GILEAD SCIENCES INC
Form 10-Q
November 13, 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 September 30, 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)	(IRS 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 October 31, 2001: 95,943,935

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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)

	September 30, 2001	December 31, 2000
	(unaudited)	(Note)
Assets		
Current assets:		
Cash and cash equivalents	$ 37,346	$ 197,292
Marketable securities	403,208	315,586
Accounts receivable	59,402	48,814
Inventories	31,207	20,562
Prepaid expenses and other	13,444	11,544
Total current assets	544,607	593,798
Property, plant and equipment, net	62,925	55,174
Other noncurrent assets	25,403	29,127
	$ 632,935	$ 678,099

	September 30, 2001	December 31, 2000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 15,261	$ 11,605
Accrued clinical and preclinical expenses	16,374	9,925
Accrued compensation and employee benefits	14,904	9,995
Other accrued liabilities	18,839	19,324
Deferred revenue	3,899	4,355
Long-term obligations due within one year	2,467	3,034
Total current liabilities	71,744	58,238
Long-term deferred revenue	7,405	10,730
Accrued litigation settlement expenses	4,895	5,769
Long-term obligations due after one year	752	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: 95,502,573 shares at September 30, 2001 and 94,287,602 shares at December 31, 2000	96	94
Additional paid-in capital	876,913	857,942
Accumulated other comprehensive income (loss)	6,445	(901)
Deferred compensation	(1)	(3)
Accumulated deficit	(585,314)	(506,008)
Total stockholders' equity	298,139	351,124
	$ 632,935	$ 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 September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000

	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenues:				
Product sales, net	$ 44,707	$ 37,403	$ 131,336	$ 111,737
Royalty revenue, net	4,424	3,609	16,982	19,331
Contract revenue	234	4,077	7,794	9,222
Contract revenue SAB 101	1,550	150	3,326	2,790
Total revenues	50,915	45,239	159,438	143,080
Costs and expenses:				
Cost of goods sold	9,208	9,383	30,586	26,014
Research and development	45,728	35,318	140,952	89,024
Selling, general and administrative	32,047	21,329	83,665	58,919
Total costs and expenses	86,983	66,030	255,203	173,957
Loss from operations	(36,068)	(20,791)	(95,765)	(30,877)
Gain on sale of unconsolidated affiliate	8,754		8,754	
Interest income	6,305	4,441	20,195	12,746
Interest expense	(3,513)	(604)	(10,482)	(3,659)
Loss before provision for income taxes, equity in loss of unconsolidated affiliate and cumulative effect of change in accounting principle	(24,522)	(16,954)	(77,298)	(21,790)
Provision for income taxes	174	214	967	1,046
Equity in loss of unconsolidated affiliate	500	246	2,130	1,885
Loss before cumulative effect of change in accounting principle	(25,196)	(17,414)	(80,395)	(24,721)
Cumulative effect of change in accounting principle			1,089	(13,670)
Net loss	$ (25,196)	$ (17,414)	$ (79,306)	$ (38,391)
Basic and diluted net loss per common share:				
Loss before cumulative effect of change in accounting principle	$ (0.26)	$ (0.19)	$ (0.85)	$ (0.27)
Cumulative effect of change in accounting principle			0.01	(0.15)
Net loss	$ (0.26)	$ (0.19)	$ (0.84)	$ (0.42)
Common shares used to calculate basic and diluted net loss per common share	95,306	92,178	94,822	90,014

See accompanying notes.

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

	Nine Months Ended September 30,	
	2001	**2000**
OPERATING ACTIVITIES:		
Net loss	$ (79,306)	$ (38,391)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net effect of change in accounting principle	(1,089)	10,880
Depreciation and amortization	10,846	8,687
Equity in loss of unconsolidated affiliate	2,130	1,885
Net unrealized (gain)/loss on foreign currency transactions	(2,581)	1,066
Gain on sale of unconsolidated affiliate	(8,754)	
Other non-cash transactions	889	1,663
Changes in assets and liabilities:		
Accounts receivable	(8,152)	(4,384)
Inventories	(10,645)	1,732
Prepaid expenses and other assets	(6,739)	(556)
Accounts payable	3,656	(2,692)
Accrued liabilities	9,675	2,759
Deferred revenue (excluding net effect of change in accounting principle)	(2,692)	2,557
Net cash used in operating activities	(92,762)	(14,794)
INVESTING ACTIVITIES:		
Purchases of marketable securities	(278,828)	(130,409)
Sales of marketable securities	104,064	19,950
Maturities of marketable securities	93,525	109,153
Capital expenditures	(16,659)	(11,575)
Investment in unconsolidated affiliate		(2,450)
Proceeds from sale of unconsolidated affiliate	14,300	
Net cash used in investing activities	(83,598)	(15,331)
FINANCING ACTIVITIES:		
Proceeds from issuances of common stock	18,885	26,567
Repayments of long-term debt	(2,053)	(2,462)
Net cash provided by financing activities	16,832	24,105
Effect of exchange rate changes on cash	(418)	2,383
Net decrease in cash and cash equivalents	(159,946)	(3,637)
Cash and cash equivalents at beginning of period	197,292	47,011
Cash and cash equivalents at end of period	$ 37,346	$ 43,374

	Nine Months Ended September 30,	
NON-CASH ACTIVITIES:		
Common stock issued upon the conversion of convertible subordinated debentures	$	$ 79,508
Reclassification of deferred debt issuance costs to additional paid in capital upon conversion of debentures	$	$ 1,585

See accompanying notes.

GILEAD SCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 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 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 company that include a net exercise feature 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 nine months of 2001 was not significant. Additionally, as of September 30, 2001, Gilead had 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. Correspondingly, Gilead recognized a $1.1 million credit to its results of operations recorded as a cumulative change in accounting principle and an increase in other comprehensive income of $0.6 million.

During the nine months ended September 30, 2001, a $1.2 million loss on hedging contracts has been recognized in the income statement and a $0.5 million reduction in the fair value of derivatives is recognized in other comprehensive income. At September 30, 2001, fair value gains and losses on the balance sheet were not material.

4. Inventories

Inventories are summarized as follows (in thousands):

	September 30, 2001	December 31, 2000
Raw materials	$ 19,292	$ 9,647
Work in process	5,648	7,781
Finished goods	6,267	3,134
Total inventories	$ 31,207	$ 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 also agreed to 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. Through September 2001, two of these milestones had been met and Gilead paid $4.2 million related to those milestones. These payments have 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. Sale of Unconsolidated Affiliate

On August 31, 2001, Gilead sold its 49 percent interest in Proligo L.L.C. ("Proligo") to Degussa Corporation for $14.3 million in cash. Proligo was a joint venture between Gilead and SKW Americas, Inc. focused on the manufacturing of oligonucleotides. SKW Americas, a subsidiary of Degussa Corporation, held the remaining 51 percent of Proligo. The proceeds, net of Gilead's investment in Proligo, are reflected as a gain on the sale of unconsolidated affiliate in the three months ended September 30, 2001. The recognized gain was $8.8 million.

7. Comprehensive Loss

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

	Three months ended September 30,		Nine months ended September 30,	
	2001	2000	2001	2000
Net loss	$ (25,196)	$ (17,414)	$ (79,306)	$ (38,391)
Net foreign currency translation gain (loss)	773	85	836	(281)
Net unrealized gain on cash flow hedges	510		127	
Net unrealized gain on available-for-sale securities	3,137	1,205	6,383	1,136
Comprehensive loss	$ (20,776)	$ (16,124)	$ (71,960)	$ (37,536)

8. 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 September 30,		Nine months ended September 30,	
	2001	2000	2001	2000
AmBisome®	$ 41,113	$ 35,047	$ 121,926	$ 105,484
Other	3,594	2,356	9,410	6,253
Consolidated total	$ 44,707	$ 37,403	$ 131,336	$ 111,737

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 September 30,		Nine months ended September 30,	
	2001	2000	2001	2000
United States	$ 9,351	$ 8,866	$ 32,895	$ 25,273
United Kingdom	7,312	5,761	20,653	18,130
Germany	4,988	5,725	14,442	16,259
Spain	4,593	3,985	13,332	11,236
France	4,532	2,389	11,390	6,727
Italy	4,321	3,428	13,948	12,760
Other European countries	10,094	11,304	36,920	39,512
Other countries	5,724	3,781	15,858	13,183
Consolidated total	$ 50,915	$ 45,239	$ 159,438	$ 143,080

For the nine months ended September 30, 2001, product sales to any one distributor did not exceed 10% of total revenues. Product sales to one distributor accounted for approximately 13% of total revenues for the first nine months of 2000. For the nine months ended September 30, 2001, sales to and royalties from Fujisawa Healthcare, Inc. ("Fujisawa") were approximately 17% of total revenues compared to approximately 13% of total revenues during the first nine months of 2000.

9. 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.

10. New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued Statements of Financial Accounting Standards No. 141, "Business Combinations" (SFAS 141), and No. 142, "Goodwill and Other Intangible Assets" (SFAS 142). SFAS 141 eliminates the pooling-of-interests method of accounting for business combinations except for qualifying business combinations that were initiated prior to July 1, 2001. SFAS 141 further clarifies the criteria to recognize intangible assets separately from goodwill. The requirements of SFAS 141 are effective for any business combination accounted for by the purchase method that is completed after June 30, 2001. Under SFAS 142, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) for impairment. Separable intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful lives (but with no maximum life). The amortization provisions of SFAS 142 apply to goodwill and intangible assets acquired after June 30, 2001. The adoption of SFAS 141 on July 1, 2001 did not have a material impact on the Company's financial position or results of operations and we do not expect the adoption of SFAS 142 on January 1, 2002 will have a material impact on the Company's financial position or results of operations.

In August, 2001, the FASB issued SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS 144 supercedes SFAS 121, "Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of" and the accounting and reporting provisions of Accounting Principles Board Opinion No. 30, "Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring

Events and Transactions," for the disposal of a segment of a business. SFAS 144 establishes a single accounting model for assets to be disposed of by sale whether previously held and used or newly acquired. SFAS 144 retains the provisions of APB No. 30 for presentation of discontinued operations in the income statement, but broadens the presentation to include a component of an entity. SFAS 144 is effective for fiscal years beginning after December 15, 2001 and the interim periods within. The Company does not believe that the adoption of SFAS 144 on January 1, 2002 will have a material impact on the Company's financial position or results of operations.

11. Subsequent Events

On October 23, 2001, Gilead out-licensed all remaining intellectual property rights under the SELEX (Systemic Evolution of Ligands through EXponential Enrichment) process patent estate to Archemix Corporation, a privately held company. Under the terms of the agreement, Archemix agreed to pay Gilead $17.5 million in cash, with $9.0 million due in 2001 and $8.5 million due in the second quarter of 2002. Additionally, Gilead has received a warrant to purchase common stock of Archemix.

On October 26, 2001, the U.S. Food and Drug Administration approved the use of the Company's antiretroviral agent Viread (tenofovir disoproxil fumarate) for the treatment of human immunodeficiency virus ("HIV") infection when taken in combination with other antiretroviral agents. Initial product shipments commenced in October 2001.

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. As of September 30, 2001, we marketed 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. On October 26, 2001, we received U.S. marketing approval for Viread for the treatment of HIV and began marketing that product. 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 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 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.

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; the 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. It is also too early to determine if Viread

will achieve significant market penetration, particularly for use in treatment naïve patients given that the data supporting Viread's U.S. approval is in a treatment experienced patient population.

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.

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 September 30, 2001, our accumulated deficit was $585.3 million.

Results of Operations

Revenues

We had total revenues of $50.9 million for the quarter ended September 30, 2001, compared with $45.2 million for the quarter ended September 30, 2000. Total revenues were $159.4 million for the first nine months of 2001, and $143.1 million for the first nine months of 2000. Included in total revenues are net product sales, royalty income and contract revenue, including research and development collaborations.

Net product sales were $44.7 million for the three months ended September 30, 2001, compared with $37.4 million for the quarter ended September 30, 2000, representing an increase of 20%. Sales of AmBisome accounted for 92% of revenues from product sales in the quarter ended September 30, 2001, and 94% of revenues from product sales in the comparable quarter last year. Excluding the impact of foreign currencies relative to the U.S. Dollar in 2001, sales of AmBisome would have increased 20% in the third quarter of 2001 over the comparable period in 2000. In the first nine months of 2001, net product sales were $131.3 million, versus $111.7 million in the comparable period of 2000, an increase of 18%. Sales of AmBisome accounted for 93% of revenues from product sales in

the nine months ended September 30, 2001. This compares to 94% in the nine months ended September 30, 2000. Excluding the impact of the decline in foreign currencies, sales of AmBisome would have increased 21% in the first nine months of 2001 over the same period in 2000. In addition, Gilead recorded other product sales of $3.6 million during the quarter ended September 30, 2001 and $2.4 million for the same period of 2000. Other product sales during the nine months ended September 30, 2001 were $9.4 million, compared with $6.3 million for the first nine months of 2000. A 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 $4.4 million for the third quarter of 2001, compared with $3.6 million for the same period in 2000. For the first nine months of 2001, net royalty revenue was $17.0 million versus $19.3 million for the comparable period in 2000. Royalties in the third quarter ended September 30, 2001 included $3.9 million from Fujisawa for sales of AmBisome in the United States. Royalties received from Fujisawa for the comparable period in 2000 were $3.1 million. For the nine months ended September 30, 2001, royalties received from Fujisawa were

$11.9 million compared with $8.8 million in the first nine months of 2000. These increases reflect higher sales of AmBisome in the United States. For the first nine months of 2001, royalties received from Roche were $4.1 million compared with $9.3 million in the first nine months 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 $1.8 million for the quarter ended September 30, 2001 versus $4.2 million for the comparable quarter in 2000. This decrease is primarily attributable to a milestone payment of $2.0 million received from Roche in the third quarter of 2000. Contract revenue for the third quarter of 2001 consisted primarily of $1.4 million related to work performed on behalf of Sumitomo Pharmaceuticals Co. There were no milestone payments received from Roche in the third quarter of 2001. Total contract revenue for the first nine months of 2001 was $11.1 million versus $12.0 million in the same period of 2000. This year over year decrease is primarily due to the $2.0 million decline in milestone payments received from Roche.

Cost of Goods Sold

Cost of goods sold was $9.2 million, or 21% of net product sales, for the quarter ended September 30, 2001, and $9.4 million, or 25% of net product sales, for the quarter ended September 30, 2000. For the first nine months of 2001, cost of goods sold was $30.6 million, or 23% of net product sales, versus $26.0 million, or 23% of net product sales, for the first nine months of 2000. The decrease in cost of goods sold as a percentage of net product sales for the quarter to quarter period is largely driven by the Company's product mix and to a lesser extent manufacturing efficiencies.

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. An increase or decrease in the value of these foreign currencies relative to the U.S. Dollar impacts gross margins since our manufacturing costs remain approximately the same while our revenues, which are reported in U.S. Dollars, would increase or decrease. In addition, sales of AmBisome to Fujisawa could have an effect on our overall cost of goods sold. 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 goods 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, such as the recent launch of Viread for HIV, could impact this relationship.

Operating Expenses

Research and development ("R&D") expenses for the third quarter of 2001 were $45.7 million, compared with $35.3 million for the third quarter of 2000, an increase of 29%. For the first nine months of 2001, R&D expenses were $141.0 million versus $89.0 million for the same period last year, an increase of 58%. The higher spending during the third quarter of 2001 is attributable to Gilead's expenses associated with the Phase III clinical program for adefovir dipivoxil for hepatitis B virus (HBV) and a $3.0 million clinical milestone payment to Cubist for daptomycin. The higher spending during the first nine months of 2001 was attributable in part to the recognition of $10.6 million of a $13.0 million up-front payment and $4.2 million of clinical milestone payments to Cubist. In addition, Gilead's expenses associated with the Phase III clinical trials and expanded access programs for Viread for HIV and the Phase III clinical program for adefovir dipivoxil for HBV increased significantly during the first nine months of 2001. We expect R&D expenses for the full year 2001 to be approximately 35% to 45% higher than 2000 levels due to increased spending on the continued late stage development of Viread for HIV, including the expanded access programs, adefovir dipivoxil for HBV as well as the upfront Cubist license fee.

Selling, general and administrative ("SG&A") expenses were $32.0 million for the third quarter of 2001, compared with $21.3 million for the third quarter of 2000, an increase of 50%. For the first nine months of 2001, SG&A expenses were $83.7 million versus $58.9 million for the first nine months of 2000, an increase of 42%. The increase in spending for each comparable period is primarily due to Gilead's increased global marketing efforts and the expansion of Gilead's U.S. and European sales forces in anticipation of the commercial launch of Viread for HIV. We expect SG&A expenses for the full year 2001 to be approximately 45% to 55% higher than 2000 levels due primarily to commercialization expenses related to the U.S. and anticipated European launch of Viread.

Sale of Unconsolidated Affiliate

On August 31, 2001, Gilead sold its 49 percent interest in Proligo L.L.C. ("Proligo") to Degussa Corporation for $14.3 million in cash. Proligo was a joint venture between Gilead and SKW Americas, Inc. focused on the manufacturing of oligonucleotides. SKW Americas, a

subsidiary of Degussa Corporation, held the remaining 51 percent of Proligo. The proceeds, net of Gilead's investment in Proligo, are reflected as a gain on the sale of unconsolidated affiliate in the three months ended September 30, 2001. The recognized gain was $8.8 million.

Interest Income and Interest Expense

We reported interest income of $6.3 million for the quarter ended September 30, 2001, compared with $4.4 million for the same period in 2000. Interest income was $20.2 million for the first nine months of 2001 versus $12.7 million for the first nine months 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 $3.5 million for the quarter ended September 30, 2001, compared with $0.6 million for the same period in 2000. For the first nine months of 2001, interest expense was $10.5 million versus $3.7 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 nine months ended September 30, 2000 was principally the interest on the $79.5 million outstanding balance of 6.25% subordinated debentures, which were converted to common stock in August 2000.

Equity in Loss of Unconsolidated Affiliate

For the quarter ended September 30, 2001, we recorded $0.5 million as our equity in the loss of Proligo, compared to a loss of $0.2 million recorded for the same period in 2000. For the first nine months of 2001, we recorded equity losses of Proligo of $2.1 million, versus $1.9 million for the first nine months of 2000. The loss for the three and nine months ended September 30, 2001 was derived from Gilead's 49 percent interest in Proligo prior to August 31, 2001, the date of the sale of our interest in Proligo (see above).

Liquidity and Capital Resources

Cash, cash equivalents and marketable securities totaled $440.6 million at September 30, 2001, down from $512.9 million at December 31, 2000. Cash, including the $14.3 million proceeds from the sale of our interest in Proligo and the $18.9 million from the issuances of common stock, was used primarily to fund operating activities and the purchase of $16.7 million of capital equipment.

Our accounts receivable balance at September 30, 2001 was $59.4 million compared with a balance of $48.8 million at December 31, 2000. The $10.6 million growth in accounts receivable is due primarily to an increase in net product sales for the nine months ended September 30, 2001 versus the nine months ended December 31, 2000. In certain countries where payments are typically slow, primarily Greece, Spain, Portugal and Italy, our accounts receivable balances are significant. At September 30, 2001, our past due accounts receivable for these four countries totaled approximately $25.8 million, of which $9.8 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, Portugal and Italy are collectible.

Other significant changes in working capital during the nine months ended September 30, 2001 included a $10.6 million increase in inventory due to a build-up of approximately $9.6 million in raw material, principally for the initial commercial lots of Viread. Accrued clinical expenses increased in the nine months ended September 30, 2001, primarily due to the increased activity associated with the Phase III clinical programs for Viread for HIV and adefovir dipivoxil for HBV. Accrued compensation has also increased, principally due to the expansion of the Company's U.S. sales force in anticipation of the commercial launch of Viread for HIV.

The primary reason for the decrease in other assets was the sale of our interest in Proligo. The Company's investment in Proligo at December 31, 2000 was approximately $6.9 million. The investment in Proligo of approximately $4.8 million at August 31, 2001 was written off upon completion of the sale. The decrease in other assets was partially offset by increases resulting from 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 September 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 product development 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,

European regulatory approval of Viread and its commercial performance in the U.S. and Europe,

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 September 30, 2001, our $250.0 million convertible subordinated notes had a fair value of $337.2 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 6. EXHIBITS AND REPORTS ON FORM 8-K

Reports on Form 8-K

None.

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: November 9, 2001

/s/ JOHN C. MARTIN

John C. Martin
President and Chief Executive Officer

Date: November 9, 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