Gilead Sciences Announces First Quarter 2016 Financial Results

April 28, 2016 4:04 PM ET

- Product Sales of $7.7 billion -

- GAAP Diluted EPS of $2.53 per share -

- Non-GAAP Diluted EPS of $3.03 per share -

- Reiterates Full Year 2016 Guidance -

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 28, 2016-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the first quarter ended March 31, 2016. The financial results that follow represent a year-over-year comparison of first quarter 2016 to the first quarter 2015. Total revenues were $7.8 billion in 2016 compared to $7.6 billion in 2015. Net income was $3.6 billion or $2.53 per diluted share in 2016 compared to $4.3 billion or $2.76 per diluted share in 2015. Non-GAAP net income, which excludes acquisition-related, up-front collaboration, stock-based compensation and other expenses, was $4.3 billion or $3.03 per diluted share in 2016 compared to $4.6 billion or $2.94 per diluted share in 2015.

	Three Months Ended March 31,	
(In millions, except per share amounts)	**2016**	**2015**
Product sales	$ 7,681	$ 7,405
Royalty, contract and other revenues	113	189
Total revenues	$ 7,794	$ 7,594
Net income attributable to Gilead	$ 3,566	$ 4,333
Non-GAAP net income attributable to Gilead	$ 4,274	$ 4,604
Diluted EPS	$ 2.53	$ 2.76
Non-GAAP diluted EPS	$ 3.03	$ 2.94

Product Sales

Total product sales for the first quarter of 2016 were $7.7 billion compared to $7.4 billion for the same period in 2015. Product sales for the first quarter of 2016 were $4.4 billion in the U.S., $1.6 billion in Europe, $1.1 billion in Japan and $571 million in other international locations. Product sales for the first quarter of 2015 were $5.2 billion in the U.S., $1.8 billion in Europe and $364 million in other international locations.

Antiviral Product Sales

Antiviral product sales, which include products in our HIV and liver disease areas, were $7.2 billion for the first quarter of 2016 compared to $7.0 billion for the same period in 2015.

- In the U.S., antiviral product sales were $4.0 billion for the first quarter of 2016 compared to $4.9 billion in 2015, primarily due to a decline in sales of Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg), partially offset by increases in sales of Sovaldi® (sofosbuvir 400 mg), Truvada® (emtricitabine and tenofovir disoproxil fumarate) and Genvoya® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg). Genvoya was launched in the U.S. in November 2015.

- In Europe, antiviral product sales were $1.6 billion for the first quarter of 2016 compared to $1.7 billion in 2015, primarily due to a decline in sales of Sovaldi.
- In Japan, antiviral product sales were $1.1 billion. Sovaldi and Harvoni were launched in Japan in May and September 2015, respectively.

Other Product Sales

Other product sales, which include Letairis® (ambrisentan), Ranexa® (ranolazine) and AmBisome® (amphotericin B liposome for injection), were $498 million for the first quarter of 2016 compared to $417 million for the same period in 2015.

Cost of Goods Sold

Non-GAAP* cost of goods sold increased to $983 million for the first quarter of 2016 compared to $674 million for the same period in 2015, primarily due to a $200 million litigation charge related to our sofosbuvir based product sales.

Operating Expenses

	Three Months Ended March 31,	
(In millions)	**2016**	**2015**
Non-GAAP* research and development expenses (R&D)	$ 769	$ 651
Non-GAAP* selling, general and administrative expenses (SG&A)	$ 638	$ 600

** Non-GAAP Cost of Goods Sold, R&D and SG&A expenses exclude acquisition-related, up-front collaboration, stock-based compensation and other expenses*

During the first quarter of 2016, compared to the same period in 2015:

- Non-GAAP research and development expenses increased primarily due to the progression of Gilead's clinical studies.
- Non-GAAP selling, general and administrative expenses increased primarily due to higher costs to support Gilead's geographic expansion of its business, partially offset by a decrease in our Branded Prescription Drug fee expense.

Cash, Cash Equivalents and Marketable Securities

As of March 31, 2016, Gilead had $21.3 billion of cash, cash equivalents and marketable securities compared to $26.2 billion as of December 31, 2015. During the first quarter of 2016, we utilized $8.0 billion on stock repurchases and made an upfront license fee payment of $300 million and an equity investment of $425 million related to our license and collaboration agreement with Galapagos NV. Cash flow from operating activities was $3.9 billion for the quarter.

Full Year 2016 Guidance

Gilead reiterates its full year 2016 guidance, initially provided on February 2, 2016:

(In millions, except percentages and per share amounts)	**Provided February 2, 2016**
Net Product Sales	$30,000 - $31,000
Non-GAAP*	

Product Gross Margin	88% - 90%
R&D expenses	$3,200 - $3,500
SG&A expenses	$3,300 - $3,600
Effective Tax Rate	18.0% - 20.0%
Diluted EPS Impact Related to Acquisition, Up-front Collaboration, Stock-based Compensation and Other Expenses	$1.10 - $1.16

** Non-GAAP Product Gross Margin, R&D and SG&A expenses and effective tax rate exclude acquisition-related, up-front collaboration, stock-based compensation and other expenses.*

Corporate Highlights

- Announced that Chairman and Chief Executive Officer (CEO) John C. Martin, PhD assumed the role of Executive Chairman of the company. John F. Milligan, PhD, formerly President and Chief Operating Officer, was promoted to President and CEO, effective March 10, 2016, and appointed to the company's Board of Directors.
- Announced that Gilead will provide grants for up to three years to academic institutions, nonprofit organizations and community groups engaged in HIV cure activities. The unrestricted grants are awarded to organizations with a track record of excellence in results-driven research.
- Announced that the Board of Directors approved the repurchase of an additional $12 billion of the company's common stock which commenced upon completion of the company's existing $15 billion repurchase program authorized in January 2015.

Product & Pipeline Updates announced by Gilead during the First Quarter of 2016 include:

- Announced that U.S. Food and Drug Administration (FDA) approved Odefsey® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg or R/F/TAF) for the treatment of HIV-1 infection in certain patients. Emtricitabine and tenofovir alafenamide are from Gilead while rilpivirine is from Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Odefsey is Gilead's second TAF-based regimen to receive FDA approval and represents the smallest pill of any single-tablet regimen available today for the treatment of HIV.
- Announced that the Committee for Medicinal Products for Human Use, the scientific committee of the European Medicines Agency (EMA), adopted a positive opinion on the company's Marketing Authorization Application (MAA) for two doses of Descovy® (emtricitabine 200 mg/tenofovir alafenamide 25 mg, F/TAF), an investigational fixed-dose combination for the treatment of HIV-1 infection in adults and adolescents (ages 12 years and older with body weight at least 35 kg) in combination with other HIV antiretroviral agents.
- Presented data at the 2016 Conference on Retroviruses and Opportunistic Infections, which included the announcement of:
    - 48-week results from a Phase 3 study (Study 1089) evaluating the safety and efficacy of switching virologically suppressed HIV-1 infected adult patients from regimens containing Truvada to regimens containing the investigational fixed-dose combination of emtricitabine and F/TAF. At Week 48, the F/TAF-based regimens were found to be statistically non-inferior to the emtricitabine and tenofovir disoproxil fumarate (F/TDF) -based regimens, based on percentages of patients with HIV-1 RNA levels less than 50 copies/mL. The study also demonstrated statistically significant improvements in renal and bone laboratory parameters among patients receiving F/TAF-based regimens.
    - Results from a preclinical study conducted in collaboration with researchers at Beth Israel Deaconess Medical Center evaluating a proprietary investigational oral toll-like receptor 7 (TLR7) agonist, GS-9620, and a related molecular analogue, GS-986, as part of an HIV eradication strategy. Data from the study conducted in simian immunodeficiency virus (SIV)-infected virally suppressed rhesus macaques on antiretroviral therapy (ART) demonstrate that TLR7 agonist treatment induced transient plasma SIV RNA blips and reduced SIV DNA. In addition, TLR7 agonist treatment resulted in subsequent prolonged virus suppression in some of the

macaques after stopping ART.

- Announced that the company's Type II variation application for once-daily Truvada in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection among uninfected adults at high risk, a strategy known as pre-exposure prophylaxis or PrEP, was fully validated and under evaluation by the EMA.
- Announced that the company's MAA for TAF 25 mg, an investigational, once-daily treatment for adults with chronic hepatitis B virus (HBV) infection, was fully validated and under assessment by the EMA. The company also submitted a new drug application (NDA) to FDA for TAF 25 mg for the treatment for adults with chronic HBV infection.
- Announced that FDA approved two supplemental indications for Harvoni for use in chronic hepatitis C patients with advanced liver disease. Harvoni in combination with ribavirin for 12 weeks was approved for use in chronic hepatitis C virus (HCV) genotype 1- or 4-infected liver transplant recipients without cirrhosis or with compensated cirrhosis (Child-Pugh A), and for HCV genotype 1-infected patients with decompensated cirrhosis (Child-Pugh B or C), including those who have undergone liver transplantation. Harvoni is approved for use in HCV genotypes 1, 4, 5 and 6, HCV/HIV-1 coinfection, HCV genotype 1 and 4 liver transplant recipients, and genotype 1-infected patients with decompensated cirrhosis.
- Announced that FDA granted priority review to the company's NDA for an investigational once-daily fixed-dose combination of sofosbuvir and velpatasvir (SOF/VEL), for the treatment of chronic genotype 1-6 HCV infection. FDA has set a target action date under the Prescription Drug User Fee Act of June 28, 2016.

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 2016 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/investors 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 1-877-359-9508 (U.S.) or 1-224-357-2393 (international) and dial the conference ID 76639018 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 30, 2016. To access the phone replay, please call 1-855-859-2056 (U.S.) or 1-404-537-3406 (international) and dial the conference ID 76639018.

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. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

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 tables 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 2016 financial results; Gilead's ability to sustain growth in revenues for its antiviral and other 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 investigational compounds, including GS-9620 and GS-986; Gilead's ability to initiate clinical trials in its currently anticipated timeframes; 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; Gilead's ability to receive regulatory approvals in a timely manner or at all, for new and current products, including SOF/VEL and TAF for the treatment of chronic HBV; Gilead's ability to successfully commercialize its products, including Genvoya, Odefsey and Descovy; the risk that physicians and patients may not see advantages of these products over other therapies and may therefore be reluctant to prescribe the products; the risk that estimates of patients with HCV or anticipated patient demand may not be accurate; the risk that private and public payers may be reluctant to provide, or continue to provide, coverage or reimbursement for new products, including Sovaldi and Harvoni; Gilead's ability to successfully develop its oncology, inflammation, cardiovascular and respiratory programs; safety and efficacy data from clinical studies may not warrant further development of Gilead's product candidates; the potential for pricing pressure from additional competitive HCV launches or austerity measures in European countries and Japan that may increase the amount of discount required on Gilead's products; Gilead's ability to complete its share repurchase program due to changes in its stock price, corporate or other market conditions; 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, 2015 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.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(unaudited)

(in millions, except per share amounts)

	Three Months Ended March 31,	
	2016	**2015**
Revenues:		
Product sales	$ 7,681	$ 7,405
Royalty, contract and other revenues	113	189
Total revenues	7,794	7,594
Costs and expenses:		
Cost of goods sold	1,193	882
Research and development expenses	1,265	696
Selling, general and administrative expenses	685	645
Total costs and expenses	3,143	2,223
Income from operations	4,651	5,371
Interest expense	(230)	(153)
Other income (expense), net	81	21
Income before provision for income taxes	4,502	5,239
Provision for income taxes	935	907
Net income	3,567	4,332
Net income (loss) attributable to noncontrolling interest	1	(1)
Net income attributable to Gilead	$ 3,566	$ 4,333
Net income per share attributable to Gilead common stockholders - basic	$ 2.58	$ 2.91
Shares used in per share calculation - basic	1,383	1,488
Net income per share attributable to Gilead common stockholders - diluted	$ 2.53	$ 2.76
Shares used in per share calculation - diluted	1,412	1,569
Cash dividends declared per share	$ 0.43	$ —

GILEAD SCIENCES, INC.

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION

(unaudited)

(in millions, except percentages and per share amounts)

	Three Months Ended March 31,	
	2016	**2015**
Cost of goods sold reconciliation:		
GAAP cost of goods sold	$ 1,193	$ 882
Acquisition related-amortization of purchased intangibles	(210)	(206)

Stock-based compensation expenses	(3	)	(3	)
Other[(1)]	3		1	
Non-GAAP cost of goods sold	$ 983		$ 674	
Product gross margin reconciliation:				
GAAP product gross margin	84.5	%	88.1	%
Acquisition related-amortization of purchased intangibles	2.7	%	2.8	%
Non-GAAP product gross margin[(2)]	87.2	%	90.9	%
Research and development expenses reconciliation:				
GAAP research and development expenses	$ 1,265		$ 696	
Up-front collaboration expenses	(368	)	—	
Acquisition related-IPR&D impairment	(114	)	—	
Stock-based compensation expenses	(41	)	(42	)
Other[(1)]	27		(3	)
Non-GAAP research and development expenses	$ 769		$ 651	
Selling, general and administrative expenses reconciliation:				
GAAP selling, general and administrative expenses	$ 685		$ 645	
Stock-based compensation expenses	(44	)	(47	)
Other[(1)]	(3	)	2	
Non-GAAP selling, general and administrative expenses	$ 638		$ 600	
Operating margin reconciliation:				
GAAP operating margin	59.7	%	70.7	%
Up-front collaboration expenses	4.7	%	—	%
Acquisition related-amortization of purchased intangibles	2.7	%	2.7	%
Acquisition related-IPR&D impairment	1.5	%	—	%
Stock-based compensation expenses	1.1	%	1.2	%
Other[(1)]	(0.3	)%	—	%
Non-GAAP operating margin[(2)]	69.3	%	74.7	%

Notes:

[(1)] Amounts related to consolidation of a contract manufacturer, contingent consideration and/or other individually insignificant amounts

[(2)] Amounts may not sum due to rounding

GILEAD SCIENCES, INC.

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

(unaudited)

(in millions, except percentages and per share amounts)

	Three Months Ended March 31,			
	2016		2015	
Effective tax rate reconciliation:				
GAAP effective tax rate	20.8	%	17.3	%
Up-front collaboration expenses	(1.5	)%	—	%
Acquisition related-amortization of purchased intangibles	(0.7	)%	(0.4	)%
Other [(1)]	0.1	%	—	%
Non-GAAP effective tax rate[(2)]	18.7	%	16.9	%
Net income attributable to Gilead reconciliation:				
GAAP net income attributable to Gilead	$ 3,566		$ 4,333	
Up-front collaboration expenses	368		—	
Acquisition related-amortization of purchased intangibles	204		201	
Acquisition related-IPR&D impairment	99		—	
Stock-based compensation expenses	64		69	
Other[(1)]	(27	)	1	
Non-GAAP net income attributable to Gilead	$ 4,274		$ 4,604	
Diluted earnings per share reconciliation:				
GAAP diluted earnings per share	$ 2.53		$ 2.76	
Up-front collaboration expenses	0.26		—	
Acquisition related-amortization of purchased intangibles	0.14		0.13	
Acquisition related-IPR&D impairment	0.07		—	
Stock-based compensation expenses	0.05		0.04	
Other[(1)]	(0.02	)	—	
Non-GAAP diluted earnings per share[(2)]	$ 3.03		$ 2.94	
Shares used in per share calculation (diluted) reconciliation:				
GAAP shares used in per share calculation (diluted)	1,412		1,569	
Share impact of current stock-based compensation rules	(1	)	(1	)
Non-GAAP shares used in per share calculation (diluted)	1,411		1,568	
Non-GAAP adjustment summary:				
Cost of goods sold adjustments	$ 210		$ 208	
Research and development expenses adjustments	496		45	
Selling, general and administrative expenses adjustments	47		45	
Total non-GAAP adjustments before tax	753		298	
Income tax effect	(45	)	(28	)
Other[(1)]	—		1	
Total non-GAAP adjustments after tax attributable to Gilead	$ 708		$ 271	

Notes:

(1) Amounts related to consolidation of a contract manufacturer, contingent consideration and/or other individually insignificant amounts

(2) Amounts may not sum due to rounding

GILEAD SCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in millions)

	March 31, 2016	**December 31, 2015(1)**
Cash, cash equivalents and marketable securities	$ 21,322	$ 26,208
Accounts receivable, net	6,163	5,854
Inventories	1,880	1,955
Property, plant and equipment, net	2,431	2,276
Intangible assets, net	9,923	10,247
Goodwill	1,172	1,172
Other assets	4,874	4,004
Total assets	$ 47,765	$ 51,716
Current liabilities	$ 10,910	$ 9,890
Long-term liabilities	22,836	22,711
Equity component of currently redeemable convertible notes	—	2
Stockholders' equity(2)	14,019	19,113
Total liabilities and stockholders' equity	$ 47,765	$ 51,716

Notes:

(1) Derived from the audited consolidated financial statements as of December 31, 2015. Certain amounts have been reclassified to conform to current presentation.

(2) As of March 31, 2016, there were 1,348 million shares of common stock issued and outstanding.

GILEAD SCIENCES, INC.

PRODUCT SALES SUMMARY

(Unaudited)

(in millions)

	Three Months Ended March 31,	
	2016	**2015**
Antiviral products:		

Harvoni – U.S.	$ 1,407	$ 3,016
Harvoni – Europe	555	477
Harvoni – Japan	887	—
Harvoni – Other International	168	86
	3,017	3,579
Sovaldi – U.S.	645	421
Sovaldi – Europe	280	483
Sovaldi – Japan	202	—
Sovaldi – Other International	150	68
	1,277	972
Truvada – U.S.	576	409
Truvada – Europe	251	301
Truvada – Other International	71	61
	898	771
Atripla – U.S.	489	494
Atripla – Europe	143	194
Atripla – Other International	43	46
	675	734
Stribild – U.S.	376	282
Stribild – Europe	81	61
Stribild – Other International	20	13
	477	356
Complera / Eviplera – U.S.	222	163
Complera / Eviplera – Europe	146	145
Complera / Eviplera – Other International	13	12
	381	320
Viread – U.S.	123	100
Viread – Europe	76	80
Viread – Other International	73	54
	272	234
Genvoya – U.S.	141	—
Genvoya – Europe	16	—
Genvoya – Other International	1	—
	158	—
Other Antiviral – U.S.	21	14
Other Antiviral – Europe	6	7
Other Antiviral – Other International	1	1

	28	22
Total antiviral products – U.S.	4,000	4,899
Total antiviral products – Europe	1,554	1,748
Total antiviral products – Japan	1,089	—
Total antiviral products – Other International	540	341
	7,183	6,988

GILEAD SCIENCES, INC.

PRODUCT SALES SUMMARY

(Continued)

(Unaudited)

(in millions)

	Three Months Ended March 31,	
	2016	**2015**
Total antiviral products sales	$ 7,183	$ 6,988
Other products:		
Letairis	175	151
Ranexa	144	117
AmBisome	86	85
Zydelig	49	26
Other	44	38
	498	417
Total product sales	$ 7,681	$ 7,405

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Source: Gilead Sciences, Inc.

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