Gilead Sciences Announces Second Quarter 2012 Financial Results

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- Product Sales of $2.32 Billion, Up 14 Percent over Second Quarter 2011 -

- Antiviral Product Sales of $2.01 Billion, Up 14 Percent over Second Quarter of 2011 -

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 26, 2012-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the quarter ended June 30, 2012. Total revenues for the second quarter of 2012 increased 13 percent to $2.41 billion, from $2.14 billion for the second quarter of 2011. Net income for the second quarter of 2012 was $711.6 million, or $0.91 per diluted share compared to $746.2 million, or $0.93 per diluted share for the second quarter of 2011. Non-GAAP net income for the second quarter of 2012, which excludes acquisition-related, restructuring and stock-based compensation expenses, was $767.3 million, or $0.99 per diluted share compared to $797.7 million, or $1.00 per diluted share for the second quarter of 2011.

Product Sales

Product sales increased 14 percent to $2.32 billion for the second quarter of 2012 compared to $2.04 billion for the second quarter of 2011. This increase in product sales was driven primarily by Gilead's antiviral franchise, resulting from increased sales of Atripla® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) and Complera®/Eviplera® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg) which was launched in the U.S. in August 2011.

Antiviral Franchise

Antiviral product sales increased 14 percent to $2.01 billion for the second quarter of 2012, up from $1.76 billion for the second quarter of 2011, reflecting sales growth of 21 percent in the U.S. and 3 percent in Europe. In the U.S., antiviral product sales for the second quarter of 2012 reflect the benefit of purchases by certain state AIDS Drug Assistance Programs (ADAPs) in excess of demand.

- ***Atripla***
  Sales of Atripla increased 10 percent to $904.0 million for the second quarter of 2012, up from $822.0 million for the second quarter of 2011, reflecting sales growth of 12 percent in the U.S. and 5 percent in Europe.

- ***Truvada***
  Sales of Truvada increased 10 percent to $785.9 million for the second quarter of 2012, up from $711.3 million for the second quarter of 2011, reflecting sales growth of 18 percent in the U.S. and 2 percent in Europe.

- ***Viread***
  Sales of Viread® (tenofovir disoproxil fumarate) increased 16 percent to $215.4 million for the second quarter of 2012, up from $185.7 million for the second quarter of 2011, reflecting sales growth of 27 percent in the U.S. partially offset by a decrease of 2 percent in Europe.

- ***Complera/Eviplera***
  Sales of Complera/Eviplera increased 40 percent to $72.9 million during the second quarter of 2012 from $52.2 million for the first quarter of 2012. Complera was approved in the U.S. in August 2011, and Eviplera was approved in the European Union in November 2011.

Letairis

Sales of Letairis® (ambrisentan) increased 38 percent to $101.6 million for the second quarter of 2012, up from $73.6 million for the second quarter of 2011.

Ranexa

Sales of Ranexa® (ranolazine) increased 11 percent to $95.6 million for the second quarter of 2012, up from $86.1 million for the second quarter of 2011.

Other Products

Sales of other products were $111.8 million for the second quarter of 2012 compared to $115.5 million for the second quarter of 2011 and included AmBisome® (amphotericin B) liposome for injection and Cayston® (aztreonam for inhalation solution).

Royalty, Contract and Other Revenues

Royalty, contract and other revenues were $83.9 million for the second quarter of 2012, down 14 percent from $97.7 million for the second quarter of 2011, due primarily to lower Tamiflu royalties from F. Hoffmann-La Roche Ltd., partially offset by an increase in other royalty revenues.

Research and Development

Research and development (R&D) expenses for the second quarter of 2012 were $396.2 million compared to $282.4 million for the second quarter of 2011. Non-GAAP R&D expenses for the second quarter of 2012, which exclude acquisition-related, restructuring and stock-based compensation expenses, were $371.4 million compared to $262.6 million for the second quarter of 2011. The increase in non-GAAP R&D expenses was due primarily to the continued advancement of Gilead's product pipeline, particularly in the liver disease and oncology franchises.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses in the second quarter of 2012 were $332.5 million compared to $304.3 million for the second quarter of 2011. Non-GAAP SG&A expenses for the second quarter of 2012, which exclude acquisition-related, restructuring and stock-based compensation expenses, were $298.7 million compared to $276.4 million for the second quarter of 2011. The increase in non-GAAP SG&A expenses was due primarily to increased expenses to support the ongoing growth of Gilead's business.

Interest Expense and Other Income (Expense), Net

Interest expense for the second quarter of 2012 was $88.4 million compared to $46.1 million for the second quarter of 2011. The increase was due primarily to the additional debt issued in connection with the acquisition of Pharmasset Inc. (Pharmasset) in the first quarter of 2012. Other income (expense), net for the second quarter of 2012 was a net expense of $1.1 million compared to net income of $12.0 million in the second quarter of 2011. The change was due primarily to decreased interest income from lower cash, cash equivalents and marketable securities.

Net Foreign Currency Exchange Impact

The net foreign currency exchange impact on second quarter 2012 product sales and pre-tax earnings was an unfavorable $31.7 million and $17.4 million, respectively, compared to the second quarter of 2011.

Cash, Cash Equivalents and Marketable Securities

As of June 30, 2012, Gilead had $2.27 billion of cash, cash equivalents and marketable securities compared to $9.96 billion as of December 31, 2011. The decrease was due to the acquisition of Pharmasset in the first quarter of 2012. Gilead generated $1.74 billion of operating cash flow during the first six months of 2012 including $1.29 billion generated in the second quarter of 2012 driven by the collection of $460 million of past due accounts receivable in Spain contributing to a 15 day reduction in days sales outstanding.

Corporate Highlights

Antiviral Franchise

In April, Gilead announced interim data from the Phase 2 ATOMIC study examining a 12-week course of treatment with the investigational once-daily nucleotide GS-7977 plus pegylated interferon and ribavirin (RBV) in treatment-naïve patients with genotype 1 chronic hepatitis C virus (HCV) infection. The study found that 90 percent of patients achieved a 12-week sustained virologic response (SVR12), defined as maintaining undetectable viral load 12 weeks after the completion of therapy. These findings were presented at the 47th Annual Meeting of the European Association for the Study of the Liver (EASL) in Barcelona, Spain.

Also in April, Gilead announced interim data from the Phase 2 ELECTRON study examining GS-7977 plus RBV in treatment-naïve patients with genotype 1 chronic HCV infection. Of the 25 patients who completed 12 weeks of treatment, 88 percent achieved a four-week sustained virologic response (SVR4). Three patients experienced viral relapse. These findings were presented at EASL.

Lastly in April, Gilead announced interim results from the Phase 2 QUANTUM study examining a 12-week duration of GS-7977 plus RBV in treatment-naïve patients. Twenty-five patients were randomized to the 12-week treatment arm: 19 genotype 1 patients; four genotype 3 patients; and two genotype 2 patients. At the four-week post-treatment time period, data were available for 17 genotype 1 patients. Of these, 59 percent achieved SVR4 and 41 percent experienced viral relapse. Additionally, seven of the patients who reached the eight-week post-treatment time period, and who achieved SVR4, remained HCV RNA undetectable.

In May, Gilead announced that the Antiviral Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted to support approval of once-daily oral Truvada to reduce the risk of HIV-1 infection among uninfected adults, an HIV prevention strategy called pre-exposure prophylaxis or PrEP. The Antiviral Drugs Advisory Committee also voted 13 to one in support of approval of Quad, a complete single tablet regimen of elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil fumarate, for the treatment of HIV-1 infection in treatment-naïve adults.

Also in May, Gilead announced that the Marketing Authorisation Application (MAA) for cobicistat had been validated by the European Medicines Agency (EMA). Cobicistat is Gilead's pharmacoenhancing or “boosting” agent that increases blood levels of certain commercially available protease inhibitors, including atazanavir and darunavir, in order to enable once-daily dosing. In June, Gilead submitted a New Drug Application (NDA) to the FDA for marketing approval of cobicistat.

In June, Gilead announced that its NDA and MAA for elvitegravir, an integrase inhibitor for the treatment of HIV-1 infection in treatment-experienced patients, had been submitted to the FDA and validated by the EMA, respectively. Elvitegravir, a component of Gilead's once-daily Quad single tablet regimen, is currently under U.S. and European regulatory review for treatment-naïve adult patients.

Oncology Franchise

In May, Gilead announced that the first patient had been dosed in a Phase 3 clinical trial evaluating the efficacy and safety of GS-1101 in combination with rituximab in previously treated chronic lymphocytic leukemia patients. GS-1101 is an investigational, first-in-class specific inhibitor of the phosphoinositide-3 kinase delta isoform.

Conference Call

At 4:15 p.m. Eastern Time today, Gilead's management will host a conference call and a simultaneous webcast to discuss results from its second quarter 2012, provide an update on Gilead's full year 2012 guidance, as well as provide a general business update. To access the webcast live via the internet, please connect to the company's website at www.gilead.com 15 minutes prior to the conference call to ensure adequate time for any software download that may be needed to hear the webcast. Alternatively, please call 1-866-783-2140 (U.S.) or 1-857-350-1599 (international) and dial the participant passcode 60422538 to access the call.

A replay of the webcast will be archived on the company's website for one year, and a phone replay will be available approximately two hours following the call through July 29, 2012. To access the phone replay, please call 1-888-286-8010 (U.S.) or 1-617-801-6888 (international) and dial the participant passcode 39788296.

About Gilead

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Asia Pacific.

Non-GAAP Financial Information

Gilead has presented certain financial information in accordance with U.S. GAAP (GAAP) and also on a non-GAAP basis for the second quarter of 2012 and 2011. Management believes this non-GAAP information is useful for investors, taken in conjunction with Gilead's GAAP financial statements, because management uses such information internally for its operating, budgeting and financial planning purposes. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of Gilead's operating results as reported under U.S. GAAP. A reconciliation between GAAP and non-GAAP financial information is provided in the table on page 7.

Forward-looking Statements

Statements included in this press release that are not historical in nature are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Gilead cautions readers that forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include: Gilead's ability to achieve its anticipated full year 2012 financial results, including the possibility that its full year 2012 guidance may be revised at a later date; Gilead's ability to sustain growth in revenues for its antiviral, cardiovascular and respiratory franchises; unpredictable variability of Tamiflu royalties and the strong relationship between this royalty revenue and global pandemic planning and supply; the availability of funding for state ADAPs and their ability to purchase at levels to support the number of patients that rely on ADAPs; continued fluctuations in ADAP purchases driven by federal and state grant cycles which may not mirror patient demand and may cause fluctuations in Gilead's earnings; the possibility that the proportion of patients who maintain a sustained virologic response 4 and 12 weeks post-treatment will not be as favorable as the sustained virologic response rates reported in this press release and the possibility of unfavorable results from additional arms of the ATOMIC, ELECTRON and QUANTUM studies and subsequent clinical trials involving GS-7977 and RBV and GS-7977 plus pegylated interferon and RBV; the levels of inventory held by wholesalers and retailers which may cause fluctuations in Gilead's earnings; Gilead's ability to submit NDAs and MAAs for new product candidates in the timelines currently anticipated, including GS-7977 for the treatment of HCV; Gilead's ability to receive regulatory approvals in a timely manner or at all, for new and current products, including Quad, cobicistat or elvitegravir; Gilead's ability to successfully commercialize its products, including Complera/Eviplera; Gilead's ability to successfully develop its respiratory, cardiovascular and oncology franchises; safety and efficacy data from clinical studies may not warrant further development of Gilead's product candidates, including GS-7977 and GS-1101; the potential for additional austerity measures in European countries that may increase the amount of discount required on Gilead's products; fluctuations in the foreign exchange rate of the U.S. dollar that may cause an unfavorable foreign currency exchange impact on Gilead's future revenues and pre-tax earnings; Gilead's ability to advance Pharmasset's product pipeline or develop an all-oral antiviral regimen for HCV; and other risks identified from time to time in Gilead's reports filed with the U.S. Securities and Exchange Commission. In addition, Gilead makes estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. Gilead bases its estimates on historical experience and on various other market-specific and other relevant assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates. You are urged to consider statements that include the words may, will, would, could, should, might, believes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal, or the negative of those words or other comparable words to be uncertain and forward-looking. Gilead directs readers to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2012 and other subsequent disclosure documents filed with the Securities and Exchange Commission and press releases. Gilead claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information on Gilead Sciences, Inc., please visit www.gilead.com or call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235).

GILEAD SCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenues:				
Product sales	$2,321,240	$2,039,588	$4,529,582	$3,903,166
Royalty, contract and other revenues	83,946	97,665	158,053	160,181
Total revenues	2,405,186	2,137,253	4,687,635	4,063,347
Costs and expenses:				
Cost of goods sold	617,345	533,863	1,198,276	1,007,974
Research and development	396,244	282,403	854,455	536,849
Selling, general and administrative	332,505	304,269	775,626	599,837
Total costs and expenses	1,346,094	1,120,535	2,828,357	2,144,660
Income from operations	1,059,092	1,016,718	1,859,278	1,918,687
Interest expense	(88,418)	(46,107)	(185,688)	(87,323)
Other income (expense), net	(1,075)	11,978	(35,160)	25,810
Income before provision for income taxes	969,599	982,589	1,638,430	1,857,174
Provision for income taxes	263,525	240,130	494,825	467,412
Net income	706,074	742,459	1,143,605	1,389,762
Net loss attributable to noncontrolling interest	5,490	3,768	9,915	7,606
Net income attributable to Gilead	$711,564	$746,227	$1,153,520	$1,397,368
Net income per share attributable to Gilead common stockholders - basic	$0.94	$0.95	$1.52	$1.77
Net income per share attributable to Gilead common stockholders - diluted	$0.91	$0.93	$1.48	$1.73
Shares used in per share calculation - basic	756,951	784,807	756,619	790,430
Shares used in per share calculation - diluted	780,506	800,800	779,246	806,462

GILEAD SCIENCES, INC.

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION

(unaudited)

(in thousands, except percentages and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Cost of goods sold reconciliation:				
GAAP cost of goods sold	$617,345	$533,863	$1,198,276	$1,007,974

Stock-based compensation expenses	(2,119)	(2,887)	(4,220)	(5,531)
Acquisition related-amortization of purchased intangibles	(15,836)	(17,408)	(31,672)	(34,815)
Non-GAAP cost of goods sold	$599,390	$513,568	$1,162,384	$967,628
Product gross margin reconciliation:				
GAAP product gross margin	73.5 %	73.9 %	73.6 %	74.2 %
Stock-based compensation expenses	0.1 %	0.1 %	0.1 %	0.1 %
Acquisition related-amortization of purchased intangibles	0.7 %	0.9 %	0.7 %	0.9 %
Non-GAAP product gross margin[(1)]	74.3 %	74.9 %	74.4 %	75.3 %
Research and development expenses reconciliation:				
GAAP research and development expenses	$396,244	$282,403	$854,455	$536,849
Stock-based compensation expenses	(20,355)	(19,420)	(138,978)	(36,140)
Restructuring expenses	(1,576)	(767)	(7,090)	(554)
Acquisition related-transaction costs	(345)	—	(345)	(446)
Acquisition related-contingent consideration remeasurement	(2,570)	418	(5,306)	418
Non-GAAP research and development expenses	$371,398	$262,634	$702,736	$500,127
Selling, general and administrative expenses reconciliation:				
GAAP selling, general and administrative expenses	$332,505	$304,269	$775,626	$599,837
Stock-based compensation expenses	(25,929)	(27,818)	(147,873)	(57,924)
Restructuring expenses	(7,251)	353	(10,407)	(1,666)
Acquisition related-transaction costs	(594)	(365)	(10,874)	(743)
Non-GAAP selling, general and administrative expenses	$298,731	$276,439	$606,472	$539,504
Operating margin reconciliation:				
GAAP operating margin	44.0 %	47.6 %	39.7 %	47.2 %
Stock-based compensation expenses	2.0 %	2.3 %	6.2 %	2.5 %
Restructuring expenses	0.4 %	0.0 %	0.4 %	0.1 %
Acquisition related-transaction costs	— %	0.0 %	0.2 %	0.0 %
Acquisition related-amortization of purchased intangibles	0.7 %	0.8 %	0.7 %	0.9 %
Acquisition related-contingent consideration remeasurement	0.1 %	—	0.1 %	0.0 %
Non-GAAP operating margin[(1)]	47.2 %	50.7 %	47.3 %	50.6 %
Interest expense reconciliation:				
GAAP interest expense	$(88,418)	$(46,107)	$(185,688)	$(87,323)
Acquisition related-transaction costs	—	—	7,333	—
Non-GAAP interest expense	$(88,418)	$(46,107)	$(178,355)	$(87,323)
Net income attributable to Gilead reconciliation:				
GAAP net income attributable to Gilead, net of tax	$711,564	$746,227	$1,153,520	$1,397,368
Stock-based compensation expenses	35,236	37,915	264,840	74,529
Restructuring expenses	6,426	324	12,772	1,661
Acquisition related-transaction costs	651	365	13,542	1,189
Acquisition related-amortization of purchased intangibles	11,529	13,170	23,119	26,053
Acquisition related-contingent consideration remeasurement	1,871	(313)	3,873	(313)
Non-GAAP net income attributable to Gilead, net of tax	$767,277	$797,688	$1,471,666	$1,500,487
Diluted earnings per share reconciliation:				
GAAP diluted earnings per share	$0.91	$0.93	$1.48	$1.73

Stock-based compensation expenses	0.05	0.05	0.34	0.09
Restructuring expenses	0.01	—	0.02	—
Acquisition related-transaction costs	—	0.00	0.02	0.00
Acquisition related-amortization of purchased intangibles	0.01	0.02	0.03	0.03
Acquisition related-contingent consideration remeasurement	0.00	(0.00)	—	(0.00)
Non-GAAP diluted earnings per share[(1)]	$0.99	$1.00	$1.89	$1.87
Shares used in per share calculation (diluted) reconciliation:				
GAAP shares used in per share calculation (diluted)	780,506	800,800	779,246	806,462
Share impact of current stock-based compensation rules	(1,573)	(2,010)	(1,671)	(1,993)
Non-GAAP shares used in per share calculation (diluted)	778,933	798,790	777,575	804,469
Non-GAAP adjustment summary:				
Cost of goods sold adjustments	$17,955	$20,295	$35,892	$40,346
Research and development expenses adjustments	24,846	19,769	151,719	36,722
Selling, general and administrative expenses adjustments	33,774	27,830	169,154	60,333
Interest expense adjustments	—	—	7,333	—
Total non-GAAP adjustments before tax	76,575	67,894	364,098	137,401
Income tax effect	(20,862)	(16,433)	(45,952)	(34,282)
Total non-GAAP adjustments after tax	$55,713	$51,461	$318,146	$103,119

Note:
(1) Amounts may not sum due to rounding

GILEAD SCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2012 (unaudited)	**December 31, 2011 (Note 1)**
Cash, cash equivalents and marketable securities	$2,271,674	$9,963,972
Accounts receivable, net	1,702,818	1,951,167
Inventories	1,603,401	1,389,983
Property, plant and equipment, net	811,799	774,406
Intangible assets, net	11,751,191	1,062,864
Goodwill	1,078,919	1,004,102
Other assets	1,282,148	1,156,640
Total assets	$20,501,950	$17,303,134
Current liabilities	$4,986,674	$2,514,790
Long-term liabilities	7,431,889	7,920,995
Stockholders' equity (Note 2)	8,083,387	6,867,349
Total liabilities and stockholders' equity	$20,501,950	$17,303,134

Notes:
(1) Derived from the audited consolidated financial statements as of December 31, 2011.
(2) As of June 30, 2012, there were 756,153 shares of common stock issued and outstanding.

GILEAD SCIENCES, INC.

PRODUCT SALES SUMMARY

(unaudited)

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	**2011**	**2012**	**2011**
Antiviral products:				
Atripla – U.S.	$570,835	$510,237	$1,132,879	$973,004
Atripla – Europe	280,125	267,153	550,821	520,210
Atripla – Other International	53,063	44,602	107,919	73,290
	904,023	821,992	1,791,619	1,566,504
Truvada – U.S.	393,013	334,064	766,339	654,177
Truvada – Europe	328,814	322,007	650,690	621,163
Truvada – Other International	64,106	55,230	127,167	109,072
	785,933	711,301	1,544,196	1,384,412
Viread – U.S.	102,112	80,228	183,768	152,708
Viread – Europe	84,108	86,123	168,993	162,135
Viread – Other International	29,194	19,366	54,346	39,269
	215,414	185,717	407,107	354,112
Complera / Eviplera – U.S.	65,004	—	113,643	—
Complera / Eviplera – Europe	7,198	—	10,465	—
Complera / Eviplera – Other International	707	—	981	—
	72,909	—	125,089	—
Hepsera – U.S.	8,172	14,765	20,981	28,639
Hepsera – Europe	15,420	20,582	29,385	42,070
Hepsera – Other International	2,599	3,309	5,122	6,043
	26,191	38,656	55,488	76,752
Emtriva – U.S.	4,770	3,914	8,863	7,816
Emtriva – Europe	1,741	1,705	3,552	3,390
Emtriva – Other International	1,302	1,113	2,175	2,102
	7,813	6,732	14,590	13,308
Total Antiviral products – U.S.	1,143,906	943,208	2,226,473	1,816,344
Total Antiviral products – Europe	717,406	697,570	1,413,906	1,348,968
Total Antiviral products – Other International	150,971	123,620	297,710	229,776
	2,012,283	1,764,398	3,938,089	3,395,088
AmBisome	83,653	88,625	168,417	167,131
Letairis	101,634	73,637	188,922	135,811
Ranexa	95,555	86,077	178,756	154,370
Other products	28,115	26,851	55,398	50,766
	308,957	275,190	591,493	508,078

Total product sales	$2,321,240	$2,039,588	$4,529,582	$3,903,166

Source: Gilead Sciences, Inc.

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