

Gilead Sciences Announces Third Quarter 2004 Financial Results

October 21, 2004 4:01 PM ET

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 21, 2004--Gilead Sciences, Inc. (Nasdaq:GILD)

- Total Quarterly Revenues of \$326 Million, Up 63 Percent over Third Quarter 2003
- Total Nine Month Revenues of \$955 Million Surpasses Total Full Year Revenues for 2003
- GAAP EPS of \$0.25 Per Share

Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the third quarter ended September 30, 2004. Total revenues for the third quarter were \$326.2 million, up 63 percent, compared to total revenues of \$200.4 million for the third quarter of 2003. Operating cash flow for the quarter increased by 207 percent to \$166.6 million, compared to \$54.3 million for the same period last year.

Net income for the third quarter of 2004 was \$113.2 million, or \$0.25 per diluted share, an increase of 55 percent compared to net income of \$73.1 million, or \$0.17 per diluted share, for the third quarter of 2003. The third quarter of 2003 included a \$13.2 million reimbursement that Gilead received after settling a contractual dispute with a vendor. This reimbursement was recorded as a reduction of research and development expenses and increased prior period earnings per share by nearly \$0.03. Pre-tax income for the third quarter of 2004 increased substantially to \$166.5 million, an increase of 116 percent, when compared to \$77.0 million in the third quarter of 2003. The difference between the pre-tax and after-tax growth rates is principally due to the Company's effective tax rate, which increased to 32 percent during the third quarter of 2004 compared to 5 percent for the same period last year.

Net revenues from product sales totaled \$310.7 million, up 60 percent from the third quarter of 2003. This growth was primarily driven by higher revenues from our HIV products, which includes Viread(R) (tenofovir disoproxil fumarate), Emtriva(R) (emtricitabine) and Truvada (TM) (emtricitabine and tenofovir disoproxil fumarate). HIV product sales were \$228.1 million during the third quarter of 2004, up from \$121.4 million in the third quarter of 2003, an increase of 88 percent. U.S. sales of the Company's HIV products in the third quarter of 2004 were \$139.4 million, including Viread sales of \$108.5 million, Truvada sales of \$18.2 million, and Emtriva sales of \$12.8 million. Growth in HIV product sales in the United States during the third quarter of 2004 was driven primarily by higher prescription volumes of Viread and Emtriva, as well as the launch of Truvada in August 2004. This growth was offset in part by additional reductions in U.S. distribution channel inventory levels of Viread as the three major wholesalers achieved the targets stipulated under our recently implemented inventory management agreements. HIV product sales outside the United States totaled \$88.7 million, including Viread sales of \$85.4 million and Emtriva sales of \$3.2 million. Ex-U.S. HIV product sales growth for the third quarter of 2004 was driven by higher prescription volumes and a favorable currency environment. HIV product sales in the third quarter of 2004 were \$5.9 million higher due primarily to a stronger European currency environment compared to the same quarter last year. AmBisome(R) (amphotericin B) liposome for injection sales for the third quarter of 2004 were \$49.8 million, a decrease of 3 percent compared to the third quarter of 2003. This decrease was due to lower volumes resulting from increased competition in Europe, which offset a favorable currency impact of \$2.8 million due to the stronger European currency when compared to the third quarter of 2003. Sales of Hepsera(R) (adefovir dipivoxil 10 mg) were \$29.7 million for the third quarter of 2004, a substantial increase of 81 percent from \$16.4 million in the third quarter of 2003. This was primarily driven by prescription growth in the United States and Europe, offset in part by reductions in U.S. distribution channel inventory levels as the three major wholesalers achieved the targets stipulated under our inventory management agreements.

"We are pleased with the third quarter results and the overall growth of our HIV franchise -- in particular, Truvada's rapid uptake and solid revenue performance after only nine weeks on the market," said John C. Martin, PhD, President and Chief Executive Officer of Gilead Sciences. "We continue to leverage our antiviral expertise and solid financial position to successfully grow our global HIV franchise."

For the third quarter of 2004, royalty and contract revenues resulting from collaborations with corporate partners totaled \$15.5 million, compared to \$6.3 million in the third quarter of 2003. Significant components of royalty and contract revenues for the third quarter of 2004 include royalties of \$3.6 million on sales of AmBisome primarily in the United States by Gilead's co-promotion partner Fujisawa Healthcare, a \$2.9 million milestone payment earned from EyeTech Pharmaceuticals upon the filing of a new drug application in Europe for Macugen(TM) (pegaptanib sodium injection) and \$2.1 million received from Medarex, Inc. in conjunction with a royalty buyout agreement.

Research and development (R&D) expenses for the third quarter of 2004 were \$49.2 million. R&D expenses for the third quarter of 2003 were \$36.0 million, which included the favorable impact of a \$13.2 million reimbursement resulting from the settlement of a contractual dispute with a vendor. Excluding the impact of this reimbursement, third quarter 2003 spending would have been \$49.2 million. During prior periods, certain European phase IV clinical trial expenses that are now recorded as R&D expenses were recorded as selling, general and administrative expenses (SG&A). Such expenses for the third quarter of 2003 of \$4.3 million have been reclassified from SG&A to R&D to be consistent with the current period presentation. Third quarter 2004 R&D expenses remained flat from the third quarter of 2003 primarily due to higher research spending associated with Gilead's proprietary prodrug technology and hepatitis C programs, offset by a lower level of clinical trials activity in the third quarter 2004.

SG&A expenses for the three months ended September 30, 2004 were \$72.4 million, compared to \$59.3 million for the same quarter of 2003 after the European phase IV clinical trial reclassification of \$4.3 million to R&D expenses. The higher expenses are due primarily to increased global marketing efforts, the significant expansion of Gilead's U.S. and European sales forces toward the latter part of 2003, increased infrastructure costs, as well as the U.S. launch of Truvada.

The net foreign exchange impact on pre-tax earnings, including revenue and expenses generated from outside the United States, as well as hedging activity for the three and nine months ended September 30, 2004, was a favorable \$7.9 million and \$23.0 million, respectively, due primarily to a stronger Euro relative to the U.S. dollar.

Gilead also reported its results of operations for the nine months ended September 30, 2004. The Company recorded net revenues from product sales of \$886.6 million and aggregate royalty and contract revenues of \$68.4 million, up 53 percent and 189 percent, respectively, compared to the same period last year. Total revenues for the first nine months of 2003 included product sales of \$580.7 million and aggregate royalty and contract revenues of \$23.6 million. Sales of HIV products for the nine months ended September 30, 2004 were \$646.7 million, up from \$395.7 million in the nine months ended September 30, 2003. On a volume basis, for the nine months ended September 30, 2004, HIV product volume increased by 66 percent when compared to the first nine months of 2003; volume increased 58 percent in the U.S. and 82 percent in ex-U.S. countries. AmBisome sales for the nine months ended September 30, 2004 were \$156.7 million compared to \$143.8 million, a 9 percent increase over the nine months ended September 30, 2003. Due to the favorable currency environment, sales in the first nine months of 2004 were \$21.2 million and \$13.6 million higher for HIV and AmBisome products, respectively, when compared to the same period last year. Sales of Hepsera totaled \$76.6 million for the first nine months of 2004, an increase of 121 percent over the \$34.7 million in the first nine months of 2003.

Net income for the nine months ended September 30, 2004 was \$339.1 million, or \$0.74 per diluted share. This compares to a net loss of \$264.6 million, or \$0.66 per diluted share for the nine months ended September 30, 2003 which included a charge of \$488.6 million for in-process research and development associated with the acquisition of Triangle Pharmaceuticals, Inc. in January 2003. Excluding this in-process research and development charge, non-GAAP earnings would have been \$211.4 million or \$0.49 per diluted share for the nine months ended September 30, 2003, which includes the impact of dilutive stock options and convertible debt.

Research and development expenses for the nine months ended September 30, 2004 and 2003 were \$153.4 million and \$122.9 million, respectively, which includes the reclassification of phase IV clinical trial expenses to R&D of \$11.3 million for the first nine months of 2003. Excluding the \$13.2 million vendor contract settlement mentioned above, R&D expenses for the nine months ended September 30, 2003 would have been \$136.1 million. The higher expenses during the first nine months of 2004 are primarily attributable to increased headcount, costs associated with the development of Truvada and research spending related to the Company's proprietary prodrug technology.

Selling, general and administrative expenses for the nine months ended September 30, 2004 were \$217.4 million, compared to \$160.1 million for the first nine months ended September 30, 2003, which includes the reclassification of phase IV clinical trial expenses to R&D of \$11.3 million for the nine months of 2003. The significant increase in expenses is primarily due to Gilead's increased global marketing efforts and the expansion of Gilead's U.S. and European sales forces to support the commercial launches of Viread, Hepsera, Emtriva and Truvada.

As of September 30, 2004, the Company had cash, cash equivalents and marketable securities of \$1.15 billion, compared to \$707.0 million at December 31, 2003. The increase in cash, cash equivalents and marketable securities is primarily attributable to strong operating cash flow of \$387.3 million for the nine months ended September 30, 2004.

In late July 2004, Gilead announced that its Board of Directors approved a two-for-one split of the Company's outstanding common stock, payable to shareholders of record as of August 12, 2004. The Company's stock began trading at the post-split price on September 7, 2004. All share and per share data in this press release reflect this two-for-one stock split.

Corporate Highlights

In July 2004, Gilead announced that it had entered into inventory management agreements (IMAs) with AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation, three major pharmaceutical wholesalers that distribute about 90 percent of the portfolio of products Gilead sells in the United States.

In September, Gilead announced that Kevin Young joined the Company as Executive Vice President, Commercial Operations, a newly-created position following the Company's expansion and reorganization of its commercial operations earlier this year.

In early October, Gilead announced that the Company was calling for redemption on November 20, 2004 all of its outstanding 2% Convertible Senior Notes due December 15, 2007 (the Notes). The aggregate principal amount outstanding of the Notes is \$345.0 million as of September 30, 2004.

Product and Pipeline Highlights

"This quarter saw our HIV franchise continue its strong growth with the approval of Truvada, our third once-a-day HIV therapeutic and

fourth once-a-day antiviral approved by the FDA in less than three years," said Dr. Martin. "With this once-daily fixed-dose product, doctors and patients now have a new weapon in their fight against HIV that may make it easier to construct convenient combination regimens. Additionally, we were pleased to announce our collaboration with Genelabs Technologies to develop novel compounds for the treatment of hepatitis C, a serious life-threatening disease that represents an important unmet medical need."

HIV/AIDS Franchise

In July, Gilead announced a 37 percent reduction in the price of Viread for use in the developing world. Gilead provides Viread through the Global Access Program at a no-profit price in every country in Africa and in 15 additional countries in other parts of the world classified as "least developed" by the United Nations. This reduction resulted from improvements in the manufacturing process for Viread and increased economies of scale.

Also in July, the Company announced the publication of results from two separate studies evaluating the efficacy and safety of Viread and Emtriva, respectively, compared with stavudine (d4T), in combination with other antiretroviral agents. These data appeared in the July 14, 2004 edition of the Journal of the American Medical Association, a special issue that was published to coincide with the 15th International AIDS Conference, which took place in Bangkok, Thailand.

In early August, Gilead announced that the U.S. Food and Drug Administration granted expedited approval for Truvada, a fixed-dose combination of the Company's anti-HIV medications Emtriva and Viread. Gilead began shipping Truvada to wholesalers within days of approval.

In mid-August, the Company announced that it will provide access to Truvada through Gilead's Global Access Program and Advancing Access Program. The Advancing Access Program helps ensure access to the Company's products for patients in the United States who cannot obtain reimbursement or afford to pay for the product.

In late August, Gilead announced positive preliminary data from a planned interim 24-week analysis of the Company's ongoing Study 934. This study, a 48-week clinical trial, was designed to compare a regimen of Viread, Emtriva and efavirenz to Combivir(R) (lamivudine 150 mg/zidovudine 300 mg) and efavirenz in more than 500 treatment-naive patients with HIV.

In September, the Company announced the acceptance of a late breaker presentation of the 24-week interim data from Study 934 at the 44th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Washington, DC. The data will be presented on Sunday, October 31, 2004 at 4:20 p.m. Eastern.

Today, Gilead announced the discontinuation of early stage development programs for GS 7340 and GS 9005 for the potential treatment of HIV.

Hepatitis Franchise

At the end of the quarter, Gilead and Genelabs Technologies, Inc. (Nasdaq: GNLB) announced that the companies have signed an agreement to collaborate in the research, development and commercialization of novel nucleoside polymerase inhibitors for the treatment of infection caused by the hepatitis C virus.

Conference Call

At 4:30 p.m. Eastern today, Gilead will webcast a conference call live on the Company's website to discuss its quarterly results and outlook. During the call, Gilead will be discussing additional financial and statistical information. That information can be found on the Company's website at www.gilead.com, under "About Gilead," "Investors." For Internet access to the live webcast or the archive, which will be available for one year, log on to www.gilead.com. 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 view the webcast.

Alternatively, please call 1-800-299-9086 (U.S.) or 1-617-786-2903 (international) and dial the participant passcode 24175007 to access the call. Telephone replay is available approximately two hours after the call through 6:30 p.m. Eastern, November 1, 2004. To access the replay, please call 1-888-286-8010 (U.S.) or 1-617-801-6888 (international), and dial the participant passcode 99013977.

About Gilead

Gilead Sciences is a biopharmaceutical Company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases worldwide. The Company has seven marketed products and focuses its research and clinical programs on anti-infectives. Headquartered in Foster City, CA, Gilead has operations in North America, Europe and Australia.

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. These statements include those that can affect Gilead's future financial results, including those relating to: revenues, research and development expenses, and selling, general and administrative expenses; the efficacy of any marketed or pipeline development products; the ability and timing to file for or obtain marketing approval for Gilead's pipeline development products; or the market introduction, competitive positioning and commercial arrangements for sale of its marketed or pipeline development products. Gilead cautions readers that forward-looking statements are subject to certain risks and uncertainties, which could cause actual results to differ materially. These risks and uncertainties include those that can cause fluctuations in our financial results, such as our ability and the ability of our partners to successfully introduce and market our products and maintain revenue growth, in particular, our ability to sustain the uptake and revenues for our HIV franchise; our ability to accurately estimate end-user demand since we must make numerous assumptions and must rely on incomplete data to make these estimations; our ability to effectively manage wholesaler inventory levels and the impact of those efforts on revenues; our ability to generate additional positive clinical data and expand the labels for our existing products; our ability to control the timing and amount of spending in our research and clinical programs; fluctuations in foreign currency against the U.S. dollar; our ability to achieve and the timing of milestones, as well as risk and uncertainties that affect our future prospects such as the risk that we may not continue to observe the safety, tolerability and efficacy data for Viread, Hepsera, Emtriva and Truvada that we are observing today; the risk that the safety and efficacy data obtained in controlled clinical trials for Viread and Emtriva will not be observed in an uncontrolled clinical setting, and the risk that physicians and regulatory agencies may not see advantages of Truvada over other antiretrovirals and may therefore be reluctant to prescribe or grant regulatory approval for Truvada; the risk that the safety and efficacy data obtained through 24 weeks of Study 934 will not be observed through 48 weeks or in other studies; and other risks identified from time to time in the Company's reports filed with the U.S. Securities and Exchange Commission.

The Company directs readers to its Annual Report on Form 10-K, for the year ended December 31, 2003, filed in March 2004 and subsequent quarterly reports on Form 10-Q. 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.

Viread, Emtriva, AmBisome, and Hepsera are registered trademarks and Truvada is a trademark of Gilead Sciences, Inc.

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

Macugen is a trademark of EyeTech Pharmaceuticals, Inc.

Combivir is a registered trademark of GlaxoSmithKline.

For more information on Gilead Sciences, 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 OPERATIONS
(in thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Revenues:				
Product sales	\$310,727	\$194,075	\$886,644	\$580,707
Royalty and contract revenue	15,460	6,297	68,392	23,640
Total revenues	326,187	200,372	955,036	604,347
Cost of goods sold	40,842	25,936	117,883	79,414
Gross profit	285,345	174,436	837,153	524,933
Operating expenses:				
Research and development(1)	49,204	35,980	153,392	122,861
Selling, general and administrative(1)	72,371	59,283	217,370	160,125
In-process research and				

development	-	-	-	488,599
Total operating expenses	121,575	95,263	370,762	771,585
Income (loss) from operations	163,770	79,173	466,391	(246,652)
Gain on EyeTech warrants	-	-	20,576	-
Interest and other income, net	4,801	3,316	13,137	10,577
Interest expense	(2,042)	(5,538)	(6,202)	(16,721)
Income (loss) before provision for income taxes	166,529	76,951	493,902	(252,796)
Provision for income taxes	53,289	3,855	154,775	11,790
Net income (loss)	\$113,240	\$73,096	\$339,127	\$(264,586)
Net income (loss) per share - basic(2)	\$0.26	\$0.18	\$0.79	\$(0.66)
Net income (loss) per share - diluted(2)(3)	\$0.25	\$0.17	\$0.74	\$(0.66)
Shares used in per share calculation - basic(2)	431,273	403,348	429,230	400,184
Shares used in per share calculation - diluted(2)(3)	465,474	466,864	462,980	400,184

Notes:

(1) Certain prior period amounts associated with phase IV clinical trial expenses totaling \$4.9 million, \$4.3 million and \$11.3 million for the nine months ended September 30, 2004 and the three and nine months ended September 30, 2003, respectively, have been reclassified from selling, general and administrative to research and development to be consistent with the current period presentation.

(2) Net income (loss) per share and the number of shares used in the per share calculation for all periods presented reflect the two-for-one stock split effective August 12, 2004.

(3) In accordance with Statement of Financial Accounting Standard No. 128, using the If-Converted Method, interest expense related to convertible debt of \$1.3 million and \$3.9 million has been added back to net income for purposes of calculating diluted net income per share for the quarter and nine months ended September 30, 2004, respectively, and \$4.6 million for the quarter ended September 30, 2003. The shares used in the calculation of net income per diluted share for the quarter and nine months ended September 30, 2004 includes the effect of 19.5 million and 19.1 million stock options outstanding, respectively, and the effect of the \$345.0 million 2% convertible senior debt, which converts to approximately 14.7 million shares. The shares used in the calculation of net income per diluted share for the quarter ended September 30, 2003 includes the effect of 28.5 million stock options outstanding and the effect of the \$345.0 million 2% convertible senior debt and \$250.0 million 5% convertible

subordinated debt, which convert to approximately 14.7 million and 20.4 million shares, respectively.

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

	September 30, 2004	December 31, 2003
	----- (unaudited)	----- (note 1)
Assets		
Cash, cash equivalents and marketable securities	\$1,148,421	\$707,000
Other current assets	558,947	558,898
	-----	-----
Total current assets	1,707,368	1,265,898
Property, plant and equipment, net	211,809	198,200
Other noncurrent assets	66,499	90,624
	-----	-----
	\$1,985,676	\$1,554,722
	=====	=====
Liabilities and stockholders' equity		
Current liabilities	\$217,526	\$185,895
Long-term obligations	372,878	365,853
Stockholders' equity	1,395,272	1,002,974
	-----	-----
	\$1,985,676	\$1,554,722
	=====	=====

Notes:

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

GILEAD SCIENCES, INC.
NON-GAAP CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

The non-GAAP financial information presented below is utilized by Gilead management to help gain a better understanding of the comparative operating performance of the Company. The Company believes that the presentation of this non-GAAP financial table is useful in excluding those unusual activities or transactions that are not necessarily relevant to obtaining an understanding of the trends in the results of the Company.

	Nine months ended September 30, 2004		Nine months ended Sept. 30, 2003	
	-----	-----	-----	-----
	GAAP	Adjustment (1)	Non-GAAP	Non- GAAP (2)
	-----	-----	-----	-----
Revenues:				
Product sales	\$886,644	\$-	\$886,644	\$580,707

Royalty and contract revenue	68,392	-	68,392	23,640
Total revenues	955,036	-	955,036	604,347
Cost of goods sold	117,883	-	117,883	79,414
Gross profit	837,153	-	837,153	524,933
Operating expenses:				
Research and development(3)	153,392	-	153,392	136,111
Selling, general and administrative(3)	217,370	-	217,370	160,125
Total operating expenses	370,762	-	370,762	296,236
Income from operations	466,391	-	466,391	228,697
Gain on EyeTech warrants	20,576	(20,576)	-	-
Interest and other income, net	13,137	-	13,137	10,577
Interest expense	(6,202)	-	(6,202)	(16,721)
Income (loss) before provision for (benefit from) income taxes	493,902	(20,576)	473,326	222,553
Provision for (benefit from) income taxes	154,775	(8,025)	146,750	11,127
Net income (loss)	\$339,127	\$(12,551)	\$326,576	\$211,426
Net income per share - basic(4)	\$0.79		\$0.76	\$0.53
Net income per share - diluted(4)(5)	\$0.74		\$0.71	\$0.49
Shares used in per share calculation - basic(4)	429,230		429,230	400,184
Shares used in per share calculation - diluted(4)(5)	462,980		462,980	460,762

Notes:

(1) The adjustment reflects a pre-tax gain of \$20.6 million related to our warrants in EyeTech Pharmaceuticals, Inc., which completed its initial public offering during the first quarter.

(2) The non-GAAP results for the nine months ended September 30, 2003 exclude the first quarter in-process research and development charge of \$488.6 million from the acquisition of Triangle Pharmaceuticals, Inc., as well as the third quarter reimbursement to Gilead of \$13.2 million of research and development expenses resulting from the

settlement of a contractual dispute with a vendor.

(3) Certain prior period amounts associated with phase IV clinical trial expenses totaling \$4.9 million and \$11.3 million for the nine months ended September 30, 2004 and 2003, respectively, have been reclassified from selling, general and administrative to research and development to be consistent with the current period presentation.

(4) Net income per share and the number of shares used in the per share calculation for all periods presented reflect the two-for-one stock split effective August 12, 2004.

(5) In accordance with Statement of Financial Accounting Standard No. 128, using the If-Converted Method, interest expense related to convertible debt of \$3.9 million has been added back to net income for purposes of calculating diluted net income per share for the nine months ended September 30, 2004, and \$13.8 million for the nine months ended September 30, 2003. The shares used in the calculation of net income per diluted share for the nine months ended September 30, 2004 includes the effect of 19.1 million stock options outstanding and the effect of the \$345.0 million 2% convertible senior debt, which converts to approximately 14.7 million shares. The shares used in the calculation of net income per diluted share for the nine months ended September 30, 2003 includes the effect of 25.5 million stock options outstanding and the effect of the \$345.0 million 2% convertible senior debt and \$250.0 million 5% convertible subordinated debt, which convert to approximately 14.7 million and 20.4 million shares, respectively.

CONTACT: Gilead Sciences, Inc.
John Milligan, 650-522-5756
Susan Hubbard, 650-522-5715

SOURCE: Gilead Sciences, Inc.