



July 28, 2010

Vertex Pharmaceuticals Reports Second Quarter 2010 Financial Results and Highlights Recent Business and Clinical Progress

- Hepatitis C: Rolling submission of New Drug Application underway; data from second pivotal Phase 3 trial - REALIZE - expected in the third quarter of 2010-**
- Cystic Fibrosis: Phase 3 registration program for VX-770 fully enrolled; data expected in first half of 2011-**
- Financial: Vertex ends second quarter with cash position of approximately \$980 million-**

CAMBRIDGE, Mass., Jul 28, 2010 (BUSINESS WIRE) -- [Vertex Pharmaceuticals Incorporated](#) (Nasdaq: VRTX) today provided an update on recent progress in its development programs in hepatitis C virus (HCV) infection, cystic fibrosis (CF) and other diseases and reported consolidated financial results for the quarter ended June 30, 2010.

"We remain on track to complete the New Drug Application submission process for telaprevir later this year and to complete the buildout of our commercial function in advance of the potential launch of telaprevir," said Matthew Emmens, Chairman, President and Chief Executive Officer of Vertex Pharmaceuticals. "In the first half of this year, we established a seasoned commercial leadership team with broad experience in the area of infectious diseases, and we continue to bolster the internal infrastructure needed to support a field-based sales force for telaprevir and other potential future medicines.

"Our Phase 3 registration program in cystic fibrosis is now fully enrolled, positioning us for the planned submission of a New Drug Application for VX-770 in the second half of 2011. There is an urgent need for new and more effective therapies in cystic fibrosis, and we are committed to working toward improving the lives of people affected by this disease.

"As our development programs and commercial efforts advance, we remain focused on the management of our capital structure. We ended the second quarter of 2010 with a cash position of approximately \$980 million, positioning us for continued investment in key activities to help support a successful potential launch for telaprevir," concluded Mr. Emmens.

Recent Clinical Development Progress

Telaprevir Phase 3 Program in Hepatitis C

- Vertex expects efficacy and safety data from the supplemental Phase 3 ILLUMINATE trial to become available in August 2010, followed by efficacy and safety data from the pivotal Phase 3 REALIZE trial in September 2010.
- The ILLUMINATE trial of telaprevir-based regimens is designed to evaluate the comparability of the sustained viral response (SVR), or viral cure, rates between the 24-week and 48-week treatment arms in treatment-naïve people with genotype 1 hepatitis C who achieved undetectable virus levels at weeks 4 and 12 of treatment (eRVR) and who remained in the trial through week 20. Patients who met these criteria were randomized at week 20 to receive either 24 or 48 total weeks of therapy.
- The REALIZE trial is being conducted by Vertex's collaborator Tibotec and is evaluating telaprevir in people with genotype 1 hepatitis C who did not achieve SVR, or a viral cure, with a prior pegylated interferon-based treatment, including difficult-to-treat null responder patients and patients who had a partial response or relapse in prior therapy. This is the only current Phase 3 trial of an investigational therapy for hepatitis C to enroll a difficult-to-treat patient population that includes patients who had a null response to a prior course of pegylated-interferon and ribavirin therapy.
- Data from ILLUMINATE are expected to supplement the data obtained in the two pivotal Phase 3 trials of telaprevir - ADVANCE and REALIZE - as part of the planned New Drug Application (NDA) submission for telaprevir.

Rolling NDA Submission Underway

- Vertex recently submitted the Non-clinical and the Chemistry, Manufacturing and Controls (CMC) sections of its NDA to the U.S. FDA as part of a rolling NDA submission for telaprevir. The company remains on track to complete the NDA submission for telaprevir in the second half of 2010.

Phase 3b Trial to Evaluate Twice-Daily (BID) Compared to Three-Times-Daily Dosing of Telaprevir

- In the fourth quarter of 2010, Vertex and its collaborator Tibotec expect to initiate 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). This trial is expected to enroll approximately 700 treatment-naïve people with genotype 1 hepatitis C in two telaprevir-based treatment arms and will be conducted in the U.S., E.U. and certain other countries. Based on advice from regulatory authorities in the U.S. and E.U., the trial will not include a control arm of pegylated-interferon and ribavirin.

Telaprevir/VX-222 Combination Trial

- Vertex is currently conducting the first clinical trial to evaluate telaprevir dosed in combination with Vertex's lead HCV polymerase inhibitor, VX-222. This Phase 2 proof-of-concept trial is designed to evaluate SVR, or viral cure, rates using multiple 12-week response-guided regimens of telaprevir/VX-222-based combination therapy, including two-drug regimens that contain only telaprevir and VX-222. Vertex expects to obtain on-treatment clinical data from this trial in the second half of 2010.

Phase 3 Registration Program for VX-770

- Three trials of the novel Cystic Fibrosis Transmembrane Conductance Regulator protein (CFTR) potentiator VX-770 are now fully enrolled as part of a global Phase 3 registration program focused on patients with the G551D mutation. These trials include the Phase 3 STRIVE trial in patients aged 12 years and older with the G551D mutation, the Phase 3 ENVISION trial in patients aged six to 11 years with the G551D mutation, and the Phase 2 DISCOVER trial in patients aged 12 and older homozygous for the F508del mutation.
- Data from the Phase 3 registration program of VX-770 are expected in the first half of 2011.

Planned Combination Trial of VX-770 and VX-809

- Vertex expects to initiate a Phase 2a clinical trial that will evaluate combination regimens of VX-809 and VX-770 later this year. The trial will enroll patients who are homozygous for the F508del mutation.

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

- Vertex is currently conducting Phase 2 proof-of-concept clinical trials of the novel caspase-1 inhibitor VX-765 in epilepsy and of the novel Janus kinase 3 (JAK3) inhibitor VX-509 in rheumatoid arthritis (RA).
- Enrollment is complete in the trial of VX-765, and interim data are expected in the second half of 2010. Interim data from the trial of VX-509 are expected in 2011.

Second Quarter Results

For the quarter ended June 30, 2010, the Company's GAAP net loss was \$200.0 million, or \$1.00 per share, including certain charges totaling \$57.5 million, compared to a GAAP net loss for the quarter ended June 30, 2009 of \$171.3 million, or \$0.99 per share, including certain charges totaling \$42.0 million.

The non-GAAP loss, before certain charges, for the quarter ended June 30, 2010 was \$142.5 million, or \$0.71 per share, compared to \$129.3 million, or \$0.75 per share, for the quarter ended June 30, 2009. The increase in the Company's 2010 non-GAAP loss was principally attributable to an increase in total operating expenses as the company prepares for the potential launch of telaprevir and conducts a Phase 3 registration program for VX-770.

Total revenues for the quarter ended June 30, 2010 were \$31.6 million, compared to \$19.1 million for the second quarter of 2009. The increase is primarily attributable to higher collaborative revenues.

Research and development (R&D) expenses for the quarter ended June 30, 2010 were \$155.1 million, compared to \$139.3 million for the second quarter of 2009. The increase primarily reflects greater commercial supply investment for telaprevir.

Sales, general and administrative (SG&A) expenses for the quarter ended June 30, 2010 were \$40.9 million, compared to \$32.5 million for the second 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 June 30, 2010, Vertex had \$979.1 million in cash, cash equivalents and marketable securities.

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. The company is revising its guidance for 2010 GAAP net loss from approximately \$700 million to approximately \$750 million to reflect the timing of certain non-cash expenses and revenues related to the company's 2009 financial transactions and the milestone payments the company is eligible to earn from Janssen.

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 second 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-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, epilepsy, cancer, and pain.

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) the expectation that the company will complete the NDA submission for telaprevir later in the year, (ii) the expectation that safety and efficacy data will be available from REALIZE in September 2010 and from ILLUMINATE in August 2010, (iii) the company remaining on track to complete the buildout of its commercial function in advance of the potential launch of telaprevir, (iv) the company being positioned to submit a New Drug Application for VX-770 in the second half of 2011, (v) the company's cash position positioning it for continued investment in key activities to help support a successful potential launch for telaprevir, (vi) the expectation that the ILLUMINATE data will supplement the data obtained from ADVANCE and REALIZE, (vii) the expectation that a Phase 3b clinical trial to evaluate twice-daily dosing of telaprevir will be initiated in the fourth quarter of 2010 and a Phase 2a clinical trial to evaluate combination regimens of VX-809 and VX-770 will be initiated later this year, (viii) the expected clinical trial designs for the Phase 3b clinical trial of telaprevir and the VX-809/VX-770 clinical trial, (ix) the anticipated timing of receiving clinical data from the Phase 3 registration program of VX-770 and from clinical trials of telaprevir/VX-222, VX-509 and VX-765 and (x) the company's guidance regarding 2010 GAAP and non-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 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 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. The company disclaims any obligation to update the information contained in this press release as new information becomes available.

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

(unaudited)			
Three Months Ended		Six Months Ended	
June 30,		June 30,	
2010	2009	2010	2009

Revenues:				
Royalty revenues	\$ 7,262	\$ 5,917	\$ 13,669	\$ 12,057
Collaborative revenues	24,360	13,147	40,382	30,986
Total revenues	<u>31,622</u>	<u>19,064</u>	<u>54,051</u>	<u>43,043</u>
Costs and expenses:				
Royalty expenses	3,086	3,267	6,453	6,843
Research and development expenses (R&D)	155,082	139,331	298,094	282,912
Sales, general & administrative expenses (SG&A)	40,915	32,526	76,467	61,046
Restructuring expense	2,112	1,107	2,892	3,509
Acquisition-related expenses (Note 2)	---	---	---	7,793
Total costs and expenses	<u>201,195</u>	<u>176,231</u>	<u>383,906</u>	<u>362,103</u>
Loss from operations	<u>(169,573)</u>	<u>(157,167)</u>	<u>(329,855)</u>	<u>(319,060)</u>
Net interest expense (Note 1)	(3,199)	(1,836)	(6,699)	(2,615)
Change in fair value of derivative instruments (Note 1)	(27,234)	---	(28,723)	---
Loss on exchange of convertible subordinated notes (Note 3)	---	(12,294)	---	(12,294)
Net loss	<u>\$ (200,006)</u>	<u>\$ (171,297)</u>	<u>\$ (365,277)</u>	<u>\$ (333,969)</u>
Basic and diluted net loss per common share	\$ (1.00)	\$ (0.99)	\$ (1.83)	\$ (2.03)
Basic and diluted weighted-average number of common shares outstanding	200,397	172,563	199,670	164,258
Non-GAAP Loss and Loss per Common Share Reconciliation	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
GAAP Net Loss	\$ (200,006)	\$ (171,297)	\$ (365,277)	\$ (333,969)
Pro Forma Adjustments:				
Stock-based compensation and executive transition expenses included in R&D	\$ 17,735	\$ 22,162	\$ 32,055	\$ 40,735
Stock-based compensation and executive transition expenses included in SG&A	<u>6,714</u>	<u>6,415</u>	<u>11,727</u>	<u>11,620</u>
Total stock-based compensation and executive transition expenses	\$ 24,449	\$ 28,577	\$ 43,782	\$ 52,355
Expenses related to September 2009 financial transactions (Note 1)	30,936	---	36,008	---
Loss on exchange of convertible subordinated notes (Note 3)	---	12,294	---	12,294
Restructuring expense	2,112	1,107	2,892	3,509
Acquisition-related expenses (Note 2)	---	---	---	7,793
Non-GAAP Loss	<u>\$ (142,509)</u>	<u>\$ (129,319)</u>	<u>\$ (282,595)</u>	<u>\$ (258,018)</u>
Basic and diluted non-GAAP loss per common share	\$ (0.71)	\$ (0.75)	\$ (1.42)	\$ (1.57)

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. In the second quarter of 2010 and the first half of 2010, the Company recorded interest expense of \$3.7 million and \$7.3 million, respectively, related to its secured notes (due 2012) and an additional aggregate expense of \$27.2 million and \$28.7 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.

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.

Condensed Consolidated Balance Sheets Data

(in thousands)
(unaudited)

	June 30, 2010	December 31, 2009
Assets		
Cash, cash equivalents and marketable securities	\$979,145	\$1,284,913
Other current assets	25,410	22,113
Property and equipment, net	60,438	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	10,317	11,068
Total assets	\$1,654,202	\$1,955,488
Liabilities and Stockholders' Equity		
Other liabilities	\$164,104	\$172,273
Accrued restructuring expense	33,924	34,017
Deferred tax liability (Note 2)	160,278	160,278
Deferred revenues	273,496	300,531
Convertible notes (Note 3)	---	32,071
Liabilities related to milestone transactions (Note 1)	195,265	159,972
Stockholders' equity (Note 3)	827,135	1,096,346
Total liabilities and stockholders' equity	\$1,654,202	\$1,955,488
Common shares outstanding (Note 3)	202,533	199,955

Conference Call and Webcast: Second Quarter Financial Results

Vertex Pharmaceuticals will host a conference call and webcast today, Wednesday, July 28, 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/finances. 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. To listen to the call on the telephone, dial (888) 510-1762 (U.S. and Canada) or (719) 457-2647 (International) using conference ID number 1949937. 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 July 28, 2010 at 8:00 p.m. ET running through 5:00 p.m. ET on August 4, 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 1949937. Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. ET on August 11, 2010.

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

(VRTX-GEN)

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