GILEAD SCIENCES INC Form 10-O August 14, 2001

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES $|\mathbf{x}|$ **EXCHANGE ACT OF 1934**

For the period ended June 30, 2001

or

11 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES **EXCHANGE ACT OF 1934**

For the transition period from _____ to ____

Commission File No. 0-19731

GILEAD SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

94-3047598 (I.R.S. Employer

(State or other jurisdiction of incorporation or organization) Identification No.)

333 Lakeside Drive, Foster City, California (Address of principal executive offices)

94404 (Zip Code)

650-574-3000

Registrant's telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes /x/ No //

Number of shares outstanding of the issuer's common stock, par value \$.001 per share, as of July 31, 2001: 95,206,066

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

GILEAD SCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

		June 30, 2001		December 31, 2000
	_	(unaudited)		(Note)
Assets				
Current assets:				
Cash and cash equivalents	\$	46,921	\$	197,292
Marketable securities		409,101		315,586
Accounts receivable		54,354		48,814
Inventories		23,720		20,562
Prepaid expenses and other		12,095		11,544
	_			
Total current assets		546,191		593,798
Property, plant and equipment, net		60,141		55,174
Other noncurrent assets		30,330		29,127

		June 30, 2001	D	ecember 31, 2000
	\$	636,662	\$	678,099
Liabilities and stockholders' equity Current liabilities:				
	¢	10.146	¢	11 (05
Accounts payable	\$	12,146	\$	11,605
Accrued clinical and preclinical expenses		12,975		9,925
Accrued compensation and employee benefits		10,357		9,995
Other accrued liabilities		16,487		19,324
Deferred revenue		2,116		4,355
Long-term obligations due within one year		2,609		3,034
Total current liabilities		56,690		58,238
Long-term deferred revenue		8,954		10,730
Accrued litigation settlement expenses		5,192		5,769
Long-term obligations due after one year		1,411		2,238
Convertible subordinated notes		250,000		250,000
C ommitments and contingencies				
Stockholders' equity: Common stock, par value \$.001 per share; 500,000,000 shares authorized; shares issued and outstanding: 95,165,636 shares at June 30, 2001 and 94,287,602 shares at December 31,				
2000		95		94
Additional paid-in capital		872,415		857,942
Accumulated other comprehensive income (loss)		2,025		(901)
Deferred compensation		(2)		(3)
Accumulated deficit		(560,118)		(506,008)
Total stockholders' equity		314,415		351,124
	\$	636,662	\$	678,099

Note: The condensed consolidated balance sheet at December 31, 2000 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

See accompanying notes.

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GILEAD SCIENCES, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Months Ended June 30,	Six Months Ended June 30,			
001	2000	2001	2000		

		Three Months Ended June 30,			Six Months Ended June 30,				
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	
Total revenues		50,687		50,129		108,523		97,841	
Costs and expenses:									
Cost of products sold		10,797		8,684		21,378		16,631	
Research and development		44,078		27,460		95,224		53,706	
Selling, general and administrative		29,707		19,620		51,618		37,590	
Total costs and expenses		84,582		55,764		168,220		107,927	
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		525 718		793 1,630		832	
Equity in loss of unconsolidated affiliate		1,240	_	/18		1,030	_	1,639	
Loss before cumulative effect of change in accounting principle		(32,387)		(4,036)		(55,199)		(7,307)	
Cumulative effect of change in accounting principle		(-))		())		1,089		(13,670)	
Net loss	\$	(32,387)	\$	(4,036)	\$	(54,110)	\$	(20,977)	
Basic and diluted net loss per common share:									
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)	*	(0.01)	7	0.01	~	(0.15)	
- manage in accounting principle			_		_	0.01	_	(0.13)	
Net loss	\$	(0.34)	\$	(0.04)	\$	(0.57)	\$	(0.23)	
Common shares used to calculate basic and diluted net loss per common share		94,779		89,182		94,576		88,931	
	_	,	-	,	_	, ,	_	,	
See accor	monuir	na notes							

See accompanying notes.

GILEAD SCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited) (in thousands)

	Six Months Ended June 30,			
	2001		2000	
OPERATING ACTIVITIES:				
Net loss	\$ (54,110)	\$	(20,977)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Net effect of change in accounting principle	(1,089)		11,030	
Depreciation and amortization	7,053		5,977	
Equity in loss of unconsolidated affiliate	1,630		1,639	
Net unrealized loss on foreign currency transactions	1,530		165	
Other non-cash transactions	731		399	
Changes in assets and liabilities:				
Accounts receivable	(7,168)		(2,182)	
Inventories	(3,158)		667	
Prepaid expenses and other assets	(3,013)		2,377	
Accounts payable	541		(4,992)	
Accrued liabilities	(595)		(4,605)	
Deferred revenue (excluding net effect of change				
in accounting principle)	(4,015)		5,469	
Net cash used in operating activities	(61,663)		(5,033)	
INVESTING ACTIVITIES:				
Purchases of marketable securities	(208,878)		(109,384)	
Sales of marketable securities	63,616		8,993	
Maturities of marketable securities	54,993		94,898	
Capital expenditures	(11,037)		(5,973)	
Investment in unconsolidated affiliate	(11,007)		(2,450)	
			(_,)	
Net cash used in investing activities	(101,306)		(13,916)	
	(101,000)		(10,910)	
FINANCING ACTIVITIES:				
Proceeds from issuances of common stock	14,364		15,105	
Repayments of long-term debt	(1,252)		(1,724)	
Net cash provided by financing activities	13,112		13,381	
Effect of exchange rate on cash	(514)		1,297	
Net decrease in cash and cash equivalents	(150,371)		(4,271)	
Cash and cash equivalents at beginning of period	 197,292		47,011	
Cash and cash equivalents at end of period	\$ 46,921	\$	42,740	
NON-CASH ACTIVITIES:				
Common stock issued upon the conversion of convertible subordinated notes		\$	25	

See accompanying notes.

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GILEAD SCIENCES, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2001 (unaudited)

1. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of Gilead Sciences, Inc. ("Gilead", the "Company" or "we") believes is necessary for fair presentation of the balances and results for the periods presented. These interim financial results are not necessarily indicative of results to be expected for the full fiscal year.

Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Examples include provisions for sales returns, bad debts and accrued clinical and preclinical expenses. Actual results may differ from these estimates. The accompanying consolidated financial statements include the accounts of the Company and its wholly and majority-owned subsidiaries. Significant intercompany transactions have been eliminated. Certain prior period amounts have been reclassified to conform to the current presentation. The accompanying financial information should be read in conjunction with the audited consolidated financial statements for the fiscal year ended December 31, 2000 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC").

Basic and Diluted Net Loss Per Common Share

For all periods presented, both basic and diluted net loss per common share are computed by dividing the net loss by the number of weighted average common shares outstanding during the period. Stock options, warrants and convertible subordinated notes could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per common share as their effect is antidilutive for the periods presented. All fiscal 2000 share and per share amounts have been restated to reflect the two-for-one stock split, effected in the form of a 100% stock dividend, completed on February 22, 2001.

2. Changes in Accounting Principles

Gilead adopted Statement of Financial Accounting Standards Nos. 133 and 138, collectively referred to as SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, in the first quarter of 2001. The change was accounted for as a change in accounting principle. See Note 3, "Derivative Financial Instruments." Effective in the first quarter of 2000, Gilead adopted the SEC's Staff Accounting Bulletin No. 101 (SAB 101), Revenue Recognition in Financial Statements, and the change was also accounted for as a change in accounting principle.

3. Derivative Financial Instruments

On January 1, 2001, Gilead adopted SFAS 133. The standard requires that Gilead recognize all derivatives as either assets or liabilities measured at fair value. If the derivative is designated as, and meets the definition of, a fair value hedge, the changes in the fair value of the derivative and of the hedged item attributable to the hedged risk are recognized in earnings. If the derivative is designated as, and meets the definition of, a cash flow hedge, the effective portions of changes in the fair value of the derivative are recorded in other comprehensive income and are recognized in the income statement when the hedged item affects earnings. Ineffective portions of changes in the fair value of cash flow

hedges are recognized in earnings immediately. SFAS 133 also requires that warrants to purchase capital stock of a non-public company, which include a net exercise feature, are to be recorded in the balance sheet at fair value with an offsetting amount recorded in the results of operations. The fair value of the warrants are required to be remeasured at each balance sheet date, with changes in the fair value of the warrants recorded in results of operations.

Gilead has forward currency contracts with maturities of 12 months or less related to its foreign currency denominated accounts receivable and to its forecasted future foreign currency denominated raw material purchases. These forward currency contracts have been designated as and qualify as cash flow hedges. These derivative instruments are employed to eliminate or minimize certain foreign currency exposures that can be confidently identified and quantified. In accordance with SFAS 133, hedges related to unrecognized firm commitments and forecasted foreign currency cash flows associated with accounts receivable are designated and documented at the inception of the respective hedge as cash flow hedges and evaluated for effectiveness quarterly. As the terms of the forward contract and the underlying transaction are matched at inception, forward contract effectiveness is calculated by comparing the fair value of the contract to the change in the forward value of the underlying hedged item, with the effective portion of the gain or loss on the derivative instrument reported as a component of other comprehensive income in stockholders' equity and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. All values reported in other comprehensive income will be reclassified to earnings within 12 months. Any residual change in fair value of the instruments or other ineffectiveness is recognized immediately in selling, general and administrative expense. Ineffectiveness in the first six months of 2001 was not significant. Additionally, Gilead has a warrant to purchase stock in a non-public company. This warrant has a net exercise feature and is considered a derivative instrument under SFAS 133.

Upon adoption of SFAS 133 on January 1, 2001, Gilead recognized an increase in other assets of approximately \$1.7 million, representing \$1.1 million in the fair value of a warrant and \$0.6 million for the unrealized gain on forward hedge contracts along with an increase in other comprehensive income of \$0.6 million. In addition, Gilead recognized an aggregate credit to the results of operations recorded as a cumulative change in accounting principle of \$1.1 million, representing the fair market value of the warrant.

During the six months ended June 30, 2001, a \$0.8 million loss on hedging contracts has been recognized in the income statement and a \$1.0 million reduction in the fair value of derivatives is recognized in other comprehensive income. At June 30, 2001, fair value gains and losses on the balance sheet were not material.

4. Inventories

Inventories are summarized as follows (in thousands):

	Ju	ne 30, 2001	December 31, 2000		
Raw materials	\$	12,457	\$	9,647	
Work in process	Φ	7,084	φ	9,047 7,781	
Finished goods		4,179		3,134	
Total inventories	\$	23,720	\$	20,562	

5. Collaborative Arrangements and Contracts

In January 2001, Gilead entered into an agreement with Cubist Pharmaceuticals, Inc. ("Cubist") relating to Cubist's antibacterial compound daptomycin, including Cidecin , an intravenous formulation of the compound that is currently in Phase III clinical trials for treatment of bacterial infections. Under

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the terms of the agreement, Gilead paid Cubist an upfront license fee of \$13.0 million and received exclusive commercial rights to the compound in sixteen European countries ("Gilead's territory") as well as the right to develop the compound for commercialization in this territory. Research and development expense has been charged for \$10.6 million of the \$13.0 million payment. The \$2.4 million balance is included in other noncurrent assets because if, prior to January 2002, Gilead terminates its rights under the agreement with respect to a preclinical oral formulation of daptomycin being developed by Cubist, or if Cubist discontinues development of that oral formulation, Gilead would be entitled to receive a refund of this amount from Cubist. Subsequent to January 2002, this refundable amount is reduced ratably on a monthly basis over a four year period and will be amortized to research and development expense. Cubist will continue to be responsible for worldwide clinical development of Cidecin and the preclinical oral formulation. Gilead will be responsible for both regulatory filings and marketing and selling of the product within Gilead's territory. Gilead may make additional payments to Cubist of up to \$31.0 million if certain clinical and regulatory milestones related to Cidecin and the oral formulation are reached. In April 2001, one of these milestones had been met and Gilead paid the \$1.25 million related to that milestone. This amount has been recorded as research and development expense. Additionally, if Cidecin is successfully commercialized in Gilead's territory, Gilead will pay Cubist a royalty on net sales of the product.

6. Comprehensive Loss

Following are the components of comprehensive loss (in thousands):

	Three months ended June 30,			Six months ended June 30,				
		2001 2000		2001			2000	
Net loss	\$	(32,387)	\$	(4,036)	\$	(54,110)	\$	(20,977)
Net foreign currency translation gain (loss)		(219)	·	(170)		63		(366)
Net unrealized loss on cash flow hedges		(334)				(383)		
Net unrealized gain (loss) on available-for-sale securities		173		207		3,246		(69)
Comprehensive loss	\$	(32,767)	\$	(3,999)	\$	(51,184)	\$	(21,412)
							_	

7. Disclosures about Segments of an Enterprise and Related Information

The Company has determined that it has only one reportable segment because management has organized the business around its functional lines.

Product sales consisted of the following (in thousands):

	Th	Three months ended June 30,				Six months ended June 30,			
		2001		2000		2001		2000	
AmBisome® Other	\$	38,912 2,653	\$	35,851 2,143	\$	80,813 5,816	\$	70,437 3,897	
Consolidated total	\$	41,565	\$	37,994	\$	86,629	\$	74,334	
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The following table summarizes total revenues from external customers and collaborative partners by geographic region. Revenues are attributed to countries based on the location of Gilead's customer or collaborative partner (in thousands).

	Three months ended June 30,			Six months ended June 30,				
		2001		2000		2001		2000
United States	\$	10,809	\$	9,841	\$	23,544	\$	16,407
United Kingdom		5,598		6,526		13,341		12,369
Italy		5,093		4,984		9,627		9,332
Germany		4,686		5,141		9,454		10,534
Spain		4,203		3,674		8,739		7,251
France		3,535		1,991		6,858		4,338
Switzerland		2,160		5,987		6,660		12,703
Other European countries		8,720		7,674		20,166		15,505
Other countries		5,883		4,311		10,134		9,402
Consolidated total	\$	50,687	\$	50,129	\$	108,523	\$	97,841

Product sales to one distributor accounted for approximately 12% of total revenues for the first six months of 2001 and approximately 13% of total revenues for the same period of 2000. For the six months ended June 30, 2001, sales to and royalties from Fujisawa Healthcare, Inc. ("Fujisawa") were 17% of total revenue. Revenues from Fujisawa were approximately 12% of total revenues during the first six months of 2000.

8. Increase in Authorized Shares of Common Stock

On February 2, 2001, at a special meeting of stockholders, the stockholders approved an amendment to Gilead's certificate of incorporation to increase the number of authorized shares of common stock from 100,000,000 to 500,000,000.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

Gilead was incorporated in Delaware on June 22, 1987, and is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. We discover, develop, manufacture and commercialize proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial diseases) and cancer. We also have expertise in liposomal drug delivery technology. Currently, we market AmBisome® ((amphotericin B) liposome for injection), an antifungal agent; DaunoXome® (daunorubicin citrate liposome injection), a drug approved for the treatment of Kaposi's Sarcoma; and VISTIDE® (cidofovir injection) for the treatment of cytomegalovirus retinitis. Hoffmann-La Roche Inc. ("Roche") markets Tamiflu (oseltamivir phosphate), a product we co-developed with Roche, for the treatment and prevention of influenza, under a collaborative agreement with us. In addition, we are developing products to treat diseases caused by human immunodeficiency virus ("HIV"), hepatitis B virus ("HBV"), bacterial infections and cancer.

Gilead completed a two-for-one stock split, effected in the form of a 100% stock dividend, on February 22, 2001. Accordingly, all fiscal 2000 share and per share amounts have been restated to retroactively reflect the split.

In the quarter ended March 31, 2001, Gilead adopted SFAS 133, Accounting for Derivative Instruments and Hedging Activities, which resulted in a cumulative effect of change in accounting principle.

Certain prior period amounts have been reclassified to conform to the current presentation.

Forward-Looking Statements and Risk Factors

The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in any forward-looking statements. Some of the factors that could cause or contribute to these differences are listed below. You should also read the "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2000 for more detailed information regarding these and other risks and uncertainties that can affect our actual financial and operating results. All forward-looking statements are based on information currently available to Gilead, and we assume no obligation to update any such forward-looking statements.

AmBisome Sales. We rely on sales of AmBisome for a significant portion of our operating income. There are lower priced products that compete with AmBisome; a product that was recently approved that competes with AmBisome; and products being developed that could compete with AmBisome in the future. If these other products achieve further market acceptance, or if the products in development become commercially available, revenues from sales of AmBisome would likely decrease, resulting in a reduction of operating income.

Regulatory Process. The U.S. Food and Drug Administration and foreign agencies could reject or limit the commercialization of our products for a number of reasons including: if they disagree with the results or designs of our clinical trials; if they believe our products have unacceptable efficacy, toxicity or tolerability; or if they believe our products cannot be safely and efficiently manufactured on a commercial basis. If these agencies reject or limit the commercialization of our products, our financial results would be adversely affected. The clinical trials required for regulatory approval of our products are extremely expensive, and it is difficult for us to accurately predict or control the amount or timing of these expenses from quarter to quarter. In addition, regulatory agencies could require us to conduct additional unanticipated clinical trials on our products, the cost of which could be substantial.

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Market Acceptance of Products. The ability of our products to achieve and sustain market acceptance will depend on a number of factors, including: the receipt and scope of regulatory approvals; the availability of public and private insurance and reimbursement for our products; safety, efficacy, tolerability and cost of our products; and how our products compare to competitive products. If our products do not achieve and sustain market acceptance, our results of operations will suffer. Tamiflu is in a new class of drugs that represent a new approach to treating and preventing the flu. In order for Tamiflu to achieve market acceptance, our marketing partner, Roche, must change attitudes toward the treatment and prevention of influenza.

Collaborations. We depend on collaborations for the development and commercialization of certain products and for revenue, including the collaboration with Roche for sales of Tamiflu worldwide, the collaboration with Fujisawa for sales of AmBisome in the United States and Canada and the collaboration with Cubist for the clinical development of Cidecin. These collaborations could fail for a number of reasons, including if our partners do not devote sufficient resources to the development, commercialization or marketing of our products, or if disputes arise with our partners. We will also seek additional collaborations. If our collaborations fail or if we are unable to establish additional collaborations, our financial results would be adversely affected.

Foreign Currency Fluctuations. A significant majority of our product sales is denominated in foreign currencies. Increases in the value of the U.S. Dollar against these foreign currencies in the past have reduced, and in the future may reduce, our U.S. Dollar return on these sales and negatively impact our financial condition. We do not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. We do hedge accounts receivable balances denominated in foreign currencies, which minimizes but does not eliminate our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected.

Uncertain Financial Results. We expect that our financial results will continue to fluctuate from quarter to quarter and that such fluctuations may be substantial. The fluctuations can be caused by many factors that are beyond our control, including the risk factors listed above. We have never been profitable on a full-year basis and we may never achieve or sustain profitability. As of June 30, 2001, our accumulated deficit was \$560.1 million.

Results of Operations

Revenues

We had total revenues of \$50.7 million for the quarter ended June 30, 2001 compared with \$50.1 million for the quarter ended June 30, 2000. Total revenues were \$108.5 million for the first half of 2001, and \$97.8 million for the first half of 2000. Included in total revenues are net product sales, royalty income and contract revenue, including research and development collaborations.

Net product sales were \$41.6 million for the three months ended June 30, 2001, compared with \$38.0 million for the quarter ended June 30, 2000, representing an increase of 9%. Sales of AmBisome accounted for 94% of revenues from product sales in each of the quarters ended June 30, 2001 and June 30, 2000. Excluding the impact of the decline in foreign currencies relative to the U.S. Dollar in 2001, sales of AmBisome would have increased 16% in the second quarter of 2001 over the comparable period in 2000. In the first half of 2001, net product sales were \$86.6 million, versus \$74.3 million in the comparable period of 2000, an increase of 17%. Sales of AmBisome accounted for 93% of revenues from product sales in the six months ended June 30, 2001. This compares to 95% in the six months ended June 30, 2000. Excluding the impact of the decline in foreign currencies, sales of AmBisome would have increased 22% in the first half of 2001 over the same period in 2000. In addition, Gilead recorded other product sales of \$2.7 million during the quarter ended June 30, 2001 and \$2.1 million for the same period of 2000. Other product sales during the six months ended

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June 30, 2001 were \$5.8 million, compared with \$3.9 million for the first half of 2000. A significant majority of Gilead's product sales is denominated in foreign currencies. We do not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. We do hedge accounts receivable balances denominated in foreign currencies, which minimizes but does not eliminate our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected.

Net royalty revenue was \$6.4 million for the second quarter of 2001 compared with \$7.7 million for the same period in 2000 and \$12.6 million for the first half of 2001 versus \$15.7 million for the comparable period in 2000. Royalties in the second quarter ended June 30, 2001 included \$4.2 million from Fujisawa for sales of AmBisome in the United States. Royalties received from Fujisawa for the comparable period in 2000 were \$3.5 million. For the six months ended June 30, 2001, royalties received from Fujisawa were \$7.9 million compared with \$5.7 million in the first half of 2000. These increases reflect higher sales of AmBisome in the United States. Additionally, we received \$1.8 million in the quarter ended June 30, 2001 from Roche for sales of Tamiflu worldwide. Royalties received from Roche in the quarter ended June 30, 2000 were \$3.7 million. For the first half of 2001, royalties received from Roche were \$3.9 million compared with \$9.1 million in the first half of 2000. We record royalties from Roche in the quarter following the quarter in which the related Tamiflu sales occur. The declines in Tamiflu royalties resulted from the 2000-2001 flu season being the lightest in terms of the number of reported cases in at least six years and from substantial inventory returns in the U.S. by Roche's wholesale and retail customers at the end of the flu season.

Total contract revenue, including contract revenue related to the adoption of SAB 101, was \$2.7 million for the quarter ended June 30, 2001 versus \$4.4 million for the comparable quarter in 2000. This decrease is attributable to a milestone payment of \$2.0 million received from Roche in the second quarter of 2000. Contract revenue for the second quarter of 2001 consisted primarily of \$0.8 million related to marketing agreements, and recognition of \$1.5 million related to work performed on behalf of Sumitomo Pharmaceuticals Co. There were no milestone

payments received from Roche in the second quarter of 2001. Total contract revenue for the first half of 2001 was \$9.3 million versus \$7.8 million in the same period of 2000. This increase is primarily due to the recognition of \$3.3 million in 2001 for work associated with marketing agreements.

Cost of Product Sales

Cost of products sold was \$10.8 million, or 26% of net product sales, for the quarter ended June 30, 2001, and \$8.7 million, or 23% of net product sales, for the quarter ended June 30, 2000. For the first half of 2001, cost of products sold was \$21.4 million, or 25% of net product sales, versus \$16.6 million, or 22% of net product sales, for the first half of 2000. In connection with most of our European product sales, we price our products in the currency of the country into which the products are sold. A significant majority of our manufacturing cost is in U.S. Dollars. A decline in the value of these foreign currencies relative to the U.S. Dollar negatively impacts gross margins since our manufacturing costs remain approximately the same while our revenues, which are reported in U.S. Dollars, decline. In the second quarter and first half of 2001, the gross margins were negatively impacted by the factors identified in the product sales section under the caption "Revenues" above. In addition, we increased our sales of AmBisome to Fujisawa for the quarter and six months ended June 30, 2001 versus the comparable periods of a year ago. Under the terms of our agreement with Fujisawa, Gilead supplies AmBisome at manufacturing cost.

Except for the potential impact of unpredictable and uncontrollable changes in payment currencies relative to the U.S. Dollar and the impact of direct sales to Fujisawa, we expect that cost of products sold as a percentage of net product sales for the full year 2001 to be in the 20% to 25% range. In future periods, changes in the nature or mix of our product sales could impact this relationship.

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Operating Expenses

Research and development ("R&D") expenses for the second quarter of 2001 were \$44.1 million, compared with \$27.5 million for the second quarter of 2000, an increase of 61%. For the first half of 2001, R&D expenses were \$95.2 million versus \$53.7 million for the same period last year, an increase of 77%. The substantially higher spending for each comparable period can be attributed to Gilead's expenses associated with the Phase III clinical programs for Viread (tenofovir disoproxil fumarate) for HIV and adefovir dipivoxil for HBV, including the initiation of an early access program and clinical supply costs for Viread. Additionally, \$10.6 million of a \$13.0 million upfront license fee paid to Cubist for daptomycin was expensed in the first half of 2001. We expect R&D expenses for the full year 2001 to be approximately 30% to 45% higher than 2000 levels due to increased spending on the continued late stage development of Viread for HIV, including the expanded access program, adefovir dipivoxil for HBV as well as the upfront Cubist license fee.

Selling, general and administrative ("SG&A") expenses were \$29.7 million for the second quarter of 2001, compared with \$19.6 million for the second quarter of 2000. For the first half of 2001, SG&A expenses were \$51.6 million versus \$37.6 million for the first half of 2000. The increase for each comparable period was due to sales and marketing and related activities necessary to prepare for the anticipated U.S. and European commercial launch of Viread. We expect SG&A expenses for the year 2001 to be approximately 25% to 40% higher than 2000 levels due primarily to commercialization expenses related to the anticipated launch of Viread.

Interest Income and Interest Expense

We reported interest income of \$6.5 million for the quarter ended June 30, 2001, compared with \$4.4 million for the same period in 2000. Interest income was \$13.9 million for the first half of 2001 versus \$8.3 million for the first half of 2000. The increase is primarily due to significantly higher investment balances in 2001. In December of 2000, we received approximately \$242 million from the issuance of convertible subordinated notes, net of debt issuance costs.

Interest expense was \$3.4 million for the quarter ended June 30, 2001, compared with \$1.5 million for the same period in 2000. For the first half of 2001, interest expense was \$7.0 million versus \$3.0 million for the same period in 2000. The largest component of interest expense in 2001 was interest on our \$250.0 million 5% convertible subordinated notes issued in December 2000. Interest expense for the quarter and six months ended June 30, 2000 was principally the interest on the \$79.5 million outstanding balance of 6.25% subordinated debentures, which were subsequently converted to common stock in August 2000.

Equity in Loss of Unconsolidated Affiliate

For the quarter ended June 30, 2001, we recorded \$1.2 million as our equity in the loss of Proligo L.L.C. ("Proligo"), representing our 49% share of Proligo's losses for its quarter ended June 30, 2001. This compares to a loss of \$0.7 million recorded for the same period in 2000. For the first half of 2001, we recorded equity losses of Proligo of \$1.6 million, the same as the recorded losses for the first half of 2000. Our investment in Proligo is reported in other noncurrent assets on the balance sheet, and was \$5.0 million at June 30, 2001. We have no

commitments to provide additional funding to Proligo.

Liquidity and Capital Resources

Cash, cash equivalents and marketable securities totaled \$456.0 million at June 30, 2001, down from \$512.9 million at December 31, 2000. Cash was used primarily to fund operating activities.

Our accounts receivable balance at June 30, 2001 was \$54.4 million compared with a balance of \$48.8 million at December 31, 2000. The \$5.6 million growth in accounts receivable is due primarily to

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an increase in net product sales for the six months ended June 30, 2001 versus the six months ended December 31, 2000. In certain countries where payments are typically slow, primarily Greece, Spain and Italy, our accounts receivable balances are significant. At June 30, 2001, our past due accounts receivable for Greece, Spain and Italy totaled approximately \$20.0 million, of which \$8.3 million was more than 120 days past due. This compares to past due receivables of approximately \$19.3 million at December 31, 2000 for these same countries, of which \$10.9 million was more than 120 days past due. To date, we have experienced only modest losses with respect to the collection of our accounts receivable and believe that the past due accounts receivable for Greece, Spain and Italy are collectible.

Other significant changes in working capital during the six months ended June 30, 2001 included a \$3.2 million increase in inventory due to a build-up of approximately \$2.8 million in raw material, principally for the initial commercial lots of Viread. Accrued clinical expenses increased in the six months ended June 30, 2001, primarily due to the increased activity associated with the Phase III clinical programs for Viread for HIV and adefovir dipivoxil for HBV. We also made our semi annual interest payment on our convertible debt, leading to a decrease in our other accrued liabilities. The decrease in current deferred revenue is primarily due to \$1.7 million amortization of an upfront license fee from EyeTech.

The primary elements of the increase in other assets were the \$2.4 million unrecognized portion of the \$13.0 million license fee payment to Cubist and the \$1.1 million valuation of a warrant to purchase stock in EyeTech recognized in accordance with SFAS 133.

Through April 2001 we maintained a \$10.0 million unsecured line of credit with a major financial institution bearing interest at a floating rate. Under the terms of the line of credit, we were required to maintain certain financial ratios and there were limitations on our ability to incur additional debt or to engage in certain significant transactions. The line of credit, which included a foreign exchange facility, expired in April, 2001. We renewed the foreign exchange facility but did not renew the line of credit. Under the terms of the new foreign exchange facility we will be required to maintain a minimum cash investment balance with the financial institution. Our cash investment balance with that institution presently exceeds the minimum balance. There are no required financial ratios or limitations on debt or other transactions under the foreign exchange facility.

We believe that our existing capital resources, supplemented by net product sales, contract and royalty revenues will be adequate to satisfy our capital needs for the foreseeable future. As of June 30, 2001, we are entitled to additional cash payments of up to \$9.6 million from Roche, if and when Roche achieves specific additional Tamiflu developmental and regulatory milestones. We are also entitled to additional cash payments from EyeTech of up to \$25.0 million, if and when EyeTech achieves certain NX 1838 milestones. We cannot be assured that any of these milestones will be met. Our future capital requirements will depend on many factors, including:

the progress of our research and development efforts,

the success of our partners' research and development efforts and commercialization of their products,

the scope and results of preclinical studies and clinical trials,

the cost, timing and outcome of regulatory reviews,

the rate of technological advances,

determinations as to the commercial potential of our products under development,

the commercial performance of AmBisome and any of our products in development that receive marketing approval,

regulatory approval of Viread and if approved, its commercial performance,

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administrative expenses,

the status of competitive products,

the establishment of manufacturing capacity or third-party manufacturing arrangements,

the expansion of sales and marketing capabilities,

our possible geographic expansion, and

the establishment of additional collaborative relationships with other companies.

We may in the future require additional funding, which could be in the form of proceeds from equity or debt financings or additional collaborative agreements with corporate partners. If such funding is required, we cannot be assured that it will be available on favorable terms, if at all.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of June 30, 2001, our \$250.0 million convertible subordinated notes had a fair value of \$345.0 million. There have been no other significant changes in our market risk compared to the disclosures in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2000.

PART II. OTHER INFORMATION

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS

The Annual Meeting of Stockholders was held on May 24, 2001 in Redwood City, California. Of the 94,452,768 shares of Gilead Common Stock entitled to vote at the meeting, 78,989,592 shares were represented at the meeting in person or by proxy, constituting a quorum. The voting results are presented below.

The stockholders elected six directors to serve for the ensuing year and until their successors are elected. A seventh director, Cordell W. Hull, was elected by the Board of Directors to fill a vacancy in April 2001. The votes regarding the election of directors were as follows:

Name	Shares Voted For	Votes Withheld
Paul Berg	78,867,691	121,901
Etienne F. Davignon	78,880,737	108,855
James M. Denny	78,879,712	109,880
John C. Martin	70,569,521	8,420,071
Gordon E. Moore	78,870,357	119,235
George P. Shultz	78,866,927	122,665

The stockholders approved the amendment and restatement of the 1991 Stock Option Plan and the reservation of two million additional shares under the plan. There were 54,772,422 votes cast for the proposal, 24,126,840 votes cast against, 68,870 abstentions, and 21,460 broker non-votes.

The stockholders approved the ratification of Ernst & Young LLP as Gilead's independent auditors for the year ending December 31, 2001. There were 78,919,108 votes cast for the proposal, 42,321 votes cast against, 28,163 abstentions, and no broker non-votes.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

Reports on Form 8-K

None.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GILEAD SCIENCES
(Registrant)
Date: August 13, 2001
/s/ JOHN C. MARTIN
John C. Martin
President and Chief Executive Officer
Date: August 13, 2001
/s/ SHARON A. SURREY-BARBARI
Sharon A. Surrey-Barbari
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)
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