Gilead Sciences Announces Third Quarter 2013 Financial Results

October 29, 2013 4:03 PM ET

- Total Revenues of $2.78 billion, Up 15 percent over Third Quarter 2012 -
- Revised Full Year 2013 Guidance -

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 29, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the quarter ended September 30, 2013. Total revenues for the third quarter of 2013 increased 15 percent to $2.78 billion, from $2.43 billion for the third quarter of 2012. Product sales increased 15 percent to $2.71 billion for the third quarter of 2013 compared to $2.36 billion for the third quarter of 2012. Net income for the third quarter of 2013 was $788.6 million, or $0.47 per diluted share compared to $675.5 million, or $0.43 per diluted share for the third quarter of 2012. Non-GAAP net income for the third quarter of 2013, which excludes acquisition-related, restructuring and stock-based compensation expenses, was $879.1 million, or $0.52 per diluted share compared to $788.9 million, or $0.50 per diluted share for the third quarter of 2012.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except per share amounts)	**2013**	**2012**	**2013**	**2012**
Product sales	$2,709,652	$2,357,978	$7,760,505	$6,887,560
Royalty, contract and other revenues	73,181	68,619	321,357	226,672
Total revenues	$2,782,833	$2,426,597	$8,081,862	$7,114,232
Net income attributable to Gilead	$788,606	$675,505	$2,283,397	$1,829,025
Non-GAAP net income attributable to Gilead	$879,081	$788,940	$2,520,749	$2,260,606
Diluted EPS	$0.47	$0.43	$1.35	$1.17
Non-GAAP diluted EPS	$0.52	$0.50	$1.49	$1.44

Product Sales

Product sales were driven primarily by growth in Gilead's antiviral franchise during the third quarter of 2013. Significantly contributing to the increase were sales of Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) which launched in the third quarter of 2012 and sales of Complera®/Eviplera® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg). Product sales for the third quarter increased 20 percent in the U.S. and 5 percent in Europe compared to the third quarter of 2012.

Antiviral Product Sales

Antiviral product sales increased 14 percent to $2.33 billion for the third quarter of 2013, up from $2.04 billion for the third quarter of 2012, reflecting sales growth of 19 percent in the U.S. and 6 percent in Europe. The increase reflects strong underlying demand for our new single tablet regimen products, specifically Stribild and Complera/Eviplera.

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In thousands, except percentages)	**2013**	**2012**	**% Change**	**2013**	**2012**	**% Change**
Antiviral product sales	$2,326,727	$2,035,833	14 %	$6,700,052	$5,973,922	12 %
Atripla	899,669	865,378	4 %	2,714,850	2,656,997	2 %
Truvada	813,652	804,190	1 %	2,321,673	2,348,386	(1)%
Viread	231,555	214,909	8 %	692,075	622,016	11 %
Complera/Eviplera	210,736	99,297	112 %	547,608	224,386	144 %

Stribild	143,953	17,511	722	%	335,495	17,511	1,816	%

Cardiovascular Product Sales

Cardiovascular product sales increased 25 percent to $250.9 million for the third quarter of 2013.

	Three Months Ended September 30,				Nine Months Ended September 30,			
(In thousands, except percentages)	**2013**	**2012**	**% Change**		**2013**	**2012**	**% Change**	
Cardiovascular product sales	$250,887	$200,120	25	%	$700,134	$567,798	23	%
Letairis	135,072	105,054	29	%	381,436	293,976	30	%
Ranexa	115,815	95,066	22	%	318,698	273,822	16	%

Operating Expenses and Other

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 primarily due to the ongoing growth and expansion of Gilead's business in preparation for the anticipated launch of sofosbuvir.

Interest expense decreased primarily due to the maturity of the May 2013 convertible senior notes and the repayment of $850.0 million in bank debt issued in connection with the acquisition of Pharmasset Inc.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except percentages)	**2013**	**2012**	**2013**	**2012**
Non-GAAP research and development expenses	$488,535	$383,553	$1,436,282	$1,086,289
Non-GAAP selling, general and administrative expenses	$376,841	$287,205	$1,086,241	$893,677
Non-GAAP Interest expense	$(73,949)	$(89,322)	$(233,744)	$(267,677)

Note: Non-GAAP R&D, SG&A and interest 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 third quarter 2013 product sales and pre-tax earnings was an unfavorable $17.5 million and $15.9 million, respectively, compared to the third quarter of 2012.

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2013, Gilead had $2.76 billion of cash, cash equivalents and marketable securities compared to $2.58 billion as of December 31, 2012. During the first nine months of 2013, Gilead generated $2.38 billion in operating cash flow.

Full Year 2013 Guidance

Gilead revised its full year 2013 guidance, which it initially provided on February 4, 2013 and reiterated on July 25, 2013:

(In millions, except percentages and per share amounts)	**Initially provided February 4, 2013; Reiterated July 25, 2013**	**Updated October 29, 2013**

Net Product Sales	$10,000 - $10,200	$10,300 - $10,400
Non-GAAP*		
Product Gross Margin	74% - 76%	74% - 76%
R&D	$1,800 - $1,900	$1,950 - $2,000
SG&A	$1,550 - $1,650	$1,500 - $1,550
Effective Tax Rate	26% - 28%	26% - 27%
Diluted EPS Impact of Acquisition-Related, Restructuring and Stock-Based Compensation Expenses	$0.21 - $0.24	$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.

Product & Pipeline Updates Announced by Gilead During the Third Quarter of 2013 Include:

Antiviral Program

- Results from a Phase 2 study (Study 102) evaluating an investigational once-daily single tablet regimen containing tenofovir alafenamide (TAF) for the treatment of HIV-1 infection. At 48 weeks, a regimen of elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/TAF 10 mg was found to be similar to Stribild based on the percentage of patients with HIV RNA levels less than 50 copies/mL, and was associated with more favorable renal and bone safety markers. These results were presented at the 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy in Denver.
- Granting of marketing authorization by the European Commission for once-daily Tybost®, a pharmacokinetic enhancer that boosts blood levels of certain HIV medicines. Tybost is indicated as a boosting agent for the HIV protease inhibitors atazanavir 300 mg once daily and darunavir 800 mg once daily as part of antiretroviral combination therapy in adults with HIV-1 infection. This approval allows for the marketing of Tybost in all 28 countries of the European Union.

Oncology Program

- Submission of a New Drug Application to the U.S. Food and Drug Administration for marketing approval to support the use of idelalisib, an investigational, targeted, oral inhibitor of PI3K delta, for the treatment of indolent non-Hodgkin's lymphoma (iNHL) for patients with iNHL that is refractory (non-responsive) to rituximab and to alkylating-agent-containing chemotherapy.

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 third 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 1-866-825-3209 (U.S.) or 1-617-213-8061 (international) and dial the participant passcode 95755257 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 November 1, 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 81078378.

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, 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 2013 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, the fixed-dose combination of sofosbuvir/ledipasvir, TAF and idelalisib; 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, including the fixed-dose combination of 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 sofosbuvir for the treatment of HCV and idelalisib for iNHL; Gilead's ability to successfully commercialize its products, including Stribild and Tybost; 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, including sofosbuvir, the fixed-dose combination of sofosbuvir/ledipasvir, TAF and idelalisib; 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, Quarterly Report on Form 10-Q for the quarter ended June 30, 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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
Product sales	$2,709,652	$2,357,978	$7,760,505	$6,887,560
Royalty, contract and other revenues	73,181	68,619	321,357	226,672
Total revenues	2,782,833	2,426,597	8,081,862	7,114,232
Costs and expenses:				
Cost of goods sold	681,868	597,269	2,000,979	1,795,545
Research and development	546,244	465,831	1,567,778	1,320,286
Selling, general and administrative	406,860	319,583	1,186,147	1,095,209
Total costs and expenses	1,634,972	1,382,683	4,754,904	4,211,040
Income from operations	1,147,861	1,043,914	3,326,958	2,903,192
Interest expense	(73,949)	(89,322)	(233,744)	(275,010)
Other income (expense), net	5,777	(3,505)	2,222	(38,665)
Income before provision for income taxes	1,079,689	951,087	3,095,436	2,589,517
Provision for income taxes	294,473	280,052	824,892	774,877
Net income	785,216	671,035	2,270,544	1,814,640
Net loss attributable to noncontrolling interest	3,390	4,470	12,853	14,385
Net income attributable to Gilead	$788,606	$675,505	$2,283,397	$1,829,025
Net income per share attributable to Gilead common stockholders - basic	$0.51	$0.45	$1.50	$1.21
Net income per share attributable to Gilead common stockholders - diluted	$0.47	$0.43	$1.35	$1.17
Shares used in per share calculation - basic	1,532,105	1,514,770	1,526,847	1,514,064
Shares used in per share calculation - diluted	1,691,898	1,584,608	1,689,647	1,567,648

GILEAD SCIENCES, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION
(unaudited)
(in thousands, except percentages and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Cost of goods sold reconciliation:				
GAAP cost of goods sold	$681,868	$597,269	$2,000,979	$1,795,545
Stock-based compensation expenses	(1,823)	(1,864)	(6,296)	(6,084)
Acquisition related-amortization of purchased intangibles	(21,264)	(15,837)	(63,792)	(47,509)
Non-GAAP cost of goods sold	$658,781	$579,568	$1,930,891	$1,741,952
Product gross margin reconciliation:				
GAAP product gross margin	74.8 %	74.7 %	74.2 %	74.0 %
Stock-based compensation expenses	0.1 %	0.1 %	0.1 %	0.1 %
Acquisition related-amortization of purchased intangibles	0.8 %	0.7 %	0.8 %	0.7 %
Non-GAAP product gross margin[(1)]	75.7 %	75.5 %	75.1 %	74.8 %

Research and development expenses reconciliation:

GAAP research and development expenses	$546,244	$465,831	$1,567,778	$1,320,286
Stock-based compensation expenses	(27,740)	(23,236)	(79,261)	(162,214)
Restructuring expenses	31	(232)	(4,793)	(7,322)
Acquisition related-transaction costs	—	—	—	(345)
Acquisition related-contingent consideration remeasurement	(30,000)	(58,810)	(47,442)	(64,116)
Non-GAAP research and development expenses	$488,535	$383,553	$1,436,282	$1,086,289
Selling, general and administrative expenses reconciliation:				
GAAP selling, general and administrative expenses	$406,860	$319,583	$1,186,147	$1,095,209
Stock-based compensation expenses	(33,010)	(29,364)	(94,736)	(177,237)
Restructuring expenses	2,972	(2,792)	2,534	(13,199)
Acquisition related-transaction costs	300	(222)	(6,860)	(11,096)
Acquisition related-amortization of purchased intangibles	(281)	—	(844)	—
Non-GAAP selling, general and administrative expenses	$376,841	$287,205	$1,086,241	$893,677
Operating margin reconciliation:				
GAAP operating margin	41.2 %	43.0 %	41.2 %	40.8 %
Stock-based compensation expenses	2.2 %	2.2 %	2.2 %	4.9 %
Restructuring expenses	(0.1)%	0.1 %	0.0 %	0.3 %
Acquisition related-transaction costs	0.0 %	0.0 %	0.1 %	0.2 %
Acquisition related-amortization of purchased intangibles	0.8 %	0.7 %	0.8 %	0.7 %
Acquisition related-contingent consideration remeasurement	1.1 %	2.4 %	0.6 %	0.9 %
Non-GAAP operating margin[(1)]	45.2 %	48.5 %	44.9 %	47.7 %
Interest expense reconciliation:				
GAAP interest expense	$(73,949)	$(89,322)	$(233,744)	$(275,010)
Acquisition related-transaction costs	—	—	—	7,333
Non-GAAP interest expense	$(73,949)	$(89,322)	$(233,744)	$(267,677)
Net income attributable to Gilead reconciliation:				
GAAP net income attributable to Gilead, net of tax	$788,606	$675,505	$2,283,397	$1,829,025
Stock-based compensation expenses	46,576	39,442	132,335	304,282
Restructuring expenses	(2,076)	2,165	3,048	14,937
Acquisition related-transaction costs	(300)	123	6,860	13,665
Acquisition related-amortization of purchased intangibles	16,275	11,462	47,667	34,581
Acquisition related-contingent consideration remeasurement	30,000	60,243	47,442	64,116
Non-GAAP net income attributable to Gilead, net of tax	$879,081	$788,940	$2,520,749	$2,260,606

GILEAD SCIENCES, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION - (Continued)
(unaudited)
(in thousands, except percentages and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Diluted earnings per share reconciliation:				
GAAP diluted earnings per share	$0.47	$0.43	$1.35	$1.17
Stock-based compensation expenses	0.03	0.02	0.08	0.19

Restructuring expenses	(0.00)	0.00	0.00	0.01
Acquisition related-transaction costs	(0.00)	0.00	0.00	0.01
Acquisition related-amortization of purchased intangibles	0.01	0.01	0.03	0.02
Acquisition related-contingent consideration remeasurement	0.02	0.04	0.03	0.04
Non-GAAP diluted earnings per share[1]	$0.52	$0.50	$1.49	$1.44
Shares used in per share calculation (diluted) reconciliation:				
GAAP shares used in per share calculation (diluted)	1,691,898	1,584,608	1,689,647	1,567,648
Share impact of current stock-based compensation rules	(1,139)	(2,620)	(1,281)	(2,854)
Non-GAAP shares used in per share calculation (diluted)	1,690,759	1,581,988	1,688,366	1,564,794
Non-GAAP adjustment summary:				
Cost of goods sold adjustments	$23,087	$17,701	$70,088	$53,593
Research and development expenses adjustments	57,709	82,278	131,496	233,997
Selling, general and administrative expenses adjustments	30,019	32,378	99,906	201,532
Interest expense adjustments	—	—	—	7,333
Total non-GAAP adjustments before tax	110,815	132,357	301,490	496,455
Income tax effect	(20,340)	(18,922)	(64,138)	(64,874)
Total non-GAAP adjustments after tax	$90,475	$113,435	$237,352	$431,581

[1] Amounts may not sum due to rounding.

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2013	**December 31, 2012[1]**
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 2,755,557	$ 2,582,086
Accounts receivable, net	1,971,926	1,751,388
Inventories	1,946,048	1,744,982
Property, plant and equipment, net	1,133,032	1,100,259
Intangible assets, net	12,034,457	11,736,393
Goodwill	1,188,157	1,060,919
Other assets	1,439,251	1,263,811
Total assets	$ 22,468,428	$ 21,239,838
Current liabilities	$ 4,895,124	$ 4,270,020
Long-term liabilities	6,380,831	7,418,949
Stockholders' equity[2]	11,192,473	9,550,869
Total liabilities and stockholders' equity	$ 22,468,428	$ 21,239,838

[1] Derived from the audited consolidated financial statements as of December 31, 2012.

[2] As of September 30, 2013, there were 1,534,028 shares of common stock issued and outstanding.

GILEAD SCIENCES, INC.
PRODUCT SALES SUMMARY
(unaudited)

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	**2012**	**2013**	**2012**
Antiviral products:				
Atripla – U.S.	$575,533	$539,797	$1,740,689	$1,672,676
Atripla – Europe	256,853	270,273	805,848	821,094
Atripla – Other International	67,283	55,308	168,313	163,227
	899,669	865,378	2,714,850	2,656,997
Truvada – U.S.	430,173	414,452	1,153,575	1,180,791
Truvada – Europe	313,963	329,936	970,982	980,626
Truvada – Other International	69,516	59,802	197,116	186,969
	813,652	804,190	2,321,673	2,348,386
Viread – U.S.	108,718	98,969	305,311	282,737
Viread – Europe	86,177	81,962	262,425	250,955
Viread – Other International	36,660	33,978	124,339	88,324
	231,555	214,909	692,075	622,016
Complera / Eviplera – U.S.	126,888	82,099	350,372	195,742
Complera / Eviplera – Europe	74,025	14,306	172,288	24,771
Complera / Eviplera – Other	9,823	2,892	24,948	3,873
	210,736	99,297	547,608	224,386
Stribild – U.S.	134,700	17,511	323,639	17,511
Stribild – Europe	7,911	—	9,759	—
Stribild – Other International	1,342	—	2,097	—
	143,953	17,511	335,495	17,511
Hepsera – U.S.	8,578	12,615	31,399	33,596
Hepsera – Europe	9,760	11,999	30,251	41,384
Hepsera – Other International	1,978	2,705	6,545	7,827
	20,316	27,319	68,195	82,807
Emtriva – U.S.	5,127	4,717	14,424	13,580
Emtriva – Europe	1,560	1,617	4,895	5,169
Emtriva – Other International	159	895	837	3,070
	6,846	7,229	20,156	21,819
Total Antiviral products – U.S.	1,389,717	1,170,160	3,919,409	3,396,633
Total Antiviral products – Europe	750,249	710,093	2,256,448	2,123,999
Total Antiviral products – Other International	186,761	155,580	524,195	453,290
	2,326,727	2,035,833	6,700,052	5,973,922
Letairis	135,072	105,054	381,436	293,976
Ranexa	115,815	95,066	318,698	273,822
AmBisome	97,812	87,448	258,224	255,865
Other products	34,226	34,577	102,095	89,975

	382,925	322,145	1,060,453	913,638
Total product sales	$2,709,652	$2,357,978	$7,760,505	$6,887,560

Source: Gilead Sciences, Inc.

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