

GILEAD SCIENCES INC  
Form 10-Q  
August 06, 2004

**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 June 30, 2004**

**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**

**94-3047598**

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(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification No.)

**333 Lakeside Drive, Foster City, California**

**94404**

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(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 ☒ No ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rules 12b-2 of the Exchange Act). Yes ☒ No ☐

Number of shares outstanding of the issuer's common stock, par value \$.001 per share, as of July 31, 2004: 215,283,438

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## GILEAD SCIENCES, INC.

## INDEX

		Page No.
<u>PART I.</u>	<u>FINANCIAL INFORMATION</u>	
	<u>Item 1.</u>	
	<u>Condensed Consolidated Financial Statements:</u>	
	<u>Condensed Consolidated Balance Sheets</u> <u>at June 30, 2004 and December 31, 2003</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Operations</u> <u>for the three and six months ended June 30, 2004 and 2003</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Cash Flows</u> <u>for the six months ended June 30, 2004 and 2003</u>	<u>5</u>
	<u>Notes to Condensed Consolidated Financial Statements</u>	<u>6</u>
	<u>Item 2.</u>	
	<u>Management's Discussion and Analysis of Financial Condition and</u> <u>Results of Operations</u>	<u>12</u>
	<u>Item 3.</u>	
	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>21</u>
	<u>Item 4.</u>	
	<u>Controls and Procedures</u>	<u>22</u>
<u>PART II.</u>	<u>OTHER INFORMATION</u>	
	<u>Item 4.</u>	
	<u>Submission of Matters to a Vote of Securities Holders</u>	<u>23</u>
	<u>Item 6.</u>	
	<u>Exhibits and Reports on Form 8-K</u>	<u>23</u>
<u>SIGNATURES</u>		<u>24</u>

We own or have rights to various trademarks, copyrights and trade names used in our business including the following: GILEAD®, GILEAD SCIENCES®, HEPSERA®, Leaf and Shield Design, Leaf and Shield Design (b/w), Liver Design, Tablet Design (b/w), Tablet Design (color), VIREAD®, VISTIDE®, DAUNOXOME®, AMBISOME®, EMTRIVA®, TRUVADA®, TAMIFLU® is a registered trademark belonging to Hoffmann-La Roche. This report also includes other trademarks, service marks and trade names of other companies.

**PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****GILEAD SCIENCES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except per share amounts)

	June 30, 2004 (unaudited)	December 31, 2003 (Note)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 226,563	\$ 194,719
Marketable securities	749,025	512,281
Accounts receivable, net	277,305	235,217
Inventories	105,963	98,102
Deferred tax assets	135,974	197,567
Prepaid expenses and other current assets	36,946	28,012
Total current assets	1,531,776	1,265,898
Property, plant and equipment, net	206,789	198,200
Noncurrent deferred tax assets	32,769	52,494
Other noncurrent assets	37,133	38,130
	\$ 1,808,467	\$ 1,554,722
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 29,986	\$ 35,649
Accrued clinical and preclinical expenses	10,906	11,859
Accrued compensation and employee benefits	32,809	35,772
Income taxes payable	16,368	13,305
Other accrued liabilities	72,170	83,836
Deferred revenue	12,590	5,474
Total current liabilities	174,829	185,895
Long-term deferred revenue	21,171	20,530
Long-term obligations	304	323
Convertible senior debt	345,000	345,000
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value \$.001 per share; 500,000 shares authorized; 215,211 and 213,253 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	215	213
Additional paid-in capital	1,492,961	1,453,203
Deferred compensation	(851)	(1,306)
Accumulated other comprehensive income	2,594	4,507
Accumulated deficit	(227,756)	(453,643)

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Total stockholders' equity		1,267,163		1,002,974
	\$	1,808,467	\$	1,554,722

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Note: The condensed consolidated balance sheet at December 31, 2003 has been derived from audited consolidated 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 June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Revenues:				
Product sales	\$ 299,332	\$ 230,668	\$ 575,917	\$ 386,632
Royalty and contract revenue	20,390	8,202	52,932	17,343
Total revenues	319,722	238,870	628,849	403,975
Costs and expenses:				
Cost of goods sold	42,092	32,106	77,041	53,478
Research and development	45,643	43,318	104,188	86,882
Selling, general and administrative	73,789	55,674	144,999	100,841
In-process research and development				488,599
Total costs and expenses	161,524	131,098	326,228	729,800
Income (loss) from operations	158,198	107,772	302,621	(325,825)
Gain on EyeTech warrants			20,576	
Interest and other income, net	5,408	3,444	8,336	7,261
Interest expense	(2,071)	(5,569)	(4,160)	(11,183)
Income (loss) before provision for income taxes	161,535	105,647	327,373	(329,747)
Provision for income taxes	50,076	5,275	101,486	7,935
Net income (loss)	\$ 111,459	\$ 100,372	\$ 225,887	\$ (337,682)
Net income (loss) per share - basic	\$ 0.52	\$ 0.50	\$ 1.06	\$ (1.69)
Net income (loss) per share - diluted	\$ 0.49	\$ 0.46	\$ 0.99	\$ (1.69)
Shares used in per share calculation - basic	214,562	200,236	214,098	199,288
Shares used in per share calculation - diluted	230,989	230,340	230,586	199,288

See accompanying notes.



## GILEAD SCIENCES, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Six Months Ended June 30,	
	2004	2003
<b>OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ 225,887	\$ (337,682)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	11,861	9,550
In-process research and development		488,599
Gain on EyeTech warrants	(20,576)	
Deferred tax assets	81,318	
Other non-cash transactions	(478)	3,171
Changes in assets and liabilities:		
Accounts receivable	(46,989)	(66,278)
Inventories	(7,861)	(11,906)
Prepaid expenses and other assets	(12,092)	(3,107)
Accounts payable	(5,663)	(5,867)
Accrued liabilities	(12,470)	4,143
Deferred revenue	7,757	(239)
Net cash provided by operating activities	220,694	80,384
<b>INVESTING ACTIVITIES:</b>		
Purchases of marketable securities	(616,023)	(474,647)
Sales of marketable securities	278,628	215,854
Maturities of marketable securities	122,687	70,563
Acquisition of Triangle net assets, net of cash acquired		(375,507)
Capital expenditures	(18,197)	(7,813)
Net cash used in investing activities	(232,905)	(571,550)
<b>FINANCING ACTIVITIES:</b>		
Proceeds from issuances of common stock	39,760	49,821
Repayments of long-term debt	(68)	(1,760)
Net cash provided by financing activities	39,692	48,061
Effect of exchange rates on cash	4,363	(4,471)
Net increase (decrease) in cash and cash equivalents	31,844	(447,576)
Cash and cash equivalents at beginning of period	194,719	616,931
Cash and cash equivalents at end of period	\$ 226,563	\$ 169,355

See accompanying notes.



**GILEAD SCIENCES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2004**

(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 a fair presentation of 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 condensed consolidated financial statements include the accounts of the Company and its wholly 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 year ended December 31, 2003 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC).

During the second quarter 2004, in order to better reflect the nature of certain clinical trials being performed in Europe, the Company recorded certain phase IV clinical trial expenses as research and development which were previously recorded as selling, general and administrative. Such expenses totaling \$4.9 million, \$4.5 million and \$6.9 million for the three months ended March 31, 2004 (included in the six months ended June 30, 2004) and the three and six months ended June 30, 2003, respectively, have been reclassified from selling, general and administrative to research and development expenses to be consistent with the current period presentation.

*Basic and Diluted Net Income (Loss) Per Share*

For all periods presented, basic net income (loss) per share is computed based on the weighted average number of shares of common stock outstanding during the period. For the three and six months ended June 30, 2004, diluted net income per share includes the effect of options to purchase 9.1 million shares of common stock and the \$345.0 million 2% convertible senior debt, which would convert into approximately 7.3 million shares of common stock. Options to purchase approximately 3.1 million additional shares of common stock were outstanding during the

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three and six months ended June 30, 2004, but were not included in the computation of diluted earnings per share because the options' exercise prices were greater than the average market price of our common stock during these periods; therefore, their effect is antidilutive. Diluted net income per share for the three months ended June 30, 2003 includes the effect of options to purchase 12.6 million shares of common stock, the \$250.0 million 5% convertible subordinated debt, which was converted into approximately 10.2 million shares of common stock in December 2003 and the effect of the \$345.0 million 2% convertible senior debt. Diluted net loss per share for the six months ended June 30, 2003, does not include the effect of options to purchase 11.5 million shares of common stock, the effect of the \$250.0 million 5% convertible subordinated debt, or the effect of the \$345.0 million 2% convertible senior debt as they were antidilutive.

*Stock-Based Compensation*

In accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure* (collectively, SFAS 123), we have elected to continue to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation - an Interpretation of APB Opinion No. 25* (FIN 44), in accounting for our employee stock option plans. Under APB 25, if the exercise price of Gilead's employee and director stock options equals or exceeds the fair value of the underlying stock on the date of grant, no compensation expense is recognized. Although we have elected to follow the intrinsic value method prescribed by APB 25, we will continue to evaluate our approach to accounting for stock options in light of ongoing industry and regulatory developments.

The table below presents the combined net income (loss) and basic and diluted net income (loss) per share if compensation cost for the Gilead, NeXstar Pharmaceuticals, Inc. and Triangle Pharmaceuticals, Inc. (Triangle) stock option plans and the employee stock purchase plan (ESPP) had been determined based on the estimated fair value of awards under those plans on the grant or purchase date in accordance with SFAS 123 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income (loss) as reported	\$ 111,459	\$ 100,372	\$ 225,887	\$ (337,682)
Add: Total stock-based employee compensation expense included in reported net income (loss), net of related tax effects	99	170	278	242
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(22,297)	(20,794)	(39,760)	(39,102)
Pro forma net income (loss)	\$ 89,261	\$ 79,748	\$ 186,405	\$ (376,542)
Net income (loss) per share:				
Basic - as reported	\$ 0.52	\$ 0.50	\$ 1.06	\$ (1.69)
Basic - pro forma	\$ 0.42	\$ 0.40	\$ 0.87	\$ (1.89)
Diluted - as reported	\$ 0.49	\$ 0.46	\$ 0.99	\$ (1.69)
Diluted - pro forma	\$ 0.39	\$ 0.37	\$ 0.82	\$ (1.89)

Fair values of awards granted under the stock option plans and ESPP were estimated at grant or purchase dates using a Black-Scholes option valuation model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. To calculate the estimated fair value of the awards, we used the multiple option approach and the following assumptions:



	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Expected life in years (from vesting date):				
Stock options	1.84	1.82	1.84	1.82
ESPP	1.60	1.34	1.60	1.34
Discount rate:				
Stock options	3.2%	2.3%	3.0%	2.7%
ESPP	1.7%	1.9%	1.7%	1.9%
Volatility	49%	80%	49%	80%
Expected dividend yield	0%	0%	0%	0%

In the fourth quarter of 2003, we changed the volatility assumption we used to arrive at a fair value for our stock awards. We began to use an approximate two-year time period for purposes of calculating the expected volatility. After considering such factors as our stage of development, the length of time that we have been a public company and several drug approvals over the past few years which have enabled us to achieve positive cash flow from operations, we believe this volatility rate better reflects the expected volatility of our stock going forward.

## 2. Inventories

Inventories are summarized as follows (in thousands):

	June 30, 2004		December 31, 2003	
Raw materials	\$	72,038	\$	54,178
Work in process		9,007		11,775
Finished goods		24,918		32,149
Total inventories	\$	105,963	\$	98,102

## 3. Comprehensive Income (Loss)

The components of comprehensive income (loss) are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income (loss)	\$ 111,459	\$ 100,372	\$ 225,887	\$ (337,682)
Net foreign currency translation gain (loss)	174	1,612	(538)	4,806
Net unrealized gain (loss) on cash flow hedges	(4,190)	834	(832)	1,855
Net unrealized loss on available-for-sale securities	(1,382)	(635)	(543)	(1,424)

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Comprehensive income (loss)	\$	106,061	\$	102,183	\$	223,974	\$	(332,445)
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#### **4. EyeTech Warrants**

In March 2000, we entered into an agreement with EyeTech Pharmaceuticals, Inc. (EyeTech) relating to our proprietary aptamer EYE001, currently known as Macugen. Pursuant to this agreement, we received a warrant to purchase 791,667 shares of EyeTech series B convertible preferred stock, exercisable at a price of \$6.00 per share. In January 2004, EyeTech completed an initial public offering of its common stock at which time we adjusted the fair value of the warrant resulting in a gain of \$20.6 million which we included in our condensed consolidated statement of operations for the six months ended June 30, 2004. The fair value of the warrant was estimated using the Black-Scholes valuation model with a volatility rate of 50% and a discount rate of 2.8%. At the end of the first quarter of 2004, we exercised the warrant on a net basis utilizing shares of EyeTech common stock as consideration and subsequently held 646,841 shares of EyeTech common stock.

In the second quarter of 2004, we sold all of the EyeTech shares we held and realized a gain of approximately \$2.3 million, which is included in interest and other income, net, in our condensed consolidated statements of operations for the three and six months ended June 30, 2004.

#### **5. Asset Impairment**

During 2003, we recorded an asset impairment charge of \$10.2 million on certain of our long-lived assets, primarily leasehold improvements and manufacturing and laboratory equipment, which we have classified as held for use. This non-cash charge was driven by the decision to terminate our liposomal research and development activities in San Dimas and discontinue the DaunoXome product line. The impairment was based on our analysis of the undiscounted cash flows to be generated from the affected assets as compared to their carrying value. As the carrying value exceeded the related undiscounted cash flows, we wrote the carrying value of the long-lived assets down to fair value in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Fair value was derived using an expected cash flow approach.

Subsequent to our decision to discontinue the DaunoXome product line and the filing of our Annual Report on Form 10-K, we received unanticipated requests in Europe asking Gilead to reconsider selling DaunoXome. As a result of these requests, management decided to continue selling this product in certain countries and is currently evaluating our supply and sales strategy with respect to DaunoXome. Based on these new facts and circumstances, our fourth quarter 2003 asset impairment charge of \$10.2 million would have been reduced, thereby reducing our 2003 net loss per share. In accordance with SFAS No. 144, however, the write down in 2003 of the assets held for use related to the DaunoXome product line established a new cost basis for such assets that will not be adjusted for these new facts and circumstances.

#### **6. Disclosures about Segments of an Enterprise and Related Information**

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS 131), establishes standards for the way public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. SFAS 131 also establishes standards for related disclosures about products and services, geographic areas, and major customers.

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The Company operates in one business segment, which primarily focuses on the development and commercialization of human therapeutics for infectious diseases. All products have been aggregated into one segment, because our major products, Viread and AmBisome, which accounted for 95% of product sales in 2003 and 86% of product sales in the six months ended June 30, 2004, have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods, and regulatory environment.

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The Company derives its revenues primarily from product sales of Viread and AmBisome as well as royalty and contract revenue. Royalty revenue relates primarily to sales of Tamiflu by Hoffman-La Roche (Roche) as well as sales of AmBisome by Fujisawa Healthcare, Inc. (Fujisawa). Contract revenue in the three and six month periods ended June 30, 2004 and 2003 primarily relates to license and milestone payments from GlaxoSmithKline (GSK) in connection with the development of Hepsera and payments from OSI Pharmaceuticals, Inc. (OSI) under a manufacturing agreement for the production of NX 211 and GS 7904L. Contract revenue in the three and six month periods ended June 30, 2004 also includes a milestone payment from EyeTech in connection with our license agreement.

Product sales consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Viread	\$ 197,162	\$ 167,035	\$ 390,258	\$ 274,307
AmBisome	54,965	51,163	106,838	92,221
Other	47,205	12,470	78,821	20,104
Consolidated total	\$ 299,332	\$ 230,668	\$ 575,917	\$ 386,632

The following table summarizes total revenues from external customers and collaborative partners by geographic region. Revenues are attributed to countries based on the location of Gilead's customer or collaborative partner (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
United States	\$ 166,340	\$ 133,468	\$ 309,417	\$ 212,654
France	30,353	23,492	61,265	41,343
Spain	25,254	18,644	51,401	34,521
United Kingdom	20,445	15,787	37,915	28,006
Italy	18,301	11,058	34,677	20,085
Germany	13,876	10,848	25,823	17,818
Switzerland	12,074	4,674	41,692	9,849
Other European countries	20,818	13,358	44,372	29,230
Other countries	12,261	7,541	22,287	10,469
Consolidated total	\$ 319,722	\$ 238,870	\$ 628,849	\$ 403,975

Due to the consolidated nature of the distributor market in the United States, our largest market, we have a concentration of credit risk among the three major US wholesalers as outlined below (in % of total revenues):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Amerisource	10%	20%	11%	16%
Cardinal	13%	18%	15%	16%
McKesson	8%	12%	9%	11%



**7. Subsequent Events**

On July 28, 2004, the Company announced that its Board of Directors approved a two-for-one stock split of the Company's outstanding common stock. Stockholders of record as of the close of business on August 12, 2004 will receive a stock dividend of one additional share of common stock for every share of common stock they own. Based on the total number of shares outstanding as of June 30, 2004, the stock split will increase the total number of shares outstanding from approximately 215,211,000 to 430,422,000. None of the share amounts within this quarterly report have been modified to reflect this stock split.

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

**Overview**

We are a biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases. We are a multinational company, with seven approved products and marketing operations in ten countries. We focus our research and clinical programs on anti-infectives. Currently, we market Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine) and Truvada (emtricitabine and tenofovir disoproxil fumarate) for the treatment of HIV infection; Hepsera (adefovir dipivoxil) for the treatment of chronic hepatitis B infection; AmBisome (amphotericin B liposome for injection), an antifungal agent; and Vistide (cidofovir injection) for the treatment of CMV retinitis. Roche markets Tamiflu (oseltamivir phosphate) for the treatment of influenza, under a royalty paying collaborative agreement with us. In December 2003, we made the decision to discontinue selling DaunoXome (daunorubicin citrate liposome injection), a drug approved for the treatment of Kaposi's Sarcoma; however, we received unanticipated requests in Europe to reconsider selling DaunoXome and as a result we have decided to continue selling this product in certain countries. We are seeking to add to our existing portfolio of products through our internal discovery and clinical development programs and through an active product acquisition and in-licensing strategy, such as our acquisition of the assets of Triangle Pharmaceuticals, Inc. (Triangle) completed in January 2003. Our internal discovery activities include identification of new molecular targets, target screening and medicinal chemistry. In addition, we are currently developing clinical stage products to treat HIV infection and chronic hepatitis B.

**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 23 through 30 of our Annual Report on Form 10-K for the year ended December 31, 2003 filed on March 11, 2004 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.

*Dependence on Viread and AmBisome.* We currently depend on sales of Viread and AmBisome for a significant portion of our operating income. If we are unable to continue growing Viread revenues or to maintain AmBisome sales, our results of operations are likely to suffer and we may need to scale back our operations. Our sales of these products may decline for many of the reasons described in this Risk Factors section. In particular, we face significant competition with these products from businesses that have substantially greater resources than we do.

*New Products and New Indications.* If we do not introduce new products or increase revenues from our existing products, we will not be able to grow our revenues. Each new product commercialization effort will face the risks outlined in this Risk Factors section. In particular, Hepsera is a new drug that faces a competitive marketplace in which we have little experience. We expect that new products for the treatment of hepatitis B virus will be introduced that will be significant competitors to Hepsera. In addition, we may not be successful in marketing Truvada, our new fixed-dose co-formulation of tenofovir (Viread) with emtricitabine (Emtriva). If we fail to increase our sales of Hepsera or if we

do not successfully market Truvada, we may not be able to increase revenues and expand our research and development efforts. GlaxoSmithKline, a company with greater resources than Gilead, has recently launched a fixed-dose combination product for the treatment of HIV which may be significant competition for Truvada and may limit our success in marketing Truvada.

*Safety.* As our products, including Viread, AmBisome, Hepsera, Emtriva and Truvada, are used over longer periods of time in many patients, new safety issues may arise that could require us to provide additional warnings on our labels or to narrow our approved indications, each of which could reduce the market acceptance of these products. If serious safety issues with our marketed products were to arise, sales of these products could be halted by us or by regulatory authorities.

*Regulatory Process.* The products that we develop must be approved for marketing and sale by regulatory authorities and will be subject to extensive regulation by the FDA and comparable regulatory agencies in other countries. In addition, even after our products are marketed, the products and their manufacturers are subject to continual review. We are continuing clinical trials for AmBisome, Viread, Hepsera, Emtriva and Truvada for currently approved and additional uses and anticipate filing for marketing approval in additional countries and for additional products over the next several years. If products fail to receive marketing approval on a timely basis, or if approved products are the subject of regulatory changes, actions or recalls, our results of operations may be adversely affected. In the European Union, marketing approval of Truvada may be delayed if we are required to conduct additional studies.

*Clinical Trials.* We are required to demonstrate the safety and effectiveness of products we develop in each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. Even successfully completed large-scale clinical trials may not result in marketable products. If any of our products under development fail to achieve their primary endpoint in clinical trials or if safety issues arise, commercialization of that drug candidate could be delayed or halted. In addition, clinical trials involving our commercial products could raise additional safety issues for our products.

*Manufacturing.* We depend on third parties to perform manufacturing activities effectively and on a timely basis. If these third parties fail to perform as required, this could impair our ability to deliver our products on a timely basis or cause delays in our clinical trials and applications for regulatory approval, and these events could harm our competitive position. Third-party manufacturers may develop problems over which we have no control and these problems may adversely affect our business.

We manufacture AmBisome and DaunoXome at our facilities in San Dimas, California. This is our only formulation and manufacturing facility for these products. In the event of a natural disaster, including an earthquake, equipment failure or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and would be unable to manufacture AmBisome and DaunoXome to meet market needs.

*Collaborations.* We rely on a number of significant collaborative relationships with major pharmaceutical companies for our sales and marketing performance. These include collaborations with Fujisawa and Sumitomo for AmBisome, GSK for Hepsera, Roche for Tamiflu, Pfizer for Vistide and Japan Tobacco for Viread and Emtriva. In certain countries, we rely on international distributors for sales of AmBisome, Viread and Emtriva and in some European and Asian countries, we rely on international distributors for sales of Hepsera. Some of these relationships also involve



the clinical development of products by our partners. Reliance on collaborative relationships poses a number of risks, including that we will not be able to control the resources our partners devote to our programs, disputes may arise with respect to the ownership of rights to technology, disagreements could cause delays or termination of projects, contracts may fail to provide protection or to be effectively enforced if a partner fails to perform, our partners may pursue competing technologies or devote fewer resources to the marketing of our products than they do to products of their own development and our partners may be unable to pay us. Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaboration efforts. If these efforts fail, our product development or commercialization of new products could be delayed and revenue from existing products could decline.

We recently announced that we are in discussions with Bristol-Myers Squibb Company and Merck & Co., Inc. on the development of a once-daily, fixed-dose combination of three anti-HIV drugs. We are also discussing co-packaging options for the individual products. No agreement has been reached on the terms of this arrangement. We have not reached agreement on several significant commercial terms and we may not be able to complete a final agreement. In addition, we cannot assure that if an agreement is reached, we will be able to obtain regulatory approval of the three-drug fixed-dose combination.

*Fluctuations in Operating Results.* The clinical trials required for regulatory approval of our products are extremely expensive. It is difficult to accurately predict or control the amount or timing of these expenses from quarter to quarter. Uneven and unexpected spending on these programs may cause our operating results to fluctuate from quarter to quarter. In addition, approximately 90% of our product sales in the United States is conducted with three distributors, Amerisource Bergen Corp., McKesson Corp. and Cardinal Health, Inc. We do not know whether the inventory management agreements we recently entered into with our three major US wholesalers will be effective in matching inventory levels to end user demand, as we rely on the wholesalers to estimate end user demand. Inventory levels held by these and other wholesalers may fluctuate significantly, which could cause our operating results to fluctuate unpredictably from quarter to quarter.

*Foreign Currency Risk.* A significant percentage of our product sales are 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 equivalent sales and negatively impact our financial condition and results of operations. We have a hedging program to mitigate the impact of foreign currency fluctuations on our results of operations; however, these efforts may not be successful and any such fluctuation could adversely affect our results of operations.

*Credit Risks.* We are particularly subject to credit risk from our European customers. 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, we may not be able to collect on amounts due to us from these customers and our financial position and results of operations would be adversely affected.

*Imports.* Our sales in countries with relatively higher prices may be reduced if products can be imported into those countries from lower price markets. There have been cases in which pharmaceutical products were sold at steeply discounted prices in the developing world and then re-exported to European countries where they could be resold at much higher prices. If this happens with our products, particularly Viread, which we provide at our cost to all countries in Africa and to the 15 other countries designated Least Developed Countries by the United Nations, our revenues would be adversely affected. In addition, in the European Union, we are required to permit cross border sales. This allows buyers in countries where government-approved prices for our products are relatively high to purchase our products legally from countries where they are sold at lower prices. Additionally, some U.S. consumers have been able to purchase products, including HIV medicines, from Internet pharmacies in other countries at substantial discounts. Such cross-border sales could adversely affect our revenues. In a number of developing countries, manufacturers are able to sell generic versions of pharmaceutical products. If generic versions of our products are sold in developing countries, exports from these countries may compete with our products in our

commercial markets.

*Pharmaceutical Pricing and Reimbursement Pressures.* Successful commercialization depends, in part, on the availability of governmental and third party payor reimbursement for the cost of our products. Government authorities and third-party payors increasingly are challenging the price of medical products and services, particularly for innovative new products and therapies. Our business may be adversely affected by an increase in U.S. or international pricing pressures. In the U.S. in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the health care system, either nationally or at the state level. Our results of operations could be adversely affected by future health care reforms. In Europe, the success of Hepsera, Tamiflu, Emtriva, Viread and Truvada also depends, largely on obtaining and maintaining government reimbursement because in many European countries, patients will not pay for prescription drugs out of their own pocket. Even if reimbursement is available, reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In addition, in many international markets, governments control the prices of prescription pharmaceuticals.

*Insurance Coverage.* The testing, manufacturing, marketing and use of our products as well as products in development involve substantial risk of product liability claims. Although we maintain prudent limits on our product liability insurance, it is not cost effective or in most cases possible to purchase sufficient limits to insure against all risks. Additionally, a successful product liability claim against us may not be covered by our insurance. As a result, a successful product liability or other claim could require us to pay amounts beyond that provided by our insurance, which could impair our financial condition and our ability to clinically test and to market our products.

*Litigation.* We are named as a defendant in a lawsuit regarding use of average wholesale price and reimbursement rates under Medicaid. Other defendants in this lawsuit have been named in numerous other lawsuits with comparable allegations. We have also been named in lawsuits alleging violations of the federal securities laws. Adverse results from these lawsuits could result in material damages.

*Tax Rate.* Various factors may have favorable or unfavorable effects on our effective tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, future levels of R&D spending, future levels of capital expenditures, changes in the mix of earnings in the various tax jurisdictions in which we operate and changes in overall levels of pre-tax earnings. An increase in our effective tax rate would have a negative impact on our results of operations.

#### **Critical Accounting Policies and Estimates**

Reference is made to Critical Accounting Policies and Estimates included on pages 37 through 39 of our Annual Report on Form 10-K for the year ended December 31, 2003. 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, 2003 and has not otherwise concluded that any of these policies have become out of date or are misleading.

**Results of Operations**

*Executive Summary*

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Sales increased significantly compared to the second quarter 2003, due primarily to strong sales of Viread. This resulted in strong growth in pretax income of 53% and a substantial increase in cash flow from operations of 106% compared to the same period last year. We expect our HIV drug sales to grow in the near term, although we expect it to be at a slower rate than we have experienced in the past. Enabling this growth is the increasing importance of once-daily regimens in prescribing HIV medications. The availability of Viread, Emtriva and Truvada now provide physicians the ability to construct once-daily regimens.

*Total Revenues*

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We had total revenues of \$319.7 million for the quarter ended June 30, 2004 compared with \$238.9 million for the quarter ended June 30, 2003. Total revenues were \$628.8 million for the first half of 2004, and \$404.0 million for the first half of 2003. Included in total revenues are product sales and royalty and contract revenue, including revenue from research and development (R&D) and manufacturing collaborations.



# Product Sales

Product sales consisted of the following (in thousands):

	Three Months Ended June 30, 2004		Change	Three Months Ended June 30, 2003		Six Months Ended June 30, 2004		Change	Six Months Ended June 30, 2003	
Viread	\$	197,162	18%	\$	167,035	\$	390,258	42%	\$	274,307
AmBisome		54,965	7%		51,163		106,838	16%		92,221
Other		47,205	279%		12,470		78,821	292%		20,104
Total product sales	\$	299,332	30%	\$	230,668	\$	575,917	49%	\$	386,632

The increase in product sales is primarily due to the increase in the volume of sales of Viread, which was approved for sale in the U.S. in October 2001 and in the European Union in February 2002. Sales of Viread in the second quarter of 2004 were 66% of total product sales, compared to 72% of total product sales in the same period of 2003. Of the Viread sales in the second quarter of 2004, \$109.2 million were U.S. sales, a decrease of 5% compared to the second quarter of 2003, and \$87.9 million were international sales, an increase of 71% compared to the same period in 2003. We believe the decrease in the U.S. compared to last year is due to significant increases in U.S. wholesaler inventory levels that occurred in the second quarter of 2003. International sales in 2004 were positively impacted by \$5.8 million due to a more favorable currency environment compared to the second quarter of 2003. In 2004, we expect product sales from our HIV franchise, which includes Viread, Emtriva and Truvada, to be \$850 million to \$875 million for the full year.

Sales of AmBisome accounted for 18% of product sales in the quarter ended June 30, 2004 compared to 22% of product sales in the quarter ended June 30, 2003. AmBisome sales in the second quarter of 2004 were \$3.5 million higher due to the favorable currency environment compared to the same quarter last year. On a volume basis, AmBisome sales increased in Latin America and Asia when compared to the second quarter of 2003. We continue to experience increased competition, particularly in Europe, and as a result, believe that AmBisome sales for 2004 will be lower than 2003 and in the range of \$170 million to \$190 million for the full year.

Other product sales consist primarily of Hepsera and Emtriva. Sales of Hepsera totaled \$28.0 million during the quarter ended June 30, 2004, an increase of 126% compared to the second quarter of 2003. This increase was primarily driven by prescription growth in both the U.S. and Europe. Sales of Emtriva totaled \$16.5 million for the quarter ended June 30, 2004. Emtriva was approved for marketing in the U.S. in July 2003 and in the European Union in October 2003.

In the first six months of 2004, net product sales were \$575.9 million, versus \$386.6 million in the comparable period of 2003, an increase of 49%. Sales of Viread for the six months ended June 30, 2004 were \$390.3 million, or 68% of total product sales, compared to \$274.3 million, or 71% of total product sales, in the six months ended June 30, 2003. The significant increase in Viread sales is due to increased prescription volume in both the U.S. and Europe. Of the \$390.3 million in Viread sales, \$225.1 million were U.S. sales and \$165.1 million were international sales. International sales of Viread in the first six months of 2004 were positively impacted by \$15.3 million due to the more favorable currency environment compared to the same period last year. We also recognized \$106.8 million in AmBisome sales for the first six months of 2004, a 16% increase over the six months ended June 30, 2003. Reported AmBisome sales in the first six months of 2004 were \$10.8 million higher due to the favorable currency environment. On a volume basis, AmBisome sales in the first six months of 2004 increased by 4% in Europe.



*Royalty and Contract Revenue*

Royalty and contract revenue was \$20.4 million for the second quarter of 2004 compared with \$8.2 million for the comparable quarter in 2003. The most significant source of royalty and contract revenue recorded in the second quarters of 2004 and 2003 was from worldwide sales of Tamiflu by Roche, which generated royalties of \$9.7 million and \$3.0 million, respectively. We also recorded \$4.8 million of contract revenue during the second quarter of 2004 related to the Macugen NDA filing by EyeTech. For the six months ended June 30, 2004, royalty and contract revenue was \$52.9 million compared to \$17.3 million for the six months ended June 30, 2003. Royalty revenue from worldwide sales of Tamiflu was \$37.1 million for the six months ended June 30, 2004 compared to \$7.3 million for the comparable prior year period. The significant period over period increases in Tamiflu royalty was due primarily to the severe U.S. flu season in 2003. We record royalties from Roche in the quarter following the quarter in which the related Tamiflu sales occur.

*Cost of Goods Sold*

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Cost of goods sold was \$42.1 million in the second quarter of 2004, compared with \$32.1 million in the second quarter of 2003 and \$77.0 million in the first six months of 2004 versus \$53.5 million in the same period of 2003. The increases from 2003 to 2004 can primarily be attributed to increases in the volume of Viread sold, which grew 18% and 42% in the three and six months ended June 30, 2004, respectively, versus the same periods of last year.

### *Gross Margins*

Product gross margins were 85.9% in the second quarter of 2004, compared with 86.1% in the same period of 2003. For the first half of 2004, product gross margins were 86.6% compared to 86.2% in the same period of 2003. The slight increase from the first half of 2003 to the first half 2004 is primarily driven by product mix as Viread and Hepsera, both higher margin products, contributed more significantly to net product sales in 2004 compared to the same period in 2003.

Foreign exchange impacts gross margins as we price our products in the currency of the country into which the products are sold while a majority of our manufacturing costs are in U.S. Dollars. For example, 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 after being translated into U.S. Dollars, will increase. In the second quarter and first six months of 2004, gross margins were positively impacted by the weakening U.S. dollar compared to the second quarter and first six months of 2003, as discussed in the *Product sales* section above. Except for the potential impact of unpredictable and uncontrollable changes in exchange rates relative to the U.S. dollar, we expect gross margins for the remainder of 2004 to remain relatively stable compared to 2003.

### *Research and Development Expenses*

Research and development (R&D) expenses were \$45.6 million for the second quarter of 2004. In order to better reflect the nature of certain clinical trials being performed in Europe, the Company recorded certain phase IV clinical trial expenses as R&D during the second quarter of 2004 that previously had been recorded as sales and marketing expenses. The comparative amounts in prior periods were also reclassified to be consistent with the current period presentation. The reclassified amounts were \$4.5 million and \$6.9 million for the three and six months ended June 30, 2003, respectively, and \$4.9 million for the three months ended March 31, 2004 (included in the six months ended June 30, 2004). On a reclassified basis, R&D for the three months ended June 30, 2004, increased by 5% compared to the same period last year. For the first half of 2004, R&D expenses were \$104.2 million versus \$86.9 million for the same period last year, an increase of 20%. The increases in R&D expenses for the second quarter and first half of 2004 are primarily attributable to increased headcount, costs associated with the development of Truvada, and research spending on prodrug technology. Based on current budgeted programs, we expect R&D expenses for the

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full year 2004 to be approximately \$200 million to \$220 million, or approximately 20% to 30% higher than 2003, reflecting the costs associated with the development of Truvada.

### *Selling, General and Administrative Expenses*

Selling, general and administrative (SG&A) expenses were \$73.8 million for the second quarter of 2004. This compares to \$55.7 million for the second quarter of 2003 after a reclassification to be consistent with the current period presentation of phase IV clinical trial expenses as discussed above under R&D. For the first half of 2004, SG&A expenses were \$145.0 million versus \$100.8 million for the first half of 2003. The period to period increases from 2003 to 2004 are primarily due to increased global marketing efforts, launch costs for Emtriva and Hepsera and the expansion of our U.S. and European sales forces. In 2004, we expect SG&A expenses for the full year to be approximately \$300 million to \$320 million, or 28% to 37% higher than 2003 levels, primarily due to the increase in marketing activities associated with the continued promotion of Viread, Emtriva, Hepsera and AmBisome and launch activities associated with Truvada.

### *Purchased In-Process Research and Development*

In connection with the acquisition of the net assets of Triangle completed in January 2003, we recorded in-process research and development expenses of \$488.6 million in the first quarter of 2003. The charge was due to Triangle's incomplete research and development programs that had not yet reached technological feasibility and had no alternative future use as of the acquisition date. A summary of these programs at the acquisition date and updated for subsequent developments follows:

Program	Description	Status of Development	Value (in millions)
Emtricitabine for HIV - Single Agent	A nucleoside analogue that has been shown to be an inhibitor of HIV replication in patients.	Four phase 3 studies completed prior to the acquisition date. U.S. marketing approval received from the FDA in July 2003 and European Union approval received from the European Commission in October 2003.	\$ 178.8
Emtricitabine/Tenofovir DF Fixed Dose Combination for HIV Therapy	A potential fixed-dose co-formulation of tenofovir and emtricitabine.	As of the acquisition date, work had not yet commenced on the potential co-formulation except to the extent that work on emtricitabine as a single agent was progressing. We have since completed co-formulating tenofovir and emtricitabine into a single pill, completed three stability studies and a bioequivalence study required for approval. In March 2004, applications for marketing approval were submitted in the U.S. and European Union.	\$ 106.4
Amdoxovir for HIV	A purine dioxolane nucleoside that may offer advantages over other marketed nucleosides because of its activity against drug resistant viruses as	Phase 2 trials at acquisition date. In January 2004, we announced our intent to terminate the licensing agreement with Emory University and the University of Georgia Research Foundation, Inc. and development was discontinued.	\$ 114.8

exhibited in patients with  
HIV infection.

Clevudine for HBV	A pyrimidine nucleoside analogue that has been shown to be an inhibitor of HBV replication in patients chronically infected with HBV.	Phase 1/2 trials at acquisition date. Effective August 6, 2003, the licensing agreement with Bukwang Pharm. Ind. Co., Ltd was terminated and development was discontinued.	\$	58.8
Emtricitabine for HBV	An inhibitor of HBV replication in patients chronically infected with HBV.	One phase 3 trial completed.	\$	29.8

The efforts required to complete Triangle's remaining research and development projects primarily consist of clinical trials, the cost, length and success of which are extremely difficult to predict. Feedback from regulatory authorities or results from clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that emtricitabine for the treatment of chronic hepatitis B will be approved in the U.S. or the European Union, whether marketing approvals will have significant limitations on its use, or whether it will be successfully commercialized. We have terminated our rights with respect to the other potential products that we acquired with the acquisition of Triangle's assets. Emtricitabine for the treatment of chronic hepatitis B faces significant uncertainties associated with pricing, efficacy, and the cost to produce that may not be successfully resolved. As a result, we may make a strategic decision to discontinue development of this product, as we did with clevudine and amdoxovir.

The value of the acquired in-process research and development was determined by estimating the related future net cash flows between 2003 and 2020 using a present value risk adjusted discount rate of 15.75%. This discount rate is a significant assumption and is based on our estimated weighted average cost of capital adjusted upward for the risks associated with the projects acquired. The projected cash flows from the acquired projects were based on estimates of revenues and operating profits related to the projects considering the stage of development of each potential product acquired, the time and resources needed to complete the development and approval of each product, the life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target markets.

#### *EyeTech Warrants*

In March 2000, we entered into an agreement with EyeTech relating to our proprietary aptamer EYE001, currently known as Macugen. Pursuant to this agreement, we received a warrant to purchase 791,667 shares of EyeTech series B convertible preferred stock, exercisable at a price of \$6.00 per share. In January 2004, EyeTech completed an initial public offering of its common stock at which time we adjusted the fair value of the warrant resulting in a gain of \$20.6 million included in our condensed consolidated statement of operations for the six months ended June 30, 2004. The fair value of the warrant was estimated using the Black-Scholes valuation model with a volatility rate of 50% and a discount rate of 2.8%. At the end of the first quarter of 2004, we exercised the warrant on a net basis utilizing shares of EyeTech common stock as consideration and subsequently held 646,841 shares of EyeTech common stock.

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In the second quarter of 2004, we sold all of the EyeTech shares and realized a gain of approximately \$2.3 million, which is included in interest and other income, net, in our condensed consolidated statements of operations for the three and six months ended June 30, 2004.

### *Interest and Other Income, net*

We reported interest and other income of \$5.4 million for the quarter ended June 30, 2004, up from \$3.4 million for the quarter ended June 30, 2003. Interest income was \$8.3 million for the first half of 2004 versus \$7.3 million for the first half of 2003. The increases in 2004 to the comparable periods is primarily attributable to the higher cash balances over the past year and also the realized gain of approximately \$2.3 million from the sale of all of our shares of EyeTech common stock during the second quarter of 2004.

### *Interest Expense*

Interest expense was \$2.1 million for the quarter ended June 30, 2004 and \$5.6 million for the quarter ended June 30, 2003. For the first half of 2004, interest expense was \$4.2 million versus \$11.2 million for the same period in 2003. The decreases in 2004 to the comparable periods can be attributed to the conversion of the \$250.0 million 5% convertible subordinated debt into common stock in December 2003. The only outstanding debt during the first half of 2004 consisted of the \$345.0 million 2% convertible senior debt issued in December 2002.

### *Income Taxes*

Our effective tax rate was 31% for the second quarter and first half of 2004. Our provision for income taxes for the second quarter of 2004 was \$50.1 million compared to \$5.3 million for the second quarter of 2003. Our provision for income taxes for the first half of 2004 was \$101.5 million compared to \$7.9 million for the first half of 2003. The provision in the second quarter and first half of 2003 was primarily associated with income earned by our foreign subsidiaries and federal alternative minimum tax. The effective tax rate for the second quarter and first half of 2004 is different from the statutory rate primarily as a result of permanently reinvested earnings of our foreign operations. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be permanently reinvested.

Various factors may have favorable or unfavorable effects on our effective tax rate during the remainder of 2004 and in subsequent years. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, future levels of R&D spending, future levels of capital expenditures, changes in the mix of earnings in the various tax jurisdictions in which we operate and changes in overall levels of pre-tax earnings.

### *Foreign Exchange*

The impact to pre-tax earnings during the three and six months ended June 30, 2004 as a result of the strengthening Euro versus the comparable period last year was a positive \$4.4 million and \$15.0 million, respectively. This includes the impact from revenues and international spending,



as well as hedging activity.

### **Liquidity and Capital Resources**

Cash, cash equivalents and marketable securities totaled \$975.6 million at June 30, 2004, up from \$707.0 million at December 31, 2003. The increase of \$268.6 million was primarily due to net cash provided by operations of \$220.7 million and proceeds from issuances of stock under employee stock plans of \$39.8 million, partially offset by \$18.2 million of capital expenditures. In addition, we sold our shares of EyeTech common stock for total proceeds of approximately \$23.5 million during the second quarter, following our net exercise of the EyeTech warrant during the first quarter when EyeTech completed an initial public offering.

Working capital at June 30, 2004 was \$1,357.0 million compared to \$1,080.0 million at December 31, 2003. Significant changes in working capital in addition to the increase in our cash, cash equivalents and marketable securities during the first six months of 2004, included a \$61.6 million decrease in current deferred tax assets, a \$47.0 million increase in net accounts receivable, a \$12.5 million decrease in accrued liabilities, and a \$12.1 million increase in prepaid expenses and other assets. The \$61.6 million decrease in current deferred tax assets was due to the utilization of net operating loss carryforwards to reduce the amount of income taxes payable. The accounts receivable increase was primarily due to increased sales of Viread in the U.S. and Europe. The \$12.5 million decrease in accrued liabilities is primarily the result of a reduction in the liability associated with the fair value of our hedge contracts as the Euro has weakened in value during the first six months of 2004. The \$12.1 million increase in prepaid expenses and other assets is primarily attributable to the \$5.0 million receivable recorded upon completion of the Macugen NDA filing by EyeTech.

We believe that our existing capital resources, 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 and the adequacy of our resources will depend on many factors, including:

- the commercial performance of our current and future products,
- the progress and scope of our research and development efforts, including preclinical studies, and clinical trials,
- the cost, timing and outcome of regulatory reviews,
- the expansion of our sales and marketing capabilities,
- administrative expenses,
- the possibility of acquiring manufacturing capabilities or additional office facilities,
- the possibility of acquiring other companies or new products, and
- the establishment of additional collaborative relationships with other companies, and
- adverse results of litigation.

We may in the future require additional funding, which could be in the form of proceeds from equity or debt financings, such as from our universal shelf registration filed in December 2003 for the potential issuance of up to \$500.0 million of our securities, 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.

#### **Subsidiaries and Other**

We have established a variety of subsidiaries in various countries for the purpose of conducting business in those locations. All of these subsidiaries are consolidated in our financial statements. We do not have any special purpose entities that are unconsolidated in our financial

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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, raw material supply agreements and clinical research organization contracts.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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As of June 30, 2004, our \$345.0 million convertible senior notes had a fair value of \$497.6 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, 2003.

**ITEM 4. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

An evaluation as of June 30, 2004 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (the Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that subject to the limitations described below, our disclosure controls and procedures were sufficiently effective to ensure that information required to be disclosed by us in this quarterly report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules on Form 10-Q.

### **Changes in Internal Controls over Financial Reporting**

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2004, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Limitations on the Effectiveness of Controls**

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

**PART II. OTHER INFORMATION**

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





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The Annual Meeting of Stockholders was held on May 25, 2004 in Redwood City, California. Of the 213,989,757 shares of Gilead Common Stock entitled to vote at the meeting, 186,535,589 shares were represented at the meeting in person or by proxy, constituting a quorum. The voting results are presented below.

The stockholders elected eight directors to serve for the ensuing year and until their successors are elected. The votes regarding the election of directors were as follows:

Name	Shares Voted For	Votes Withheld
Paul Berg	175,314,697	11,220,892
Etienne F. Davignon	176,565,947	9,969,642
James M. Denny	175,975,965	10,559,624
John C. Martin	176,639,490	9,896,099
Gordon E. Moore	166,717,710	19,817,879
Nicholas G. Moore	163,778,559	22,757,030
George P. Shultz	172,962,786	13,572,803
Gayle E. Wilson	167,242,540	19,293,049

The stockholders approved the ratification of Ernst & Young LLP as Gilead's independent auditors for the year ending December 31, 2004. There were 184,728,369 votes cast for the proposal, 1,751,151 votes cast against, 56,069 abstentions, and no broker non-votes.

The stockholders approved the adoption of Gilead's 2004 Equity Incentive Plan. There were 121,053,896 votes cast for the proposal, 41,767,356 votes cast against, 211,869 abstentions, and 23,502,468 broker non-votes.

The stockholders approved an amendment to Gilead's Restated Certificate of Incorporation to increase the authorized number of shares of Gilead common stock from 500,000,000 to 700,000,000 shares. There were 180,963,190 votes cast for the proposal, 5,454,302 votes cast against, 118,097 abstentions, and no broker non-votes.

### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

No. 10.75 Gilead Sciences, Inc. 2004 Equity Incentive Plan, as Amended July 29, 2004  
No. 31.1 Certification  
No. 31.2 Certification  
No. 32 Certification

(b) Reports on Form 8-K

On April 22, 2004, the Company filed an 8-K announcing the earnings of the Company for the first quarter ended March 31, 2004.

On May 11, 2004, the Company filed an 8-K announcing the implementation of a stock trading program in accordance with Rule 10b5-1 of the Securities Exchange Act of 1934.

**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: August 5, 2004

/s/ John C. Martin  
John C. Martin  
President and Chief Executive Officer

Date: August 5, 2004

/s/ John F. Milligan  
John F. Milligan  
Executive Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

**Exhibit Index**

(a) Exhibits

No. 10.75 Gilead Sciences, Inc. 2004 Equity Incentive Plan, as Amended July 29, 2004  
No. 31.1 Certification  
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