Gilead Sciences Announces First Quarter 2013 Financial Results

May 2, 2013 4:06 PM ET

- Product Sales of $2.39 billion, Up 8 percent over First Quarter 2012 -

- Total Revenues of $2.53 billion, Up 11 percent over First Quarter 2012 -

- Reiterates Full Year 2013 Guidance -

FOSTER CITY, Calif.--(BUSINESS WIRE)--May. 2, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the quarter ended March 31, 2013. Total revenues for the first quarter of 2013 increased 11 percent to $2.53 billion, from $2.28 billion for the first quarter of 2012. Product sales increased 8 percent to $2.39 billion for the first quarter of 2013 compared to $2.21 billion for the first quarter of 2012. Net income for the first quarter of 2013 was $722.2 million, or $0.43 per diluted share compared to $442.0 million, or $0.28 per diluted share for the first quarter of 2012. Non-GAAP net income for the first quarter of 2013, which excludes acquisition-related, restructuring and stock-based compensation expenses, was $801.9 million, or $0.48 per diluted share compared to $704.4 million, or $0.45 per diluted share for the first quarter of 2012.

	Three Months Ended March 31,	
	2013	**2012**
Product sales	$2,393,568	$2,208,342
Royalty, contract and other revenues	138,067	74,107
Total revenues	$2,531,635	$2,282,449
Net income attributable to Gilead	$722,186	$441,956
Non-GAAP net income attributable to Gilead	$801,943	$704,389
Diluted EPS	$0.43	$0.28
Non-GAAP diluted EPS	$0.48	$0.45

Product Sales

The increase in product sales during the first quarter of 2013 was due primarily to Gilead's antiviral franchise, resulting from increased sales of Complera®/Eviplera® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg) and the launch of Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) in the third quarter of 2012.

Antiviral Product Sales

Antiviral product sales increased 7 percent to $2.06 billion for the first quarter of 2013, up from $1.93 billion for the first quarter of 2012, reflecting sales growth of 8 percent in Europe and 7 percent in the U.S. The increase reflects strong underlying demand, specifically for Complera/Eviplera and Stribild, partially offset by a decrease in sales of Truvada® (emtricitabine and tenofovir disoproxil fumarate).

	Three Months Ended March 31,			
	2013	**2012**	**% Change**	
Antiviral product sales	$2,061,078	$1,925,806	7	%
Atripla	877,073	887,596	(1	)%
Truvada	700,242	758,263	(8	)%

Viread	210,332	191,693	10	%
Complera/Eviplera	148,189	52,180	184	%
Stribild	92,148	—	—	

Cardiovascular Product Sales

Cardiovascular product sales increased 26 percent to $214.4 million for the first quarter of 2013, up from $170.5 million for the first quarter of 2012 driven primarily by strong Letairis® (ambrisentan) sales.

	Three Months Ended March 31,			
	2013	2012	% Change	
Cardiovascular product sales	$214,393	$170,489	26	%
Letairis	118,107	87,288	35	%
Ranexa	96,286	83,201	16	%

Operating Expenses and Other

Non-GAAP research and development (R&D) expenses increased due to Gilead's continued investment in its product pipeline, particularly in liver disease and oncology. Non-GAAP selling, general and administrative (SG&A) expenses increased primarily due to expenses to support the ongoing growth of Gilead's business.

Interest expense decreased primarily due to the repayment of bank debt issued in connection with the acquisition of Pharmasset Inc. Gilead repaid bank debt totaling $1.40 billion in 2012. The change in other income (expense), net was due primarily to a $40.1 million loss during the first quarter of 2012 resulting from the Greek government's debt restructuring.

	Three Months Ended March 31,	
	2013	2012
Non-GAAP research and development expenses [(1)]	$459,976	$331,338
Non-GAAP selling, general and administrative expenses [(1)]	$333,064	$307,741
Interest expense	$(81,787)	$(97,270)
Other income (expense), net	$(3,324)	$(34,085)

[(1)] Non-GAAP R&D expenses and SG&A expenses exclude the impact of acquisition-related, restructuring and stock-based compensation expenses where applicable.

Net Foreign Currency Exchange Impact

The net foreign currency exchange impact on first quarter 2013 product sales and pre-tax earnings was an unfavorable $7.3 million and $6.3 million, respectively, compared to the first quarter of 2012.

Cash, Cash Equivalents and Marketable Securities

As of March 31, 2013, Gilead had $2.63 billion of cash, cash equivalents and marketable securities compared to $2.58 billion as of December 31, 2012. During the first quarter of 2013, we generated $672.1 million in operating cash flow, utilized $378.6 million for the acquisition of YM BioSciences Inc. (YM) and repaid $247.1 million in debt.

Full Year 2013 Guidance Reiterated

Gilead reiterates its full year 2013 guidance which it provided on February 4, 2013:
(in millions, except percentages and per share amounts)

Net Product Sales	$10,000 - $10,200
Non-GAAP *	
Product Gross Margin	74% - 76%
R&D	$1,800 - $1,900
SG&A	$1,550 - $1,650
Effective Tax Rate	26% - 28%
Diluted EPS Impact of Acquisition-Related, Restructuring and Stock-Based Compensation Expenses	$0.21 - $0.24

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

Corporate Highlights

In February, Gilead announced the completion of its acquisition of YM, a publicly-held drug development company that was primarily focused on advancing its lead product candidate momelotinib (formally known as CYT387), an orally administered, once-daily, selective inhibitor of the Janus kinase (JAK) family. The acquisition of YM represents an opportunity to add a complementary clinical program in the area of hematologic cancers to our growing oncology portfolio.

Also in February, Gilead announced that it reached an agreement in principle with Teva Pharmaceuticals to settle the ongoing patent litigation concerning the patents protecting Viread® (tenofovir disoproxil fumarate), a treatment for HIV infection and chronic hepatitis B infection. Under the terms of the settlement, Teva will be allowed to launch a generic version of Viread on December 15, 2017.

Product & Pipeline Update

Antiviral Program

In January, Gilead announced:

- Full clinical trial results from one cohort of the ongoing Phase 2 ELECTRON study examining a 12-week course of all-oral therapy with sofosbuvir (formerly GS-7977), ledipasvir (formerly GS-5885) and ribavirin (RBV) among genotype 1 hepatitis C virus (HCV) patients who had previously failed to respond to an interferon (IFN)-containing regimen, or "null responders." The data confirmed that all patients in this cohort achieved a sustained virologic response four weeks (SVR4) after stopping therapy.
- Initiation of the Phase 3 ION-1 study evaluating the fixed-dose combination of sofosbuvir/ledipasvir with and without RBV for 12 or 24 weeks in treatment-naïve genotype 1 patients.
- Screening of patients for the second Phase 3 ION-2 study evaluating the fixed-dose combination of sofosbuvir/ledipasvir with RBV for 12 weeks and with and without RBV for 24 weeks of therapy in treatment-experienced genotype 1 HCV patients.
- Enrollment of patients in LONESTAR, a Phase 2 study evaluating sofosbuvir/ledipasvir for 12 weeks and sofosbuvir/ledipasvir with and without RBV for eight weeks in genotype 1 treatment-naïve patients. Two additional arms in this trial will evaluate this combination with and without RBV for 12 weeks in treatment-experienced genotype 1 patients who had previously received a protease inhibitor-containing regimen.
- Initiation of two Phase 3 clinical trials (Study 104 and 111) evaluating a single tablet regimen containing tenofovir alafenamide (TAF) for the treatment of HIV-1 infection in treatment-naïve adults.

In February, Gilead announced:

- Topline results from the Phase 3 FISSION study, evaluating therapy with either a 12-week course of sofosbuvir plus RBV or standard of care with 24 weeks of treatment with pegylated interferon (peg-IFN) plus RBV in genotype 2 or 3 HCV patients. The study met its primary efficacy endpoint of non-inferiority of sofosbuvir plus RBV to peg-IFN plus RBV, with

67 percent of patients achieving SVR in the sofosbuvir plus RBV treatment group versus 67 percent in the peg-IFN plus RBV treatment group.
- Topline results from the Phase 3 NEUTRINO study, evaluating a 12-week course of therapy with sofosbuvir, RBV and peg-IFN in genotype 1, 4, 5 or 6 HCV patients. This study met its primary efficacy endpoint of superiority compared to a predefined historic control SVR rate of 60 percent, with 90 percent of patients achieving a sustained virologic response 12 weeks after completing therapy.
- Topline results from the Phase 3 FUSION study evaluating 12- and 16-week courses of therapy with the once-daily sofosbuvir plus RBV in treatment-experienced patients with genotype 2 or 3 chronic HCV infection. The study met its primary efficacy endpoint of superiority compared to a predefined historic control SVR rate of 25 percent.

In March, Gilead announced:

- Results from a 24-week Phase 2 study (Study 102) evaluating a once-daily single tablet regimen containing TAF for the treatment of HIV-1 infection. A regimen of TAF 10 mg/elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg was found to be similar to Stribild based on the percentage of patients with HIV RNA levels less than 50 copies/mL at 24 weeks of treatment.
- The Committee for Medicinal Products for Human Use, the scientific committee of the European Medicines Agency, adopted a positive opinion on the company’s Marketing Authorisation Application for the once-daily, single tablet regimen Stribild for the treatment of HIV-1 infection in adult patients who are antiretroviral-naïve or are infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild.
- An update on the Phase 3 ION-1 study evaluating a once-daily fixed-dose combination of sofosbuvir/ledipasvir with and without RBV for 12 or 24 weeks in treatment naïve genotype 1 HCV patients. A planned review by the study's Data and Safety Monitoring Board of safety data from patients in all four arms and of SVR4 rates from patients in the two 12-week duration arms concluded that the trial should continue without modification. This recommendation was based upon the observed SVR4 rates exceeding the predefined threshold and the absence of significant safety issues. Enrollment of the remaining patients in ION-1 is underway.
- Completion of enrollment in the second Phase 3 ION-2 study evaluating the fixed-dose combination of sofosbuvir/ledipasvir with RBV for 12 weeks, and with and without RBV for 24 weeks, in treatment-experienced genotype 1 HCV patients.

Cardiovascular Program

In March, Gilead announced data from the Phase 4 TERISA (Type 2 Diabetes Evaluation of Ranolazine In Subjects With Chronic Stable Angina) study, which demonstrated that the addition of ranolazine to background antianginal therapy in chronic angina patients with type 2 diabetes significantly reduced the frequency of weekly angina episodes compared to background antianginal therapy alone.

Conference Call

At 4:30 p.m. Eastern Time today, Gilead's management will host a conference call and a simultaneous webcast to discuss results from its first quarter 2013 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 1-866-318-8617 (U.S.) or 1-617-399-5136 (international) and dial the participant passcode 81259571 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 May 5, 2013. To access the phone replay, please call 1-888-286-8010 (U.S.) or 1-617-801-6888 (international) and dial the participant passcode 57408121.

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. generally accepted accounting principles (GAAP) and also on a non-GAAP basis. 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 GAAP. A reconciliation between GAAP and non-GAAP financial information is provided in the table on pages 8 and 9.

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 2013 financial results; Gilead's ability to sustain growth in revenues for its antiviral, cardiovascular and respiratory franchises; 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, the fixed-dose combination of sofosbuvir/ledipasvir and single tablet regimens containing TAF for the treatment of HIV-1 infection; the levels of inventory held by wholesalers and retailers which may cause fluctuations in Gilead's earnings; Gilead's ability to submit new drug applications for new product candidates in the timelines currently anticipated, including sofosbuvir and sofosbuvir/ledipasvir 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 Stribild from the European Medicines Agency; Gilead's ability to successfully commercialize its products, including Stribild; Gilead's ability to successfully develop its respiratory, cardiovascular and oncology/inflammation franchises; safety and efficacy data from clinical studies may not warrant further development of Gilead's product candidates, including sofosbuvir; 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 YM's product pipeline; 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 press releases, Annual Report on Form 10-K for the year ended December 31, 2012 and other subsequent disclosure documents filed with the Securities and Exchange Commission. 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,	
	2013	**2012**
Revenues:		
Product sales	$2,393,568	$2,208,342
Royalty, contract and other revenues	138,067	74,107
Total revenues	2,531,635	2,282,449
Costs and expenses:		
Cost of goods sold	634,448	580,931
Research and development	497,632	458,211
Selling, general and administrative	374,296	443,121
Total costs and expenses	1,506,376	1,482,263
Income from operations	1,025,259	800,186
Interest expense	(81,787)	(97,270)
Other income (expense), net	(3,324)	(34,085)
Income before provision for income taxes	940,148	668,831
Provision for income taxes	222,438	231,300
Net income	717,710	437,531
Net loss attributable to noncontrolling interest	4,476	4,425
Net income attributable to Gilead	$722,186	$441,956
Net income per share attributable to Gilead common stockholders - basic [(1)]	$0.47	$0.29
Net income per share attributable to Gilead common stockholders - diluted [(1)]	$0.43	$0.28
Shares used in per share calculation - basic [(1)]	1,521,372	1,512,572
Shares used in per share calculation - diluted [(1)]	1,665,060	1,554,776

[(1)] Net income per share and the number of shares used in the per share calculations for all periods presented reflect the two-for-one stock split in the form of a stock dividend declared on December 10, 2012 which took effect on January 25, 2013.

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,	
	2013	**2012**
Cost of goods sold reconciliation:		
GAAP cost of goods sold	$634,448	$580,931
Stock-based compensation expenses	(1,841)	(2,101)
Acquisition related-amortization of purchased intangibles	(21,264)	(15,836)
Non-GAAP cost of goods sold	$611,343	$562,994
Product gross margin reconciliation:		
GAAP product gross margin	73.5 %	73.7 %
Stock-based compensation expenses	0.1 %	0.1 %
Acquisition related-amortization of purchased intangibles	0.9 %	0.7 %

Non-GAAP product gross margin[1]	74.5 %	74.5 %
Research and development expenses reconciliation:		
GAAP research and development expenses	$497,632	$458,211
Stock-based compensation expenses	(26,875)	(118,623)
Restructuring expenses	(4,757)	(5,514)
Acquisition related-contingent consideration remeasurement	(6,024)	(2,736)
Non-GAAP research and development expenses	$459,976	$331,338
Selling, general and administrative expenses reconciliation:		
GAAP selling, general and administrative expenses	$374,296	$443,121
Stock-based compensation expenses	(33,051)	(121,944)
Restructuring expenses	(744)	(3,156)
Acquisition related-transaction costs	(7,156)	(10,280)
Acquisition related-amortization of purchased intangibles	(281)	—
Non-GAAP selling, general and administrative expenses	$333,064	$307,741
Operating margin reconciliation:		
GAAP operating margin	40.5 %	35.1 %
Stock-based compensation expenses	2.4 %	10.6 %
Restructuring expenses	0.2 %	0.4 %
Acquisition related-transaction costs	0.3 %	0.5 %
Acquisition related-amortization of purchased intangibles	0.9 %	0.7 %
Acquisition related-contingent consideration remeasurement	0.2 %	0.1 %
Non-GAAP operating margin[1]	44.5 %	47.3 %
Interest expense reconciliation:		
GAAP interest expense	$(81,787)	$(97,270)
Acquisition related-transaction costs	—	7,333
Non-GAAP interest expense	$(81,787)	$(89,937)
Net income attributable to Gilead reconciliation:		
GAAP net income attributable to Gilead, net of tax	$722,186	$441,956
Stock-based compensation expenses	45,380	229,604
Restructuring expenses	5,368	6,346
Acquisition related-transaction costs	7,156	12,891
Acquisition related-amortization of purchased intangibles	15,829	11,590
Acquisition related-contingent consideration remeasurement	6,024	2,002
Non-GAAP net income attributable to Gilead, net of tax	$801,943	$704,389
Diluted earnings per share[2] reconciliation:		
GAAP diluted earnings per share	$0.43	$0.28
Stock-based compensation expenses	0.03	0.15
Restructuring expenses	0.00	0.00
Acquisition related-transaction costs	0.00	0.01
Acquisition related-amortization of purchased intangibles	0.01	0.01
Acquisition related-contingent consideration remeasurement	0.00	0.00
Non-GAAP diluted earnings per share[1]	$0.48	$0.45

Shares used in per share calculation (diluted)[2] reconciliation:

GAAP shares used in per share calculation (diluted)	1,665,060	1,554,776
Share impact of current stock-based compensation rules	(1,716)	(4,076)
Non-GAAP shares used in per share calculation (diluted)	1,663,344	1,550,700

Non-GAAP adjustment summary:

Cost of goods sold adjustments	$23,105	$17,937
Research and development expenses adjustments	37,656	126,873
Selling, general and administrative expenses adjustments	41,232	135,380
Interest expense adjustments	—	7,333
Total non-GAAP adjustments before tax	101,993	287,523
Income tax effect	(22,236)	(25,090)
Total non-GAAP adjustments after tax	$79,757	$262,433

(1) Amounts may not sum due to rounding.

(2) The earnings per share calculation and the number of shares used in the per share calculation reflect the two-for-one stock split in the form of a stock dividend declared on December 10, 2012 which took effect on January 25, 2013.

GILEAD SCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2013 (unaudited)	**December 31, 2012(1)**
Cash, cash equivalents and marketable securities	$ 2,631,030	$ 2,582,086
Accounts receivable, net	1,945,189	1,751,388
Inventories	1,799,618	1,744,982
Property, plant and equipment, net	1,125,794	1,100,259
Intangible assets, net	12,077,548	11,736,393
Goodwill	1,188,157	1,060,919
Other assets	1,444,332	1,263,811
Total assets	$ 22,211,668	$ 21,239,838
Current liabilities	$ 4,290,215	$ 4,270,020
Long-term liabilities	7,528,980	7,418,949
Stockholders' equity(2)	10,392,473	9,550,869
Total liabilities and stockholders' equity	$ 22,211,668	$ 21,239,838

(1) Derived from the audited consolidated financial statements as of December 31, 2012.

(2) As of March 31, 2013, there were 1,524,383 shares of common stock issued and outstanding.

GILEAD SCIENCES, INC.

PRODUCT SALES SUMMARY

(unaudited)

(in thousands)

Three Months Ended

	March 31, 2013	2012
Antiviral products:		
Atripla – U.S.	$553,826	$562,044
Atripla – Europe	278,215	270,696
Atripla – Other International	45,032	54,856
	877,073	887,596
Truvada – U.S.	307,861	373,326
Truvada – Europe	332,027	321,876
Truvada – Other International	60,354	63,061
	700,242	758,263
Viread – U.S.	82,628	81,656
Viread – Europe	88,206	84,885
Viread – Other International	39,498	25,152
	210,332	191,693
Complera / Eviplera – U.S.	103,297	48,639
Complera / Eviplera – Europe	38,962	3,267
Complera / Eviplera – Other International	5,930	274
	148,189	52,180
Stribild – U.S.	91,978	—
Stribild – Other International	170	—
	92,148	—
Hepsera – U.S.	12,950	12,809
Hepsera – Europe	11,223	13,965
Hepsera – Other International	2,250	2,523
	26,423	29,297
Emtriva – U.S.	4,529	4,093
Emtriva – Europe	1,751	1,811
Emtriva – Other International	391	873
	6,671	6,777
Total Antiviral products – U.S.	1,157,069	1,082,567
Total Antiviral products – Europe	750,384	696,500
Total Antiviral products – Other International	153,625	146,739
	2,061,078	1,925,806
Letairis	118,107	87,288
Ranexa	96,286	83,201
AmBisome	85,275	84,764
Other products	32,822	27,283
	332,490	282,536
Total product sales	$2,393,568	$2,208,342

Source: Gilead Sciences, Inc.

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