Gilead Sciences Announces Third Quarter 2008 Financial Results

October 16, 2008 4:06 PM ET

- Record Total Revenues of $1.37 Billion, Up 30 Percent over Third Quarter 2007 - - Record Product Sales of $1.34 Billion, Up 39 Percent over Third Quarter 2007 - - Third Quarter EPS of $0.52 per Share - - Third Quarter Non-GAAP EPS of $0.55 per Share - - Announces $750 Million Accelerated Share Repurchase Program -

FOSTER CITY, Calif.--(BUSINESS WIRE)--

Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the quarter ended September 30, 2008. Total revenues for the third quarter of 2008 were $1.37 billion, up 30 percent compared to total revenues of $1.06 billion for the third quarter of 2007. Net income for the third quarter of 2008 was $504.0 million, or $0.52 per diluted share, including after-tax stock-based compensation expense of $30.1 million. Non-GAAP net income for the third quarter of 2008, which excludes after-tax stock-based compensation expense, was $534.1 million, or $0.55 per diluted share. Non-GAAP net income for the third quarter of 2007, which excluded after-tax stock-based compensation expense of $31.8 million, was $430.1 million, or $0.45 per diluted share.

Product Sales

Product sales increased 39 percent to a record $1.34 billion for the third quarter of 2008, compared to $961.9 million in the third quarter of 2007. This growth was driven primarily by Gilead's antiviral franchise, including the strong growth of Atripla(R) (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) sales as well as the continued growth of Truvada(R) (emtricitabine and tenofovir disoproxil fumarate) sales.

Antiviral Franchise

Antiviral product sales increased 39 percent to $1.23 billion in the third quarter from $885.0 million for the same period in 2007. The increase was driven primarily by the sales volume growth of Atripla and Truvada, as well as a favorable foreign currency exchange impact.

-- Truvada

Truvada sales increased 34 percent to $549.1 million for the third quarter of 2008 from $409.1 million in the third quarter of 2007, driven primarily by sales volume growth in the United States and Europe, and a favorable foreign currency exchange impact.

-- Atripla

Atripla sales increased 77 percent to $427.6 million for the third quarter of 2008 from $241.1 million in the third quarter of 2007, driven primarily by the continued uptake in the United States, as well as launches in certain European countries.

-- Viread

Viread(R) (tenofovir disoproxil fumarate) sales increased five percent to $156.0 million for the third quarter of 2008 from $149.1 million in the third quarter of 2007.

-- Hepsera

Sales of Hepsera(R) (adefovir dipivoxil) for chronic hepatitis B increased 15 percent to $91.2 million for the third quarter of 2008 from $79.3 million in the third quarter of 2007, driven primarily by a favorable foreign currency exchange impact and sales volume growth in North America and certain European markets.

AmBisome

Sales of AmBisome(R) (amphotericin B) liposome for injection for severe fungal infections increased six percent to $72.9 million for the third quarter of 2008 from $68.5 million for the third quarter of 2007. The increase in AmBisome sales was driven primarily by a favorable foreign currency exchange impact.

Royalty, Contract and Other Revenues

Royalty, contract and other revenues resulting primarily from collaborations with corporate partners were $32.8 million, a decrease of 66 percent from $96.9 million in the third quarter of 2007. This decrease was driven primarily by lower Tamiflu(R) (oseltamivir phosphate) royalties from F. Hoffmann-La Roche Ltd of $8.6 million in the third quarter of 2008 compared to Tamiflu royalties of $77.4 million in the third quarter of 2007. This change was due to decreased sales related to pandemic planning initiatives worldwide.

Research and Development

Research and development (R&D) expenses in the third quarter of 2008 were $188.1 million compared to $140.4 million for the same quarter in 2007. Non-GAAP R&D expenses, which exclude stock-based compensation expense, were $170.4 million, compared to $122.0 million for the same quarter in 2007 as a result of increased clinical study activity, research and related expenses as well as higher headcount related to the growth in Gilead's business.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses in the third quarter of 2008 were $189.2 million compared to $173.0 million for the same quarter in 2007. Non-GAAP SG&A expenses, which exclude stock-based compensation expense, were $167.9 million, compared to $148.4 million for the same quarter in 2007 primarily as a result of increased compensation and benefits as well as infrastructure and technology costs to support the continued growth in Gilead's business.

Net Foreign Currency Exchange Impact

The net foreign currency exchange impact on third quarter 2008 revenues and pre-tax earnings, which includes revenues and expenses generated from outside the United States, was a favorable $58.8 million and $36.7 million, respectively, compared to the same period in 2007.

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2008, Gilead had cash, cash equivalents and marketable securities of $3.26 billion compared to $2.72 billion as of December 31, 2007. For the first nine months of 2008, Gilead generated $1.56 billion of operating cash flows including $555.2 million in the third quarter.

Share Repurchase Program

Gilead intends to enter into an agreement to repurchase $750.0 million of its common stock on an accelerated basis. These shares will be purchased under the $3.0 billion share repurchase program announced on October 22, 2007. The commencement of this repurchase program is contingent on market conditions and on Gilead not possessing material non-public information on the commencement date.

Corporate Highlights

In July 2008, Gilead announced that Richard J. Whitley, MD was appointed to Gilead's Board of Directors, increasing the number of Directors to 11. Dr. Whitley is Professor of Pediatrics, Microbiology, Medicine and Neurosurgery at the University of Alabama at Birmingham.

In September 2008, Gilead announced that Seigo Izumo, MD joined the company as Senior Vice President, Cardiovascular Therapeutics. Dr. Izumo oversees Gilead's growing cardiovascular franchise and serves as a member of Gilead's executive committee.

Product and Pipeline Highlights

Antiviral Franchise

In July 2008, Gilead announced that it had begun enrolling patients in a Phase III clinical trial of its investigational antiretroviral agent elvitegravir (GS 9137), a novel oral integrase inhibitor that is being evaluated for the treatment of HIV. The study will enroll 700 treatment-experienced HIV-infected patients, at approximately 125 sites in the United States and Puerto Rico.

In August 2008, Gilead and Merck & Co., Inc. (Merck) announced that the companies had entered into an agreement through which Gilead assumed the lead role for distribution of Atripla for the treatment of HIV in 12 countries located primarily in Latin America and the Asia-Pacific region. There are now 138 countries covered under agreements between Gilead and Merck or Bristol-Myers Squibb Company.

Also in August 2008, Gilead announced that the U.S. Food and Drug Administration (FDA) had granted marketing approval for Viread for the treatment of chronic hepatitis B. Viread was approved for the treatment of chronic hepatitis B in Canada in September 2008 and in the European Union, Turkey, Australia and New Zealand earlier this year.

Respiratory Franchise

In September 2008, Gilead announced that it had received a complete response letter from the FDA for its New Drug Application for aztreonam lysine for inhalation, an investigational therapy in development for people with cystic fibrosis who have Pseudomonas aeruginosa. The agency stated that they could not approve the application in its current form and an additional clinical study has been requested.

Conference Call

At 4:30 p.m. Eastern Time today, Gilead will host a conference call with a simultaneous webcast to discuss the results of its third quarter of 2008. During this call/webcast, Gilead's management will discuss the company's third quarter of 2008 results and provide a general business update. The webcast will be available live via the internet by accessing Gilead's website at www.gilead.com. To access the webcast, please connect to the company's website at least 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 1-866-831-6270 (U.S.) or 1-617-213-8858 (international) and dial the participant passcode 48487372 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 October 19, 2008. To access the phone replay, please call 1-888-286-8010 (U.S.) or 1-617-801-6888 (international) and dial the participant passcode 67732439.

About Gilead

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. Gilead'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 Australia.

Non-GAAP Financial Information

Non-GAAP net income and net income per diluted share for the three months ended September 30, 2008 and 2007, and nine months ended September 30, 2007, are presented excluding the after-tax impact of stock-based compensation expense and the related methodology for computing dilutive securities for net income per diluted share purposes. Non-GAAP net

income and net income per diluted share for the nine months ended September 30, 2008 are presented excluding the after-tax impact of the purchased in-process research and development expense incurred in connection with the acquisition of all of Navitas Assets, LLC's assets related to its cicletanine business, as well as the after-tax impact of stock-based compensation expense and the related methodology for computing dilutive securities for net income per diluted share purposes. Non-GAAP R&D expenses and SG&A expenses for the 2008 and 2007 periods are presented excluding the impact of stock-based compensation expense. 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 the company's operating results as reported under United States generally accepted accounting principles.

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 sustain growth in revenues for its antiviral and cardiovascular franchises; unpredictable variability of Tamiflu royalties and the strong relationship between this royalty revenue and global pandemic planning and supply; Gilead's ability to receive regulatory approvals in a timely manner or at all, for new and current products; Gilead's ability to successfully commercialize any products that receive regulatory approvals; Gilead's ability to successfully develop its respiratory and cardiovascular franchises; initiating and completing clinical trials may take longer or cost more than expected; fluctuations in the foreign exchange rate of the U.S. dollar that may reduce or eliminate the favorable foreign currency exchange impact on Gilead's future revenues and pre-tax earnings; Gilead's ability to commence the accelerated stock repurchase program when intended, or at all, depends upon market conditions and whether, at the time of commencement, Gilead possesses material, non-public information that would make it illegal for Gilead to commence the program as intended; and other risks identified from time to time in Gilead's reports filed with the U.S. Securities and Exchange Commission. 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 Annual Report on Form 10-K for the year ended December 31, 2007, its Quarterly Report on Form 10-Q for the first and second quarters of 2008 and its subsequent current reports on Form 8-K. 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.

Truvada, Viread, Hepsera, AmBisome and Letairis are registered trademarks of Gilead Sciences, Inc.

Atripla is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC.

Tamiflu is a registered trademark of F. Hoffmann-La Roche Ltd.

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

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(unaudited)
(in thousands, except per share amounts)

Three Months Ended September 30,	Nine Months Ended September 30,

	2008	2007	2008	2007
Revenues:				
Product sales	$1,338,502	$ 961,931	$3,697,024	$2,707,214
Royalty, contract and other revenues	32,766	96,872	210,521	428,108
Total revenues	1,371,268	1,058,803	3,907,545	3,135,322
Costs and expenses:				
Cost of goods sold (1)	300,183	198,460	805,715	553,229
Research and development (1)	188,062	140,357	519,905	406,378
Selling, general and administrative (1)	189,189	172,956	603,679	525,693
Purchased in-process research and development (2)	-	-	10,851	-
Total costs and expenses	677,434	511,773	1,940,150	1,485,300
Income from operations	693,834	547,030	1,967,395	1,650,022
Interest and other income, net	3,637	29,502	40,363	80,295
Interest expense	(2,951)	(2,989)	(9,230)	(10,243)
Minority interest	2,160	2,478	6,195	7,032
Income before provision for income taxes	696,680	576,021	2,004,723	1,727,106
Provision for income taxes (1)	192,675	177,702	561,763	513,450
Net income	$ 504,005	$ 398,319	$1,442,960	$1,213,656
Net income per share - basic	$ 0.55	$ 0.43	$ 1.56	$ 1.31
Net income per share - diluted	$ 0.52	$ 0.42	$ 1.50	$ 1.26
Shares used in per share calculation - basic	920,807	926,963	923,894	928,519
Shares used in per share calculation - diluted	960,585	959,043	964,267	962,804

Notes:

(1) The following is the stock-based compensation expense included in the respective captions of the condensed consolidated statements of income above:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007

Stock-based compensation expense:				
Cost of goods sold	$ 2,592	$ 3,138	$ 7,134	$ 8,350
Research and development	17,680	18,360	49,945	56,129
Selling, general and administrative	21,322	24,563	57,526	86,683
Income tax effect	(11,513)	(14,284)	(32,114)	(44,939)
Total stock-based compensation expense, net of tax	$ 30,081	$ 31,777	$ 82,491	$ 106,223

(2) For the nine months ended September 30, 2008, Gilead incurred $10.9 million of purchased in-process research and development expense as a result of the acquisition of all of Navitas Assets, LLC's assets related to its cicletanine business.

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

Below is a reconciliation of Gilead's GAAP operating results and diluted per share amounts as reported in the attached press release. Non-GAAP net income and net income per diluted share for the three months ended September 30, 2008 and 2007, and the nine months ended September 30, 2007, are presented excluding the after-tax impact of stock-based compensation expense and the related methodology for computing dilutive securities for net income per diluted share purposes. Non-GAAP net income and net income per diluted share for the nine months ended September 30, 2008 is presented excluding the after-tax impact of the purchased in-process research and development expense incurred in connection with the acquisition of all of Navitas Assets, LLC's assets related to its cicletanine business, as well as the after-tax impact of stock-based compensation expense and the related methodology for computing dilutive securities for net income per diluted share purposes. 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 the company's operating results as reported under GAAP.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net income (GAAP)	$504,005	$398,319	$1,442,960	$1,213,656
Stock-based compensation expense, net of tax	30,081	31,777	82,491	106,223
Purchased in-process research and development expense, net of tax	-	-	7,769	-
Net income (Non-GAAP)	$534,086	$430,096	$1,533,220	$1,319,879
Shares used in per share calculation - diluted (GAAP)	960,585	959,043	964,267	962,804

Dilutive securities	1,924	1,780	2,103	2,108
Shares used in per share calculation - diluted (Non-GAAP)	962,509	960,823	966,370	964,912
Net income per share - diluted (GAAP)	$ 0.52	$ 0.42	$ 1.50	$ 1.26
Net income per share - diluted (Non-GAAP)	$ 0.55	$ 0.45	$ 1.59	$ 1.37

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

	September 30, 2008	December 31, 2007
	(unaudited)	(Note 1)
Cash, cash equivalents and marketable securities	$ 3,256,262	$2,722,422
Other current assets	2,407,389	1,856,314
Property, plant and equipment, net	512,281	447,696
Other noncurrent assets	798,196	808,284
Total assets	$ 6,974,128	$5,834,716
Current liabilities	$ 1,259,134	$ 736,275
Long-term liabilities and minority interest	1,549,084	1,638,451
Stockholders' equity	4,165,910	3,459,990
Total liabilities and stockholders' equity	$ 6,974,128	$5,834,716

Notes:
(1) Derived from audited consolidated financial statements at that date.

GILEAD SCIENCES, INC.
PRODUCT SALES SUMMARY
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
		(Note 1)		(Note 1)
Antiviral products:				
Truvada - U.S.	$ 262,065	$ 206,681	$ 736,999	$ 579,725
Truvada - Europe	257,315	183,016	716,593	501,000
Truvada - Other International	29,721	19,387	91,043	59,657
	549,101	409,084	1,544,635	1,140,382
Atripla - U.S.	346,377	240,217	965,254	641,706
Atripla - Europe	71,028	-	122,727	-

Atripla - Other International	10,218	884	18,960	1,962
	427,623	241,101	1,106,941	643,668
Viread - U.S.	63,431	63,488	184,913	194,841
Viread - Europe	66,320	62,944	193,309	199,892
Viread - Other International	26,207	22,676	81,084	69,950
	155,958	149,108	459,306	464,683
Hepsera - U.S.	36,744	32,387	102,600	94,647
Hepsera - Europe	49,437	42,122	148,431	119,754
Hepsera - Other International	5,036	4,764	13,573	11,389
	91,217	79,273	264,604	225,790
Emtriva - U.S.	4,001	3,315	11,945	10,213
Emtriva - Europe	2,762	2,408	7,437	9,014
Emtriva - Other International	871	738	4,729	5,161
	7,634	6,461	24,111	24,388
Total Antiviral products - U.S.	712,618	546,088	2,001,711	1,521,132
Total Antiviral products - Europe	446,862	290,490	1,188,497	829,660
Total Antiviral products - Other International	72,053	48,449	209,389	148,119
	1,231,533	885,027	3,399,597	2,498,911
AmBisome	72,884	68,508	213,680	194,764
Letairis	31,656	6,153	76,679	6,266
Other products	2,429	2,243	7,068	7,273
	106,969	76,904	297,427	208,303
Total product sales	$1,338,502	$ 961,931	$3,697,024	$2,707,214

(1) Certain prior period amounts have been reclassified to conform to current period presentation.

Source: Gilead Sciences, Inc.