

## Gilead Sciences Announces Second Quarter 2001 Financial Results

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*Company Announces Viread (VIR-ee-ad) as Trade Name for Tenofovir DF*

### Foster City, CA -- July 26, 2001

Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the second quarter ended June 30, 2001. For the second quarter, Gilead recorded revenues from net product sales of \$41.6 million, royalty revenues of \$6.4 million and contract revenues of \$2.7 million. Total revenues for the second quarter ended June 30, 2001, were \$50.7 million compared to total revenues of \$50.1 million for the second quarter of 2000. Revenues for the second quarter of 2000 included net product sales of \$38.0 million, royalty revenues of \$7.7 million and contract revenues of \$4.4 million.

The net loss for the second quarter 2001 was \$32.4 million, or \$0.34 per share. This compares to a net loss in the second quarter 2000 of \$4.0 million, or \$0.04 per share.

Net revenues from product sales were primarily derived from sales of AmBisome® (amphotericin B) liposome for injection, accounting for 94 percent of product sales for the second quarter of 2001. AmBisome sales for the second quarter of 2001 were \$38.9 million, an increase of nine percent compared to the second quarter of 2000. Excluding the impact of the decline in foreign currencies relative to the U.S. dollar, AmBisome sales grew 16 percent for the second quarter of 2001 over the comparable quarter of 2000. In addition, Gilead recorded other product sales of \$2.7 million during the second quarter of 2001, compared to \$2.1 million in the second quarter of 2000.

For the second quarter of 2001, royalty and contract revenues resulting from collaborations with corporate partners totaled \$9.1 million. These revenues include contract revenues for research and development projects, royalties on sales of AmBisome in the United States by Gilead's co-promotion partner Fujisawa Healthcare, royalties on sales of Tamiflu™ (oseltamivir phosphate) by Hoffmann-La Roche and royalties on product sales of Vistide® (cidofovir injection) outside the United States by Pharmacia Corporation.

Research and development expenses for the second quarter of 2001 were \$44.1 million, compared to \$27.5 million for the same quarter in 2000. The higher spending during the second quarter of 2001 is attributable to Gilead's expenses associated with the Phase III clinical programs for Viread™ (tenofovir disoproxil fumarate) for HIV and adefovir dipivoxil for hepatitis B virus (HBV), including the ongoing expanded access program and drug supply costs for Viread.

Selling, general and administrative expenses for the three months ended June 30, 2001 were \$29.7 million, compared to \$19.6 million for the same quarter of 2000. The additional spending is primarily due to Gilead's increased global marketing efforts associated with the anticipated commercial launch of Viread.

Net interest income for the second quarter 2001 was \$3.1 million, compared to \$2.8 million for the same quarter in 2000.

The company also reported equity in the loss of its unconsolidated affiliate of \$1.2 million and \$0.7 million for the second quarter ended June 30, 2001 and 2000, respectively. The losses are derived from Gilead's 49 percent interest in Proligo L.L.C., a manufacturing joint venture between Gilead and SKW Americas, Inc.

Gilead also reported its results of operations for the six months ended June 30, 2001. The company recorded net revenues from product sales of \$86.6 million and aggregate contract and royalty revenues of \$21.9 million. Accounting for 93 percent of product sales, AmBisome sales for the six months ended June 30, 2001 were \$80.8 million, a 15 percent increase over the six months ended June 30, 2000. Excluding the impact of the decline in foreign currencies relative to the U.S. dollar, AmBisome sales grew by 22 percent in the first six months of 2001 over the comparable period of 2000. Net revenues of \$108.5 million in the six months ended June 30, 2001 compare to net revenues of \$97.8 million in the first six months of 2000. Net revenues for the first six months of 2000 included product sales of \$74.3 million and aggregate contract and royalty revenues of \$23.5 million.

The net loss for the six months ended June 30, 2001, including the cumulative effect of a change in accounting principle related to the company's adoption of Statement of Financial Accounting Standards No. 133, was \$54.1 million, or \$0.57 per share. This

compares to a net loss of \$21.0 million, or \$0.23 per share for the six months ended June 30, 2000, including the cumulative effect of the adoption of Staff Accounting Bulletin 101 of \$13.7 million, or \$0.15 per share.

Research and development expenses for the six months ended June 30, 2001 and 2000 were \$95.2 million and \$53.7 million, respectively. The higher spending during the first half of 2001 was attributable in part to the recognition of \$10.6 million of a \$13 million up-front payment to Cubist Pharmaceuticals related to the European licensing agreement for daptomycin signed in January 2001. In addition, Gilead's expenses associated with the Phase III clinical programs for Viread for HIV and adefovir dipivoxil for HBV increased significantly during the first half of 2001.

Selling, general and administrative expenses for the six months ended June 30, 2001 were \$51.6 million compared to \$37.6 million for 2000. The additional spending is again primarily due to Gilead's increased global marketing efforts associated with the anticipated commercial launch of Viread.

Net interest income for the six months ended June 30, 2001 was \$6.9 million, compared to \$5.2 million for 2000.

The company also reported equity in the loss of its unconsolidated affiliate of \$1.6 million for each of the six months ended June 30, 2001 and 2000.

As of June 30, 2001, the company had cash, cash equivalents and marketable securities of \$456.0 million, compared to \$512.9 million at December 31, 2000.

### **Products and Pipeline Highlights**

"During the second quarter we achieved several significant milestones in our antiviral programs," said John C. Martin, Ph.D., President and Chief Executive Officer, Gilead Sciences. "By rapidly submitting our NDA and MAA for Viread and meeting the primary efficacy endpoint in our first Phase III study of adefovir dipivoxil for HBV, we made important progress toward commercializing the next wave of Gilead's products. Over the remainder of the year, we are focused on preparing for the launch of Viread in the United States and Europe, and we look forward to announcing results of our second pivotal Phase III study of adefovir dipivoxil."

### **Viread™ (tenofovir disoproxil fumarate) for HIV**

Today, Gilead announced that Viread has been selected as the brand name for tenofovir disoproxil fumarate in the United States and European Union.

In May, Gilead submitted a New Drug Application to the U.S. Food and Drug Administration (FDA) for marketing approval of Viread. In June, Gilead was notified by the FDA that the filing has been granted priority review classification; Gilead expects FDA review and action within six months of the submission.

Also in May, Gilead submitted a Marketing Authorisation Application (MAA) to the European Agency for the Evaluation of Medicinal Products seeking approval of Viread. The MAA is being reviewed under the centralized licensing procedure, which, if approved, will provide marketing authorization in all 15 member states of the European Community. The French authorities are the rapporteur, and the Spanish authorities are the co-rapporteur for the procedure.

In June, Gilead presented in vitro data further characterizing the resistance profile of Viread. These data were presented at the 5th International Workshop on HIV Drug Resistance and Treatment Strategies in Scottsdale, Arizona. In this study, the resistance profile of tenofovir was evaluated using phenotypic analyses of nearly 5,000 clinically-derived HIV samples from predominantly treatment-experienced patients, which were provided and analyzed by Tibotec-Virco. Results of this study indicate that over 88 percent of the samples were fully susceptible to Viread and were within the normal three-fold range. In two additional presentations, Gilead researchers presented data describing the unique structural and enzymological features of tenofovir that may help to explain the compound's favorable resistance profile.

### **Adefovir Dipivoxil for Hepatitis B Virus**

In June, Gilead unblinded 48-week data from Study 437, a randomized, double-blind, placebo-controlled Phase III trial designed to evaluate the safety and efficacy of adefovir dipivoxil given once daily, compared to placebo in 515 patients with chronic HBV infection. Results from this intent-to-treat analysis met the study's primary endpoint of improvement in liver histology at week 48 compared to baseline. A number of secondary endpoints were met as well, including a higher rate of seroconversion, a greater reduction in ALT levels and a larger decrease in circulating HBV DNA in the treatment arm as compared to placebo. Through the

first 48 weeks of Study 437, the discontinuation rate, incidence of grade 3 and 4 laboratory abnormalities and clinical adverse events were similar between the treatment and placebo arms.

Also in June, Gilead initiated Phase I trials of adefovir dipivoxil for the treatment of chronic HBV infection in China. The adefovir dipivoxil clinical program design in China will include three separate Phase I trials that will be conducted in sequential order. After the completion of Phase I studies, a final report reviewing the safety and pharmacokinetic (PK) profile of the drug will be submitted to the People's Republic of China State Drug Administration (SDA). The Class 1 designation of adefovir dipivoxil allows for an expedited review of these data. After the SDA's review and subject to its approval, Gilead anticipates initiating a Phase II/III study of adefovir dipivoxil in China.

### **Cidecin® (daptomycin for injection) for Gram-Positive Bacterial Infections**

Cubist Pharmaceuticals, Inc. announced earlier this month it completed enrollment of Study 9801, the second of its pivotal Phase III trials examining the efficacy and safety of investigational drug Cidecin for the treatment of complicated skin and soft tissue infection (cSST) in the United States. Preliminary results from Study 9801 are expected to be announced at the 39th Infectious Disease Society of America meeting in San Francisco in October. Further results from the first Phase III study, 9901, will be presented at the 41st Interscience Conference on Antimicrobial Agents and Chemotherapy 2001 in Chicago this September. Cubist anticipates filing for regulatory approval of Cidecin in the United States mid-2002, and Gilead expects to follow with a filing in Europe. Gilead holds the exclusive rights to commercialize and market Cidecin in Europe.

### **Conference Call**

Gilead will host a conference call today, July 26, 2001, at 4:30 p.m. ET. The dial-in number for the call is 888-849-9214 domestic; 212-676-5013 international. The replay of this call will be available from 7:00 p.m. July 26, 2001, until 7:00 p.m. on July 29, 2001. The dial-in number for the replay is 800-633-8284 domestic, 858-812-6440 international; the password is 19302054. Gilead also will be webcasting the conference call; this feature will be available on our website at [www.gilead.com](http://www.gilead.com). The information provided on the teleconference and on the webcast is only accurate at the time of the call, and Gilead will take no responsibility for providing updated information.

### **About Gilead**

Gilead Sciences, Inc., headquartered in Foster City, CA, is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. Gilead discovers, develops, manufactures and commercializes proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial infections) and cancer. Gilead maintains research, development or manufacturing facilities in Foster City, CA; Boulder, CO; San Dimas, CA; Cambridge, UK, and Dublin, Ireland, and sales and marketing organizations in the United States, 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 regarding Gilead's future financial results, including: revenues, research and development expenses, selling, general and administrative expenses, the efficacy of any marketed or pipeline development products, the ability to file for or obtain marketing approval for Gilead's pipeline development products, or the competitive positioning 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 market our products and maintain revenue growth; 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 our products and product candidates that we are observing today; other risks relating to the regulatory approval of our products and product candidates; 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, 2000, filed in March 2001, and its 2001 Quarterly Report on Form 10-Q filed in May 2001 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.

**GILEAD SCIENCES, INC**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2001	2000	2001	2000
	(unaudited)		(unaudited)	
Revenues:				
Product sales, net	\$ 41,565	\$ 37,994	\$ 86,629	\$ 74,334
Royalty revenue, net	6,376	7,680	12,558	15,722
Contract revenue	1,123	4,305	7,560	5,145
Contract revenue - SAB 101	1,623	150	1,776	2,640
Net revenues	50,687	50,129	108,523	97,841
Cost of goods sold	10,797	8,684	21,378	16,631
Gross profit	39,890	41,445	87,145	81,210
Operating expenses:				
Research and development	44,078	27,460	95,224	53,706
Selling, general and administrative	29,707	19,620	51,618	37,590
Total operating expenses	73,785	47,080	146,842	91,296
Loss from operations	(33,895)	(5,635)	(59,697)	(10,086)
Interest income	6,507	4,360	13,890	8,305
Interest expense	(3,436)	(1,518)	(6,969)	(3,055)
Loss before provision for income taxes, equity in loss of unconsolidated affiliate and cumulative effect of change in accounting principle	(30,824)	(2,793)	(52,776)	(4,836)
Provision for income taxes	323	525	793	832
Equity in loss of unconsolidated affiliate	1,240	718	1,630	1,639
Loss before cumulative effect of change in accounting principle				
Cumulative effect of change in accounting principle (note 1)	-	-	1,089	(13,670)
Net loss	\$ (32,387)	\$ (4,036)	\$ (54,110)	\$ (20,977)
Basic and diluted amounts per common share: (note 2)				
Loss before cumulative effect of change in accounting principle	\$ (0.34)	\$ (0.04)	\$ (0.58)	\$ (0.08)
Cumulative effect of change in accounting principle	-	-	0.01	(0.15)
Net loss	\$ (0.34)	\$ (0.04)	\$ (0.57)	\$ (0.23)
Common shares used in the calculation of basic and diluted amounts per share	94,779	89,182	94,576	88,931

Notes:

- (1) Gilead adopted Statement of Financial Accounting Standards No. 133 (SFAS 133) *Accounting for Derivative Instruments and Hedging Activities* effective January 1, 2001 and also the SEC's Staff Accounting Bulletin No. 101 (SAB 101) *Revenue Recognition in Financial Statements* effective January 1, 2000. These changes were accounted for as the cumulative effect of a change in accounting principle.
- (2) The net loss per share and number of shares used in the per share calculation for all periods presented reflect the two-for-one stock split effective February 22, 2001.
- (3) Certain prior period amounts have been reclassified to conform to the current presentation.

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

	June 30, 2001 <u>(unaudited)</u>	December 31, 2000 <u>(note 1)</u>
<i>Assets</i>		
Cash, cash equivalents and marketable securities	\$ 456,022	\$ 512,878
Other current assets	<u>90,169</u>	<u>80,920</u>
Total current assets	546,191	593,798
Property, plant and equipment, net	60,141	55,174
Other noncurrent assets	<u>30,330</u>	<u>29,127</u>
	<u>\$ 636,662</u>	<u>\$ 678,099</u>
<i>Liabilities and stockholders' equity</i>		
Current liabilities	\$ 56,690	\$ 58,238
Long-term obligations	265,557	268,737
Stockholders' equity	<u>314,415</u>	<u>351,124</u>
	<u>\$ 636,662</u>	<u>\$ 678,099</u>

Notes:

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