Gilead Sciences Announces First Quarter 2014 Financial Results

April 22, 2014 4:03 PM ET

- Product Sales of $4.87 billion -

- Sovaldi Sales of $2.27 billion -

- Non-GAAP EPS of $1.48 per share -

- Reiterates Full Year 2014 Guidance -

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 22, 2014-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the quarter ended March 31, 2014. Total revenues for the first quarter of 2014 increased to $5.00 billion from $2.53 billion for the first quarter of 2013. Product sales increased to $4.87 billion for the first quarter of 2014 compared to $2.39 billion for the first quarter of 2013. Net income for the first quarter of 2014 was $2.23 billion, or $1.33 per diluted share compared to $722.2 million, or $0.43 per diluted share for the first quarter of 2013. Non-GAAP net income for the first quarter of 2014, which excludes acquisition-related, restructuring and stock-based compensation expenses, was $2.49 billion, or $1.48 per diluted share compared to $801.9 million, or $0.48 per diluted share for the first quarter of 2013.

	Three Months Ended March 31,	
(In thousands, except per share amounts)	**2014**	**2013**
Product sales	$ 4,870,974	$ 2,393,568
Royalty, contract and other revenues	127,982	138,067
Total revenues	$ 4,998,956	$ 2,531,635
Net income attributable to Gilead	$ 2,227,410	$ 722,186
Non-GAAP net income attributable to Gilead	$ 2,487,809	$ 801,943
Diluted EPS	$ 1.33	$ 0.43
Non-GAAP diluted EPS	$ 1.48	$ 0.48

Product Sales

Compared to the first quarter of 2013, U.S. product sales for the first quarter of 2014 increased to $3.63 billion from $1.40 billion and Europe product sales increased to $1.02 billion from $818.3 million.

Antiviral Product Sales

Antiviral product sales increased to $4.51 billion for the first quarter of 2014, up from $2.06 billion for the first quarter of 2013 largely due to sales of Sovaldi® (sofosbuvir 400 mg), which launched in December 2013, and increases in sales of Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) and Complera/Eviplera® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg). This increase was partially offset by a decrease in wholesaler and sub-wholesaler inventories in the United States associated primarily with our HIV products, which also impacted antiviral product sales in the first quarter of 2014 compared to the fourth quarter of 2013.

	Three Months Ended March 31,		
(In thousands, except percentages)	**2014**	**2013**	**% Change**

Antiviral product sales	$ 4,508,497	$ 2,061,078	119	%
Sovaldi	2,274,349	—	—	%
Atripla	779,594	877,073	(11)	%
Truvada	759,700	700,242	8	%
Complera/Eviplera	250,733	148,189	69	%
Stribild	215,271	92,148	134	%
Viread	210,625	210,332	—	%

Cardiovascular Product Sales

Cardiovascular product sales increased to $234.5 million for the first quarter of 2014, up from $214.4 million for the first quarter of 2013 primarily driven by strong Ranexa® (ranolazine) sales.

	Three Months Ended March 31,			
(In thousands, except percentages)	**2014**	**2013**	**% Change**	
Cardiovascular product sales	$ 234,503	$ 214,393	9	%
Letairis	122,885	118,107	4	%
Ranexa	111,618	96,286	16	%

Operating Expenses and Other

During the first quarter of 2014, compared to the same period in 2013:

- Non-GAAP research and development (R&D) expenses increased due to the progression of Gilead's clinical studies, particularly in oncology and HIV.
- Non-GAAP selling, general and administrative (SG&A) expenses increased to support the expansion of Gilead's business, particularly in hepatitis C virus (HCV) and in preparation for the anticipated launch of idelalisib.

	Three Months Ended March 31,	
(In thousands)	**2014**	**2013**
Non-GAAP research and development expenses	$ 557,805	$ 459,976
Non-GAAP selling, general and administrative expenses	$ 500,105	$ 333,064

Note: Non-GAAP R&D and SG&A expenses exclude the impact of acquisition-related, restructuring and stock-based compensation expenses.

Cash, Cash Equivalents and Marketable Securities

As of March 31, 2014, Gilead had $6.86 billion of cash, cash equivalents and marketable securities compared to $2.57 billion as of December 31, 2013. This increase was primarily due to the issuance of senior unsecured notes in March 2014 for a total aggregate principal amount of $4.00 billion. These proceeds will be for general corporate purposes, which may include the repayment of debt and related payments, working capital and the repurchase of outstanding common stock under the authorized share repurchase program. During the first three months of 2013, Gilead generated $1.57 billion in operating cash flow.

Full Year 2014 Guidance

Gilead reiterates its full year 2014 guidance, initially provided on February 4, 2014, which excludes the impact of Sovaldi product sales:

(In millions, except percentages and per share amounts)	Provided February 4, 2014
Net Product Sales	$11,300 - $11,500
Non-GAAP*	
Product Gross Margin	75% - 77%
R&D	$2,200 - $2,300
SG&A	$2,100 - $2,200
Effective Tax Rate	28% - 29%
Diluted EPS Impact of Acquisition-Related, Restructuring and Stock-Based Compensation Expenses	$0.63 - $0.66

** Non-GAAP product gross margin, expenses and effective tax rate exclude the impact of acquisition-related, restructuring and stock-based compensation expenses, where applicable.*

Product & Pipeline Updates Announced by Gilead During the First Quarter of 2014 Include:

Antiviral Program

- The European Commission granted marketing authorization for Sovaldi in combination with other antiviral agents ribavirin and pegylated interferon alpha in all 28 countries of the European Union.
- Submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for a once-daily fixed-dose combination of the NS5A inhibitor ledipasvir (LDV) 90 mg and the nucleotide analog polymerase inhibitor sofosbuvir (SOF) 400 mg for the treatment of chronic hepatitis C genotype 1 infection in adults for eight or 12 weeks, depending on prior treatment history and whether they have cirrhosis. The FDA has assigned LDV/SOF a Breakthrough Therapy designation, which is granted to investigational medicines that may offer major advances in treatment over existing options. The FDA has set a target review date under the Prescription Drug User Fee Act (PDUFA) of October 10, 2014.
- Announced that the company’s Marketing Authorisation Application for LDV/SOF has been fully validated and is now under assessment by the European Medicines Agency. The application was submitted on February 27, 2014.

Oncology Program

- Announced FDA acceptance for review of the company’s NDA for idelalisib, a targeted, oral inhibitor of PI3K delta, for the treatment of relapsed chronic lymphocytic leukemia with priority review and a target review date under PDUFA of August 6, 2014 and for the treatment of refractory indolent non-Hodgkin’s lymphoma with a standard review and a target review date under PDUFA of September 11, 2014.

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 first quarter 2014 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 1-844-795-1482 (U.S.) or 1-931-229-4695 (international) and dial the conference ID 17493454 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 April 24, 2014. To access the phone replay, please call 1-855-859-2056 (U.S.) or 1-404-537-3406 (international) and dial the conference ID 17493454.

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 transform and simplify care for people with life-threatening illnesses around the

word. Headquartered in Foster City, California, Gilead has operations in North and South America, Europe and Asia-Pacific.

Non-GAAP Financial Information

Gilead has presented certain financial information in accordance with U.S. generally accepted accounting principles (GAAP) and also on a non-GAAP basis. Management believes this non-GAAP information is useful for investors, when considered 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 GAAP. A reconciliation between GAAP and non-GAAP financial information is provided in the table on pages 7 and 8.

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 2014 financial results; Gilead's ability to sustain growth in revenues for its antiviral, cardiovascular and respiratory programs; availability of funding for state AIDS Drug Assistance Programs (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 of unfavorable results from clinical trials involving sofosbuvir, including in combination with other product candidates such as LDV; the levels of inventory held by wholesalers and retailers which may cause fluctuations in Gilead's earnings; Gilead's ability to submit NDAs for new product candidates in the timelines currently anticipated; Gilead's ability to receive regulatory approvals in a timely manner or at all, for new and current products, including the fixed-dose combination of LDV/SOF and idelalisib; Gilead's ability to successfully commercialize its products, including Sovaldi, Stribild, Vitekta and Tybost; the risk that estimates of patients with HCV or anticipated patient demand may not be accurate; Gilead's ability to successfully develop its respiratory, cardiovascular and oncology/inflammation programs; safety and efficacy data from clinical studies may not warrant further development of Gilead's product candidates; 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; and other risks identified from time to time in Gilead's reports filed with the U.S. Securities and Exchange Commission (SEC). 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 press releases, Annual Report on Form 10-K for the year ended December 31, 2013 and other subsequent disclosure documents filed with the SEC. 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.

CONSOLIDATED STATEMENTS OF INCOME

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2014	**2013**
Revenues:		
Product sales	$4,870,974	$2,393,568
Royalty, contract and other revenues	127,982	138,067
Total revenues	4,998,956	2,531,635
Costs and expenses:		
Cost of goods sold	813,205	634,448
Research and development	594,978	497,632
Selling, general and administrative	548,123	374,296
Total costs and expenses	1,956,306	1,506,376
Income from operations	3,042,650	1,025,259
Interest expense	(76,269)	(81,787)
Other income (expense), net	(17,912)	(3,324)
Income before provision for income taxes	2,948,469	940,148
Provision for income taxes	725,882	222,438
Net income	2,222,587	717,710
Net loss attributable to noncontrolling interest	4,823	4,476
Net income attributable to Gilead	$2,227,410	$722,186
Net income per share attributable to Gilead common stockholders - basic	$1.45	$0.47
Net income per share attributable to Gilead common stockholders - diluted	$1.33	$0.43
Shares used in per share calculation - basic	1,536,525	1,521,372
Shares used in per share calculation - diluted	1,679,871	1,665,060

GILEAD SCIENCES, INC.

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION

(unaudited)

(in thousands, except percentages and per share amounts)

	Three Months Ended March 31,	
	2014	**2013**
Cost of goods sold reconciliation:		
GAAP cost of goods sold	$813,205	$634,448
Stock-based compensation expenses	(2,642)	(1,841)
Acquisition related-amortization of purchased intangibles	(199,230)	(21,264)
Non-GAAP cost of goods sold	$611,333	$611,343

Product gross margin reconciliation:

GAAP product gross margin	83.3	%	73.5	%
Stock-based compensation expenses	0.1	%	0.1	%
Acquisition related-amortization of purchased intangibles	4.1	%	0.9	%
Non-GAAP product gross margin[(1)]	87.4	%	74.5	%

Research and development expenses reconciliation:

GAAP research and development expenses	$594,978	$497,632
Stock-based compensation expenses	(34,350)	(26,875)
Restructuring expenses	(145)	(4,757)
Acquisition related-contingent consideration remeasurement	(2,678)	(6,024)
Non-GAAP research and development expenses	$557,805	$459,976

Selling, general and administrative expenses reconciliation:

GAAP selling, general and administrative expenses	$548,123	$374,296
Stock-based compensation expenses	(45,233)	(33,051)
Restructuring expenses	(3)	(744)
Acquisition related-transaction costs	(448)	(7,156)
Acquisition related-amortization of purchased intangibles	(2,334)	(281)
Non-GAAP selling, general and administrative expenses	$500,105	$333,064

Operating margin reconciliation:

GAAP operating margin	60.9	%	40.5	%
Stock-based compensation expenses	1.6	%	2.4	%
Restructuring expenses	0.0	%	0.2	%
Acquisition related-transaction costs	0.0	%	0.3	%
Acquisition related-amortization of purchased intangibles	4.0	%	0.9	%
Acquisition related-contingent consideration remeasurement	0.1	%	0.2	%
Non-GAAP operating margin[(1)]	66.6	%	44.5	%

Other income (expense) reconciliation:

GAAP other income (expense), net	$(17,912)	$(3,324)
Acquisition related-transaction costs	(1,853)	—
Non-GAAP other income (expense), net	$(19,765)	$(3,324)

GILEAD SCIENCES, INC.

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION - (Continued)

(unaudited)

(in thousands, except percentages and per share amounts)

	Three Months Ended March 31,			
	2014		**2013**	
Effective tax rate reconciliation:				
GAAP effective tax rate	24.6	%	23.7	%
Restructuring expenses	—	%	(0.1	)%
Acquisition related-amortization of purchased intangibles	(1.4	)%	—	%
Acquisition related-contingent consideration remeasurement	—	%	(0.1	)%
Non-GAAP effective tax rate[(1)]	23.2	%	23.5	%

Net income attributable to Gilead reconciliation:		
GAAP net income attributable to Gilead, net of tax	$ 2,227,410	$ 722,186
Stock-based compensation expenses	63,136	45,380
Restructuring expenses	148	5,368
Acquisition related-transaction costs	(975)	7,156
Acquisition related-amortization of purchased intangibles	195,412	15,829
Acquisition related-contingent consideration remeasurement	2,678	6,024
Non-GAAP net income attributable to Gilead, net of tax	$ 2,487,809	$ 801,943
Diluted earnings per share reconciliation:		
GAAP diluted earnings per share	$ 1.33	$ 0.43
Stock-based compensation expenses	0.04	0.03
Restructuring expenses	0.00	0.00
Acquisition related-transaction costs	(0.00)	0.00
Acquisition related-amortization of purchased intangibles	0.12	0.01
Acquisition related-contingent consideration remeasurement	0.00	0.00
Non-GAAP diluted earnings per share[(1)]	$ 1.48	$ 0.48
Shares used in per share calculation (diluted) reconciliation:		
GAAP shares used in per share calculation (diluted)	1,679,871	1,665,060
Share impact of current stock-based compensation rules	(911)	(1,716)
Non-GAAP shares used in per share calculation (diluted)	1,678,960	1,663,344
Non-GAAP adjustment summary:		
Cost of goods sold adjustments	$ 201,872	$ 23,105
Research and development expenses adjustments	37,173	37,656
Selling, general and administrative expenses adjustments	48,018	41,232
Other income (expense) adjustments	(1,853)	—
Total non-GAAP adjustments before tax	285,210	101,993
Income tax effect	(24,811)	(22,236)
Total non-GAAP adjustments after tax	$ 260,399	$ 79,757

[(1)] Amounts may not sum due to rounding.

GILEAD SCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2014 (unaudited)	**December 31, 2013[(1)]**
Cash, cash equivalents and marketable securities	$ 6,858,901	$ 2,570,590
Accounts receivable, net	3,236,195	2,100,286
Inventories	2,140,228	2,055,788
Property, plant and equipment, net	1,303,029	1,166,181
Intangible assets, net	11,707,830	11,900,106
Goodwill	1,171,561	1,169,023
Other assets	1,659,948	1,534,811

Total assets	$28,077,692	$22,496,785
Current liabilities	$5,914,776	$6,325,421
Long-term liabilities	8,414,955	4,363,032
Equity component of currently redeemable convertible notes	45,767	63,831
Stockholders' equity[(2)]	13,702,194	11,744,501
Total liabilities and stockholders' equity	$28,077,692	$22,496,785

[(1)] Derived from the audited consolidated financial statements as of December 31, 2013.

[(2)] As of March 31, 2014, there were 1,537,642 shares of common stock issued and outstanding.

GILEAD SCIENCES, INC.

PRODUCT SALES SUMMARY

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2014	**2013**
Antiviral products:		
Sovaldi – U.S.	$2,097,791	$—
Sovaldi – Europe	163,691	—
Sovaldi – Other International	12,867	—
	2,274,349	—
Atripla – U.S.	489,929	553,826
Atripla – Europe	236,508	278,215
Atripla – Other International	53,157	45,032
	779,594	877,073
Truvada – U.S.	367,782	307,861
Truvada – Europe	323,186	332,027
Truvada – Other International	68,732	60,354
	759,700	700,242
Complera / Eviplera – U.S.	130,426	103,297
Complera / Eviplera – Europe	108,994	38,962
Complera / Eviplera – Other International	11,313	5,930
	250,733	148,189
Stribild – U.S.	187,090	91,978
Stribild – Europe	23,630	—
Stribild – Other International	4,551	170
	215,271	92,148
Viread – U.S.	81,053	82,628
Viread – Europe	84,065	88,206
Viread – Other International	45,507	39,498

	210,625	210,332
Hepsera – U.S.	2,230	12,950
Hepsera – Europe	7,718	11,223
Hepsera – Other International	1,775	2,250
	11,723	26,423
Emtriva – U.S.	4,817	4,529
Emtriva – Europe	1,560	1,751
Emtriva – Other International	125	391
	6,502	6,671
Total antiviral products – U.S.	3,361,118	1,157,069
Total antiviral products – Europe	949,352	750,384
Total antiviral products – Other International	198,027	153,625
	4,508,497	2,061,078
Letairis	122,885	118,107
Ranexa	111,618	96,286
AmBisome	92,093	85,275
Other products	35,881	32,822
	362,477	332,490
Total product sales	$4,870,974	$2,393,568

Source: Gilead Sciences, Inc.

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