

**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): **July 30, 2012**

**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))

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**Item 2.02. Results of Operations and Financial Condition.**

On July 30, 2012, we issued a press release in which we reported our consolidated financial results for the quarter ended June 30, 2012. 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 July 30, 2012.

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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)





Vertex Pharmaceuticals Incorporated  
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www.vrtx.com

## News Release

### Vertex Reports Second Quarter 2012 Financial Results and Provides Updates on Progress in Research and Development Programs in Hepatitis C and Cystic Fibrosis

*-Second quarter 2012 total revenues of \$418 million, including second quarter 2012 net product revenues of approximately \$328 million for INCIVEK in hepatitis C and \$46 million for KALYDECO in cystic fibrosis; company revises financial guidance for full-year 2012 INCIVEK net revenues-*

*-Cystic Fibrosis: Ongoing label-expansion studies for KALYDECO monotherapy and recent data from study of KALYDECO and VX-809 in combination support goal to help more people with cystic fibrosis; company recently announced European approval of KALYDECO-*

*-Hepatitis C: Positive seven-day viral kinetic data for nucleotide analogue ALS-2200 provide flexibility in the development of multiple all-oral approaches to treatment of hepatitis C, including Phase 2 all-oral studies planned for this year-*

**Cambridge, MA, July 30, 2012** — Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today reported consolidated financial results for the quarter ended June 30, 2012.

Vertex reported total revenues of approximately \$418 million for the second quarter of 2012, including net product revenues of approximately \$328 million from INCIVEK® (telaprevir) and approximately \$46 million from KALYDECO™ (ivacaftor). Royalty revenues related to the sale of INCIVO® in Europe by our collaborator were approximately \$28 million for the second quarter of 2012. In the second quarter of 2012, the company reported GAAP net loss of approximately \$(65) million, or \$(0.31) per share, and non-GAAP net income of approximately \$100 million, or \$0.46 per share. The non-GAAP income excludes charges related to Vertex stock-based compensation expense, charges related to an increase in the fair value of expected future payments under our Alios collaboration and a reserve against the potential for excess

INCIVEK inventory. Vertex also updated financial guidance for full-year 2012 INCIVEK net revenues. The company expects full-year 2012 INCIVEK net revenues to be in the range of \$1.1 billion to \$1.25 billion. Additionally, Vertex today provided updates on a number of ongoing and planned trials in cystic fibrosis, hepatitis C, rheumatoid arthritis and other diseases. In a separate press release issued today, Vertex announced positive viral kinetic data for ALS-2200, a nucleotide analogue in development for the treatment of hepatitis C, which was well-tolerated and showed a median 4.54 log<sub>10</sub> reduction in hepatitis C virus RNA after seven days of dosing with 200 mg of ALS-2200 once daily.

“During the first half of the year, Vertex delivered several important advancements across our broad pipeline. In cystic fibrosis, we obtained U.S. and E.U. approval of KALYDECO earlier than anticipated, and we announced promising data for a combination of VX-809 and KALYDECO that accelerated our plans to begin a pivotal program early next year in people with the most common type of cystic fibrosis. We also announced today the first results for our nucleotide analogue ALS-2200, which enhance our portfolio of potential hepatitis C medicines and provide flexibility in the future development of multiple all-oral treatments for this disease,” said Jeffrey Leiden, M.D., Ph.D., Chair, President and Chief Executive Officer of Vertex.

Dr. Leiden concluded, “Our ability to consistently discover, develop and launch transformative medicines has created significant value for our shareholders. Vertex is positioned for continued leadership in the treatment of hepatitis C and cystic fibrosis, and our efforts to bring forward additional new medicines for other serious diseases are moving forward rapidly.”

#### Cystic Fibrosis (CF)

- **KALYDECO Gains Approval in Europe; Additional Global Launches Planned:** Vertex recently announced that the European Commission approved KALYDECO in the European Union for people with cystic fibrosis ages six and older who have at least one copy of the G551D mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene. An estimated 1,100 people in Europe have this mutation. In addition, KALYDECO is under Priority Review by the Therapeutic Product Directorate (TPD) of Health Canada, and an application for review has been submitted to the Therapeutic Goods Administration (TGA) of Australia.

- **KALYDECO Studies in Other Types of CF:** Vertex recently initiated two Phase 3 trials for people with CF who have certain *CFTR* gene mutations that were not evaluated in previous Phase 3 studies. The first study will enroll people 6 years of age and older who have at least one R117H mutation, and a second study will enroll people 6 years of age and older with at least one non-G551D *CFTR* gating mutation. A third Phase 3 study will be initiated later this year for children with CF aged 2 to 5 years who have at least one gating mutation.

- **CF Combination Studies:** In June, Vertex announced data from a Phase 2 study that evaluated dosing of KALYDECO and VX-809 in combination in people with CF who have one or two copies of the F508del *CFTR* mutation. Based on these data, Vertex plans to initiate a pivotal program in early 2013 to evaluate a combination of KALYDECO and VX-809 in people with two copies of the F508del *CFTR* mutation, pending discussions with regulatory agencies. A Phase 2 study of VX-661, a second *CFTR* corrector, dosed in combination with KALYDECO for people with two copies of the F508del mutation is also ongoing, with final data expected next year.

#### Hepatitis C

- **Global Availability of Telaprevir:** Telaprevir (INCIVEK, INCIVO, TELAVIC®) is now available in more than 25 countries around the world, including countries in North America, Europe, South America and the Asia-Pacific region. Vertex’s collaborator, Janssen, is marketing telaprevir in Europe and

other regions as INCIVO, while Vertex's collaborator Mitsubishi Tanabe Pharma markets this medicine in Japan as TELAVIC.

- **Ongoing Studies to Potentially Expand Use of INCIVEK:** Vertex is evaluating whether treatment with INCIVEK can be effectively reduced to twice-daily (BID) dosing instead of three-times-daily dosing. Data from a pivotal study evaluating BID dosing are expected later this year, and pending the results, Vertex plans to submit this revised dosing schedule to the U.S. Food and Drug Administration (FDA) as part of a supplemental New Drug Application (sNDA). To fulfill post-marketing commitments, Vertex also has trials underway for people co-infected with hepatitis C and HIV, people with recurrent hepatitis C following a liver transplant and African Americans with hepatitis C who were not cured with a prior treatment of pegylated-interferon and ribavirin.
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- **Alios Nucleotide Analogues:** Vertex today announced positive data from a seven-day viral kinetic study of ALS-2200, a nucleotide analogue in development for the treatment of hepatitis C. In the study, there was a median 4.54 log<sub>10</sub> reduction in hepatitis C virus (HCV) RNA in people with genotype 1 hepatitis C who were new to treatment (n=8) after seven days of dosing with 200 mg of ALS-2200 once daily. ALS-2200 was well-tolerated in this study, and no patients discontinued due to adverse events. Based on these data, Vertex plans to begin Phase 2 studies of 12-week all-oral regimens including ALS-2200 in people with genotype 1 hepatitis C, pending discussions with regulatory agencies. Additional details on the viral kinetic data and planned next steps for ALS-2200 are available in a separate press release issued today. Another viral kinetic study is ongoing for a second nucleotide analogue, ALS-2158, with data expected in the next few months.

### Pipeline Programs

- **Phase 2b Study of VX-509 Underway in Rheumatoid Arthritis:** Enrollment is ongoing in the U.S. and Europe in a Phase 2b study of VX-509, an oral, selective JAK3 inhibitor, in people with moderate to severe rheumatoid arthritis (RA). Vertex is also preparing to start additional studies of VX-509 in other immune-mediated inflammatory diseases beginning in early 2013.
- **Phase 2 Study of VX-787 Ongoing in Influenza:** Vertex expects data from an ongoing Phase 2 study of VX-787 in influenza in the second half of 2012. VX-787 is an investigational medicine that is designed to treat influenza A, including recent H1 (pandemic) and H5 (avian) influenza strains.

### Second Quarter 2012 Financial Results

**Total Revenues:** Total revenues were \$418.3 million for the second quarter of 2012, compared with \$114.4 million for the second quarter of 2011. Key components of total revenues for the second quarter 2012 were:

- **Net Product Revenues from INCIVEK:** Net product revenues from INCIVEK were \$327.7 million.
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- **Net Product Revenues from KALYDECO:** Net product revenues from KALYDECO were \$45.5 million.

- **Royalty Revenues:** Vertex recognized \$33.5 million in royalty revenues, including \$28.0 million in INCIVO royalty revenues from our collaborator Johnson and Johnson.

- **Collaborative Revenues:** Vertex recognized \$11.6 million in collaborative revenues.

**Cost of Product Revenues:** Cost of product revenues was \$104.5 million in the second quarter of 2012, including a \$78.0 million charge to reserve against the potential for excess INCIVEK inventory.

**Research and Development (R&D) Expenses:** R&D expenses were \$196.5 million in the second quarter of 2012, including \$19.7 million of Vertex stock-based compensation expense and \$3.7 million in Alios expenses related to the accounting for the collaboration with Vertex, compared to \$173.6 million for the second quarter of 2011, including \$20.5 million of stock-based compensation expense and \$0.5 million in Alios expenses related to the accounting for the collaboration with Vertex. The increase in Vertex's R&D investment is principally due to development activities related to ongoing and planned clinical trials in influenza, RA, hepatitis C and CF.

**Sales, general and administrative (SG&A) expenses:** SG&A expenses were \$117.5 million in the second quarter of 2012, including \$11.5 million of Vertex stock-based compensation expense and \$1.0 million in Alios expenses related to the accounting for the collaboration with Vertex, compared to \$96.7 million for the second quarter of 2011, including \$11.4 million of Vertex stock-based compensation expense and \$0.3 million in Alios expenses related to the accounting for the collaboration with Vertex. This increase reflects the expansion of the company's global commercial organization, costs related to the commercial launch of KALYDECO in the U.S. and launch preparation activities for KALYDECO in Europe and other countries.

**GAAP Net Income (Loss) Attributable to Vertex:** Vertex's GAAP net loss was \$(64.9) million, or \$(0.31) per diluted share, for the second quarter of 2012 compared to the GAAP net loss of \$(174.1) million, or \$(0.85) per share, for the second quarter of 2011.

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**Non-GAAP Net Income (Loss) Attributable to Vertex:** Vertex's non-GAAP net income was \$99.8 million, or \$0.46 per diluted share, for the second quarter of 2012, excluding \$31.2 million in stock-based compensation expense, a \$56.2 million charge related to an increase in the fair value of expected future payments under our Alios collaboration following the positive viral kinetic data announced today and a \$78.0 million charge in cost of product revenues to reserve against the potential for excess INCIVEK inventory. The non-GAAP net loss was \$(136.4) million, or \$(0.67) per share, for the second quarter of 2011.

### 2012 Financial Guidance

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

**Full-Year INCIVEK Revenues:** Vertex today revised guidance for full-year 2012 INCIVEK net revenues. The company expects full-year 2012 INCIVEK net revenues to be in the range of \$1.1 billion to \$1.25 billion. The revised guidance reflects the recent downward trend in the number of patients initiating treatment within the hepatitis C market.

**Total Operating Expenses:** Vertex today reiterated its guidance for 2012 total operating expenses, excluding cost of revenues, stock-based compensation expense and Alios expenses related to the accounting for the collaboration with Vertex, to be in the range of \$1.03 billion to \$1.13 billion. This guidance was initially established on February 2, 2012.

### 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 second quarter and first half 2012 and 2011 net income (loss) excluding stock-based compensation expense, restructuring expense, inventory reserve, any revenues and expenses related to certain September 2009 financial transactions, and any items related to Vertex's collaboration with Alios. 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**  
**Second Quarter and Six Month Results**  
**Consolidated Statements of Operations Data**  
(in thousands, except per share amounts)  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
<b>Revenues:</b>				
Product revenues, net	\$ 373,273	\$ 74,535	\$ 748,648	\$ 74,535
Royalty revenues	33,480	10,010	72,461	16,071
Collaborative revenues	11,552	29,879	35,933	97,480
Total revenues	<u>418,305</u>	<u>114,424</u>	<u>857,042</u>	<u>188,086</u>
<b>Costs and expenses:</b>				
Cost of product revenues	104,549	5,404	130,467	5,404
Royalty expenses	9,874	3,902	23,167	6,568
Research and development expenses (R&D)	196,544	173,604	392,915	332,216
Sales, general & administrative expenses (SG&A)	117,514	96,663	228,660	168,186
Restructuring expense	594	741	954	1,501
Total costs and expenses	<u>429,075</u>	<u>280,314</u>	<u>776,163</u>	<u>513,875</u>
Income (loss) from operations	<u>(10,770)</u>	<u>(165,890)</u>	<u>80,879</u>	<u>(325,789)</u>
Net interest expense (Note 2)	(3,635)	(6,760)	(7,376)	(17,359)
Change in fair value of derivative instruments (Note 2)	—	(2,220)	—	(7,818)
Income (loss) before provision for income taxes	<u>(14,405)</u>	<u>(174,870)</u>	<u>73,503</u>	<u>(350,966)</u>
Provision for income taxes (Note 3)	20,063	24,448	20,095	24,448
Net income (loss)	<u>(34,468)</u>	<u>(199,318)</u>	<u>53,408</u>	<u>(375,414)</u>
Net income (loss) attributable to noncontrolling interest (Note 1)	30,463	(25,249)	26,749	(25,249)
Net income (loss) attributable to Vertex	<u>\$ (64,931)</u>	<u>\$ (174,069)</u>	<u>\$ 26,659</u>	<u>\$ (350,165)</u>
<b>Net income (loss) per share attributable to Vertex common shareholders:</b>				
Basic	\$ (0.31)	\$ (0.85)	\$ 0.13	\$ (1.72)
Diluted	\$ (0.31)	\$ (0.85)	\$ 0.12	\$ (1.72)
<b>Shares used in per share calculations:</b>				
Basic	211,344	204,413	209,681	203,377
Diluted	211,344	204,413	212,957	203,377

**Reconciliation of GAAP to Non-GAAP Financial Information-Second Quarter**  
(in thousands, except per share amounts)  
(unaudited)

Three Months Ended June 30, 2012	GAAP	Adjustments					Non-GAAP
		Alios Transaction	Stock-based Compensation Expense	Inventory Reserve	September 2009 Financial Transactions	Restructuring Expense	
Income (loss) from operations	\$ (10,770)	\$ 4,646	\$ 31,169	\$ 78,000	\$ —	\$ 594	\$ 103,639
Other income and expenses	(3,635)	(179)	—	—	—	—	(3,814)
Income (loss) before provision for income taxes	(14,405)	4,467	31,169	78,000	—	594	99,825

Provision for income taxes	20,063	(21,240)	—	1,239	—	—	62
Net income (loss)	(34,468)	25,707	31,169	76,761	—	594	99,763
Net income attributable to noncontrolling interest (Alios)	30,463	(30,463)	—	—	—	—	—
Net income (loss) attributable to Vertex	<u>\$ (64,931)</u>	<u>\$ 56,170</u>	<u>\$ 31,169</u>	<u>\$ 76,761</u>	<u>\$ —</u>	<u>\$ 594</u>	<u>\$ 99,763</u>
Net income (loss) per diluted share attributable to Vertex common shareholders (Note 4)	\$ (0.31)						\$ 0.46

Three Months Ended June 30, 2011	GAAP	Adjustments					Non-GAAP
		Alios Transaction	Stock-based Compensation Expense	Inventory Reserve	September 2009 Financial Transactions	Restructuring Expense	
Loss from operations	\$ (165,890)	\$ 801	\$ 31,879	\$ —	\$ —	\$ 741	\$ (132,469)
Other income and expenses	(8,980)	—	—	—	5,083	—	(3,897)
Loss before provision for income taxes	(174,870)	801	31,879	—	5,083	741	(136,366)
Provision for income taxes	24,448	(24,448)	—	—	—	—	—
Net loss	(199,318)	25,249	31,879	—	5,083	741	(136,366)
Net loss attributable to noncontrolling interest (Alios)	(25,249)	25,249	—	—	—	—	—
Net loss attributable to Vertex	<u>\$ (174,069)</u>	<u>\$ —</u>	<u>\$ 31,879</u>	<u>\$ —</u>	<u>\$ 5,083</u>	<u>\$ 741</u>	<u>\$ (136,366)</u>
Net loss per diluted share attributable to Vertex common shareholders (Note 4)	\$ (0.85)						\$ (0.67)

**Reconciliation of GAAP to Non-GAAP Financial Information-Six Month**  
(in thousands, except per share amounts)  
(unaudited)

Six Months Ended June 30, 2012	GAAP	Adjustments					Non-GAAP
		Alios Transaction	Stock-based Compensation Expense	Inventory Reserve	September 2009 Financial Transactions	Restructuring Expense	
Income from operations	\$ 80,879	\$ 9,732	\$ 58,796	\$ 78,000	\$ —	\$ 954	\$ 228,361
Other income and expenses	(7,376)	(241)	—	—	—	—	(7,617)
Income before provision for income taxes	73,503	9,491	58,796	78,000	—	954	220,744
Provision for income taxes	20,095	(18,960)	—	1,239	—	—	2,374
Net income	53,408	28,451	58,796	76,761	—	954	218,370
Net income attributable to noncontrolling interest (Alios)	26,749	(26,749)	—	—	—	—	—
Net income attributable to Vertex	<u>\$ 26,659</u>	<u>\$ 55,200</u>	<u>\$ 58,796</u>	<u>\$ 76,761</u>	<u>\$ —</u>	<u>\$ 954</u>	<u>\$ 218,370</u>
Net income per diluted share attributable to Vertex common shareholders (Note 4)	\$ 0.12						\$ 1.01

Six Months Ended June 30, 2011	GAAP	Adjustments					Non-GAAP
		Alios Transaction	Stock-based Compensation Expense	Inventory Reserve	September 2009 Financial Transactions	Restructuring Expense	
Loss from operations	\$ (325,789)	\$ 801	\$ 59,758	\$ —	\$ (50,000)	\$ 1,501	\$ (313,729)
Other income and expenses	(25,177)	—	—	—	18,615	—	(6,562)
Loss before provision for income taxes	(350,966)	801	59,758	—	(31,385)	1,501	(320,291)
Provision for income taxes	24,448	(24,448)	—	—	—	—	—
Net loss	(375,414)	25,249	59,758	—	(31,385)	1,501	(320,291)
Net loss attributable to noncontrolling interest (Alios)	(25,249)	25,249	—	—	—	—	—
Net loss attributable to Vertex	<u>\$ (350,165)</u>	<u>\$ —</u>	<u>\$ 59,758</u>	<u>\$ —</u>	<u>\$ (31,385)</u>	<u>\$ 1,501</u>	<u>\$ (320,291)</u>
Net loss per diluted share attributable to Vertex common shareholders (Note 4)	\$ (1.72)						\$ (1.57)

**Condensed Consolidated Balance Sheets Data**  
(in thousands)  
(unaudited)

	June 30, 2012	December 31, 2011
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 1,223,334	\$ 968,922
Restricted cash and cash equivalents (Alios) (Note 1)	56,024	51,878
Accounts receivable, net	185,618	183,135
Inventories	87,805	112,430
Other current assets	40,524	14,889
Property and equipment, net	272,561	133,176
Restricted cash	34,090	34,090
Intangible assets (Note 3)	663,500	663,500
Goodwill (Note 3)	30,992	30,992

Other non-current assets	10,408	11,268
Total assets	<u>\$ 2,604,856</u>	<u>\$ 2,204,280</u>
<b>Liabilities and Shareholders' Equity</b>		
Other liabilities	\$ 536,034	\$ 405,616
Accrued restructuring expense	24,830	26,313
Deferred tax liability (Note 3)	263,017	243,707
Deferred revenues	137,368	163,132
Convertible notes (due 2015)	400,000	400,000
Noncontrolling interest (Alios) (Note 1)	205,834	178,669
Shareholders' equity (Vertex)	1,037,773	786,843
Total liabilities and shareholders' equity	<u>\$ 2,604,856</u>	<u>\$ 2,204,280</u>
Common shares outstanding	215,435	209,304

**Note 1:** The company has consolidated the financial statements of its collaborator Alios BioPharma, Inc., as of June 30, 2012 and December 31, 2011, for the three and six months ended June 30, 2012, and for the period from June 13, 2011 through June 30, 2011. The company's interest and obligations with respect to Alios' assets and liabilities are limited to those accorded to the company in its collaboration agreement with Alios. Restricted cash and cash equivalents (Alios) reflects Alios' cash and cash equivalents, which Vertex does not have any interest in and which will not be used to fund the collaboration. Increases (decreases) in the fair value of contingent milestone and royalty payments result in gains (losses) attributable to the noncontrolling interest (Alios), which decrease (increase) net income attributable to Vertex on the Consolidated Statements of Operations Data.

**Note 2:** In the first half of 2011, a portion of the collaborative revenues, the change in fair value of derivative instruments and a portion of the net interest expense reflected in the Consolidated Statements of Operations Data relate to two financial transactions that the company entered into in September 2009 relating to milestone payments under the company's collaboration agreement with Janssen Pharmaceutica, N.V. In the first half of 2011, the company earned \$50.0 million in milestone payments from its collaborator, Janssen, which are reflected in total collaborative revenues in the Consolidated Statements of Operations Data.

**Note 3:** 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 and the company's collaboration agreement with Alios in June 2011.

**Note 4:** Shares used in Non-GAAP net income (loss) per diluted share attributable to Vertex common shareholders were 224,124,000 and 204,413,000 for the three months ended June 30, 2012 and 2011, respectively, and 221,694,000 and 203,377,000 for the six months ended June 30, 2012 and 2011, respectively.

## About Vertex

Vertex creates new possibilities in medicine. Our team discovers, develops and commercializes 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, rheumatoid arthritis, epilepsy and other life-threatening diseases.

Founded more than 20 years ago in Cambridge, Mass., we now have ongoing worldwide research programs and sites in the U.S., U.K. and Canada. Today, Vertex has more than 2,000 employees around the world, and *Science* magazine named Vertex number one on its 2011 list of Top Employers in the life sciences.

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

## INDICATION AND IMPORTANT SAFETY INFORMATION FOR KALYDECO

KALYDECO (ivacaftor) is indicated for the treatment of cystic fibrosis (CF) in patients age 6 and older who have a G551D mutation in the *CFTR* gene.

KALYDECO is not effective in patients with CF who are homozygous for the *F508del* mutation in the *CFTR* gene. KALYDECO has not been studied in other populations of patients with CF.

Therefore, use of KALYDECO in these patients is not recommended.

KALYDECO is contraindicated in any patient with hypersensitivity to the active substance or to any of the excipients.

Moderate elevations in liver function tests (transaminases) are common in subjects with CF. Overall, the incidence and clinical features of transaminase elevations in clinical trials was similar between subjects in the ivacaftor and placebo treatment groups. In the subset of patients with a medical history of elevated transaminases, increases have been reported more frequently in patients receiving KALYDECO compared to placebo. Therefore, liver function tests are recommended prior to initiating KALYDECO, every 3 months during the first year of treatment, and annually thereafter. Patients who develop unexplained increased transaminase levels during treatment should be closely monitored until the abnormalities resolve and consideration should be given to the continuation of treatment after assessment of the individual benefits and risks.

Ivacaftor is a substrate of CYP3A4 and CYP3A5 isoenzymes. Medicinal products that inhibit or induce CYP3A activity, may impact the pharmacokinetics of ivacaftor. Ivacaftor is a weak CYP3A inhibitor and may modify the pharmacokinetics of medicinal products metabolized through the CYP3A system. *In vitro* studies indicated that ivacaftor has the potential to inhibit P-glycoprotein (P-gp) and CYP2C9. The dose of KALYDECO must be adjusted when

concomitantly used with potent and moderate CYP3A inhibitors. Exposure to ivacaftor is reduced by the concomitant use of CYP3A inducers, therefore potentially resulting in loss of efficacy of KALYDECO.

The most common adverse reactions in patients treated with KALYDECO were abdominal pain (stomach ache), diarrhea, dizziness, rash, upper respiratory tract reactions (including common cold, nasal congestion, redness of the throat, sore throat, runny nose, sinus congestion, and nose and throat inflammation), headache and bacteria in sputum. Two patients reported a serious adverse reaction of abdominal pain.

Please see full U.S. Prescribing Information for KALYDECO at [www.KALYDECO.com](http://www.KALYDECO.com).

## **INDICATION AND IMPORTANT SAFETY INFORMATION FOR INCIVEK**

### **Indication**

INCIVEK® (telaprevir) is a prescription medicine used with the medicines peginterferon alfa and ribavirin to treat chronic (lasting a long time) hepatitis C genotype 1 infection in adults with stable liver problems, who have not been treated before or who have failed previous treatment. It is not known if INCIVEK is safe and effective in children under 18 years of age.

### **Important Safety Information**

INCIVEK should always be taken in combination with peginterferon alfa and ribavirin. Ribavirin may cause birth defects or death of an unborn baby. Therefore, a patient should not take INCIVEK combination treatment if she is pregnant or may become pregnant, or if he is a man with a sexual partner who is pregnant. Patients must use two forms of effective birth control during treatment and for the 6 months after treatment with these medicines. Hormonal forms of birth control, including birth control pills, vaginal rings, implants or injections, may not work during treatment with INCIVEK.

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INCIVEK and other medicines can affect each other and can also cause side effects that can be serious or life threatening. There are certain medicines patients cannot take with INCIVEK combination treatment. Patients should tell their healthcare providers about all the medicines they take, including prescription and non-prescription medicines, vitamins and herbal supplements.

INCIVEK can cause serious side effects including skin reactions, rash and anemia that can be severe. The most common side effects of INCIVEK include itching, nausea, diarrhea, vomiting, anal or rectal problems, taste changes and tiredness. There are other possible side effects of INCIVEK, and side effects associated with peginterferon alfa and ribavirin also apply to INCIVEK combination treatment. Patients should tell their healthcare providers about any side effect that bothers them or doesn't go away.

Please see full Prescribing Information for INCIVEK including the Medication Guide, available at [www.INCIVEK.com](http://www.INCIVEK.com).

### **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, without limitation, Dr. Leiden's statements in the second and third paragraphs of the press release, the information provided in the two paragraphs following the statement "This section contains forward-looking guidance about the financial outlook for Vertex Pharmaceuticals" and statements regarding (i) ongoing label-expansion studies and recent data from a study of KALYDECO and VX-809 in combination supporting Vertex's goal to help more people with cystic fibrosis; (ii) the company's flexibility in the development of multiple all-oral approaches to treatment of hepatitis C; (iii) the expectation that full-year 2012 INCIVEK net revenues will be in the range of \$1.1 billion to \$1.25 billion; (iv) information regarding the company's ongoing and planned studies, including studies to evaluate KALYDECO, KALYDECO in combination with VX-809, INCIVEK, ALS-2200, VX-509 and VX-787; (v) expectations regarding the availability of data from ongoing studies, including the viral kinetic study of ALS-2158, the ongoing Phase 2 study of VX-661, the ongoing Phase 2 study of VX-787 and the BID study of INCIVEK and (vi) the company's plans, pending results from the BID study, to submit an sNDA for INCIVEK. 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 the company's expectations regarding its 2012 INCIVEK net revenues and/or operating expenses may be incorrect (including because one or more of the company's assumptions underlying its revenue or expense expectations may not be realized), that the outcomes of Vertex's ongoing and planned clinical studies may not be favorable, that the initiation of planned studies may be delayed or prevented, 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). Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

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### **Conference Call Information**

Vertex will host a conference call and webcast today, July 30, 2012 at 5:00 p.m. ET to review financial results and recent developments. The conference call will be webcast live, and a link to the webcast may be accessed from the 'Events & Presentations' page of Vertex's website at [www.vrtx.com](http://www.vrtx.com).

To listen to the live call on the telephone, dial 1-877-250-8889 (United States and Canada) or 1-720-545-0001 (International). To ensure a timely connection, it is recommended that users register at least 15 minutes prior to the scheduled webcast.

The conference ID number for the live call and replay is 10939223.

The call will be available for replay via telephone commencing July 30, 2012 at 8:00 p.m. ET running through 5:00 p.m. ET on August 13, 2012. The replay phone number for the United States and Canada is 1-855-859-2056. The international replay number is 1-404-537-3406.

Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. ET on August 6, 2012. Vertex is also providing a podcast MP3 file available for download on the Vertex website at [www.vrtx.com](http://www.vrtx.com).



(VRTX-GEN)

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