Gilead Announces First Quarter 1999 Financial Results

April 29, 1999 5:27 PM ET

Foster City, CA -- April 29, 1999

Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the first quarter ended March 31, 1999. For the quarter, the Company reported revenue from net product sales of $1.4 million, revenue from collaborative agreements of $2.9 million and revenue from product royalties of $0.6 million, for total revenues of $4.9 million and net interest income of $3.6 million. This compares to revenues from net product sales of $1.8 million, revenues from collaborative agreements of $11.4 million and revenue from product royalties of $0.4 million, for total revenue of $13.6 million and net interest income of $5.0 million for the same quarter in 1998. The net loss for the three months ended March 31, 1999 was $15.8 million or $0.51 per share, compared to a net loss of $7.4 million or $0.25 per share for the same quarter in 1998.

Net revenue from product sales for these periods was derived from the sale of VISTIDE® (cidofovir injection), which Gilead markets independently in the United States for the treatment of cytomegalovirus (CMV) retinitis in patients with AIDS. Royalty revenue represents royalties on product sales of VISTIDE in territories outside the United States by Gilead's partner Pharmacia & Upjohn.

During the first quarter of 1999, Gilead recorded $2.9 million in contract revenue compared to $11.4 million for the same quarter in 1998. Gilead received $2.7 million of this contract revenue from F. Hoffmann-La Roche Ltd, of which $2.0 million was a milestone payment for the initiation of GS 4104 pivotal studies in Japan and $0.7 million was expense reimbursement for research and development. Gilead receives funding for its research and development of neuraminidase inhibitors for the treatment and prevention of influenza under an exclusive, worldwide development and commercialization collaboration with Roche. The decrease in contract revenues in the first quarter of 1999 as compared to the same quarter in 1998 is due primarily to Gilead's reduced role in the clinical development of GS 4104 as this product candidate approaches commercialization. GS 4104 was discovered by Gilead Sciences and is administered as an oral capsule.

Research and development expenses for the first quarter of 1999 were $15.8 million, compared to $18.9 million for the same period in 1998. The decrease in research and development expenses reflects Gilead's reduced role in the clinical develoment of GS 4104, described above.

As of March 31, 1999, the Company had cash, cash equivalents and short-term investments of $263.9 million compared to $279.9 million at December 31, 1998.

Gilead Sciences is an independent biopharmaceutical company that seeks to provide accelerated treatment solutions for patients and the people who care for them. The Company discovers, develops and commercializes proprietary therapeutics for important viral diseases, including a currently marketed product, VISTIDE, for the treatment of CMV retinitis, a sight-threatening viral infection in patients with AIDS. In addition, the Company is developing products to treat diseases caused by HIV, hepatitis B virus and influenza virus. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.

VISTIDE is a registered trademark of Gilead Sciences, Inc.

For more information on Gilead Sciences, please call the Gilead Corporate Communications 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 March 31,

	1999	1998
	(unaudited)	
Revenues		
Product sales, net	$ 1,445	$ 1,795
Contract revenue	2,941	11,407
Royalty revenue	551	358
Total Revenues	4,937	13,560
Costs and expenses		
Cost of sales	134	230
Research and development	15,786	18,930
Selling, general and administrative	8,367	6,742
Total costs and expenses	24,287	25,902
Loss from operations	(19,350)	(12,342)
Interest income, net	3,563	4,958
Net loss	$ (15,787)	$ (7,384)
Basic and diluted loss per common share	$ (0.51)	$ (0.25)
Common shares used in the calculation of basic and diluted loss per share	30,864	30,103

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 1999 (unaudited)	December 31, 1998 (Note)
Assets		
Cash, cash equivalents and short-term investments	$ 263,930	$ 279,939
Other current assets	8,113	8,371
Total current assets	272,043	288,310
Property and equipment, net	12,131	10,182
Other assets	4,444	4,368
	$ 288,619	$ 302,860
Liabilities and stockholders' equity		
Current liabilities	$ 29,308	$ 31,750
Long-term obligations	375	563
Stockholders' equity	258,936	270,547
	$ 288,619	$ 302,860

Note: Derived from audited financial statements

1999 First Quarter Highlights

Gilead Sciences is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. During the first quarter of 1999, the Company received revenues from the U.S. marketing of VISTIDE® (cidofovir injection) for the treatment of CMV retinitis as well as from royalties on product sales in the European Union, and from collaborative agreements with its pharmaceutical partners.

Total Revenues	$ 4.9 mm
Net Product Sales	$ 1.4 mm
Total Expenses	$ 24.3 mm
Net Loss	$ (15.8) mm
Net Loss per Share	$ (0.51) per share
Cash and Equivalents	$ 263.9 mm

Gilead Sciences to Merge with NeXstar Pharmaceuticals - On March 1, Gilead Sciences and NeXstar Pharmaceuticals announced a definitive agreement whereby Gilead will acquire NeXstar in an all-stock, tax-free transaction accounted for as a pooling of interests, creating a biopharmaceutical company with worldwide presence focused on infectious disease and oncology. The transaction is subject to review by the Securities and Exchange Commission and approval by the stockholders of both companies, and is expected to be completed by mid-summer.

PREVEON® Safety Data Profiled at 6th Conference on Retroviruses and Opportunistic Infections - Data from late stage clinical trials of adefovir dipivoxil, further defining its therapeutic role for the treatment of patients with HIV infection, were presented at the February conference in Chicago. Highlights included a presentation of safety data from more than 5,600 patients in the Expanded Access Program. In patients treated with adefovir dipivoxil, serious adverse renal events were uncommon occurring in less than three percent of patients who received adefovir dipivoxil for greater than 24 weeks. Creatinine elevations in patients have been generally delayed in onset, mild and resolvable with dose reduction, drug interruption or discontinuation.

PREVEON 60 mg Data Profiled at 12th International Conference on Antiviral Research - Interim data from a trial (Study 417) comparing triple-drug regimens containing the 60 mg dose of adefovir dipivoxil to the 120 mg dose demonstrated comparable anti-HIV activity in treatment-experienced patients. In addition, patients receiving the 60 mg dose of adefovir dipivoxil had an approximate 30 to 50 percent reduction in the incidence of nephrotoxicity as compared to those receiving the 120 mg dose. This study is ongoing and remains blinded to patients and physicians. Study dosing will continue through the completion of 48 weeks of therapy for enrolled patients.

HIV Expanded Access Program Continues to Underscore Need for Treatment Options - To date, more than 7,700 patients infected with HIV have been enrolled in the Adefovir Dipivoxil Expanded Access Program in the United States. Based on data from Study 417 and ongoing feedback from the FDA, the expanded access protocol was amended so that all randomized patients receiving the 120 mg dose were dose reduced to 60 mg and all patients entering the program will initiate treatment with a 60 mg once daily dose.

Adefovir Dipivoxil Multinational Phase III Clinical Trials Begin for Treatment of Chronic Hepatitis B - In March, the first patients were randomized in a two-year multinational Phase III clinical trial (Study 437) that will evaluate the long-term safety and efficacy of two active dose levels of adefovir dipivoxil (10 mg and 30 mg) for the treatment of chronic hepatitis B infection. The double-blind, placebo-controlled study is designed to enroll approximately 500 patients at nearly 100 sites in the United States, Canada, Europe, Australia and Southeast Asia.

Adefovir Dipivoxil Shows Activity Against Lamivudine-Resistant Hepatitis B Virus - In April, preliminary data were presented demonstrating adefovir dipivoxil's antiviral activity in three patients with chronic hepatitis B infection who had failed antiviral therapy with lamivudine due to the development of resistance mutations. Presented at the 34th Annual Meeting of the European Association for the Study of the Liver in Naples, Italy, these data support earlier laboratory results indicating that

adefovir remains active against lamivudine-resistant HBV.

Upcoming Milestones

NeXstar Merger	SEC clearance and stockholder votes.
PREVEON (HIV)	File New Drug Application (NDA) with U.S. FDA and Marketing Authorization Application (MAA) with European Medicines Evaluation Agency (EMEA).
Adefovir dipivoxil (HBV)	Begin additional Phase III studies; execute partner agreement.
PMPA (HIV)	Complete Phase II study; initiate Phase III program.
GS 4104 (Influenza)	Complete ongoing Phase III clinical studies; File NDA with U.S. FDA and MAA with EMEA for the treatment of influenza.

SAFE HARBOR DISCLAIMER: The Upcoming Milestones listed above contain "forward-looking" information (within the meaning of the Private Securities Litigation Reform Act of 1995) that involves substantial risk and uncertainty. Actual results may differ materially based on a variety of factors, particularly those relating to the development, approval and marketing of pharmaceutical products as described in the "Risk Factors" section of Gilead's SEC reports, including the report on Form 10-K for the year ended December 31, 1998.