Loss and Loss per Common Share Reconciliation				
	Three Months Ended December 31,	2010	2009	Twelve Months Ended December 31,
	2010	2009	2010	2009
GAAP Net Loss	\$(180,392)	\$(158,644)	\$(754,626)	\$(642,178)
Pro Forma Adjustments:				
Stock-based compensation and executive transition expenses included in R&D	\$16,164	\$13,191	\$65,198	\$67,435
Stock-based compensation and executive transition expenses included in SG&A	7,410	4,780	25,926	24,765

Total stock-based compensation and executive transition expenses	\$23,574	\$ 17,971	\$91,124	\$92,200
Expenses related to September 2009 financial transactions (Note 1)	10,551	5,312	56,297	5,312
Loss on exchanges of convertible subordinated notes (Note 3)	---	5,843	---	18,137
Restructuring expense (credit)	(2,257)	1,957	1,501	6,240
Intangible asset impairment charges, net of tax (Note 2)	---	4,975	---	4,975
Acquisition-related expenses (Note 2)	---	---	---	7,793
Non-GAAP Loss	<u>\$(148,524)</u>	<u>\$(122,586)</u>	<u>\$(605,704)</u>	<u>\$(507,521)</u>
Basic and diluted non-GAAP loss per common share	\$(0.74)	\$(0.66)	\$(3.02)	\$(2.93)

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 twelve months ended December 31, 2010, the company recorded interest expense of \$4.0 million and \$15.1 million, respectively, related to its secured notes (due 2012) and an additional aggregate expense of \$6.6 million and \$41.2 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). In the fourth quarter of 2009, the company recorded interest expense of \$3.5 million related to its secured notes (due 2012) and an additional aggregate expense of \$1.8 million 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 intangible asset impairment charges and 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.

Note 3: In 2009, the company recorded a non-cash loss related to exchanges of \$255.4 million in aggregate principal amount of 4.75% convertible senior subordinated notes due February 2013, plus interest, for 11.6 million shares of newly issued common stock.

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)

	December 31, 2010	December 31, 2009
Assets		
Cash, cash equivalents and marketable securities	\$1,031,411	\$1,284,913
Other current assets	25,628	22,113
Property and equipment, net	72,333	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	17,182	11,068
Total assets	<u>\$1,725,446</u>	<u>\$1,955,488</u>

Liabilities and Stockholders' Equity

Other liabilities	\$182,142	\$172,273
Accrued restructuring expense	29,595	34,017
Deferred tax liability (Note 2)	160,278	160,278
Deferred revenues	234,668	300,531
Convertible notes (Note 3)	400,000	32,071
Liabilities related to milestone transactions (Note 1)	214,790	159,972
Stockholders' equity (Note 3)	<u>503,973</u>	<u>1,096,346</u>
Total liabilities and stockholders' equity	<u>\$1,725,446</u>	<u>\$1,955,488</u>
Common shares outstanding (Note 3)	203,523	199,955

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About Vertex

Vertex creates new possibilities in medicine. Our team aims to discover, develop and commercialize innovative therapies so people with serious diseases can lead better lives.

Vertex scientists and our collaborators are working on new medicines to cure or significantly advance the treatment of hepatitis C, cystic fibrosis, epilepsy and other life-threatening diseases.

Founded more than 20 years ago in Cambridge, MA, we now have ongoing worldwide research programs and sites in the U.S., U.K. and Canada.

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) U.S., European and Canadian regulatory authorities providing accelerated reviews of telaprevir applications; (ii) the expectation that the first registration data for VX-770 will become available in the first quarter of 2011; (iii) the potential for VX-770 regulatory submissions for approval in the second half of 2011; (iv) the planned launch of telaprevir; (v) the company's focus on making telaprevir available to people with hepatitis C as quickly as possible; (vi) the first approval decision regarding telaprevir being expected in the U.S. in May 2011, based on the May 23, 2011 target date under the Prescription Drug User Fee Act; (vii) Vertex's expectations regarding the Phase 2 clinical trial of telaprevir and VX-222, including expectations regarding patients reaching the 12-week timepoint, the availability of on-treatment data in the first quarter of 2011 and the enrollment of patients in the three-drug treatment arm; (viii) the expectation that in 2012 Vertex will begin generating earnings as a cashflow positive company; and (ix) the information provided in the three paragraphs following the statement "This section contains forward-looking guidance about the financial outlook for Vertex Pharmaceuticals." While Vertex 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 Vertex or Janssen-Cilag could experience unforeseen delays in obtaining approval to market telaprevir, that there may be varying interpretations of the data from the telaprevir clinical trials, that the outcomes for each of Vertex's ongoing and planned clinical trials and studies may not be favorable, that regulatory authorities may require supplemental clinical trials in order to support the approval of telaprevir and/or VX-770, 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 2011 operating expenses and/or its expectation that it will begin generating earnings in 2012 as a cash flow positive company may be incorrect (including because one or more of the company's assumptions underlying its revenue or expense expectations may not be realized) 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. Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

Conference Call and Webcast

Vertex will host a conference call and webcast today, Thursday, February 3, 2011 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. 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 866-501-1537 (U.S. and Canada) 720-545-0001 (International). Vertex is also providing a podcast MP3 file available for download on the Vertex website at www.vrtx.com. The conference ID number is 38528491.

The call will be available for replay via telephone commencing February 3, 2011 at 8:00 p.m. ET running through 5:00 p.m. ET on February 10, 2011. The replay phone number for the U.S. and Canada is 800-642-1687. The international replay number is 706-645-9291. The conference ID number is 38528491. Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. ET on February 17, 2011.

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

(VRTX-GEN)

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