

GILEAD SCIENCES INC
Form 10-Q
November 14, 2002

[QuickLinks](#) -- Click here to rapidly navigate through this document

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the period ended September 30, 2002

or

o **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

(State or other jurisdiction of
incorporation or organization)

94-3047598

(I.R.S. Employer
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. Yesý No o

Number of shares outstanding of the issuer's common stock, par value \$.001 per share, as of October 31, 2002: 196,682,438

GILEAD SCIENCES, INC.

INDEX

PART I.	FINANCIAL INFORMATION	
Item 1.	Condensed Consolidated Financial Statements:	
	Condensed Consolidated Balance Sheets at September 30, 2002 and December 31, 2001	3
	Condensed Consolidated Statements of Operations For the three and nine months ended September 30, 2002 and 2001	4
	Condensed Consolidated Statements of Cash Flows For the nine months ended September 30, 2002 and 2001	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	17
PART II.	OTHER INFORMATION	
Item 4.	Controls and Procedures	17
Item 6.	Exhibits and Reports on Form 8-K	17
	SIGNATURES	18
	CERTIFICATIONS	19

PART I. FINANCIAL INFORMATION**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except per share amounts)

	September 30, 2002	December 31, 2001
	(unaudited)	(Note)
Assets		
Current assets:		
Cash and cash equivalents	\$ 121,608	\$ 123,490
Marketable securities	503,183	459,361
Accounts receivable	114,062	74,228
Inventories	38,169	39,280
Prepaid expenses and other	11,113	11,400
	788,135	707,759
Total current assets	788,135	707,759
Property, plant and equipment, net	65,709	62,828
Other noncurrent assets	22,383	24,199

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

	September 30, 2002	December 31, 2001
	<u> </u>	<u> </u>
	<u> </u>	<u> </u>
	\$ 876,227	\$ 794,786
	<u> </u>	<u> </u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 17,254	\$ 19,174
Accrued clinical and preclinical expenses	8,632	15,938
Accrued compensation and employee benefits	20,380	14,688
Other accrued liabilities	31,792	24,829
Deferred revenue	7,155	3,996
Long-term obligations due within one year	263	1,492
	<u> </u>	<u> </u>
Total current liabilities	85,476	80,117
Long-term deferred revenue	17,629	7,252
Accrued litigation settlement expenses		4,591
Long-term obligations due after one year	293	389
Convertible subordinated notes	250,000	250,000
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value \$.001 per share; 500,000 shares authorized; shares issued and outstanding: 196,567 shares at September 30, 2002 and 193,041 shares at December 31, 2001	197	193
Additional paid-in capital	937,282	898,533
Accumulated other comprehensive income	2,469	7,448
Accumulated deficit	(417,119)	(453,737)
	<u> </u>	<u> </u>
Total stockholders' equity	522,829	452,437
	<u> </u>	<u> </u>
	\$ 876,227	\$ 794,786
	<u> </u>	<u> </u>

Note: The condensed consolidated balance sheet at December 31, 2001 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,	
<u>2002</u>	<u>2001</u>	<u>2002</u>	<u>2001</u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenues:				
Product sales, net	\$ 120,201	\$ 44,707	\$ 284,700	\$ 131,336
Royalty revenue, net	4,382	4,424	16,496	16,982
Contract revenue	9,401	1,784	20,567	11,120
Total revenues	133,984	50,915	321,763	159,438
Costs and expenses:				
Cost of goods sold	20,412	9,208	50,172	30,586
Research and development	35,338	45,728	99,743	140,952
Selling, general and administrative	42,317	32,047	123,680	83,665
Total costs and expenses	98,067	86,983	273,595	255,203
Income (loss) from operations	35,917	(36,068)	48,168	(95,765)
Gain on sale of unconsolidated affiliate				
		8,754		8,754
Loss on sale of marketable securities	(16,048)		(16,048)	
Interest income	4,883	6,305	15,104	20,195
Interest expense	(3,445)	(3,513)	(10,382)	(10,482)
Income (loss) before provision for income taxes, equity in loss of unconsolidated affiliate and cumulative effect of change in accounting principle	21,307	(24,522)	36,842	(77,298)
Provision for income taxes	550	174	224	967
Equity in loss of unconsolidated affiliate		500		2,130
Income (loss) before cumulative effect of change in accounting principle	20,757	(25,196)	36,618	(80,395)
Cumulative effect of change in accounting principle				1,089
Net income (loss)	\$ 20,757	\$ (25,196)	\$ 36,618	\$ (79,306)
Amounts per common share basic:				
Income (loss) before cumulative effect of change in accounting principle	\$ 0.11	\$ (0.13)	\$ 0.19	\$ (0.42)
Cumulative effect of change in accounting principle				0.01
Net income (loss) per share basic	\$ 0.11	\$ (0.13)	\$ 0.19	\$ (0.41)
Shares used in per share calculation basic	196,140	190,612	195,044	189,643
Amounts per common share diluted:				
Income (loss) before cumulative effect of change in accounting principle	\$ 0.10	\$ (0.13)	\$ 0.18	\$ (0.42)
Cumulative effect of change in accounting principle				0.01
Net income (loss) per share diluted	\$ 0.10	\$ (0.13)	\$ 0.18	\$ (0.41)
Shares used in per share calculation diluted	206,160	190,612	206,164	189,643

Three Months Ended
September 30,

Nine Months Ended
September 30,

See accompanying notes.

4

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

	Nine Months Ended September 30,	
	2002	2001
OPERATING ACTIVITIES:		
Net income (loss)	\$ 36,618	\$ (79,306)
Adjustments to reconcile net income (loss) to net cash used in provided by (used in) operating activities:		
Net effect of change in accounting principle		(1,089)
Depreciation and amortization	10,539	10,846
Equity in loss of unconsolidated affiliate		2,130
Net unrealized gain on foreign currency transactions	(860)	(2,581)
Loss on sale of marketable securities	16,048	
Gain on sale of unconsolidated affiliate		(8,754)
Tax benefits from stock option transactions	350	
Other non-cash transactions	2,735	889
Changes in assets and liabilities:		
Accounts receivable	(41,474)	(8,152)
Inventories	1,111	(10,645)
Prepaid expenses and other assets	1,162	(6,739)
Accounts payable	(1,920)	3,656
Accrued liabilities	1,016	9,675
Deferred revenue	13,536	(2,692)
Net cash provided by (used in) operating activities	38,861	(92,762)
INVESTING ACTIVITIES:		
Purchases of marketable securities	(311,551)	(278,828)
Sales of marketable securities	105,389	104,064
Maturities of marketable securities	144,320	93,525
Capital expenditures	(12,522)	(16,659)
Proceeds from sale of unconsolidated affiliate		14,300
Net cash used in investing activities	(74,364)	(83,598)
FINANCING ACTIVITIES:		
Proceeds from issuances of common stock	38,364	18,885
Repayments of long-term debt	(1,325)	(2,053)

	Nine Months Ended September 30,	
Net cash provided by financing activities	37,039	16,832
Effect of exchange rate on cash	(3,418)	(418)
Net decrease in cash and cash equivalents	(1,882)	(159,946)
Cash and cash equivalents at beginning of period	123,490	197,292
Cash and cash equivalents at end of period	\$ 121,608	\$ 37,346

See accompanying notes.

5

GILEAD SCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2002
(unaudited)

1. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States 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 are 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. The accompanying financial information should be read in conjunction with the audited consolidated financial statements for the fiscal year ended December 31, 2001 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC").

A reclassification has been made to the December 31, 2001 balance sheet to classify a \$38.8M investment in OSI Pharmaceuticals, Inc. ("OSI") common stock as marketable securities rather than as cash and cash equivalents.

On February 22, 2001 and on March 8, 2002, we implemented two-for-one stock splits in the form of stock dividends. All share and per share amounts for all periods presented reflect both of these splits.

Per Share Computations

For the three and nine months ended September 30, 2002, basic net income per common share is computed based on the weighted average number of common shares outstanding during the period. Diluted net income per common share for the three and nine-month periods ended September 30, 2002 includes the effects of options and warrants to purchase approximately 10.0 million and 11.1 million shares of common stock, respectively. Diluted net income per share does not include the effect of the \$250.0 million 5% convertible notes that would convert to approximately 10.2 million shares, as their effect is antidilutive. For the three and nine months ended September 30, 2001, both basic and diluted net loss per common share are computed based on the weighted average number of common shares outstanding during the period. The convertible notes, stock options and warrants were excluded from the computation of diluted net loss per share in 2001, as their effect is antidilutive.

2. Cumulative Effect of Change in Accounting Principle

Gilead adopted Statement of Financial Accounting Standards (SFAS) 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.

6

3. Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, *Business Combinations*, and SFAS No. 142, *Goodwill and Other Intangible Assets*. 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 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. As Gilead has not accounted for any business combinations under the purchase method of accounting, the adoption of SFAS 141 and SFAS 142 did not have a material impact on the Company's financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. 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 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 adoption of SFAS 144 on January 1, 2002 did not have a material impact on the Company's financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS 146 requires that a liability for costs associated with an exit or disposal activity be recognized and measured initially at fair value only when the liability is incurred. SFAS 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption is not expected to have a material impact on the Company's financial position and results of operations.

4. Loss on Sale of Marketable Securities

In July 2002, the Company sold its shares of OSI Pharmaceuticals, Inc. (OSI) common stock for approximately \$22.0 million. These shares were partial consideration for the sale of our oncology assets to OSI in December 2001, at which time they were recorded at a fair market value of approximately \$38.0 million. In connection with the sale of these shares, we recognized a non-operating loss of approximately \$16.0 million that is reflected in our results for the three- and nine-month periods ended September 30, 2002.

5. Inventories

Inventories are summarized as follows (in thousands):

	September 30, 2002	December 31, 2001
Raw materials	\$ 16,577	\$ 18,086
Work in process	12,123	10,004
Finished goods	9,469	11,190
Total inventories	\$ 38,169	\$ 39,280

6. Collaborative Arrangements and Contracts

In April 2002, Gilead and GlaxoSmithKline (GSK) entered into a licensing agreement providing GSK the rights to commercialize Hepsera (adefovir dipivoxil), Gilead's antiviral for the treatment of

chronic hepatitis B, in Asia, Latin America and certain other territories. Under the agreement, Gilead retained rights to Hepsera in the United States, Canada, Eastern and Western Europe, Australia and New Zealand. GSK received exclusive rights to develop Hepsera solely for the treatment of hepatitis B in all of its territories, the most significant of which include China, Korea, Japan and Taiwan. Under the agreement, GSK paid Gilead an up-front licensing fee of \$10 million, and Gilead is entitled to receive additional cash payments of up to \$30 million upon achievement by GSK of certain regulatory, development and commercial milestones. GSK also will pay Gilead a royalty on net sales, if any, of Hepsera in the GSK territories. GSK will have full responsibility for development and commercialization of Hepsera in GSK's territories. The \$10 million up-front fee has been recorded as deferred revenue and will be amortized into contract revenue over the period of Gilead's remaining obligations under the agreement, approximately 14 years.

In September 2002, Gilead and Cubist Pharmaceuticals jointly announced the termination of their licensing agreement for the commercialization of Cidecin® (daptomycin for injection) and an oral formulation of daptomycin. The agreement, executed in January 2001, granted Gilead exclusive commercialization rights to the products in 16 European countries following regulatory approval. Under the terms of the discontinuation, Gilead does not owe any future payments to Cubist, and Cubist reacquired all European rights to both products. Upon termination, \$2.0 million was recorded to research and development expense in the third quarter ended September 30, 2002, which represented the remaining unamortized asset related to the preclinical oral formulation of daptomycin.

7. Litigation Settlement

In 1997 we reached a settlement with Elan Corporation, plc (Elan, the successor company to The Liposome Company) in which both companies agreed to dismiss all legal proceedings involving AmBisome, Gilead's liposomal formulation of amphotericin B. Under the terms of the initial settlement agreement in 1997, we made an initial payment to Elan of \$1.8 million and agreed to make additional royalty payments through 2006, based on AmBisome sales. In 1997, the Company recorded a \$10.0 million accounting charge for the accrued litigation settlement expenses, representing the net present value of all future minimum payments we were required to make. In June 2002, Elan and Gilead entered into an agreement terminating the Company's remaining AmBisome payment obligations under the initial settlement agreement in exchange for a payment to Elan of \$7.3 million. The excess of the \$7.3 million settlement amount over the remaining accrued litigation settlement expenses balance of \$6.0 million is being amortized over the remaining life of the patents, approximately four years.

8. Comprehensive Income (Loss)

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

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
Net income (loss)	\$ 20,757	\$ (25,196)	\$ 36,618	\$ (79,306)
Net foreign currency translation gain (loss)	(2,224)	773	(3,361)	836
Net unrealized gain on cash flow hedges	244	510	365	127
Net unrealized gain (loss) on available-for-sale securities	19,539	3,137	(1,983)	6,383
Comprehensive income (loss)	\$ 38,316	\$ (20,776)	\$ 31,639	\$ (71,960)

9. 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, net consisted of the following (in thousands):

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
AmBisome®	\$ 48,585	\$ 41,113	\$ 136,041	\$ 121,926
Viread®	68,933	1,484	140,832	2,352
Other	2,683	2,110	7,827	7,058
Consolidated total	\$ 120,201	\$ 44,707	\$ 284,700	\$ 131,336

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,	
	2002	2001	2002	2001
United States	\$ 70,284	\$ 9,351	\$ 147,274	\$ 32,895
United Kingdom	11,543	7,312	29,380	20,653
France	11,208	4,532	27,713	11,390
Spain	8,893	4,593	21,336	13,332
Germany	9,099	4,988	19,957	14,442
Italy	4,670	4,321	16,130	13,948
Switzerland	264	305	12,080	6,965
Other European countries	13,018	9,789	33,769	29,955
Other countries	5,005	5,724	14,124	15,858
Consolidated total	\$ 133,984	\$ 50,915	\$ 321,763	\$ 159,438

For the quarter ended September 30, 2002, product sales to three distributors exceeded 10% of total revenues and for the nine months ended September 30, 2002, product sales to one distributor exceeded 10% of total revenues. For the nine month period ended September 30, 2001, sales to and royalties from Fujisawa Healthcare, Inc. ("Fujisawa") were approximately 17% of total revenue.

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

Overview

Gilead was incorporated in Delaware on June 22, 1987. We are an independent biopharmaceutical company focused on the discovery, development and commercialization of antivirals, antibacterials and antifungals to treat life-threatening infectious diseases. We are a multinational company, with revenues from six approved products and operations in ten countries. Currently, we market Viread® for the treatment of HIV infection; Hepsera® for the treatment of chronic hepatitis B infection; AmBisome®, an antifungal agent; DaunoXome®, a drug approved for the treatment of Kaposi's sarcoma; and Vistide® for the treatment of cytomegalovirus retinitis. Hoffmann-La Roche Inc. ("Roche") markets Tamiflu® for the treatment of influenza, under a collaborative agreement with us. We are seeking to add to our existing portfolio of products through our clinical development programs, internal discovery programs and an active product acquisition and in-licensing strategy. Our internal discovery activities include identification of new molecular targets, target screening and medicinal chemistry. In addition, we are currently developing products to treat HIV infection. We also have expertise in liposomal drug delivery technology that we use to develop drugs that are safer, easier for patients to tolerate and more effective.

On February 22, 2001 and on March 8, 2002, we implemented two-for-one stock splits in the form of stock dividends. All share and per share amounts for all periods presented reflect both of these splits.

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

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 a change in accounting principle.

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 pages 31 through 41 of our Annual Report on Form 10-K for the year ended December 31, 2001 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.

Viread Sales. We rely on sales of Viread for a significant portion of our operating income. A number of drugs to treat HIV infection and AIDS are currently sold or are in advanced stages of clinical development, including 17 products currently sold in the U.S. Among the companies that are significant competitors in the HIV/AIDS market are GlaxoSmithKline, Bristol-Myers Squibb, Hoffmann-La Roche, Pfizer, Merck, Boehringer-Ingelheim and Abbott Laboratories. Given the broad range of competitors and depth of their resources, Viread's market penetration may be limited, particularly for use in treatment naïve patients, given that the data supporting Viread's marketing approval is in a treatment experienced patient population.

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

10

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.

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 manufactured on a commercial basis in compliance with the applicable safety and quality standards. 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.

Governmental Legislation and Reimbursement Programs. Regulatory, legal and legislative issues may adversely affect pricing and sales of our products. In the U.S., there is federal legislation that lowers the price for our products that are purchased or reimbursed by federal agencies, and some states have enacted legislation that can lower the prices for our products. In addition, there are a growing number of U.S. federal and state legislative proposals that if enacted would lower the price for our products. Many countries outside the U.S. have government sponsored health care programs that set lower drug prices and patient reimbursement levels. Our sales in countries with relatively higher prices may be reduced if products can be imported into those countries from lower price markets. This is of particular concern in the European Union where we are required to permit cross border sales and could be a concern in the U.S. if legislation easing import restrictions is enacted and applied.

International Credit Risk. We are subject to credit risk from our accounts receivable related to European product sales. Our European product sales to government owned or supported customers in Greece, Spain, Portugal and Italy are subject to significant payment delays due to government funding and reimbursement practices. If significant changes were to occur in the reimbursement practices of European governments or if government funding becomes unavailable, our financial position and results of operations would be adversely affected.

Compulsory Licensing and Generic Competition. In a number of developing countries, government officials and other groups have suggested that pharmaceutical companies should make drugs for HIV infection available at a low cost. In some cases, governmental authorities have indicated that where pharmaceutical companies do not do so, their patents might not be enforceable to prevent generic competition. Some major pharmaceutical companies have greatly reduced prices for HIV drugs in certain developing countries. If certain countries do not permit

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

enforcement of our patents, sales of Viread in those countries could be reduced by generic competition. Alternatively, governments in those countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of Viread in those countries, thereby reducing our Viread sales, or we could respond to governmental concerns by reducing prices for Viread. In all of these situations, our results of operations could be adversely affected.

Collaborations. We depend on collaborations for the development and commercialization of certain products and for revenue, including the collaboration with Fujisawa for sales of AmBisome in the United States and Canada, the collaboration with GlaxoSmithKline for clinical and regulatory development and commercialization of Hepsara in Asia, Latin America and certain other territories, and the collaboration with Roche for sales of Tamiflu worldwide. We may also seek additional collaborations. 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. If these existing collaborations fail, our financial results would be adversely affected.

Foreign Currency Fluctuations. A significant percentage 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. Prior to January 2002, we did not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. Effective January 2002, we have begun to use forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro currency. 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. Additionally, to mitigate the impact of currency rate fluctuations on our cash outflows for certain foreign currency-denominated raw materials purchases, we enter into foreign exchange forward contracts to hedge our foreign currency-denominated accounts payable.

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 operating basis and we may never achieve or sustain full-year operating profitability. As of September 30, 2002, our accumulated deficit was \$417.1 million.

Critical Accounting Policies and Estimates

Reference is made to "Critical Accounting Policies and Estimates" included on page 47 of our Annual Report on Form 10-K for the year ended December 31, 2001. As of the date of the filing of this Quarterly Report, the Company has not identified any critical accounting policies other than those discussed in our Annual Report for the year ended December 31, 2001 and has not otherwise concluded that any of these policies have become out of date or are misleading.

Results of Operations

Revenues

We had total revenues of \$134.0 million for the quarter ended September 30, 2002 compared with \$50.9 million for the quarter ended September 30, 2001. Total revenues were \$321.8 million for the first nine months of 2002, and \$159.4 million for the first nine months of 2001. Included in total revenues are net product sales, royalty income and contract revenue, including revenue recognized from manufacturing collaborations.

Net product sales were \$120.2 million for the three months ended September 30, 2002, compared with \$44.7 million for the quarter ended September 30, 2001, representing an increase of 169%. This increase is primarily due to the significant contribution made by Viread in the current quarter. As Viread was not approved until October 2001, minimal sales were made in the comparable period last year. Sales of Viread were \$68.9 million in the third quarter of 2002, or 57% of net product sales. Of the \$68.9 million, \$52.1 million were U.S. sales and \$16.8 million were European sales. Sales of AmBisome, at \$48.6 million, accounted for 40% of net product sales in the quarter ended September 30, 2002 compared to 92% of net product sales in the quarter ended September 30, 2001. Sales of AmBisome for the third quarter of 2002 increased 18% over the third quarter of 2001. Excluding the impact of foreign currencies relative to the U.S. Dollar, sales of AmBisome would have increased 11% in the third quarter of 2002 over the comparable period in 2001. A significant majority of AmBisome sales is denominated in foreign currencies. Prior to January 2002, we did not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. Effective

January 2002, we began to use forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the euro currency.

In the first nine months of 2002, net product sales were \$284.7 million, versus \$131.3 million in the comparable period of 2001, an increase of 117%. In the first nine months of 2002, we recognized \$140.8 million in Viread sales representing 49% of net product sales. Of the \$140.8 million, \$108.5 million were U.S. sales and \$32.3 million were European sales. We expect Viread sales to increase throughout 2002 and become a greater percentage of total revenues, although we cannot predict with any certainty what our actual Viread sales will be in 2002. Additionally, sales of AmBisome accounted for 48% of revenues from net product sales in the nine months ended September 30, 2002. This compares to 93% of net product sales in the nine months ended September 30, 2001. Sales of AmBisome for the first nine months of 2002 increased 12% over the comparable period of 2001. Excluding the impact of foreign currencies relative to the U.S. Dollar, sales of AmBisome would have increased 9% in the nine months ended September 30, 2002 over the comparable period in 2001.

Net royalty revenue was \$4.4 million for the third quarter of 2002, unchanged versus the same period in 2001 and \$16.5 million for the first nine months of 2002 versus \$17.0 million for the comparable period in 2001. Royalties in the third quarter ended September 30, 2002 included \$4.1 million from Fujisawa for sales of AmBisome in the United States. Royalties received from Fujisawa for the comparable period in 2001 were \$3.9 million. For the nine months ended September 30, 2002, royalties received from Fujisawa were \$12.1 million compared with \$11.9 million in the first nine months of 2001. The remaining royalties for each of the three- and nine-month periods ended September 30, 2002 and September 30, 2001 are derived from Roche for sales of Tamiflu worldwide. We record royalties from Roche in the quarter following the quarter in which the related Tamiflu sales occur.

Total contract revenue was \$9.4 million for the quarter ended September 30, 2002 versus \$1.8 million for the comparable quarter in 2001. The increase from last year is the result of receiving \$8.1 million from Archemix Corporation as the final payment for the licensing of a portion of the SELEX (Systemic Evolution of Ligands through EXponential Enrichment) process patent estate in October 2001. Total contract revenue for the first nine months of 2002 was \$20.6 million versus \$11.1 million in the same period of 2001.

Gross Margins

Product gross margins were 83.0% for the quarter ended September 30, 2002 versus 79.4% for the same period last year. For the first nine months of 2002, product gross margins were 82.4%, compared with 76.7% for the first nine months of 2001. The improvement is primarily driven by product mix as Viread, a higher margin product, contributed significantly to net product sales in the third quarter and first nine months of 2002, whereas minimal sales of Viread were recorded in the third quarter and first nine months of 2001.

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 costs are in U.S. Dollars. An increase in the value of these foreign currencies relative to the U.S. Dollar will positively impact gross margins since our manufacturing costs will remain approximately the same while our revenues, which are reported in U.S. Dollars, will increase. Except for the potential impact of unpredictable and uncontrollable changes in exchange rates relative to the U.S. Dollar and the mix of product sales between Viread and AmBisome, we expect that gross margins for the full year 2002 will be approximately 82%, an improvement from the 77% amount reported for the 2001 year.

Operating Expenses

Research and development ("R&D") expenses for the third quarter of 2002 were \$35.3 million, compared to \$45.7 million for the third quarter of 2001, a decrease of 23%. For the first nine months of 2002, R&D expenses were \$99.7 million versus \$141.0 million for the same period last year, a decrease of 29%. The substantially lower expenses for each comparable period can be attributed to the reduction in expenses associated with the clinical program for Viread, which was approved in October 2001, and the elimination of expenses associated with our oncology program as a result of the divestiture of our oncology program to OSI in December 2001. The decline for the first nine months of 2002 compared to the same period last year is also attributable to the recognition in 2001 of \$10.6 million of a \$13.0 million up-front license fee paid to Cubist Pharmaceuticals related to the European licensing agreement for daptomycin signed in January 2001. Upon termination of this agreement in September 2002, \$2.0 million was recorded to research and development expense in the third quarter ended September 30, 2002, which represented the remaining unamortized asset related to the preclinical oral formulation of daptomycin. Based on current budgeted programs, we expect R&D expenses for the full year 2002 to be approximately \$130 million to \$140 million, or 20% to 30% lower than 2001,

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

reflecting the sale of our oncology assets to OSI in December 2001 and the decreasing levels of activity associated with the clinical program for Viread.

Selling, general and administrative ("SG&A") expenses were \$42.3 million for the third quarter of 2002, compared with \$32.0 million for the third quarter of 2001. For the first nine months of 2002, SG&A expenses were \$123.7 million versus \$83.7 million for the first nine months of 2001. The increase for each comparable period was due to our global marketing efforts and the expansion of Gilead's U.S. and European sales forces to support the commercial launches of Viread and Hepsera. For all of fiscal 2002, we expect SG&A expenses to be approximately \$170 million to \$180 million, or 35% to 45% higher than 2001 levels, primarily due to the increase in marketing activities associated with the launches of Viread and Hepsera.

Interest Income and Interest Expense

We reported interest income of \$4.9 million for the quarter ended September 30, 2002, compared with \$6.3 million for the same period in 2001. Interest income was \$15.1 million for the first nine months of 2002 versus \$20.2 million for the first nine months of 2001. The decrease for each comparable period is attributable to the significant decline in interest rates, partially offset by interest income earned on the proceeds from the Company's divestiture of the oncology assets to OSI and the positive cash flow generated from operations for the first nine months of 2002.

Interest expense was \$3.4 million for the quarter ended September 30, 2002, compared with \$3.5 million for the same period in 2001. For the first nine months of 2002, interest expense was \$10.4 million versus \$10.5 million for the same period in 2001. The largest component of interest expense for each period was interest on our \$250.0 million 5% convertible subordinated notes due in December 2007.

Income Taxes

Income tax expense was \$0.6 million for the quarter ended September 30, 2002, compared to \$0.2 million for the same period in 2001. For the first nine months of 2002, we recorded income tax expense of \$0.2 million, compared to income tax expense of \$1.0 million for the same period in 2001. Our provision for income taxes for each period presented arose principally from taxes payable in foreign jurisdictions. The provision for the first nine months of 2002 was reduced by a change in U.S. income tax law during the first quarter of 2002. This law allows net operating loss carryforward deductions to offset 100% of alternative minimum taxable income, resulting in a reduction of U.S. income tax recorded in the previous years of \$1.3 million.

Liquidity and Capital Resources

Subsequent to our third quarter 2002 earnings release dated October 31, 2002, a misclassification was discovered in the fourth quarter 2001 and third quarter 2002 balance sheets and cash flow statements. At December 31, 2001, \$38.8 million of OSI stock received in consideration for the divestiture of our oncology assets was misclassified on the balance sheet as Cash and Cash Equivalents instead of as Marketable Securities. The net result of this misclassification on the Statement of Cash Flows for fiscal 2001 is that Net Cash Used in Operating Activities was \$88.1 million and Net Decrease in Cash and Cash Equivalents was \$35.0 million. Following the reclassification, for fiscal 2001 Net Cash Used in Operating Activities is \$127.0 million and Net Decrease in Cash and Cash Equivalents is \$73.8 million. The misclassification had no impact on Statements of Operations for any period, including revenues and net income. The financial results as reported in our third quarter 2002 earnings release have been changed in this filing to reflect the impact of this reclassification. The net change to the numbers as reported in our earnings release is that Operating Cash Flow for the third quarter 2002 was \$60.7 million, an increase of \$16.0 million over the reported \$44.7 million. There was no impact on any Balance Sheet or Statement of Operations item as reported in our third quarter 2002 earnings release.

Cash, cash equivalents and marketable securities totaled \$624.8 million at September 30, 2002, up from \$582.9 million at December 31, 2001. Cash provided by operations was \$38.9 million for the nine months ended September 30, 2002 and was primarily attributable to increased Viread sales in the U.S. In addition, cash provided by financing activities for the nine months ended September 2002 was driven by proceeds of \$38.4 million from the issuances of common stock under employee plans. These cash inflows were partially offset by cash outflows from investing activities, primarily \$12.5 million for capital expenditures.

Our accounts receivable balance at September 30, 2002 was \$114.1 million compared to a balance of \$74.2 million at December 31, 2001. The \$41.5 million growth in accounts receivable is due primarily to an increase in net product sales, particularly Viread. In certain countries where payments are typically slow, primarily Greece, Spain, Portugal and Italy, our accounts receivable balances are significant. In most cases, these slow payment practices reflect the pace at which governmental entities reimburse our customers. This, in turn, may increase the financial risk related to certain of our customers. Sales to customers in countries that tend to be relatively slow paying have in the past increased, and in

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

the future may further increase, the average length of time that accounts receivable are outstanding. At September 30, 2002, our past due accounts receivable for Greece, Spain, Portugal and Italy totaled approximately \$44.9 million, of which \$29.7 million was more than 120 days past due. This compares to past due receivables of approximately \$28.7 million at December 31, 2001 for these same countries, of which \$14.9 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 substantially all past due accounts receivable, including those due from customers in these four countries, are collectible. We continually seek to improve our collection processes to ensure that we fully collect amounts due to us and that collections are timely.

Other significant changes in working capital during the nine months ended September 30, 2002 include a decrease in accrued clinical and preclinical expenses of approximately \$7.3 million, primarily due to the decreasing activity associated with the clinical program for Viread. Other accrued liabilities increased \$7.0 million, principally due to an increase in royalty and Medicaid rebate obligations associated with higher sales of Viread, as well as interest payable on our \$250.0 million, 5% convertible subordinated notes. Deferred revenue also increased by \$13.5 million, primarily due to the receipt of a \$10.0 million up-front fee from GSK as part of the licensing agreement providing GSK the rights to develop and commercialize Hepsera (see note 6 of the Notes to Condensed Consolidated Financial Statements).

15

We do not have any "special purpose" entities that are unconsolidated in our financial statements. We are also not involved in any non-exchange traded commodity contracts accounted for at fair value. We have no commercial commitments with related parties, except for employee loans. We have contractual obligations in the form of capital and operating leases, notes payable and clinical research organization contracts.

We believe that our existing capital resources, which include all fixed income and equity securities, supplemented by net product sales and contract and royalty revenues, will be adequate to satisfy our capital needs for the foreseeable future. Our future capital requirements will depend on many factors, including:

the commercial performance of Viread, Hepsera and AmBisome,

European regulatory approval of Hepsera and if approved, its commercial performance,

the commercial performance of any of our other products in development that receive commercial approval,

the progress of our research and development efforts,

the success of our partners' research, development and commercialization efforts for the products they have partnered with us,

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,

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.

16

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of September 30, 2002, our \$250.0 million convertible subordinated notes had a fair value of \$383.4 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, 2001.

PART II. OTHER INFORMATION

ITEM 4. CONTROLS AND PROCEDURES

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in our periodic reports to the Securities and Exchange Commission. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and we cannot be certain that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

In addition we reviewed our internal controls, and there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of their last evaluation.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

No. 10.40	Employment Agreement, dated July 1, 2002, by and between Gilead Sciences, Inc. and Sharon Surrey-Barbari.
No. 99.1	Certification

(b)

Reports on Form 8-K

None.

17

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 13, 2002

/s/ JOHN C. MARTIN

John C. Martin
President and Chief Executive Officer

Date: November 13, 2002

/s/ JOHN F. MILLIGAN

John F. Milligan
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

18

CERTIFICATIONS

I, John C. Martin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gilead Sciences, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ JOHN C. MARTIN

John C. Martin
President and Chief Executive Officer

19

CERTIFICATIONS

I, John F. Milligan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gilead Sciences, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ JOHN F. MILLIGAN

John F. Milligan
Senior Vice President and Chief Financial Officer

20

QuickLinks

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

GILEAD SCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands, except 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 September 30, 2002 (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. CONTROLS AND PROCEDURES

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

SIGNATURES

CERTIFICATIONS

CERTIFICATIONS