GILEAD SCIENCES INC
Form 10-Q
May 14, 2001

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

/x/ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the period ended March 31, 2001

or

/ / **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**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
333 Lakeside Drive, Foster City, California	**94404**
(Address of principal executive offices)	(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 April 30, 2001: 94,696,787

GILEAD SCIENCES, INC.

INDEX

		Page No.
PART I. FINANCIAL INFORMATION		
Item 1.	Condensed Consolidated Financial Statements:	
	Condensed Consolidated Balance Sheets at March 31, 2001 and December 31, 2000	3
	Condensed Consolidated Statements of Operations For the three months ended March 31, 2001 and 2000	4
	Condensed Consolidated Statements of Cash Flows For the three months ended March 31, 2001 and 2000	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	10
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	15
PART II.	OTHER INFORMATION	
Item 4.	Submission of Matters to a Vote of Securities Holders	16
Item 5.	Other Matters	16
Item 6.	Exhibits and Reports on Form 8-K	16
SIGNATURES		17

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)

	March 31, 2001	December 31, 2000
	(unaudited)	(Note)
Assets		
Current assets:		
Cash and cash equivalents	$ 77,403	$ 197,292
Marketable securities	406,407	315,586
Accounts receivable	51,187	48,814
Inventories	20,537	20,562
Prepaid expenses and other	14,844	11,544
Total current assets	570,378	593,798
Property, plant and equipment, net	54,975	55,174
Other noncurrent assets	32,192	29,127

	March 31, 2001	December 31, 2000
	$ 657,545	$ 678,099
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,908	$ 11,605
Accrued clinical and preclinical expenses	11,010	9,925
Accrued compensation and employee benefits	9,908	9,995
Other accrued liabilities	18,608	19,324
Deferred revenue	2,914	4,355
Long-term obligations due within one year	2,854	3,034
Total current liabilities	55,202	58,238
Long-term deferred revenue	10,578	10,730
Accrued litigation settlement expenses	5,484	5,769
Long-term obligations due after one year	1,941	2,238
Convertible subordinated notes	250,000	250,000
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value $.001 per share; 500,000,000 shares authorized; shares issued and outstanding: 94,451,768 shares at March 31, 2001 and 94,287,602 shares at December 31, 2000	94	94
Additional paid-in capital	859,572	857,942
Accumulated other comprehensive income (loss)	2,405	(901)
Deferred compensation	(2)	(3)
Accumulated deficit	(527,729)	(506,008)
Total stockholders' equity	334,340	351,124
	$ 657,545	$ 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.

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

	Three Months Ended March 31,	
	2001	2000

	Three Months Ended March 31,	
Revenues:		
Product sales, net	$ 45,064	$ 36,340
Royalty revenue, net	6,182	8,042
Contract revenue	6,437	840
Contract revenue SAB 101	153	2,490
Total Revenues	57,836	47,712
Costs and expenses:		
Cost of products sold	10,581	7,947
Research and development	51,146	26,246
Selling, general and administrative	21,911	17,970
Total costs and expenses	83,638	52,163
Loss from operations	(25,802)	(4,451)
Interest income	7,383	3,945
Interest expense	(3,533)	(1,537)
Loss before provision for income taxes, equity in loss of unconsolidated affiliate and cumulative effect of change in accounting principle	(21,952)	(2,043)
Provision for income taxes	470	307
Equity in loss of unconsolidated affiliate	390	921
Loss before cumulative effect of change in accounting principle	(22,812)	(3,271)
Cumulative effect of change in accounting principle	1,089	(13,670)
Net loss	$ (21,723)	$ (16,941)
Basic and diluted net loss per common share:		
Loss before cumulative effect of change in accounting principle	$ (0.24)	$ (0.04)
Cumulative effect of change in accounting principle	0.01	(0.15)
Net loss	$ (0.23)	$ (0.19)
Common shares used to calculate basic and diluted net loss per common share	94,349	88,680

See accompanying notes.

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2001	2000
OPERATING ACTIVITIES:		
Net loss	$ (21,723)	$ (16,941)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net effect of change in accounting principle	(1,089)	11,180
Depreciation and amortization	3,445	2,893
Equity in loss of unconsolidated affiliate	390	921
Net unrealized loss on foreign currency transactions	1,135	1,211
Other non-cash transactions	83	94
Changes in assets and liabilities:		
Accounts receivable	(6,030)	(2,439)
Inventories	25	(27)
Prepaid expenses and other assets	(3,436)	2,926
Accounts payable	(1,600)	(2,868)
Accrued liabilities	145	(3,241)
Deferred revenue (excluding net effect of change in accounting principle)	(1,593)	732
Net cash used in operating activities	(30,248)	(5,559)
INVESTING ACTIVITIES:		
Purchases of marketable securities	(157,796)	(59,657)
Sales of marketable securities	34,592	5,990
Maturities of marketable securities	35,456	46,278
Capital expenditures	(3,254)	(3,724)
Investment in unconsolidated affiliate		(2,450)
Net cash used in investing activities	(91,002)	(13,563)
FINANCING ACTIVITIES:		
Proceeds from issuances of common stock	1,900	9,996
Repayments of long-term debt	(477)	(913)
Net cash provided by financing activities	1,423	9,083
Effect of exchange rate on cash	(62)	324
Net decrease in cash and cash equivalents	(119,889)	(9,715)
Cash and cash equivalents at beginning of period	197,292	47,011
Cash and cash equivalents at end of period	$ 77,403	$ 37,296
NON-CASH ACTIVITIES:		
Common stock issued upon the conversion of convertible subordinated notes	$	$ 25

See accompanying notes.

GILEAD SCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 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 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 share and per share amounts for all periods presented 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. Cumulative 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 the cumulative effect of 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, *Revenue Recognition in Financial Statements,* and the change was also accounted for as the cumulative effect of a change in accounting principle.

3. Derivative Financial Instruments

On January 1, 2001, Gilead adopted SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*. The standards require 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 ("OCI") 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 OCI in stockholders' equity and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. All values reported in OCI 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 quarter 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 accordingly, 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 OCI 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 three months ended March 31, 2001, a $0.4 million loss on hedging contracts had been recognized in the income statement and a $0.6 million reduction in the fair value of derivatives was recognized in OCI. At March 31, 2001, fair value gains and losses on the balance sheet were not material.

4. Inventories

Inventories are summarized as follows (in thousands):

	March 31, 2001	December 31, 2000
Raw materials	$ 9,866	$ 9,647
Work in process	4,113	7,781
Finished goods	6,558	3,134
Total inventories	$ 20,537	$ 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

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 agreed to pay the $1.25 million related to that milestone. 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 March 31,	
	2001	2000
Net loss	$ (21,723)	$ (16,941)
Net foreign currency translation gain (loss)	282	(196)
Net unrealized gain (loss) on available-for-sale securities	3,073	(276)
Net unrealized loss on cash flow hedges	(49)	
Comprehensive loss	$ (18,417)	$ (17,413)

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):

	Three months ended March 31,	
	2001	2000
AmBisome®	$ 41,901	$ 34,586
Other	3,163	1,754
Consolidated total	$ 45,064	$ 36,340

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 March 31,	
	2001	2000
United States	$ 12,735	$ 6,566
United Kingdom	7,743	5,843
Germany	4,768	5,393
Switzerland	4,500	6,716
Italy	4,534	4,348
Spain	4,536	3,577
Other European countries	14,769	10,178
Other countries	4,251	5,091
Consolidated total	$ 57,836	$ 47,712

Product sales to one distributor accounted for approximately 13% of total revenues for the first three months of 2001 and approximately 12% of total revenues for the same period of 2000. For the quarter ended March 31, 2001, sales to and royalties from Fujisawa Healthcare, Inc. ("Fujisawa") were 15% of total revenue. Revenues from Fujisawa were less than 10% of sales during the first three 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.

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 share and per share amounts for all periods presented 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 will compete 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 can not 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.

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, and the collaboration with Fujisawa for sales of AmBisome in the United States and Canada. 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 March 31, 2001, our accumulated deficit was $527.7 million.

Results of Operations

Revenues

We had total revenue of $57.8 million for the quarter ended March 31, 2001 compared with $47.7 million for the quarter ended March 31, 2000. Included in total revenue are net product sales, royalty income and contract revenue, including research and development collaborations.

Net product sales were $45.1 million for the first quarter of 2001 compared with $36.3 million for the first quarter of 2000. Sales of AmBisome accounted for 93% of revenues from product sales in the first quarter of 2001 and 95% in the first quarter of 2000. Sales of AmBisome for the first quarter of 2001 increased 21% over the first quarter of 2000. Excluding the impact of the decline in foreign currencies relative to the U.S. Dollar in 2001, sales of AmBisome would have increased 29% in the first quarter of 2001 over the comparable period in 2000. In addition, Gilead recorded product sales of $2.1 million and $1.0 million from the sale of VISTIDE and DaunoXome, respectively, during the first quarter of 2001. 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 $6.2 million for the first quarter of 2001 compared with $8.0 million for the comparable quarter in 2000. Royalties in the first quarter of 2001 included $3.8 million from

Fujisawa for sales of AmBisome in the United States, $2.1 million from Roche for sales of Tamiflu worldwide and $0.3 million for VISTIDE sales by Pharmacia Corporation ("Pharmacia") outside the United States. First quarter 2000 royalties included $5.4 million from Roche for Tamiflu, $2.2 million from Fujisawa for AmBisome and $0.4 million for VISTIDE sales by Pharmacia. Higher sales of AmBisome in the United States resulted in the $1.6 million increase in Fujisawa royalty payments. We record royalties from Roche in the quarter following the quarter in which the related Tamiflu sales occur. The $3.3 million decline 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.

Total contract revenue was $6.4 million for the quarter ended March 31, 2001 and $0.8 million for the comparable quarter in 2000. Contract revenue for the first quarter of 2001 included a $2.0 million milestone payment from Roche, $2.5 million from marketing agreements, and recognition of $1.7 million of the up-front license fee received from EyeTech Pharmaceuticals, Inc. ("EyeTech") in March 2000. Contract revenue in the first quarter of 2000 included $0.4 million for development expense reimbursements from Roche.

Additionally, first quarter 2001 contract revenue included $0.2 million related to a previously recognized initial license fee from Pharmacia that was deferred upon adoption of SAB 101 in January 2000 and will be recognized on a straight-line basis over the next twelve years. Included in contract revenue for the first quarter of 2000 was $2.5 million related to previously recognized initial license fees received from Sumitomo Pharmaceuticals Co., Ltd., Roche and Pharmacia. The up-front fees were deferred upon adoption of SAB 101, and $2.5 million is the portion of

the fees that was subsequently recognized in contract revenue in the first quarter of 2000.

Cost of Product Sales

Cost of products sold was $10.6 million, or 23% of net product sales, for the quarter ended March 31, 2001, and $7.9 million, or 22% of net product sales, for the quarter ended March 31, 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 will negatively impact gross margins since our manufacturing costs will remain approximately the same while our revenues, which are reported in U.S. Dollars, will decline. In addition, we increased our sales of AmBisome sales to Fujisawa. 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 sales as a percentage of sales revenues for the full year 2001 to be materially consistent with the 22% amount reported for the year 2000. In future periods, changes in the nature or mix of our product sales could impact this relationship.

Operating Expenses

Research and development ("R&D") expenses were $51.1 million for the first quarter of 2001, up 95% from $26.2 million for the first quarter of 2000. R&D expenses included for the first quarter of 2001 $10.6 million of the $13.0 million upfront license fee paid to Cubist for daptomycin. In addition, Gilead's expenses associated with the Phase III clinical programs for tenofovir DF for HIV and adefovir dipivoxil for HBV increased significantly during the quarter, including the initiation of an early access program and clinical supply costs for tenofovir DF. We expect R&D expenses for the full year 2001 to be approximately 20% to 30% higher than 2000 levels due to increased spending on the continued late stage development of tenofovir DF for HIV and adefovir dipivoxil for HBV as well as the up-front daptomycin license fee.

Selling, general and administrative ("SG&A") expenses were $21.9 million for the first quarter of 2001, compared to $18.0 million for the first quarter of 2000. The increase was due to sales and marketing and related activities necessary to prepare for the anticipated U.S. and European commercial launch of tenofovir DF. 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 tenofovir DF.

Interest Income and Interest Expense

We reported interest income of $7.4 million for the quarter ended March 31, 2001, up from $3.9 million for the quarter ended March 31, 2000. The increase is primarily due to significantly higher investment balances in 2001. At March 31, 2001, we had cash, cash equivalents and marketable securities of $483.8 million, up from $291.8 million at March 31, 2000.

Interest expense was $3.5 million for the quarter ended March 31, 2001, up from $1.5 million for the quarter ended March 31, 2000. The largest component of interest expense in the first quarter of 2001 was interest on our $250.0 million 5% convertible subordinated notes issued in December 2000. Interest expense for the first quarter of 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 first quarter of 2001, we recorded $0.4 million as our equity in the loss of Proligo L.L.C. ("Proligo"), representing our 49% share of Proligo's losses for its fiscal quarter ended March 31, 2001. For the first quarter of 2000, we recorded equity losses of Proligo of $0.9 million representing our portion of Proligo's loss for its first fiscal quarter ended February 29, 2000. During the fourth quarter of 2000, Proligo changed its fiscal year-end to December 31 from November 30. Our investment in Proligo is reported in other noncurrent assets on the balance sheet, and was $6.6 million at March 31, 2001. We have no commitments to provide additional funding to Proligo.

Liquidity and Capital Resources

Cash, cash equivalents and marketable securities totaled $483.8 million at March 31, 2001, down from $512.9 million at December 31, 2000. Cash was used primarily to fund operating activities.

Our accounts receivable balance at March 31, 2001 was $51.2 million compared to a balance of $48.8 million at December 31, 2000. The $2.4 million growth in accounts receivable is due primarily to an increase in net product sales. In certain countries where payments are typically

slow, primarily Greece, Spain and Italy, our accounts receivable balances are significant. At March 31, 2001, our past due accounts receivable for Greece, Spain and Italy totaled approximately $19.5 million, of which $9.2 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 three months ended March 31, 2001 included a $3.4 million increase in prepaid expenses and other assets due primarily to the $2.0 million milestone payment due from Roche and a $0.5 million increase in prepaid insurance. Accounts payable decreased in the three months ended March 31, 2001 primarily due to accrued contract obligations at December 31, 2000 that have since been paid. The decrease in current deferred revenue is primarily due to the $1.7 million amortization of the EyeTech up-front license fee.

The primary elements of the increase in other assets was 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. As of March 31, 2001, we had no outstanding borrowings under the line. The line of credit, which included a foreign exchange facility, expired on April 16, 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 March 31, 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 tenofovir DF and if approved, its commercial performance,

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 March 31, 2001, our $250.0 million convertible subordinated notes had a fair value of $169.0 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

A Special Meeting of Stockholders was held on February 2, 2001 in Redwood City, California. Of the 94,171,488 shares of Gilead Common Stock entitled to vote at the meeting, 75,664,638 shares were represented at the meeting in person or by proxy, constituting a quorum. The stockholders approved an amendment to Gilead's Certificate of Incorporation to increase the authorized number of shares of Common Stock from 100,000,000 shares to 500,000,000 shares. There were 59,152,774 votes cast for the proposal, 16,451,600 votes cast against, 60,264 abstentions and there were no broker non-votes.

ITEM 5. OTHER MATTERS

In early May 2001, Gilead submitted a New Drug Application with the U.S. Food and Drug Administration and a Marketing Authorisation Application to the European Agency for the Evaluation of Medicinal Products for marketing approval of tenofovir disoproxil fumarate (tenofovir DF), an investigational reverse transcriptase inhibitor in development for the treatment of HIV infection.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a)

Exhibits

No. 10.42 Marketing, Distribution, and Development Agreement between Cubist Pharmaceuticals, Inc. and the Registrant.*

(b)

Reports on Form 8-K

None.

*

Confidential treatment requested as to specific portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

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, INC.

(Registrant)

Date: May 14, 2001

/s/ JOHN C. MARTIN

John C. Martin
President and Chief Executive Officer

Date: May 14, 2001

/s/ SHARON A. SURREY-BARBARI

Sharon A. Surrey-Barbari
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

QuickLinks

GILEAD SCIENCES, INC. INDEX

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)
GILEAD SCIENCES, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited) (in thousands, except per share amounts)
GILEAD SCIENCES, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited) (in thousands)
GILEAD SCIENCES, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS March 31, 2001 (unaudited)

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS
ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK
PART II. OTHER INFORMATION
ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS

ITEM 5. OTHER MATTERS
ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K
SIGNATURES